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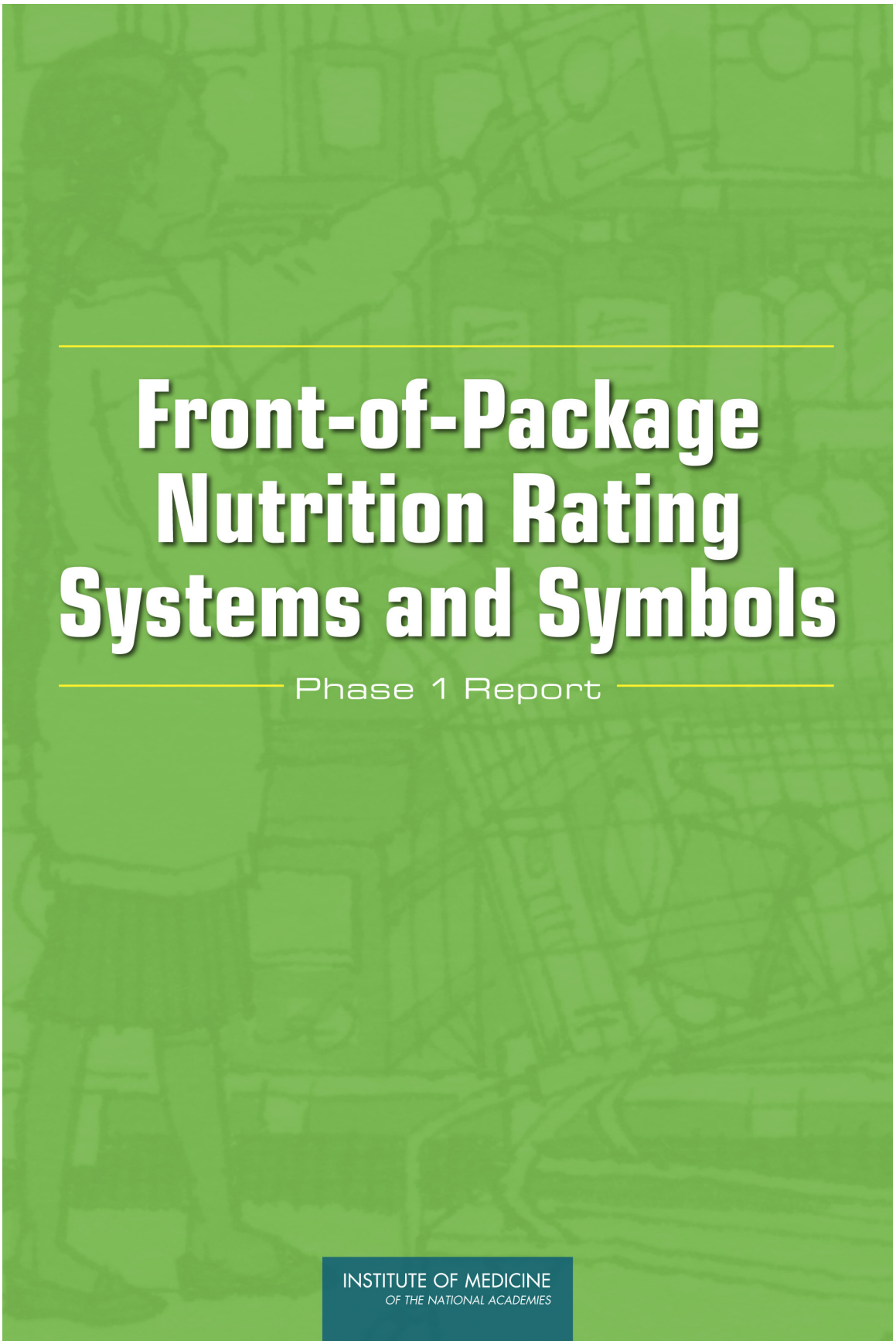

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Examination of Front-of-Package Nutrition Rating Systems and Symbols:

Phase I Report

Committee on
Examination of Front-of-Package Nutrition Rating Systems and Symbols
Food and Nutrition Board

Ellen A. Wartella, Alice H. Lichtenstein, and Caitlin S. Boon, *Editors*

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

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COMMITTEE ON EXAMINATION OF FRONT-OF-PACKAGE NUTRITION RATING SYSTEMS AND SYMBOLS

ELLEN A. WARTELLA (*Chair*), Professor, Department of Communication Studies, Northwestern University, Evanston, IL
ALICE H. LICHTENSTEIN (*Vice Chair*), Gershoff Professor, Jean Mayer USDA Human Nutrition Research Center on Aging, Tufts University, Boston, MA
LINDSAY H. ALLEN, Center Director, USDA, ARS Western Human Nutrition Research Center, Davis, CA
TRACY A. FOX, Nutrition Consultant and President, Food, Nutrition, & Policy Consultants, LLC, Washington, DC
MATTHEW W. KREUTER, Professor, Health Communication Research Laboratory, Washington University, St. Louis, MO
ANUSREE MITRA, Associate Professor, Kogod School of Business, American University, Washington, DC
FRANCES H. SELIGSON, Consultant, Hershey, PA
MARY T. STORY, Professor, Division of Epidemiology and Community Health, University of Minnesota, Minneapolis
VIRGINIA WILKENING, Alexandria, VA

IOM Staff
CAITLIN S. BOON, Study Director (through August 2010)
ROMY NATHAN, Senior Program Officer
JANET MULLIGAN, Research Associate
LAURA PILLSBURY, Research Associate
SAMANTHA ROBOTHAM, Senior Program Assistant
ANTON BANDY, Financial Officer
GERALDINE KENNEDO, Administrative Assistant
LINDA D. MEYERS, Director, Food and Nutrition Board

REVIEWERS

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 National Research Council'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:

KELLY BROWNELL, Rudd Center for Food Policy and Obesity, Yale University, New Haven, CT
NANCY CHAPMAN, N. Chapman Associates, Inc., Washington, DC
JEANNE P. GOLDBERG, Friedman School of Nutrition Science and Policy, Tufts University, Boston, MA
EDWARD GROTH, III, Consultant, Groth Consulting Services, Pelham, NY
JANE E. HENNEY, College of Medicine, University of Cincinnati, OH
REGINA HILDWINE, Grocery Manufacturers Association, Washington, DC
LINDA VAN HORN, Feinberg School of Medicine**,** Northwestern University, Chicago, IL
CONNIE M. WEAVER, Department of Food and Nutrition, Purdue University, West Lafayette, IN
CHRISTINA ZARCADOOLAS, Department of Community and Preventive Medicine, Mount Sinai School of Medicine, New York, NY

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 **ELENA O. NIGHTINGALE,** Washington, DC, and **DIANE FEICKERT BIRT,** Iowa State University. Appointed by the National Research Council and the Institute of Medicine, 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

This country is experiencing the highest rates of overweight, obesity, and diet-related chronic diseases in its history, and there is a great emphasis on consumers making healthier food choices. Against the backdrop of a pressing public health crisis, Congress requested an Institute of Medicine (IOM) study that would examine front-of-package nutrition systems and symbols and the effect that such systems and symbols could have on consumers choosing more nutritious foods.

The committee's charge was to review front-of-package nutrition rating systems and symbols, identifying the systems developed by manufacturers, supermarkets, health organizations, and governments in the United States and abroad; evaluating the scientific basis of the underlying nutrient criteria; considering the strengths and limitations of various approaches; and planning a second phase of nutrition labeling to consider the consumer aspect of front-of-package (FOP) systems. In 1990 passage of the Nutrition Labeling and Education Act (NLEA) standardized the way nutrition information is provided to the public by requiring the information to be displayed in the now iconic Nutrition Facts panel and setting criteria for nutrient claims and health claims. This study, undertaken 20 years after passage of NLEA, represents a new phase in the understanding and use of nutrition labeling.

Over a dozen systems have been developed over the years, so this was no small task, but in light of the potential public health benefit that could be achieved with front-of-package nutrition rating systems, it was a worthy one. We are pleased that the assembled committee had the individual expertise and experience as well as the collective will to serve the health of the public and had the willingness to meet the significant challenge of our charge. It was a privilege to be a part of this effort.

Over the course of the study, we met often and consulted many sources. Our first meeting set the tone as we heard from each of our study sponsors. A public workshop elicited needed input and was extremely useful to the committee's deliberations. Invited speakers and panelists included Mark Andon, Claire Boville, Adam Drewnowski, Mark Kantor, David Katz, Joanne Lupton, Marion Nestle, Jacob Seidell, Kim Stitzel, and Kathy Wiemer. These individuals and others shared their data, perspectives, and experience with us on that day or afterward by input to the project website. Jim Crimmins, Brian Elbel, and Elizabeth Howlett provided valued service as unpaid consultants during the later part of the project as we developed plans for Phase II of the study. Neal H. Hooker resigned from the committee in April 2010; we are grateful for his contributions to our early work.

On behalf of the committee, we extend our deepest thanks to the able project staff: Caitlin Boon, study director (through August 2010); Romy Nathan, senior program officer; Janet Mulligan, research associate; Laura Pillsbury, research associate; and Samantha Robotham, senior program assistant. All gave generously of their talents and time. In addition, the committee would like to thank other members of the Food and Nutrition Board staff including Linda Meyers, Food and Nutrition Board director; Anton Bandy, financial officer; Alice Vorosmarti, research associate; and Geraldine Kennedo, administrative assistant, who assisted at crucial times during the project.

The findings and conclusions in this report could not come at a better time. This year has been one of many events and new initiatives drawing even more attention to the current public health crisis of obesity, including First Lady Michelle Obama's Let's Move initiative, the

anticipated release of the 2010 *Dietary Guidelines for Americans*, and billions of dollars of government and private investments provided to our local communities in an effort to reverse the epidemic of obesity To this end, we are grateful to have been able to contribute through this Phase I report to the discussion about the important role of nutrition labeling in these endeavors.

Ellen Wartella, *Chair*
Alice Lichtenstein, *Vice-Chair*
Committee on Examination of Front-of-Package Nutrition Rating Systems and Symbols

Contents

Summary

Growing recognition of the nation's obesity crisis and the prevalence of chronic disease have led to an array of efforts aimed at increasing physical activity and promoting healthful eating, including changes in the formulation, packaging, labeling, and marketing of food and beverage products that contribute to a healthy lifestyle. In particular, the use of symbols summarizing key nutritional aspects and characteristics of food products has seen substantial growth. These symbols and the nutrition rating systems that underlie them have come to be known as front-of-package (FOP) symbols and nutrition rating systems even though the actual symbol may be found in a variety of locations on the food package or even on retail shelf tags alongside product price information. Systems and symbols have been developed by food manufacturers, retailers, health organizations, and others with the intention of helping consumers make healthier food choices.

While these systems are innovative approaches to nutrition labeling, they are not without controversy. Concerns, particularly over nutrient criteria that vary widely and sometimes conflict among the many systems in the marketplace and over the potential for FOP symbols to encourage purchases, have fueled the current debate on the future use of FOP nutrition rating systems, which has in turn led to new government initiatives to identify better and more consistent approaches for FOP systems.

THE COMMITTEE'S TASK AND APPROACH

As a step toward determining how FOP systems should be used as a nutrition education tool in the future, Congress directed the Centers for Disease Control and Prevention (CDC) to undertake a study with the Institute of Medicine (IOM) to examine and provide recommendations regarding front-of-package nutrition rating systems and symbols. The Food and Drug Administration (FDA) was also a study sponsor. The study has been undertaken in two phases. This report is the result of the initial phase and focuses on reviewing existing front-of-package systems and their underlying nutrition criteria. A second phase will focus on issues related to consumer understanding and use of FOP systems.

The study task, which guided the committee's work, is described in Box S-1. Because the committee determined that the same nutritional approach could be applied to both children and adults, it did not consider children and adults separately in Phase 1. The committee also developed four guiding principles to assist it in identifying systems and their elements that were most important for improving the health of the American people and in identifying system criteria that could be realistically implemented. The guiding principles are:

- A well-balanced, high-quality diet consistent with the *Dietary Guidelines for Americans* is essential for the health of Americans, and front-of-package labeling is one tool among many geared toward helping Americans make healthful choices. Other such tools include MyPyramid, the Nutrition Facts panel, and health and nutrient content claims.

BOX S-1
Statement of Task—Phase I

An ad hoc committee was to be convened to "review systems being used by manufacturers, supermarkets, health organizations, and governments in the United States and abroad and the overall merits of front-label nutrition icons, the advantages and disadvantages of various approaches, and the potential benefits of a single, standardized front-label food guidance system regulated by the Food and Drug Administration."

The committee was charged with the following tasks:

- Identify front-of-package systems being used by manufacturers, supermarkets, health organizations, and governments in the United States and abroad;
- Consider the purpose and overall merits of front-label icons;
- Identify the criteria underlying the systems and evaluate their scientific basis;
- Consider advantages and disadvantages of various approaches for adults and children; and
- Using knowledge gained from its compilation and assessment of front-of-package systems, plan the second phase, which will consider the potential benefits of a single, standardized front-of-package food guidance system regulated by the FDA and develop conclusions about which system(s) are most effective in promoting health and how to maximize the use and effectiveness of the system(s).

A second phase is also planned and will build on this report and consider the following:

- The potential benefits of a single, standardized front-label food guidance system regulated by the Food and Drug Administration;
- Assessment of which icons are most effective with consumer audiences; and
- Development of conclusions about the systems and icons that best promote health and how to maximize their use.

- Front-of-package systems will focus on nutrients or food components that are most strongly associated with the diet-related health risks affecting the greatest number of Americans.
- The information highlighted in front-of-package systems will be consistent with the Nutrition Facts panel.
- Front-of-package systems will apply to as many foods as possible.

The committee's deliberations were also informed by its findings about diet-related health concerns. The findings are:

Finding 1: Obesity, cardiovascular disease, type 2 diabetes, and certain types of cancers are the health risks affecting the greatest number of Americans that are also most strongly associated with diet.

Finding 2: Americans consume too many calories, saturated fats, *trans* fats, and added sugars; too much sodium; and too little Vitamin D, calcium, potassium, and fiber.

IDENTIFICATION OF EXISTING FRONT-OF-PACKAGE SYSTEMS

A number of systems have been or currently are in use in the United States or abroad. The committee chose 20 systems representative of those in the marketplace on which to base its review. General information on these systems by system category is provided in Table S-1. For the purposes of comparing systems and identifying strengths and limitations, the committee categorized systems into the categories described below.

- ***Nutrient-Specific Systems*** display on the front of the food package the amount per serving of select nutrients from the Nutrition Facts panel or use symbols based on claim criteria. The information is given in percent daily values (%DV) or guideline daily amounts (%GDA), and the display may also include traffic-light colors or words to indicate that a product contains "high," "medium," or "low" amounts of specific nutrients. A declaration of calories per serving may also be provided on the front of the food package. Systems using symbols based on claim criteria may award multiple symbols on a product indicating it is "low fat," "high fiber," etc.
- ***Summary Indicator Systems*** use a single symbol, icon, or score to provide summary information about the nutrient content of a product. No specific nutrient content information is given in these systems. The system may be based on nutrient thresholds or algorithms. Systems often use different criteria based on food categories (e.g., type of food or food product). Algorithm systems evaluate food products based on an equation that takes nutrients (positive and/or negative) into account. Products are given a numeric score (i.e., 1–100) or number of symbols (e.g., 0, 1, 2, 3) to indicate the nutritional quality of the product.
- ***Food Group Information Systems*** use symbols that are awarded to a food product based on the presence of a food group or food ingredient. Some symbols indicate the presence of a serving (or partial serving) of a particular food group, while other symbols indicate the presence of ingredients considered to be important dietary components such as whole grains.

ATTRIBUTES, STRENGTHS, AND LIMITATIONS OF TYPES OF SYSTEMS

Given the number of front-of-package systems on the market and the variety of attributes that future systems may have, it was not possible to conduct an exhaustive evaluation of each system. Rather, the committee characterized the attributes, purposes, strengths, and weaknesses by defined system types (see Tables S-2, S-3, and S-4).

TABLE S-1 Overview of Existing Front-of-Package Programs

System Icon	Program Name	System Developer	Criteria Publicly Available	Basis for Nutrient Criteria
Nutrient-Specific Systems				
	General Mills Nutrition Highlights[a]	Food manufacturer	Yes	FDA %DVs
	General Mills Goodness Corner[b]	Food manufacturer	Yes	FDA regulations for nutrient content claims
[Image withheld at the request of the retailer]	Harris Teeter Wellness Keys[c]	Retailer	Yes	FDA regulations for nutrient content claims
	Kellogg's Nutrition at a Glance[d]	Food manufacturer	Yes	FDA %DVs presented as %GDAs
	UK Traffic Light[e]	Government agency	Yes	EC regulation No. 1924/2006 for green/amber boundaries; COMA and SACN advice for amber/red boundaries
	Wegmans Wellness Keys[f]	Retailer	Yes	FDA regulations for nutrient content claims

[a]Reprinted with permission of General Mills.
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System Icon	Program Name	System Developer	Criteria Publicly Available	Basis for Nutrient Criteria
	Summary Indicator Systems			
	Choices (EU)[g]	Non-industry experts	Yes	WHO guidelines for saturated and *trans* fats, sodium, sugars; dietary guidelines from 21 countries
	Guiding Stars[h]	Retailer	No	Proprietary algorithm based upon FDA, USDA, USDHHS, IOM, and WHO recommendations and regulations
	Canada's Health Check[i]	Nonprofit organization	Yes	Canada's Food Guide
Reprint permission pending	Giant Food Healthy Ideas[j]	Retailer	Yes	Dietary Guidelines for Americans, implied nutrient content claims, and health claims
	AHA Heart Check[k]	Nonprofit organization	Yes	FDA %DVs, implied nutrient content claims, coronary heart disease health claims

[g] Front-of-Pack device of the Choices Programme. Exact wording on the logo varies with the local language. Image provided by Choices International Foundation.
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[i] Reprinted with permission of Canada's Heart & Stroke Foundation.
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[k] Heart Check Mark is a registered trademark of the American Heart Association.

System Icon	Program Name	System Developer	Criteria Publicly Available	Basis for Nutrient Criteria
No symbol exists at this time	Nutrient Rich Foods Index	Non-industry experts	Yes	FDA %DVs
	NuVal[l]	Non-industry experts	No	Proprietary algorithm based upon Dietary Guidelines for Americans and DRIs, as well as established data in scientific literature
	Kraft Sensible Solution[m]	Food manufacturer	Yes	Dietary Guidelines for Americans, and authoritative statements from NAS and FDA
	Smart Choices[n]	Industry and non-industry consortium	Yes	Dietary Guidelines for Americans, and authoritative statements from NAS and FDA
Reprint permission pending	PepsiCo Smart Spot[o]	Food manufacturer	Yes	Authoritative statements from FDA and NAS
	Sweden National Food Administration Keyhole[p]	Government agency	Yes	National Food Administration Regulation LIVSFS 2005:9

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[o] Reprint permission pending.
[p] The Swedish National Food Administration.

System Icon	Program Name	System Developer	Criteria Publicly Available	Basis for Nutrient Criteria
Reprint permission pending	Australia/New Zealand Tick Programme[q]	Industry and non-industry working group	Yes	Working-group determined values
Food Group Information Systems				
	ConAgra Start Making Choices[r]	Food manufacturer	Yes	USDA's MyPyramid
	Whole Grain Council Whole Grain Stamp[s]	Industry and non-industry consortium	Yes	USDA's MyPyramid

[q] Reprint permission pending.
[r] START MAKING CHOICES® is a registered trademark of ConAgra Foods RDM, Inc.
[s] Courtesy Oldways and the Whole Grains Council, wholegrainscouncil.org.

TABLE S-2 Comparison of Front-of-Package Scheme Types According to Attribute or Potential to Fulfill Specific Purposes[a]

	Nutrient Specific Information			Summary Indicator		Food Group Information	
Purpose	Calories per Serving	Nutrient Amount per Serving	Symbol Based on FDA/USDA Claim Criteria	Based on Nutrient Thresholds	Based on Algorithm	Food Groups	Food Ingredient
Provide prominent calorie content information	✓	✓	✓	✓	✓	✓	✓
Provide prominent serving size information	✓	✓	✓	✓	✓	✓	✓
Provide targeted nutrition information	✓	✓					
Indicate whether product is high or low in specific nutrient(s)	✓	✓	✓				
Summarize overall nutritional value of a product				✓	✓		
Facilitate comparisons of nutritional value *within* food categories	✓[b]	✓[b]	✓[b]	✓[c]	✓[c]		
Facilitate comparisons of nutritional value *across* food categories	✓[b]	✓[b]	✓[b]	?[d]	?[d]		
Provide information about contribution to recommended food groups				✓[e]		✓	✓
Provide guidance on products suitable for marketing to children	✓[b]	✓[b]	✓[b]	✓[c]	✓[c]		
Encourage product reformulation	✓	✓	✓	✓	✓	✓	✓

[a] A checkmark indicates a system subtype either currently does or potentially could be developed to fulfill the specified purpose.
[b] Only specific nutrient content can be compared, e.g., sodium, saturated fat, etc.
[c] Only overall nutritional value can be compared.
[d] The ability to compare products across categories would depend on how the nutrient thresholds or algorithm are set.
[e] Some summary indicator systems include criteria for food groups, but food group contribution is not depicted on FOP.

TABLE S-3 Comparison of FOP System Types According to Potential Strengths[a]

	Nutrient-Specific Information			Summary Indicator		Food Group Information	
Strength	Calories per Serving	Nutrient Amount per Serving	Symbol Based on FDA/USDA Claim Criteria	Based on Nutrient Thresholds	Based on Algorithm	Food Groups	Food Ingredient
Applies one standard or format across all or most product categories	✓	✓	✓			✓	✓
Addresses product categories according to their relative contribution to total intake				✓	✓		
Targets nutrients of public health concern	✓[b]	✓[b]	✓[b]	✓[c]	✓[c]		
Facilitates compliance with dietary recommendations from healthcare provider	✓[b]	✓[b]	✓[b]				
Helps consumers identify nutrient-dense food				✓[d]	✓[d]		
Provides measure of relative amount of nutrient if %DV, high/medium/low text, or color coding is used	✓	✓	✓				
Declares/evaluates nutrient amounts consistent with current regulations	✓	✓	✓				
Analytical methods available for monitoring compliance of nutrients in the Nutrition Facts panel	✓	✓	✓	✓	✓[e]		

[a] A checkmark indicates the strength is specific to that system subtype.
[b] Applies to individual nutrients.
[c] Nutrients of public health concern may be included in threshold criteria and algorithms but are not transparent to consumers.
[d] Nutrients contributing to nutrient density are not transparent to consumers.
[e] However, an algorithm may incorporate parameters such as the glycemic index or weighting factors that are not specific for the product evaluated, and the algorithms for NuVal and Guiding Stars are not publically available thus precluding compliance monitoring.

TABLE S-4 Comparison of FOP System Types According to Potential Limitations[a]

	Nutrient-Specific Information			Summary Indicator		Food Group Information	
Limitation	Calories per Serving	Nutrient Amount per Serving	Symbol Based on FDA/USDA Claim Criteria	Based on Nutrient Thresholds	Based on Algorithm	Food Groups	Food Ingredient
FOP label space limited for small packages		✓	✓			✓	
Too much information may reduce consumer comprehension and use	✓	✓	✓			✓	
Decreased use of Nutrition Facts panel	✓	✓	✓	✓	✓	✓	✓
No Daily Value for some nutrients, thus no basis for nutrient content claims	✓[b]	✓	✓	✓	✓		
No definition for low, medium, or high for some nutrients	✓	✓	✓	✓			
Products qualifying for any one claim may not have zero/low amounts of nutrients to limit	✓	✓	✓				
Consumers may disregard disclosure information associated with nutrient claims	✓	✓	✓			✓	✓
Nutrient disclosure amounts may be too lenient for some product categories			✓	✓			
Low claim criteria may be too strict for some nutrients in some product categories			✓	✓			
Some product nutrient criteria based on recommendations for a total dietary intake				✓			
Nutrient criteria not publicly available for some systems					✓		
Need to decide how many and which product categories to include				✓	✓		

Limitation	Nutrient-Specific Information: Calories per Serving	Nutrient-Specific Information: Nutrient Amount per Serving	Nutrient-Specific Information: Symbol Based on FDA/USDA Claim Criteria	Summary Indicator: Based on Nutrient Thresholds	Summary Indicator: Based on Algorithm	Food Group Information: Food Groups	Food Group Information: Food Ingredient
Need to decide which nutrients to include and on basis for evaluation				✓	✓		
May encourage discretionary fortification to meet threshold criteria or improve algorithm score unless rules in place				✓	✓		
May not have criteria for nutrients to limit						✓	✓
May not be able to monitor compliance				✓[c]	✓[c,d]	✓[e]	✓[e]

[a] A check mark indicates the limitation is specific to that system subtype.
[b] Current systems use 2,000 calories as a reference total daily intake.
[c] Nutrient thresholds or algorithms may include nutrients, food components, or weighting factors that are not specific to the product being evaluated and are imputed from food composition databases and literature that may or may not be publicly available.
[d] The algorithms for some systems are not publicly available.
[e] If the product is not a mixture of different foods, compliance can be monitored by comparing the declared serving size with the recommended food group servings. If the product is 100% whole grains, compliance can be monitored by reviewing the ingredient list.

CONCLUSIONS

Target Audience and Purpose

Conclusion 1: Front-of-package rating systems and symbols would be best geared toward the general population.

Conclusion 2: The committee supports the goal and purposes of front-of-package systems announced by the Food and Drug Administration in April 2010 and concludes that the most useful primary purpose of front-of-package rating systems and symbols would be to help consumers identify and select foods based on the nutrients most strongly linked to public health concerns for Americans.

Given that two-thirds of the U.S. adult population and one-third of children and adolescents are overweight or obese, chronic disease levels are high, and a healthy diet consistent with the *Dietary Guidelines for Americans* is essential for all Americans, FOP labeling would be best geared toward the general population. Thus, children are not considered separately in assessing the nutritional components in Phase I. Whether specific subpopulations, including children, may benefit from FOP labeling, will be explored in Phase II.

The committee identified a number of purposes, including those set forth by FDA in the Federal Register in April, namely that the "goal of an FOP nutrition label is to increase the proportion of consumers who readily notice, understand, and use the available information to make more nutritious choices for themselves and their families, and thereby prevent or reduce obesity and other diet-related chronic disease." [1] On balance, the latter best reflected the guiding principles and the committee considerations of potential purposes.

Nutrition Information to Include

Conclusion 3: Regardless of system type, it would be useful to declare calorie and serving size information prominently in front-of-package symbols.

Obesity and overweight, which result from calorie consumption in excess of energy expenditure, are critical public health concerns for the majority of the population. Including total calories in nutrition rating system symbols is one way to emphasize the importance of calories in the American diet, and it could help consumers identify lower-calorie foods and track the number of calories consumed. Providing serving size information in household measures gives context to the amount of food associated with the calories per serving displayed in an FOP symbol. Offering serving size information in an easy-to-understand format may help consumers better visualize realistic serving sizes and put the serving size into context with the other foods and beverages they are consuming.

[1] 75 FR 22602.

Conclusion 4: The most critical nutritional components to include in front-of-package nutrition rating systems are calories, saturated fat, *trans* fat, and sodium.

As stated in the committee's guiding principles, the committee considered it critical that FOP rating systems focus on those nutrients that are most strongly associated with the diet-related health risks affecting the greatest number of Americans. Calories, saturated fat, *trans* fat, and sodium are four of the most critical nutrients and are also nutrients that are overconsumed in the American diet. Calories are the most critical nutrient to address in reducing obesity and its various co-morbidities, including coronary heart disease (CHD) and stroke, type 2 diabetes, metabolic syndrome, and certain types of cancer. In addition, reducing sodium intake can reduce blood pressure, which in turn can reduce an individual's risk of stroke and cardiovascular disease events. Furthermore, reducing saturated and *trans* fat intake may reduce the risk of cardiovascular disease. Given the adverse health effects of excess calories, saturated fat, *trans* fat, and sodium intakes, it is critical to include these components in nutrition rating systems so as to help Americans chose foods with lower levels of these nutrients.

Conclusion 5: There is insufficient evidence at this time to suggest that including the following nutrients would be useful in all types of front-of-package rating systems or symbols: total fat, cholesterol, total carbohydrate, total or added sugars, protein, fiber, vitamins, and minerals other than sodium.

Several factors led to the conclusion that it may not be useful to include a number of nutrients in all types of FOP systems. These factors included (1) the relative importance of these nutrients to the most pressing diet-related health concerns among Americans, (2) the potential for some nutrients to track with other nutrients that are considered important to include in FOP rating systems, (3) amounts of the nutrients and food components, except for added sugars, can be found elsewhere on the package label in the Nutrition Fact panel, and (4) challenges for measuring compliance for some nutrients, particularly added sugars. A fifth factor relates to concerns about encouraging overfortification or the addition of these nutrients to food systems in which the nutrient is unstable or not biologically available, which would contradict FDA fortification policy. Issues surrounding added sugars and fiber are challenging and are addressed more fully in Chapter 4 (pages 4-3 to 4-5 and 4-10) and Chapter 7 (pages 7-6 to 7-8). Monitoring the intake of these nutrients remains important to assembling a healthful diet. However, other tools (e.g., nutrient content claims, education programs) may be more appropriate for addressing these nutrients, allowing FOP systems to focus on the most critical public health concerns. Brief rationale for not including these nutrients at the current time are listed below.

Total Fat

- Total fat includes beneficial mono- and polyunsaturated fats, whose consumption is encouraged, and saturated and *trans* fats, whose consumption should be limited. Thus, it is difficult to characterize total fat content as either a positive or negative attribute of a food product.

- Dietary guidance recommendations encourage displacing saturated and *trans* fats in the diet with unsaturated fats. Since many consumers have a negative view of all types of fat, consumers may avoid products with FOP systems showing higher levels of total fat content, especially those systems that include nutrient-specific information, and this may not be the desired behavior in all cases.

Cholesterol

- While cholesterol remains an important concern for certain subgroups of the population, overconsumption of cholesterol is not as significant a problem for the general population as overconsumption of saturated fat, *trans* fat, or sodium, making it less important to include cholesterol in FOP system criteria.
- Saturated fat criteria may help to address most major sources of cholesterol in the diet since most foods that are high in cholesterol would not be rated well because of a high saturated fat content.

Total Carbohydrates

- A variety of compounds that vary greatly in their physiological function, including monosaccharides, disaccharides, starch, fiber, pectins, and gums, are all considered carbohydrates. Because of these compounds varied physiological functions, it would be difficult in many types of nutrition rating systems to characterize total carbohydrate content as a positive or negative attribute of a food product.

Total Sugars

- There is a lack of scientific agreement about the amount of sugars that can be consumed in a healthy diet and about potential adverse health effects of sugars beyond an effect on dental caries. Thus, it is difficult to conclude that total sugars intake is of sufficient public health concern to be included in FOP rating systems.
- Total sugars include those naturally present in fruits, vegetables, and fat free or low fat dairy products, which are considered foods to encourage.

Added Sugars

- Despite the overall increase in calories that they provide to the American diet, at this time evidence and agreement are lacking about adverse health effects of added sugars, the exceptions being the extra calories that they contribute to a diet and their dilution of essential nutrient intake.
- An analytical test that can accurately determine added sugar content is unavailable, leaving the sharing of proprietary product formulations as the only apparent option for monitoring product compliance with established criteria.
- Added sugars are not included in the Nutrition Facts panel, so including added sugars in FOP system criteria would lead to inconsistencies between the Nutrition Facts panel and FOP symbols.

Protein

- Protein is not currently considered a nutrient of public health concern in the United States.

Fiber, Vitamins, and Minerals (Other Than Sodium)

- For many vitamins and minerals, there is no public health need for the general population to increase intake.
- In the case of fiber and those vitamins and minerals for which there is a public health need to increase intake, inclusion in an FOP rating system could lead to practices that may not be beneficial to consumers, such as excessive or inappropriate uses of fortification, or might inadvertently drive consumers away from foods that do not contain these components but which are otherwise considered nutritious food choices.

Nutrient Criteria

For each of the potential systems, the committee identified ways in which criteria might be set for calories, saturated fat, *trans* fat, and sodium. Given ongoing consumer research by FDA and others, as well as the plans for examination of consumer use of FOP labeling in the second phase of the committee's work, the committee decided that it would be premature at this time to try to determine the type of FOP symbol or system that would be most useful in informing consumers and facilitating dietary changes. Because of the diversity of system types, the committee was unable to suggest a universal set of criteria that can be used across all FOP rating systems. However, the committee did examine how criteria might be set for various system types. These considerations might serve as a basis for setting future FOP criteria once consumer research and testing results can determine which formats are most appropriate.

Conclusion 6: Based on the committee's review, several options exist for setting criteria for two types of rating systems (nutrient-specific information and a summary indicator based on nutrient thresholds), but further testing of consumer use and understanding is required to assess their overall viability.

The committee identified six options for setting criteria for two system types: four options for setting criteria for nutrient-specific information systems and two options for a summary indicator based on threshold systems (see Chapter 7). The committee did not find readily apparent options for setting criteria for the other types. Algorithm-based summary indicators would not be ideal because they would need to assume that the effects of saturated fat, *trans* fat, and sodium are additive for overall health outcomes, which is not the case. For systems based on food group information, no options could be identified that would provide sufficient information on the nutrients of concern.

All options include a declaration of calories and serving size, which is consistent with Conclusion 3. The four options for nutrient-specific information systems have varying levels of complexity in providing specific information on saturated fat, *trans* fat, and sodium. In characterizing "low" levels of nutrients, government regulated definitions for "low" can be used. "High" levels could be set using regulated criteria already in place for determining when

disclosure statements must accompany nutrient content claims because a given food exceeds prescribed levels for nutrients of concern. Since no claim criteria or disclosure levels exist for *trans* fat and because saturated fat and *trans* fat are both fats of concern, it might be reasonable to combine these components and use their combined content for characterizing levels. The two options identified for developing a nutrient threshold-based summary indicator are (1) to set the same criteria across all foods to allow for comparison of foods across the supermarket and (2) to develop varied criteria across food categories to make the criteria more or less stringent based on the characteristic attributes of the food category.

PLANS FOR PHASE II

The second phase of this study focuses on assessing consumer use and understanding of FOP symbols. The committee will draw on this first phase report as it considers: 1) which systems and symbols are most effective with consumer audiences and best promote health, 2) how to maximize their use, and 3) the potential benefits of a single, standardized front-label food guidance system regulated by the Food and Drug Administration.

The approach to the task includes gathering information from relevant consumer behavior literature and experts in relevant fields, including new research on FOP undertaken FDA as well as from available research from the United States and internationally. Information-gathering will include a workshop in October 2010 on *Consumer Behavior Research and Front of Package Nutrition Rating Systems and Symbols--What do consumers know, understand, and use?* Questions of interest to the committee are given in Chapter 7. The committee will be attentive to research related to consumer literacy and numeracy, as well as usability of labels by various subgroups in the population including children and adolescents. The report of the second phase is due in fall 2011.

CLOSING REMARKS

No front-of-package system is perfect—each has strengths and limitations that must be weighed against the purposes of FOP systems. Given current public health needs, FOP systems may have the greatest potential benefit if the nutrition components included are limited to those most closely related to prominent public health conditions. As implied throughout this report, decisions about which nutrients to include in FOP systems and about the underlying nutrition criteria would benefit from grounding in nutrition science as based on current consensus documents on the dietary needs of the U.S. population. Because nutrition science and labeling regulations change, it would be useful to consider developing a formalized process for reassessment of a system's nutrient criteria. Further, to ensure that labeled products actually meet FOP nutrition criteria, it will be important that the criteria be transparent and publically available, with analytical detections methods included.

Additionally, research is needed to determine the most effective way of presenting the ratings to consumers so they can make food choices that contribute to a healthy diet. As noted, some research is currently being conducted by the FDA, academic institutions, and industry and can factor into future FOP system development and adjustments. The committee welcomes such information and data as it gathers information for the second phase.

1
Introduction

Food packages have long included nutrition messages to consumers, whether to provide the consumer with nutrition information or to help market food products. The Nutrition Labeling and Education Act of 1990 (NLEA) amended the Federal Food, Drug, and Cosmetic Act to require that labels of most packaged food products regulated by the Food and Drug Administration (FDA) include a standardized nutrition label on which manufacturers are required to disclose certain nutrition information; that nutrient content claims be made only if the claims have been defined in regulations; and that health claims be used only in accordance with regulations.[1] While the statute does not apply to the labeling of meat and poultry regulated by the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA), that agency issued regulations that parallel, to the extent possible, FDA's nutrition labeling regulations.[2] Increasingly, however, unregulated nutrition information and symbols have been placed onto the front of food packages. The incorporation of these nutrition messages and symbols raised questions about reliable sources of information to guide product selection. In response, food manufacturers, health organizations, and others have developed systems and symbols for the front of the package (FOP or front of pack) with the intent of helping the consumer make healthier choices, ideally in the context of healthy diets. The end result, however, has been increasing concern from critics and the media that consumers are becoming confused as the number of systems and symbols has proliferated, each using different and often conflicting criteria.

FOP labeling has the potential to provide useful information to consumers. If standardized in an easy-to-read format and focused on critical information, it could provide a convenient educational tool to help consumers make healthful choices. In addition, having key nutrition information displayed prominently on the front of food packages could encourage manufacturers to reformulate products. Recognizing this, FDA of the Department of Health and Human Services and USDA have begun work on developing a voluntary FOP nutrition label that is "driven by sound nutrition criteria, consumer research, and design expertise."[3] Their stated goal for an FOP system is "to increase the proportion of consumers who readily notice, understand, and use the available information to make more nutritious choices for themselves and their families, and thereby prevent or reduce obesity and other diet-related chronic disease."

THE CHARGE TO THE COMMITTEE AND THE STUDY PROCESS

As a step toward determining how FOP systems should be used in the future, in FY 2009 the Congress directed the Centers for Disease Control and Prevention (CDC) to undertake a study

[1] Federal Food, Drug, and Cosmetic Act, Sec. 403(q) and (r).
[2] 58 FR 632.
[3] 75 FR 22602.

BOX 1-1
Statement of Task

The committee was charged with the following tasks:

- Identify front-of-package systems being used by manufacturers, supermarkets, health organizations, and governments in the United States and abroad;
- Consider the purpose and overall merits of front-label icons;
- Identify the criteria underlying the systems and evaluate their scientific basis;
- Consider advantages and disadvantages of various approaches for adults and children; and
- Using knowledge gained from its compilation and assessment of front-of-package systems, plan the second phase, which would consider the potential benefits of a single, standardized front-of-package food guidance system regulated by the FDA and would develop conclusions about which system or systems are most effective in promoting health and how to maximize the use and effectiveness of the systems.

with the Institute of Medicine (IOM) that would examine and provide recommendations regarding FOP nutrition rating systems and symbols.[4] In FY2010 the Congress directed the CDC to continue the study.[5] The first phase of the study, described in this report, was undertaken with support from CDC and FDA. An ad hoc committee was convened to review systems being used by manufacturers, supermarkets, health organizations, and governments in the United States and abroad and the overall merits of front-label nutrition icons, the advantages and disadvantages of various approaches, and the potential benefits of a single, standardized front label food guidance system regulated by the Food and Drug Administration. The charge to the committee was directed to FOP nutrition rating systems and symbols on labels of FDA-regulated food products. The committee recognizes that FSIS has responsibility for labels on packaged meat and poultry products using a prior label approval process. While the emphasis in this report is on FDA-regulated foods, the committee anticipates that its conclusions also will be pertinent to food products regulated by USDA.

In accordance with the IOM committee process, a committee was appointed to undertake the study. The statement of task for the study is in Box 1-1. A second phase, begun in September 2010, will draw from the Phase I report and consider (1) which icons are most effective with consumer audiences, (2) systems and icons that best promote health and how to maximize their use, and (3) the potential benefits of a single, standardized front-label food guidance system regulated by the FDA.

[4] Explanatory Statement Submitted by Mr. Obey, Chairman of the House Committee on Appropriations, Regarding HR 1105, Omnibus Appropriations Act, 2009. Division F—Labor, Health and Human Services and Education, and Related Agencies Appropriations, p. 1398.
[5] House Report 111-366, Conference Report to accompany H.R. 3288, ordered to be printed December 8, 2009.

The members of the Phase I committee had expertise in the areas of nutrition sciences, dietary assessment and dietary reference intakes, nutrition and health communication, consumer education, and nutrition labeling. Biographical sketches of the committee are in Appendix E.

In accordance with the IOM's contractual agreements with the sponsors, the committee met over a seven-month period for this first phase activity to consider its scope of work, review the nutrition science behind FOP systems, and develop its findings and conclusions. Four in-person meetings were held, along with several committee conference calls. One meeting included a public workshop to which experts on FOP systems were invited to make presentations and discuss topics of relevance. A public comment period was held during the workshop, and interested individuals and organizations were invited to present both oral and written comments to the committee. Questions posed to developers and administrators of a number of FOP systems during preparations for and as part of the Phase I public workshop are shown in Box 1-2. The names of workshop speakers and their presentation topics can be found in Appendix D.

In addressing its task, the committee reviewed a number of publicly available materials including journal articles and reports related to nutrition labeling and FOP rating systems and symbols; materials submitted to the committee's public access file; and information on existing systems from system websites, promotional materials, and public statements. The committee also reviewed the detailed algorithms of the Guiding Stars and NuVal rating systems, which are considered proprietary by Guiding Stars and NuVal. Finally, the committee gained additional insights on the development of certain existing programs during phone conversations between a few committee members and FOP system developers and administrators that were held in preparation for the public workshop.

BOX 1-2
Questions of Interest for April 2010 Workshop

Questions specific to system developers:

- The genesis of the labeling system: What made you think about developing a front-of-package labeling system?
- The perceived strengths and limitations of the system: What process did you use to come up with the symbol system you chose? What are the strengths of this approach? What are some of the limitations? What did you consider and rule out? Why did you rule it out?

Questions to system developers and other researchers:

- The potential benefits of front-of-package labeling: What are the main benefits to consumers of the information provided by various systems?
- Information about the consumer research conducted to develop and evaluate the labeling system: What sort of consumer or audience research has been used to test existing and proposed FOP symbols? What has been learned? What methodologies have been employed in FOP research, including sample size, sample characteristics, how the sample was recruited, and analysis plan? Has testing been conducted to see if the information provided by FOP symbols leads to the anticipated outcomes? What audiences have been included in research on FOP symbols? Why were these audiences chosen? To what extent have low-income populations, racial and ethnic minorities, non-English speakers, children and adolescents, or any other specific subpopulations been included in FOP research?

The process of identifying the systems to review began with internet searches using search terms including, but not limited to, "front-of-pack label," "nutrition rating system," "front panel symbol/system," and "shelf tag system/symbols." It was augmented by suggestions from committee members and others and grocery store visits to search for existing systems. The process found a number of systems from the United States and abroad. As details of systems were examined, the committee found that the systems fell into three distinct categories. The 20 systems highlighted in this report represent the varied systems both nationally and abroad. The committee found that differences in types began to diminish as additional systems were evaluated, providing little or no new information to be gained. The committee did not undertake original research. For simplicity, sources for each system's nutrient criteria are listed at the beginning of Appendix C.

The charge to the committee included the task to consider the advantages and disadvantages of various approaches for adults and children. However, the committee decided that from a nutritional perspective, the same overall nutritional approach applied to children and adults (Conclusion 1). Thus, it did not consider children and adults separately. This perspective is reinforced by the historical focus of the *Dietary Guidelines for Americans* on recommendations for a general population 2 years and over and the Nutrition Facts panel oriented to nutritional needs for the general population 4 and above. The committee will explore consumer behavior issues related to children in the second phase (see Chapter 7 for a description of Phase II activities).

Once the committee completed its initial draft report, external reviewers approved by the IOM and the National Research Council (NRC) individually reviewed the draft report. These reviewers remained anonymous until the report was finalized. The review process is intended to ensure that the report addresses the committee's charge, that the conclusions are based on scientific evidence, and that the report is presented in an effective and impartial manner.

Upon completion of this first phase of this study, the focus of the study will shift to a greater emphasis on understanding which symbols are most effective with consumers. The intention is that the nutritional considerations of the first phase will contribute toward the exploration of consumer perceptions, practices, and behavior in the second phase, and a number of questions to be addressed have been raised by the committee. These are described in Chapter 7.

GUIDING PRINCIPLES

In assessing FOP nutrition rating systems and symbols, one must consider both nutrition science aspects and consumer aspects. This first phase focuses on the nutrition science aspects. Phase II and its report will consider the consumer aspects of developing FOP nutrition rating systems and symbols.

In evaluating the nutrition science of FOP systems and symbols, the committee adopted definitions of common terms along with four guiding principles to set the stage for the nutritional assessment of FOP systems and symbols. These principles were intended to assist in identifying the systems and elements of systems that were most important for improving the health of the American public. In addition, these guiding principles were intended to assist in identifying system criteria that could be realistically implemented in the current food environment. The guiding principles are:

- A well-balanced, high-quality diet consistent with the *Dietary Guidelines for Americans* is essential for the health of Americans, and front-of-package labeling is one tool among

many geared toward helping Americans make healthful choices. Other such tools include MyPyramid, the Nutrition Facts panel, and health and nutrient content claims.

- Front-of-package systems will focus on nutrients or food components that are most strongly associated with the diet-related health risks affecting the greatest number of Americans.
- The information highlighted in FOP systems will be consistent with the Nutrition Facts panel.
- Front-of-package systems will apply to as many foods as possible.

FOP nutrition rating systems, for the purpose of this report, include systems and symbols which indicate energy content or that state that a product meets system-specific criteria either for nutrients to limit or nutrients to encourage or both. While symbols are most often placed on the front, they may also be found on the side, top, or back panels of food packages or displayed on shelf tags in food retail stores.

ORGANIZATION OF THE REPORT

This report is organized as follows: Chapter 1 provides an introduction to the work of the committee. Chapter 2 offers a history of nutrition labeling, and Chapter 3 discusses the emergence of FOP systems. Chapter 4 provides an overview of health and diet in the United States. Chapter 5 discusses the purpose and merits of FOP systems. Chapter 6 presents the committee's review of important scientific issues with implications for FOP nutrition rating systems and symbols and also identifies various system strengths and limitations. Chapter 7 presents the committee's conclusions. Five appendixes provide additional information for the reader. Appendix A provides a glossary as well as an extensive list of abbreviations and acronyms. Appendix B includes requirements for most FDA-regulated nutrient content claims. Appendix C contains sample product evaluations drawn on in Chapter 6. Appendix D provides the workshop program, and Appendix E is the committee biographical sketches.

2
History of Nutrition Labeling

Up to the late 1960s, there was little information on food labels to identify the nutrient content of the food. From 1941 to 1966, when information on the calorie or sodium content was included on some food labels, those foods were considered by the Food and Drug Administration (FDA) to be for "special dietary uses," that is, intended to meet particular dietary needs caused by physical, pathological, or other conditions.[1,2,3] At that time meals were generally prepared at home from basic ingredients and there was little demand for nutritional information (Kessler, 1989). However, as increasing numbers of processed foods came into the marketplace, consumers requested information that would help them understand the products they purchased. (WHC, 1970). In response to this dilemma, a recommendation of the 1969 White House Conference on Food, Nutrition, and Health was that FDA consider developing a system for identifying the nutritional qualities of food:

> Every manufacturer should be encouraged to provide truthful nutritional information about his products to enable consumers to follow recommended dietary regimens.(WHC, 1970)

This chapter provides a history of the milestones in nutrition labeling since 1969. These events are also detailed in the annex to this chapter.

VOLUNTARY NUTRITION LABELING

In response to the White House Conference, FDA developed a working draft of various approaches to nutrition labeling and asked for comment by nutritionists, consumer groups, and the food industry. Then in 1972 the agency proposed regulations that specified a format to provide nutrition information on packaged food labels. Inclusion of such information was to be voluntary, except when nutrition claims were made on the label, in labeling, or in advertising, or when nutrients were added to the food. In those cases, nutrition labeling would be mandatory.[4] This action was based on Section 201(n) of the Federal Food, Drug, and Cosmetic Act of 1938 (FD&C Act)[5] that stated that a food was misbranded if it "fails to reveal facts material in the light of such representation." FDA argued that when a manufacturer added a nutrient to a food or made claims about its nutrient content, nutrition labeling was necessary to present all of the material facts, both positive and negative, about that food (Hutt, 1995).

When finalized in 1973, these regulations specified that when nutrition labeling was present on labels of FDA-regulated foods, it was to include the number of calories; the grams of protein, carbohydrate, and fat; and the percent of the U.S. Recommended Daily Allowances (U.S. RDA)

[1] Federal Food, Drug, and Cosmetic Act, Sec. 411(c)(3) (21 USC Part 350).
[2] 6 FR 5921.
[3] 31 FR 8521.
[4] 37 FR 6493.
[5] Federal Food, Drug, and Cosmetic Act, Sec. 201(n).

of protein, vitamins A and C, thiamin, riboflavin, niacin, calcium, and iron.[6] Sodium, saturated fatty acids, and polyunsaturated fatty acids could also be included at the manufacturer's discretion. All were to be reported on the basis of an average or usual serving size. The U.S. RDAs were based on the Recommended Dietary Allowances (RDA) set forth by the National Academy of Sciences (NAS) in 1968 (NRC, 1968). Because of the need for a single set of standard nutrient requirements for nutrition labeling purposes, the values selected for the U.S. RDA were generally the highest value for each nutrient given in the RDA table for adult males and non-pregnant, non-lactating females. However, values for calcium and phosphorus were limited to 1 g because of their physical bulk and solubility. The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) provided for nutrition labeling of meat and poultry products in a similar manner through policy memoranda.[7]

As can be seen in the annex to this chapter, few changes were made in nutrition labeling regulations over the next decade (Hutt, 1995; Scarbrough, 1995). FDA, USDA, and the Federal Trade Commission (FTC) held hearings in 1978 to gather information on food labeling issues and suggestions on how to make improvements.[8] The vast majority of comments from the hearing favored mandatory nutrition labeling but also suggested making changes to the format to make it more useful.[9]

The Rise in Use of Undefined Nutrient Content and Health Claims on Labels

After 1973, scientific knowledge about the relationship between diet and health grew rapidly, and, as a result, consumers wanted to have more information on food labels, particularly on the labels of processed and packaged foods. Food manufacturers were eager to respond to the consumer interest and did so in a variety of ways, often through the use of an assortment of new, undefined claims on product labels that attempted to state or imply something about the special value of the food, such as "extremely low in saturated fat," in order to catch consumers' attention (Taylor and Wilkening, 2008a). The proliferation of ambiguous claims on labels and in advertising led to charges that the government was tolerating claims that were "at best confusing and at worst deceptive economically and potentially harmful" (IOM, 1990).

In addition to making claims about the nutritional content of foods, some food manufacturers were also interested in making label claims about the health benefits of their food products. FDA's regulations had prohibited the explicit discussion of disease or health on food labels since passage of the FD&C Act in 1938.[10] The implementing regulations for that act stated that a food was deemed to be misbranded if its labeling "represents, suggests, or implies: That the food because of the presence or absence of certain dietary properties is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom."[11] A food making such claims was considered to be misbranded or an illegal drug (Shank, 1989). This policy began when many of the links between diet and disease had yet to be established or substantiated. It helped prevent misleading and potentially harmful claims, but it also prevented useful and truthful claims from being made (Kessler, 1989). The agency's policy was challenged in 1984

[6] 38 FR 6493.
[7] 56 FR 60302 at 60303.
[8] 43 FR 25296.
[9] 44 FR 75990.
[10] Federal Food, Drug, and Cosmetic Act, Sec. 403.
[11] 38 FR 6950 at 6961, paragraph (i) and (i)(1).

when the Kellogg Company, in cooperation with the National Cancer Institute, began a labeling campaign using the back panel of a high-fiber breakfast cereal to link fiber consumption to a possible reduction in the risk of certain cancers. That campaign changed food labeling and marketing dramatically, as other companies, in the absence of regulatory action, began making similar claims (Geiger, 1998).

The Initiation of Rulemaking for Nutritional Claims

In August 1987, FDA published a proposed rule to change its policy by permitting health claims on food labeling if certain criteria were met.[12] The proposal generated a large number of thoughtful and often conflicting comments and was followed by a series of meetings between the agency and the food industry, consumer groups, academia, and health professionals (Shank, 1989). A congressional hearing was also held in December 1987. Subsequently, in February 1990, FDA withdrew its original proposal and published a new proposal that defined appropriate health claims more narrowly and set new criteria to be met before allowing a claim.[13] During this time FDA also was acting to increase the availability of nutrition information and to provide for more truthful nutritional claims on all foods. In an effort to respond to consumers and the food industry, FDA initiated rulemaking to provide more flexibility in making claims on foods that could be useful in reducing or maintaining body weight or calorie intake,[14] to establish policies concerning the fortification of foods,[15] to include sodium content in nutrition labeling and provide for claims about sodium[16] and cholesterol content,[17] and to allow for food labeling experiments, such as experiments on supermarket shelf labeling.[18]

The surge in consumer interest in nutrition that was fueling the food industry's desire to highlight the positive nutritional attributes of food products was due, in part, to the publication in the late 1980s of two landmark consensus reports on nutrition and health.[19] *The Surgeon General's Report on Nutrition and Health* (HHS, 1988) and the National Research Council's (NRC's) report *Diet and Health: Implications for Reducing Chronic Disease Risk* (NRC, 1989a) emphasized the relationship between diet and the leading causes of death among Americans (e.g., heart disease, cancers, strokes, and diabetes). They suggested that changes in current dietary patterns—in particular, reduced consumption of fat, saturated fatty acids, cholesterol, and sodium and increased amounts of complex carbohydrates and fiber—could lead to a reduced incidence of many chronic diseases. The Surgeon General's report also called on the food industry to reform products to reduce total fat and to carry nutrition labels on all foods. These reports made useful suggestions for planning healthy diets. However, without specific nutrition information on food labels, consumers were unable to determine how certain individual foods fit into dietary regimens that followed the recommendations of these reports. Major changes in nutrition labeling were necessary if food labels were to be useful to consumers interested in adhering to these recommendations.

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[12] 52 FR 28843.
[13] 55 FR 5176.
[14] 43 FR 43248 and 43261.
[15] 45 FR 6314.
[16] 47 FR 26580 and 49 FR 15510.
[17] 51 FR 42584.
[18] 69 FR 15236.
[19] 54 FR 32610 (first page, center column).

INITIATIVES TO STANDARDIZE AND REQUIRE NUTRITION LABELING

In the summer of 1989, concerned that food labeling did not allow Americans to take advantage of the latest advances in nutrition, Dr. Louis W. Sullivan, then Secretary of the U.S. Department of Health and Human Services (HHS), directed FDA to undertake a comprehensive initiative to revise the food label(FDA, 1990).[20] He later stated that, "As consumers shop for healthier food, they encounter confusion and frustration… The grocery store has become a Tower of Babel and consumers need to be linguists, scientists and mind readers to understand the many labels they see" (HHS, 1990). This new food labeling initiative began with the publication of an advance notice of proposed rulemaking in August 1989 asking for public comment[21] and a notice of public hearings to be held across the country to address the content and format of the nutrition label, ingredient labeling, and both nutrient content and health claims.[22] Unlike the situation surrounding the follow-up to the 1978 public hearings when few regulatory changes were made, in 1989 a number of forces, such as advances in science, recommendations for dietary change, food industry use of the label, and the entry of state governments into the food labeling arena, coalesced to propel important changes in the regulatory framework for food labeling (Scarbrough, 1995).

Developing Reference Values

By July 1990, FDA had published proposed rules for the mandatory nutrition labeling of almost all packaged foods.[23] FDA acknowledged that there was some question as to whether the agency had the legal authority under the FD&C Act to mandate nutrition labeling on all foods that were meaningful sources of calories or nutrients, so comments were requested on that issue as well as on the proposed nutrient requirements. Simultaneously, proposals were also published to replace the U.S. RDAs[24] and to establish regulations for determining serving sizes to be used in nutrition labeling.[25] In replacing the U.S. RDAs, FDA sought to base new values for vitamins and minerals, to be known as Reference Daily Intakes (RDIs), on the most recent RDAs (NRC, 1989b). In addition, FDA proposed to establish new values to be known as Daily Reference Values (DRVs) for food components considered important for good health (fat, saturated fatty acids, unsaturated fatty acids, cholesterol, carbohydrate, fiber, sodium, and potassium) for which RDAs had not been established by the NAS (also see Page 6-15). While it was necessary to establish two separate categories of nutrients (RDIs and DRVs) for regulatory purposes, FDA proposed to group the nutrients into a single set of reference values known as "Daily Values" for use in presenting nutrition information on the food label.

Establishing Required Nutrients for Food Labels

In determining which nutrients and food components to require on the label, FDA looked to *The Surgeon General's Report on Nutrition and Health* (HHS, 1988) and the NRC's report *Diet and Health: Implications for Reducing Chronic Disease Risk* (NRC, 1989a). FDA proposed that calories and nutrients would be required to be listed on nutrition labels if (1) they were of public

[20] 55 FR29487.
[21] 54 FR 32610.
[22] 54 FR 38806.
[23] 55 FR 29487.
[24] 55 FR 29478.
[25] 55 FR 29517.

health significance as defined in these two documents, and (2) specific quantitative recommendations were set by NAS or other scientific organizations. Accordingly, FDA proposed the mandatory listing of calories, fat, saturated fat, cholesterol, sodium, carbohydrate, fiber, protein, vitamins A and C, calcium, and iron. Additional nutrients were required to be listed when added to a food or when claims were made about them.

FDA considered the addition of total sugars to the list of required food components to declare on the label; but total sugars did not meet the criterion of having specific quantitative recommendations for intake by a scientific organization. Accordingly, the inclusion of total sugars on the nutrition label was made voluntary unless a claim was made about the sugars content of the food. Some of the comments received suggested that nutrition labeling of added sugars content also be required, but FDA did not propose to do so. The agency based its decision on (1) the fact that there was no scientific evidence that the body makes any physiological distinction between added and naturally occurring sugars; (2) a concern that the declaration of added sugars only would under-represent the sugars content of foods high in naturally occurring sugars, thus misleading consumers who may need to be aware of total sugars; and (3) an expectation that with mandatory nutrition labeling, consumers could differentiate between sugar-containing foods with high versus low nutrient content and could therefore determine which foods had the highest nutrient density.[26]

Moving Toward a Mandatory and Uniform Nutrition Labeling Policy

At the same time that FDA was developing its July 1990 proposal, a committee was formed at the Institute of Medicine (IOM), the health arm of NAS to consider how food labels could be improved to help consumers adopt or adhere to healthy diets. FDA and FSIS/USDA sponsored the study based on the belief that changes in eating habits could improve the health of Americans and that food labeling could aid consumers in making wise dietary choices. The committee's report, *Nutrition Labeling: Issues and Directions for the 1990s*, was issued in September 1990 (IOM, 1990). It recommended that FDA and FSIS adopt regulations to institute mandatory and uniform nutrition labeling for almost all packaged foods, and it made recommendations concerning various facets of nutrition labeling, including the content and presentation of information, in order to support findings and recommendations of *The Surgeon General's Report on Nutrition and Health* (HHS, 1988) and the NRC's report *Diet and Health: Implications for Reducing Chronic Disease Risk* (NRC, 1989a). It also recommended that FDA and USDA should define descriptors (e.g., "high," "good source of") for the content of nutrients such as fat, cholesterol, sodium, and micronutrients.

PASSAGE OF THE NUTRITION LABELING AND EDUCATION ACT (NLEA) OF 1990

Congressional concerns about food labeling had been building for some. Members of Congress were aware of consumer and industry interest in the subject and had responded by asking the General Accounting Office to investigate labeling issues and by introducing a variety of bills on the subject (Scarbrough, 1995). This culminated in November 1990 with passage of the NLEA,[27] the most significant food labeling legislation in 50 years. The NLEA amended the Federal Food, Drug, and Cosmetic Act[28] to give FDA explicit authority to require nutrition

[26] 55 FR 29487.
[27] Nutrition Labeling and Education Act of 1990. Public Law 101-535, 104 Stat 2353.
[28] Federal Food, Drug, and Cosmetic Act, sec. 403(q) and (r).

labeling on most food packages and specified the nutrients to be listed in the nutrition label. It also required that nutrients be presented in the context of the daily diet; specified that serving sizes should represent "an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food"; and provided for a voluntary nutrition labeling program for raw fruits, vegetables, and fish. It also required standard definitions to be developed that characterized the level of nutrients and required that FDA provide for approved health claims. The NLEA's requirements for the content of the nutrition label were very similar to those in FDA's 1990 proposal except that the NLEA included complex carbohydrates and sugars in the list of required nutrients. It also permitted the agency to add or delete nutrients based on a determination that such a change would "assist consumers in maintaining healthy dietary practices." On November 27, 1991, FDA proposed 26 new food label regulations to implement the NLEA. These included a new proposal on nutrition labeling and the establishment of RDIs and DRVs[29] and a proposal on serving sizes.[30] General principles for nutrient content claims and the definition of terms for claims to be allowed were also proposed,[31] as were general principles for health claims,[32] followed by individual proposals pertaining to ten possible topic areas for health claims, such as dietary fiber and cancer, which were identified in the NLEA. While the format of the nutrition label was discussed in its November 27, 1991 proposal, FDA published a more detailed proposal for the format on July 20, 1992.[33] The purpose of FDA's proposals was threefold: to clear up confusion that had surrounded nutrition labeling for years, to help consumers choose healthier diets, and to give food companies an incentive to improve the nutritional qualities of their products (Kessler, 1995).

The NLEA pertains only to those labels of food products regulated by FDA, which has label authority over the majority of foods. However, meat and poultry product labels are under the authority of FSIS in the USDA, and alcoholic beverage product labels are under the authority of the Alcohol and Tobacco Tax and Trade Bureau of the Department of the Treasury, formerly the Bureau of Alcohol, Tobacco and Firearms. Leadership at USDA strongly supported the claim that consumers need help to adopt and adhere to healthy diets. For this reason and to provide consistent regulation for all foods, the decision was made to have FSIS coordinate efforts with FDA to implement the requirements of NLEA for meat and poultry product labels (McCutcheon, 1995). To accomplish this, FSIS first published an advance notice of proposed rulemaking to solicit comments to assist in developing regulations for the nutrition labeling of meat and poultry products.[34] Then, on November 27, 1991, in conjunction with FDA, FSIS published proposed rules to establish a voluntary nutrition labeling program for single-ingredient raw meat and poultry (consistent with NLEA's provision for raw fruits, vegetables, and fish) and mandatory nutrition labeling for all other meat and poultry products.[35] It also proposed the adoption of most of FDA's proposals in regard to nutrient content claims and proposed additional definitions for "lean" and "extra lean" as unique descriptors for meat and poultry products.

The NLEA established very tight timeframes for implementing the provisions of the act. It required FDA to publish proposed regulations within 12 months and final regulations within 24

[29] 56 FR 60366.
[30] 56 FR 60394.
[31] 56 FR 60421 and 60478.
[32] 56 FR 60537.
[33] 57 FR 32058.
[34] 56 FR 13564.
[35] 56 FR 60302.

months of enactment of the act.[36] If the agency failed to publish final regulations as specified, the proposed rules were to become final rules. With those time constraints and over 40,000 written comments on the proposed rules to respond to, FDA and FSIS mobilized their staffs to accomplish the task.

Declaration of Nutrient Content

Final regulations for both agencies were published on January 6, 1993, that mandated nutrition labeling in the form of a Nutrition Facts panel on most packaged foods.[37] Exemptions were allowed for foods that were insignificant sources of calories or nutrients, foods shipped in bulk for further processing, restaurant foods, foods manufactured by some small businesses, medical foods, and infant formula (the latter having other specific rules for labeling). Nutrients to be listed on nutrition labels included calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamins A and C, calcium, and iron. By way of exception when present at insignificant amounts and when no claims were made about them, regulations allowed the declaration of calories from fat, saturated fat, cholesterol, dietary fiber, sugars, vitamins A and C, calcium or iron to be omitted if a footnote was added at the bottom of the list of nutrients stating "Not a significant source of ____" with the blank filled in by the name of the nutrients(s) omitted. If they chose to do so, manufacturers were permitted to list calories from saturated fat, polyunsaturated and monounsaturated fatty acids, potassium, soluble and insoluble fiber, sugar alcohols, other carbohydrates, and any vitamins and minerals for which RDIs were established; labeling became required, however, if vitamins and minerals were added to the product or if claims related to vitamin or mineral content were made. In order to reduce consumer confusion and avoid the potential for misleading labels, no other nutrients were allowed in the Nutrition Facts panel.

Despite being specified in the NLEA, complex carbohydrates were not included in the allowed list of nutrients. Comments had convinced FDA that there was no consensus on a definition for the term "complex carbohydrates" as it related to physiological effects, health benefits, or dietary guidance. Instead, the rules allowed for the voluntary listing of "other carbohydrates" to be calculated as that amount of carbohydrate remaining after subtraction of the amount of dietary fiber, sugars, and sugar alcohols from total carbohydrate.

Just as with the FDA proposals in 1990, the declaration of sugars also generated discussion in comments to the 1991 proposals to implement the NLEA. Based on comments received, the proposed definition of sugars as the sum of all free mono- and oligo-saccharides through four saccharide units was changed to the sum of all free mono- and disaccharides. Other comments had recommended that added sugars should be listed rather than total sugars since there was both a dietary recommendation to use sugars in moderation and a dietary recommendation for increased consumption of fruits, which are sources of naturally occurring sugars (HHS/USDA, 1990). Opposing comments reiterated concerns expressed in the proposed rule that the body makes no physiological distinction between the two types of sugars and that under-representing total sugars content could be misleading to consumers concerned about total intake of sugars. The determinative issue, however, was that there were no analytical methods for distinguishing between the two types of sugars. Product labels are checked for accuracy and compliance by FDA through laboratory analysis of the food product as packaged. That analysis yields only a

[36] *Nutrition Labeling and Education Act* of 1990. Public Law 101-535, 104 Stat 2353, Sec. 2(b).
[37] 58 FR 2079 (FDA) and 58 FR 632 (USDA).

value for total sugars. FDA policy is that it should not promulgate regulations that it cannot enforce. Accordingly, the decision was made to list only total sugars in the Nutrition Facts panel.

Several comments on the 1991 proposed rule suggested that *trans* fatty acids (*trans* fat) should be included in the nutrition label, either with saturated fat or as a separate category. FDA disagreed at the time because reports were inconsistent regarding the effects of *trans* unsaturated fats on blood cholesterol levels in humans (LSRO/FASEB, 1985; Grundy and Denke, 1990). However, soon afterwards, new data emerged indicating that *trans* fats raise LDL-cholesterol concentrations nearly as much as cholesterol-raising saturated fats (NIH, 1994). Based on its own independent evaluation of studies on the effects of *trans* fat on blood cholesterol levels, FDA concluded that under conditions of use in the United States, *trans* fats did contribute to increased serum LDL-cholesterol, which increases the risk of coronary heart disease. As a result, a proposed rule was published in 1999 to modify the Nutrition Facts panel to include *trans* fats on food products regulated by FDA.[38] In 2003, FDA issued a final rule requiring *trans* fats to be listed on a separate line immediately under saturated fat whenever present in amounts of 0.5 g or more per serving, except that it must always be listed if claims are made on the label about it.[39] USDA regulations permit, but do not require, *trans* fat to be listed on nutrition labels of meat and poultry products provided the declaration and definitions of trans fat adhere to the FDA regulations.[40]

Determination of Reference Values

As discussed above, for declaring amounts of vitamins and minerals FDA had proposed replacing U.S. RDAs with RDIs based on the most current scientific knowledge as incorporated in the 1989 RDAs from the NAS (NRC, 1989b). It also proposed to use a population-adjusted mean of the RDA values for the various age–sex groups for each nutrient rather than the highest value for each nutrient.[41] However, on October 6, 1992, Congress passed the Dietary Supplement Act of 1992 that, in section 203, instructed FDA not to promulgate for at least one year any regulations that required the use of, or were based upon, RDAs other than those in effect at that time.[42] Inasmuch as the NLEA required that final rules be promulgated by November 6, 1992, FDA was unable to wait long enough to utilize the 1989 RDAs. Instead, FDA proceeded to change the name of the U.S. RDAs to RDIs to reduce confusion with the RDAs developed by the NAS while maintaining the values based on the NAS 1968 RDAs.[43] Once the moratorium on using newer RDA values was over, FDA decided to wait until revisions then in progress at the NAS were finalized. It did, however, proceed to establish RDIs for those nutrients for which RDA values had not been established in 1968: vitamin K, selenium, manganese, chromium, molybdenum, and chloride.[44] The agency also asked the NAS to convene a committee to provide scientific guidance about how to use the new Dietary Reference Intakes from the NAS to update the nutrient reference values used in the Nutrition Facts panel. The committee's report became

[38] 64 FR 62746.
[39] 68 FR 41434.
[40] A Guide to Federal Food Labeling Requirements for Meat and Poultry Products, Available online: http://www.fsis.usda.gov/pdf/labeling_requirements_guide.pdf [accessed September 19, 2010].
[41] 55 FR 29476 and 56 FR 60366.
[42] *Dietary Supplement Act* of 1992, Public Law 102-571.
[43] 58 FR 2206.
[44] 60 FR 67164.

available in 2003 (IOM, 2003). Then, in 2007, FDA issued an advance notice of proposed rulemaking asking for comment on which reference values the agency should use to calculate the percent of daily value in the Nutrition Facts panel and whether certain nutrients should be added or removed from the labels.[45]

Establishment of Daily Reference Values

A challenge presented by the NLEA was the requirement that the nutritional information "be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet."[46] This requirement necessitated reporting in relation to a daily reference value the amounts of all nutrients listed and not just the amounts of vitamins and minerals, as had been done since voluntary nutrition labeling rules were put in place in 1973. In accordance with its 1990 proposal, the final nutrition labeling rules established for the first time reference values, known as Daily Reference Values (DRVs), that would be used in reporting values of total fat, saturated fatty acids, cholesterol, total carbohydrate, dietary fiber, sodium, and potassium—for which RDAs had not been established in 1989—and for protein.[47] The DRVs were based largely on recommendations from *The Surgeon General's Report on Nutrition and Health* (HHS, 1988), the NRC's report *Diet and Health: Implications for Reducing Chronic Disease Risk* (NRC, 1989a), and the National Cholesterol Education Program's "Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction" (NIH, 1990). The recommendations used for total fat were 30 percent of calories or less; for saturated fat, less than 10 percent of calories; for cholesterol, less than 300 mg; for total carbohydrate, 60 percent of calories; for sodium, 2,400 mg; for potassium, 3,500 mg; and for protein, 10 percent of calories (so that calorie-providing nutrients sum to 100 percent of calories). The DRV for fiber, for which the two consensus documents had not provided a recommendation, was instead based on a recommendation in a report of the Life Sciences Research Organization of the Federation of American Societies for Experimental Biology that fiber intake be 10 to 13 g per 1000 calories (LRSO, 1987). No recommendations existed for intake of sugars, so no DRV was established. For those nutrients for which the recommendation was for a percent of calories, the DRVs were based on a caloric intake of 2,000 calories. For example, the level for total fat was derived by calculating 30 percent of 2,000 calories and dividing by 9, which is the number of calories per gram of fat. The resulting value, 66.7 g, was then rounded down to 65 g for ease of use. In an effort to show consumers how the values would differ with different caloric intakes, the regulations called for a footnote on larger food packages that would state, "Your daily values may be higher or lower depending on your calorie needs," followed by a table showing the daily values for both a 2,000- and 2,500-calorie diet.

Basic Format of Nutrition Label

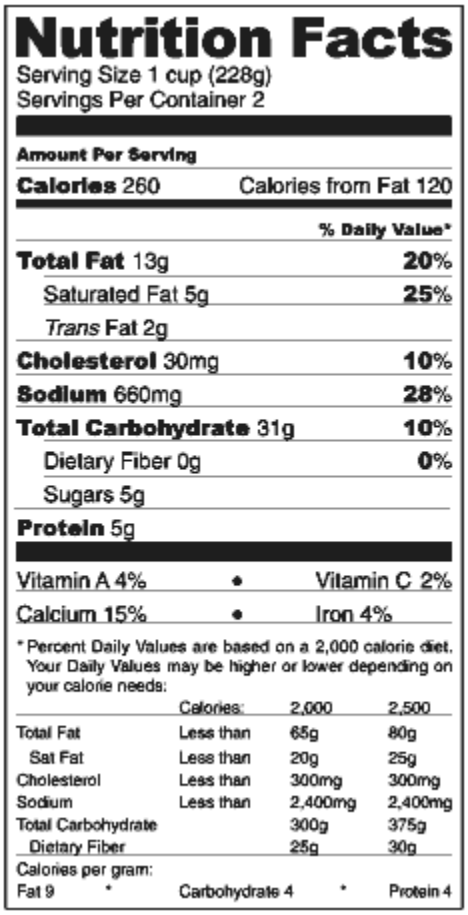
The format to be used for the nutrition label had been a topic of the 1989 advance notice of proposed rulemaking[48] and the public hearings[49] on nutrition labeling. Many speakers at the

[45] 72 FR 62149.
[46] *Nutrition Labeling and Education Act* of 1990. Public Law 101-535, 104 Stat 2353, Sec. 2(b)(1)(A).
[47] 58 FR 2206.
[48] 54 FR 32610.
[49] 54 FR 38806.

public hearings supported a new label format in order to simplify the label and make it more understandable (FDA, 1990). Prior to the 1991 proposals, focus group sessions had been held (Lewis and Yetley, 1992) and experimental studies conducted (Levy et al., 1991, 1996) to determine the effectiveness of various label formats. The results were made available to the public, and comments were requested.[50] FDA also initiated a cooperative pilot program with industry to test alternative formats which led to several industry sponsored studies,[51] and it held a public meeting on the subject.[52] The research showed that graphic presentations, such as pie charts and bar graphs, were not well suited for conveying the diversity and amount of information required on nutrition labels, so FDA looked to a format based more on consumers' ability to use and comprehend numeric values (Scarbrough, 1995). The format proposed in July 1992 was one that included quantitative amounts of macronutrients but that gave particular emphasis to a column of nutrient values expressed as a percent of the label reference value, the RDIs and DRVs, which was to allow consumers to quickly determine if the food contained a little or a lot of a nutrient.[53] At the end of the comment period, when a format had been determined that provided the proper context and emphasis, FDA worked with graphic experts to design the label, taking into account research on comprehension, legibility, and literacy (Kessler et al., 2003).

The format research and comments on the proposed rule had led FDA to conclude that in nutrition labeling a consistent system of percentages makes it possible for virtually all the nutrients on the label to be provided in equivalent units—as a percent of the appropriate RDI or DRV (to be known on the Nutrition Facts panel simply as the "Percent of Daily Value").[54] That consistency is not possible when the list contains nutrients given in different units (e.g., grams and milligrams). Thus, a low value on the list is likely to be a "true" low value within the context of the daily diet, and a high value is likely to be a "true" high value. This consistency also allowed educational programs to be built around the concept that 5 percent or less of any nutrient is a small amount, whereas 20 percent or more is a large amount (Taylor and Wilkening, 2008a). Consumers had often been confused by earlier nutrition label formats when comparing nutrient amounts, such as comparing fat in grams with sodium in milligrams, so the actual quantities were moved adjacent to the name of the nutrient where they would get less attention. To put emphasis on the amount of nutrients in a serving of food "in the context of a total daily diet," the format for the Nutrition Facts panel provided for a separate column for the listing of Percent of Daily Value (% Daily Value or %DV) (see Figure 2-1). Noticeably, a few nutrients are lacking a value in the %DV column. For *trans* fat and sugars, scientific evidence was not sufficient to support the establishment of a RDI or DRV. In the case of protein, a DRV had been established, but the %DV for protein required taking into account protein quality and not just the quantity of protein present. Such a calculation requires the computation of the protein-digestibility-corrected amino acid score for a food, a costly analysis. Because the typical American diet provides enough protein of sufficiently high biological quality to meet the nutritional needs of most persons, protein intake is not a public health concern. Therefore, listing the %DV for protein is voluntary for foods intended for adults and children 4 or more years of age unless a protein claim is made for the product.

[50] 56 FR 23072.
[51] 56 FR 29963.
[52] 57 FR 11277.
[53] 57 FR 32058.
[54] 58 FR 2079.



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

FIGURE 2-1 Nutrition Facts panel.
SOURCE: 21 CFR 101.9(d)(12).

Determination of Serving Size

The serving size of a food product affects virtually every number in the Nutrition Facts panel other than those in the footnote. As a result, the development of regulations prescribing the manner in which it is to be calculated for the wide diversity of foods available in the market was of major importance. The NLEA required that serving sizes be based on amounts customarily consumed[55] rather than on recommended portion sizes, as some comments had suggested, or on a 100-g basis, as is done in some other countries. To determine the amount customarily consumed, FDA utilized food consumption data from USDA's nationwide food consumption and intake surveys, augmented by other sources of information where available.[56] In order to facilitate consumer comparisons, categories of foods that are generally used interchangeably in the diet and that have similar product characteristics were developed so that those foods would have uniform serving sizes. Statistical analyses of consumption data, using the mean, median, and modal values, were then utilized to develop Reference Amounts Customarily Consumed (RACC)

[55] *Nutrition Labeling and Education Act* of 1990. Public Law 101-535, 104 Stat 2353, Sec. 2(a)(q)(1)(A)(i).
[56] 58 FR 2229.

for each category.[57] Procedures for converting the RACC values to serving sizes expressed in common household measures were specified in the regulations.[58]

Single-Serving Containers

Single–serving-size containers proved to be particularly troublesome (Taylor and Wilkening, 2008a). The regulations require that most packages that are less than 200 percent of the applicable RACC must declare the entire package as one serving. If the package is 200 percent or more of the RACC and the whole unit can reasonably be consumed at one time, the manufacturer may, but need not, declare the package as one serving. For products that are more than 200 percent of the RACC yet intended to be consumed by one individual at one time, FDA has encouraged manufacturers to base the nutrition information on the entire contents of food in the container (CFSAN/FDA, 2004; FDA, 2004). Because there is little evidence that this is widely practiced (Taylor and Wilkening, 2008a), FDA asked in a 2005 advance notice of proposed rulemaking for comment on whether its regulations should be changed to require packages that can reasonably be consumed at one eating occasion to provide the nutrition information for the entire package, either alone or in conjunction with a listing of the serving size derived from the RACC.[59] Also, because there is evidence that Americans are eating larger portion sizes than in the 1970s and 1980s, when the food consumption surveys upon which RACCS are based were conducted (Nielsen and Popkin, 2003; Smiciklas-Wright et al., 2003), comments were requested on which RACCs may need to be updated.

Serving Size and Health Outcomes

The increase in portion sizes consumed is considered to be one of many factors leading to increased obesity in the United States (Young & Nestle, 2002). To address the issue of obesity, Mark McClellan, then FDA Commissioner, created a committee in 2003 to outline an action plan to cover critical dimensions of the obesity problem from FDA's perspective and within its regulatory authorities. Among other topics, the committee's report, entitled *Calories Count: Report of the Working Group on Obesity* (FDA, 2004), addressed food labeling issues pertaining to serving sizes and the design of the Nutrition Facts panel. The advance notice of proposed rulemaking mentioned above was an outcome of that report, as was another advance notice asking for comment on ways to increase the prominence of calorie information on the label.[60] At the time of this report, action on those issues is still awaited.

Specification of Nutrient Content Claims

In addition to requiring food labels to contain information on the amounts of certain nutrients, the NLEA also specified that claims characterizing the level of a nutrient may be made on food labels only if the characterization uses terms that have been defined in regulations.[61] The NLEA further specified that claims characterizing the relationship of any nutrient to a disease or health-related condition only be made only in accordance with regulations promulgated under the

[57] 58 FR 2229.
[58] 58 FR 2229.
[59] 70 FR 17010.
[60] 70 FR 17008.
[61] *Nutrition Labeling and Education Act* of 1990. Public Law 101-535, 104 Stat 2353, Sec. 3(a)(r)(1).

act; however, such claims, known as "health claims," are not the subject of this report and will not be discussed further here. The intent of this section of the NLEA was to allow meaningful comparisons of foods and to encourage the consumption of foods with the potential to improve dietary intake and reduce chronic disease (Taylor and Wilkening, 2008b).

Defining Descriptive Nutrient Content Claims

The act specifically required that definitions for the terms "free," "low," "light," "reduced," "less," and "high" in relation to nutrients required to be listed in the Nutrition Facts panel.[62] In addition, to allow for the use of claims that were being used on labels of conventional foods in the marketplace, FDA and USDA also defined the terms "good source," "more," "fewer," "lean," and "extra lean"[63] when implementing the NLEA and provided for the use of synonyms for many of the terms. Subsequently, both agencies also defined the implied claim "healthy."[64] The current definitions for all these claims on FDA-regulated food items can be found in Appendix B of this report. A full discussion of the rationale behind the definition of each claim can be found in the preambles to the proposed (1991) and final (1993) rules (see Annex). It should be noted that the definitions for claims on individual food products differ in some respects from those for meal and main dish items. Meal and main dish items are combinations of foods intended to contribute a larger portion of the total daily diet, which necessitates separate criteria, often based on an amount per 100 g, in order to provide for appropriate claims.[65]

Briefly, in developing the criteria for claims, FDA took into account the dietary recommendations for each nutrient; the amounts of the nutrient present per RACC, per serving size, and per 100 g; the distribution and abundance of the nutrient in the food supply; analytical methods; and the presence of other nutrients that could possibly cause a particular claim to be misleading.

Defining Levels of Nutrients to Limit

In the case of "free" claims, levels of each nutrient were selected that were at or near the reliable limit of detection for the nutrient in food and that were considered to be dietetically trivial or physiologically inconsequential.[66] In the case of foods that are inherently free of a nutrient, regulations require that the claim must refer to all foods of that type rather than to a particular brand to which the labeling is attached (e.g., "broccoli, a fat-free food").[67]

Claims for "low" levels of nutrients presented a bigger challenge and needed to be considered individually. The goal was "that the selection of a food bearing the term should assist consumers in assembling a prudent daily diet and in meeting overall dietary recommendations to limit the intake of certain nutrients."[68] For nutrients that are ubiquitous in the food supply, the definition of a "low" level was set at 2 percent of the DRV for the nutrient. If the nutrient was not ubiquitous, the amount defined to be "low" was adjusted to account for the nutrient's uneven distribution in the food supply. In that way, if a person was to consume a reasonable number of

[62] *Nutrition Labeling and Education Act* of 1990. Public Law 101-535, 104 Stat 2353, Sec. 3(b)(1)(A)(iii).
[63] 58 FR 2302 (FDA) and 58 FR 632 (USDA).
[64] 59 FR 24232 (FDA) and 59 FR 24220 (USDA).
[65] 58 FR 2302.
[66] 58 FR 2302.
[67] 58 FR 2302.
[68] 58 FR 2302.

servings of food labeled as "low," balanced with a number of servings of foods that do not contain the nutrient and a number of servings of foods that contain the nutrient at levels above the "low" level, he or she would still be able to stay within dietary recommendations. For example, the DRV for total fat was set at 65 g. Two percent of 65 g is 1.3 g, which was rounded up to 1.5 g. Since fat is not inherent in many foods (e.g., fruits, vegetables, non-dairy beverages, fat-free dairy products, jams, etc.), yet is found in more than a few foods, FDA concluded that an appropriate upper limit for a "low fat" claim should be set at two times 2 percent of the DRV, or 3 g. Balancing the number of foods that do not contain fat with those that contain more than "low" levels would allow a person consuming up to 20 foods a day to stay within the DRV of 65 g. An exception to this method of calculation was made for sodium inasmuch as the term "low sodium" had been defined 8 years earlier as 140 mg or less per serving (rather than 96 mg if following the new procedure) with no apparent concerns about that level. Also, unique to sodium, there was a regulatory definition for "very low sodium" at 35 mg or less per serving. Responding to comments, FDA maintained these definitions for use by individuals wishing to reduce total sodium intake and those on medically restricted diets.[69]

Defining Levels of Nutrients to Encourage

Claims for "positive" nutrients (e.g., vitamins and minerals) are used to emphasize the presence of a nutrient. Regulations provide for claims at two levels, "high" and "good source."[70] The definition for "high" was set at 20 percent or more of the appropriate RDI or DRV per serving. The IOM Committee had suggested a criterion of greater than 20 percent for "high" claims (IOM, 1990), and in a review of its food consumption database FDA found that the 20-percent cut would permit a sufficient number of foods to make the claim. This in turn would enable consumers using the claim to select a diet from a wide variety of foods rather than from a few highly fortified foods.[71] "Good source" claims, defined as 10 to 19 percent of the DRV, were intended to emphasize the presence of a nutrient at a mid-range of nutrient content, drawing consumers' attention to foods that contain a significant amount of a nutrient and that are likely to help meet dietary recommendations.[72]

Implied Claims

As opposed to claims about the specific amount of a nutrient present in a food, "implied claims" are claims that describe a food or an ingredient in such a manner that the consumer is led to assume that a nutrient is absent or present in a certain amount (e.g., "high in wheat bran" implies that the food is high in fiber).[73] Implied claims can also suggest that the food may be useful in maintaining healthy dietary practices. To that end, following publication of the final rules implementing NLEA, FDA and USDA issued proposed[74] and final rules[75] to define the implied claim implicit in "healthy." The term "healthy" was considered a unique nutrient content claim because it not only characterized the level of the nutrients in a food but also implied a

[69] 58 FR 2302.
[70] 58 FR 2302.
[71] 56 FR 60421.
[72] 56 FR 60421.
[73] 56 FR 60421.
[74] 58 FR 2944 (FDA) and 58 FR 688 (USDA).
[75] 59 FR 24232 (FDA) and 59 FR 24220 (USDA).

judgment about the food. Comments on the proposed rule suggested that consumers had varying ideas of what the term meant, leading FDA to find that the "fundamental purpose of a 'healthy' claim is to highlight those foods that, based on their nutrient levels, are particularly useful in constructing a diet that conforms to current dietary guidelines."[76] This led the FDA and USDA to set criteria that limited use of the term to foods that had "low" levels of fat and saturated fat and slightly more moderate levels of cholesterol and sodium (see Appendix B). In addition, the food, (other than raw fruits or vegetables, a single ingredient or a mixture of canned or frozen fruits or vegetables or enriched cereal grain products that conform to a standard identity) had to contain at least 10 percent of the RDI or DRV of vitamin A, vitamin C, calcium, iron, protein, or fiber. As for sodium, FDA was persuaded that levels of it should be restricted so that foods bearing the "healthy" claim would be helpful in reaching dietary goals. Yet the agency found that the majority of products bearing the claim would be disqualified from doing so if sodium levels were set at a level as low as 360 mg per serving. Therefore, to provide time for the industry to reformulate their products and for consumers to become accustomed to lower levels of sodium, final regulations issued on May 10, 1994, provided a two-tier approach to sodium levels, specifying a maximum level for individual foods at 480 mg per serving, with a requirement that the level drop to 360 mg per serving by January 1, 1998. Prior to the 1998 date, FDA and USDA received petitions from a food manufacturer asking that the more restrictive second tier be eliminated or at least delayed until there were advances in food technology that allowed for the development of acceptable products with reduced sodium content. The agencies found that issues raised relative to technological and safety concerns of reduced-sodium foods merited further consideration, so it extended the effective date.[77] This process continued until final rules were issued which abandoned the more restrictive sodium requirements altogether because of the documented technical difficulties in finding suitable alternatives for sodium that would be acceptable to consumers.[78]

NUTRITION LABELING AS AN EVOLVING PROCESS

Nutrition labeling is a tool for consumers to use in selecting healthy diets that meet dietary recommendations. To accomplish this, it must be flexible enough to accommodate continuing advances in science and nutrition as well as changes in consumer behavior. The need for these changes is evidenced by the current advance notices of proposed rulemaking pertaining to modifications to give more prominence to calories,[79] amendments to serving size regulations,[80] and the establishment of new reference values.[81] Current activities regarding front-of-package labeling are another example of innovative approaches to nutrition labeling designed to help consumers select foods that may lead to more healthful diets.

[76] 59 FR 24232.
[77] 62 FR 15390 (FDA) and 63 FR 7279 (USDA).
[78] 70 FR 56828 (FDA) and 71 FR 1683 (USDA).
[79] 70 FR 17008.
[80] 70 FR 17101.
[81] 72 FR 62149.

REFERENCES

CFSAN/FDA (Center for Food Safety and Applied Nutrition). 2004. Letter to food manufacturers about accurate serving size declaration on food products. College Park, MD: FDA.

FDA (Food and Drug Administration). 1990. *Food labeling reform.* Washington, DC: FDA. Pp. 1–23

FDA. 2004. *Calories count: report of the working group on obesity*. Washington, DC: Food and Drug Administration.

Geiger, C. 1998. Health claims: History, current regulatory status, and consumer research. *Journal of the American Dietetic Association* 98:1312–1322.

Grundy, S., and M. Denke. 1990. Dietary influences on serum lipids and lipoproteins. *Journal of Lipid Research* 31:1149–1172.

Hutt, P. 1995. A brief history of FDA regulation relating to the nutrient content of food. In *Nutrition labeling handbook*, edited by R. Shapiro, New York City: Marcel Dekker. Pp. 1–27.

HHS (Department of Health and Human Services). 1988. The Surgeon General's Report on Nutrition and Health. *DHHS Publication No. 88–50210*. Washington, DC: U.S. Government Printing Office.

HHS. 1990. Remarks by Louis W. Sullivan, M.D., Secretary of Health and Human Services at the National Food Policy Conference (pp. 1–12). Washington, DC: HHS.

HHS/USDA (U.S. Department of Agriculture). 1990. *Dietary guidelines for Americans.* Washington, DC: U.S. Government Printing Office.

IOM (Institute of Medicine. 1990. *Nutrition labeling, issues and directions for the 1990s.* Washington, DC: National Academy Press.

IOM. 2003. *Dietary reference intakes: Guiding principles for nutrition labeling and fortification.* Washington, DC: The National Academies Press.

Kessler, D. A. 1989. The federal regulation of food labeling, promoting foods to prevent disease. *New England Journal of Medicine* 321:717–725.

Kessler, D. A. 1995. The evolution of national nutrition policy. In *Annual Review of Nutrition,* Vol. 15, edited by D. B. McCormick. Palo Alto, CA: Annual Reviews.

Kessler, D. A., J. R. Mande, F. E. Scarbrough, R. Schapiro, and K. Feiden. 2003. Developing the "Nutrition Facts" food label. *Harvard Health Policy Review* 4:13–24.

Levy, A., S. Fein, and R. Schucker. 1991. Nutrition labeling formats: Performance and preference. *Food Technology* 45:116–121.

Levy, A., S. Fein, S., and R. Schucker. 1996. Performance characteristics of seven nutrition label formats. *Journal of Public Policy & Marketing* 15:1–15.

Lewis, C., and E. Yetley. 1992. Focus group sessions on formats of nutrition labels. *Journal of the American Dietetic Association* 92:62–66.

LSRO (Life Sciences Research Office). 1987. *Physiological effects and health consequences of dietary fiber.* Bethesda, MD: Federation of American Societies for Experimental Biology.

LSRO/FASEB (Federation of American Societies for Experimental Biology). 1985. *Health effects of dietary trans fatty acids.* Bethesda, MD: FASEB.

McCutcheon, J. 1995. Nutrition labeling of meat and poultry products—An overview of regulations from the U.S. Department of Agriculture. In *Nutrition labeling handbook*, edited by R. Shapiro. New York City: Marcel Dekker. Pp. 53-63.

Nielsen, S., and B. Popkin. 2003. Patterms and trends in food portion sizes, 1977–1998. *Journal of the American Medical Association* 289:450–453.

NIH (National Institutes of Health). 1990. *National cholesterol education program: Report of the expert panel on population strategies for blood cholesterol reduction*. Wasington, DC: U.S. Government Printing Office.

NIH. 1994. Expert panel on detection, evaluation, and treatment of high blood cholesterol in adults National Cholesterol Education Program: Second report of the expert panel on detection, evaluation, and treatment of high blood cholesterol in adults (Adult Treatment Panel II). *Circulation* 89:1329–1445.

NRC (National Research Council). 1968. *Recommended dietary allowances*. Washington, DC: National Research Council.

NRC. 1989a. *Diet and health: Implications for reducing chronic disease risk*. Washington, DC: National Academy Press.

NRC. 1989b. *Recommended dietary allowances*. 10th edition. Washington, DC: National Academy Press.

Scarbrough, F. 1995. Perspectives on Nutrition Labeling and Education Act. In *Nutrition labeling handbook*, edited by R. Shapiro. New York City: Marcel Dekker. Pp. 29–52.

Shank, F. A. 1989. Health claims on food labels: The direction in which we're headed. *Journal of the Association of Food & Drug* Officials: 53:45–49.

Smiciklas-Wright, H., D. Mitchell, S. Mickle, and J. Goldman, J. 2003. Foods commonly eaten in the United States, 1989–1991 and 1994–1996: Are portion sizes changing? *Journal of the American Dietetic Association* 103:41–47.

Taylor, C. ,and V. Wilkening. 2008a. How the nutrition food label was developed, Part 1: The nutrition facts panel. *Journal of the American Dietetic Association* 108:437–442.

Taylor, C., and V. Wilkening. 2008b. How the nutrition food label was developed, Part 2: The purpose and promise of nutrition claims. *Journal of the American Dietetic Association* 108:618–623.

WHC (White House Conference on Food, Nutrition and Health) 1970. *White House conference on food, nutrition, and health: Final report.* 1970. Washington, DC: U.S. Government Printing Office.

Young, L. R., and M. Nestle. 2002. The contribution of expanding portion sizes to the US obesity epidemic. American Journal of Public Health 92:246-249.

Annex
Milestones in Nutrition Labeling

TABLE 2-1 Milestones in Nutrition Labeling

Date	Activity	References	Nutrition Labeling	Claims
1941	Proposed rule to prescribe label statements for dietary properties of foods represented as being for special dietary use and to establish minimum daily requirement values for vitamins and minerals	6 FR 3304-3310; 21 CFR Part 125		X
1941	Final rule prescribing label statements for dietary properties of foods represented as being for special dietary use and establishing minimum daily requirements for vitamins and minerals	6 FR 5921-5926; 21 CFR Part 125		X
1962	Proposed rules for food for special dietary uses that would define terms for label statements relating to vitamins and minerals, for use in weight control (e.g., “low calorie”), and for use in regulating the intake of sodium	27 FR 58155818; 21 CFR Part 125		X
1966	Final rules for food for special dietary uses that defined terms for label statements relating to vitamins, minerals, and protein; for use in weight control (e.g., “low calorie”); and for use in regulating the intake of sodium	31 FR 8521-8524; 21 CFR Part 125		X
1969	White House Conference on Food, Nutrition and Health recommends that FDA consider the development of a system for identifying the nutritional qualities of food			
1971	Proposed rule on labeling of foods with information on cholesterol, fat, and fatty acid composition	36 FR 11521-11522; 21 CFR Part 125.12	X	

Date	Activity	References	Nutrition Labeling	Claims
1972	Proposed rules for voluntary nutrition labeling of packaged foods (except mandatory when nutrient claims are made or nutrients added) and for Recommended Daily Allowances to be used as a reference standard for nutrition labeling	37 FR 6493-6497; 21 CFR Part 1.16	X	
1972	Final rule on label statements for foods intended to regulate the intake of sodium	37 FR 9763-9764; 21 CFR Part 125.9		X
1973	Final rule establishing rules for voluntary nutrition labeling of packaged foods (except mandatory when nutrient claims are made or nutrients added) and U.S. Recommended Daily Allowances (U.S. RDAs) to be used as a reference standard	38 FR 2125-2132; 21 CFR Part 1.17	X	
1973	Final rule on labeling of foods with information on cholesterol, fat, and fatty acid composition (separate from nutrition label)	36 FR 2132-2137; 21 CFR Part 1.18	X	
1973	Amendments to final rules on nutrition labeling and labeling of information on cholesterol, fat, and fatty acid composition	38 FR 6950-6964; 21 CFR Parts 1.17 and 1.18	X	
1977	Tentative order on label statements for special dietary foods for use in reducing or maintaining weight or calorie intake (e.g., “low calorie”)	42 FR 37166-37176; 21 CFR Parts 105.66 and 105.67		X
1978	Announcement of five public hearings to discuss food labeling, including nutrition labeling and claims	43 FR 25296-25307	X	X
1978	Final rule on label statements for special dietary foods for use in reducing or maintaining weight or calorie intake (e.g., “low calorie”)	43 FR 43248-43262; 21 CFR Parts 105.66 and 105.67		X
1978	Proposed rule to permit “reduced calorie” claim for bread with 25% reduction in calories	43 FR 43261-43262; 21 CFR Part 105.66		X

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Date	Activity	References	Nutrition Labeling	Claims
1979	Tentative positions of FDA, USDA, and FTC on food labeling issues as a result of public hearings	44 FR 75990-76020	X	X
1980	Final policy statement on the addition of nutrients to food (i.e., fortification)	45 FR 6314-6324; 21 CFR Part 104.20		
1982	Proposed rule to establish definitions for sodium claims (e.g., “sodium free,” “reduced sodium,” “no salt added”) and safety review	47 FR 26580-26595; 21 CFR Part 105.69		X
1983	Temporary exemption from food labeling rules for conducting authorized food labeling experiments aimed at providing consumers with more useful food labeling information (e.g., shelf labeling)	48 FR 15236-15241; 21 CFR Part101.108	X	
1984	Final rule establishing definitions for sodium claims and requiring inclusion of sodium in nutrition labeling information whenever nutrition labeling appears on food labels	49 FR 15510-15535; 21 CFR Parts 101.9, 101.13 and 105.69	X	X
1986	Proposed rule to establish definitions for cholesterol claims (e.g., “cholesterol free”) and amend nutrition labeling rules to require that the declaration of either fatty acid or cholesterol content information will require that both be provided in nutrition labeling	51 FR 42584-42593; 21 CFR Parts 101.9 and 101.25	X	X
1987	Proposed rule to exclude nondigestible dietary fiber when determining the calorie content of a food for nutrition labeling purposes.	52 FR 28690-28691; 21 CFR Part 101.9	X	
1987	Proposed rule to codify and clarify the agency’s policy on the appropriate use of health messages on food labeling	52 FR 28843-28849; 21 CFR Part 101.9		X
1989	Advance notice of proposed rulemaking to announce a major initiative of HHS to improve food labeling with request for public comment on labeling requirements, including nutrition labeling and claims	54 FR 32610-32615	X	X

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Date	Activity	References	Nutrition Labeling	Claims
1989	Announcement of four public hearings to discuss food labeling issues, including nutrition labeling and claims	54 FR 38806-38807	X	X
1990	Reproposed rule to provide for the use of health messages on food labeling and to withdraw the August 4, 1987, proposal	55 FR 5176-5192; 21 CFR Part 101.9	X	X
1990	Tentative final rule establishing definitions for cholesterol claims and requiring that declaration of either fatty acid or cholesterol content information triggers declaration of both in nutrition labeling	55 FR 29456-29473; 21 CFR Parts 101.9 and 101.25	X	X
1990	Proposed rule to replace U.S. RDAs with Reference Daily Intakes (RDIs) for protein and 26 vitamins and minerals and to establish Daily Reference Values (DRVs) for fat, saturated fatty acids, unsaturated fatty acids, cholesterol, carbohydrate, fiber, sodium, and potassium	55FR 29476-29486; 21 CFR Parts 101.3, 101.9, and 104.20	X	
1990	Proposed rule to require nutrition labeling on most packaged foods and to revise the list of required nutrients and conditions as well as the format for listing nutrients in nutrition labeling	55 FR 29487-29517; 21 CFR Part 101.9	X	
1990	Proposed rule to define serving size on the basis on the amount of food commonly consumed per eating occasion and to establish standard serving sizes for 159 food product categories to assure uniform serving sizes upon which consumers can make nutrition comparisons among food products	55 FR 2951729533; 21 CFR Parts 101.8, 101.9 and 101.12	X	
1990	Passage of the Nutrition Labeling and Education Act of 1990 (NLEA) mandating nutrition labeling on most packaged foods and providing for nutrient content claims and health claims on food labels	Public Law 101-585 (Sec. 403(q) & (r) of the Federal Food, Drug and Cosmetic Act)	X	X
1991	Proposed rule with notice of FDA's plans to respond to passage of NLEA	56 FR 1151-1152	X	X
1991	Notice of public meeting to discuss issues related to how serving size should be determined and presented as a part of nutrition labeling	56 FR 8084-8092	X	

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Date	Activity	References	Nutrition Labeling	Claims
1991	Advance notice of proposed rulemaking to solicit comment on nutrition labeling of meat and poultry products (USDA)	56 FR 13564-13573	X	
1991	Notice of availability of a report on food label formats conducted by FDA and request for comment on nutrition label format research	56 FR 23072-23083	X	
1991	In response to requirements of the NLEA , proposed rule to modify proposal of July 19, 1990, on mandatory nutrition labeling and the establishment of RDIs and DRVs for use in nutrition labeling	56 FR 60366-60394; 21 CFR Parts 101.9 and 101.36	X	
1991	In response to requirements of the NLEA and comments received, proposed rule to modify proposal of July 19, 1990, on serving sizes for use in nutrition labeling	56 FR 60394-60421; 21 CFR Parts 101.9 and 101.12	X	
1991	Proposed rule to define nutrient content claims for calories, sugar, and sodium and for claims such as “source,” “high,” “more,” and “light,” and to provide for their use on food labels	56 FR 60421-60478; 21 CFR Parts 101.13, 101.54, 101.60, 101.61, 101.69, 101.95, 105.66		X
1991	Proposed rule to define nutrient content claims for fat, fatty acids, and cholesterol and to provide for their use on food labels	56 FR 60478- 60512; 21 CFR Parts 101.25 and 101.62		X
1991	Proposed rule to establish general requirements for health claims that characterize the relationship of a food component to a disease or health-related condition on the labels and in labeling of foods	56 FR 60537-60566; 21 CFR Parts 101.14, 101.70 and 101.71		X
1991	Proposed rule to permit voluntary nutrition labeling of single-ingredient meat and poultry products, to establish mandatory nutrition labeling of all other meat and poultry products, and to establish nutrient content claims for use on meat and poultry product labels (USDA)	56 FR 60302-60364; 9 CFR Parts 317, 320 and 381	X	X

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Date	Activity	References	Nutrition Labeling	Claims
1992	Proposed rule on format for presenting nutrition information on food labels	57 FR 32058-32089	X	
1992	Passage of the Dietary Supplement Act of 1992, which put a one-year moratorium on regulations that required the use of, or were based upon, RDAs other than those in effect at that time	Public Law 102-571	X	
1993	Final rule requiring nutrition labeling on most packaged foods and specifying a new format for declaring nutrition information	58 FR 2079-2205; 21 CFR Part 101.9	X	
1993	Final rule establishing Reference Daily Intakes and Daily Reference Values, to be known as Daily Values, for declaring the nutrient content of a food	58 FR 2206-2228; 21 CFR Part 101.9	X	
1993	Final rule defining serving sizes based on amounts customarily consumed per eating occasion, provide for their use, and establish reference amounts for 139 food categories	58 FR 2229-2300; 21 CFR Parts 101.8, 101.9,101.12	X	
1993	Final rule establishing general principles for the use of nutrient content claims, define terms such as “free,” “low,” “lean,” ”high,” “reduced,” “light,” “less,” and “fresh,” and provide for the use of implied nutrient content claims	58 FR 2302-2426; 21 CFR Parts 101.13, 101.54-101.69,101.95		X
1993	Final rule to establish general principles for the use of health claims	58 FR 2478-2536; 21 CFR Part 101.14		X
1993	Proposed rule to define the implied nutrient content claim “healthy”	58 FR 2944-2949, 21 CFR Part 101.65		X
1993	Proposed rule to permit the term “healthy” on meat and poultry products (USDA)	58 FR 688-691; 9 CFR Parts 317.363 and 381.463		X

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Date	Activity	References	Nutrition Labeling	Claims
1993	Final rule to permit voluntary nutrition labeling on single-ingredient raw meat and poultry products, to establish mandatory nutrition labeling for all other meat and poultry products, and to establish nutrient content claims for use on meat and poultry product labels (USDA)	58 FR 632-685; 9 CFR Parts 317, 320, and 381	X	X
1994	Proposed rule to establish Reference Daily Intakes for vitamin K, selenium, manganese, fluoride, chromium, molybdenum, and chloride for use in nutrition labeling	59 FR 427-432; 21 CFR Part 101.9	X	
1994	Final rule defining the term "healthy" for use on meat and poultry product labeling (USDA)	59 FR 24220 –24229; 9 CFR Parts 317.363 and 381.463		X
1994	Final rule defining the term "healthy" for use on the food label	59 FR 24232-24250; 21 CFR Part 101.65		X
1995	Proposed rule to amend general principles for the use of nutrient content and health claims to provide additional flexibility and encourage their use in order to assist consumers in maintaining a healthy diet	60 FR 66206-66227; 21 CFR Parts 101.13 and 101.14		X
1995	Final rule to provide codified language for nutrition labeling regulations that were previously cross-referenced to FDA regulations (USDA)	60 FR 174-216; 9 CFR Parts 317 and 381	X	
1995	Final rule establishing Reference Daily Intakes for vitamin K, selenium, manganese, chromium, molybdenum, and chloride	60 FR 67164-67175; 21 CFR Part 101.9	X	
1998	Notice of availability of a guidance document on notifications for nutrient content or health claims based on an authoritative statement of a scientific body in response of FDA Modernization Act of 1997	63 FR 32102		X
1999	Proposed rule to require the addition of *trans* fatty acids to nutrition labeling and to define a nutrient content claim for the "free" level of *trans* fatty acids	64 FR 62746-62825; 21 CFR Parts 101.9, 101.13, and 101.14	X	

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Date	Activity	References	Nutrition Labeling	Claims
1999	Notice of availability of guidance on significant scientific agreement in the review of health claims for conventional foods and dietary supplements	64 FR 17494		X
2003	Proposed rule to amend regulations that pertain to sodium levels in foods that use the term “healthy” on product labels	68 FR 8163-8179; 21 CFR Part 101.65		X
2003	Final rule requiring the addition of *trans* fatty acids to nutrition labeling	68 FR 41434-41506; 21 CFR Part 101.9	X	
2005	Advance notice of proposed rulemaking to request comment on amending nutrition labeling regulations to give more prominence to calories of food labels.	70 FR 17008-17010	X	
2005	Advance notice of proposed rulemaking to request comment on amending nutrition labeling regulations concerning serving size	70 FR 17010-17014	X	
2005	Final rule amending regulations that pertain to sodium levels in foods that use the term “healthy” on product labels	70 FR 56828-56849; 21 CFR Part 101.65		X
2006	Interim final rule concerning level of sodium in labels of meat and poultry products that bear the term “healthy” (USDA)	71 FR 1683-1686; 9 CFR Parts 317.363 and 381.463		X
2006	Guidance for industry on FDA’s implementation of “qualified health claims” http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm053843.htm	May 2006		X
2007	Advance notice of proposed rulemaking to request comments on establishing new reference values (i.e., RDIs and DRVS)	72 FR 62149–62175	X	

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Date	Activity	References	Nutrition Labeling	Claims
2009	Guidance for industry on evidence-based review for the scientific evaluation of health claims http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm073332.htm	January 2009		X

NOTE: Table excludes foods for special dietary use (other than label statements about nutrient content), dietary supplements, foods for infants less than 1 year of age, individual health claims, and the voluntary nutrition labeling program for raw fruits, vegetables, and fish. Unless otherwise noted, regulations and notices have been issued by the Food and Drug Administration of the Department of Health and Human Services.

3
History and Current Status of Front-of-Package Systems

A variety of systems have been developed since the first front-of-package (FOP) nutrition rating system appeared more than 20 years ago (Table 3-1). In 1987, aiming to provide consumers with a single symbol that would indicate whether a food was "heart friendly," the American Heart Association (AHA) created the Heart Guide symbol. Since then, systems and symbols used in food labeling have proliferated. Systems have been developed by food manufacturers, retailers, non-industry experts, nonprofit organizations, industry and non-industry consortia, and government agencies.

DEVELOPMENT OF FRONT-OF-PACKAGE SYSTEMS

In the late 1980s and early 1990s, when FOP systems were first appearing, they were largely developed by nonprofit health organizations. AHA began its nutrition labeling efforts with the Heart Guide program, but it refocused its energies in 1990 to provide Food and Drug Administration (FDA) with feedback for the Nutrition Labeling and Education Act (NLEA). In 1989 Sweden developed the Keyhole symbol to be used voluntarily by food manufacturers; the use of this symbol has since expanded to Denmark and Norway. In 1995 AHA began a new iteration of its FOP system, the Heart Check program, whose criteria were based on FDA coronary heart disease risk reduction claims, focusing first on levels of total and saturated fat and cholesterol, and later on fiber content. In 1991 Australia and New Zealand's Heart Foundation created the Tick Programme aimed at improving public health.

In 1999 Canada's Heart and Stroke Foundation created the Health Check program. The program's goal was to help consumers "identify healthy food choices to achieve an overall healthy diet."[1] Both the Heart Check and the Health Check programs featured a single symbol that could appear on products meeting their respective nutrient criteria, and they were limited in scope to the risk reduction of cardiovascular disease. Food manufacturers were not involved in the development of the criteria for these programs, but they could participate in the appropriate program for a fee and receive the right to use the system symbol on products that met that system's criteria.

In 1992 research by Schucker et al. suggested that consumers purchased more products for which FOP labeling was present on grocery store shelves. In 2002 Wegmans supermarkets developed a series of symbols that were based upon FDA and U.S. Department of Agriculture (USDA) nutrient content and health claims and that were featured on store brand products. A single food item could receive multiple symbols—"low fat," "excellent source of calcium," "gluten free," and so on—with the intention that a consumer could quickly look at a product and decide if it met his or her needs. By featuring this system only on the grocery's own store brand products, Wegmans provided consumers with an incentive to purchase the house brand.

[1] Available online: http://www.healthcheck.org/page/what-health-check (accessed June 15, 2010).

TABLE 3-1 Timeline of Selected Activities Related to Front-of-Package Nutrition Rating Systems and Symbols

Year	Event
1987	• AHA launches Heart Guide initiative
1989	• Sweden's National Food Administration creates Keyhole symbol
1991	• New Zealand Heart Foundation creates Tick Programme
1992	• Study on shelf-tags shows market shares of shelf-tagged products increases (Schucker et al., 1992)
1993	• FDA and USDA publish final rules defining nutrient content claims and providing for health claims
1995	• AHA introduces Heart Check program
1999	• Canada's Heart and Stroke Foundation introduces Health Check program
2002	• Wegmans creates Wellness Keys
2004	• PepsiCo. introduces Smart Spot • General Mills introduces Goodness Corner • FDA introduces Calories Count: Report of the Working Group on Obesity
2005	• Whole Grains stamp is launched • FDA publishes an advance notice of proposed rulemaking requesting comments on displaying calories more prominently on food packaging • Kraft Foods introduces Sensible Solution • Heart Check adds an additional certification: whole grains with moderate fat content • President's Choice launches Blue Menu to designate its healthier products
2006	• CSPI petitions FDA to develop a simple, uniform, science-based rating system • Harris Teeter introduces Wellness Keys • Hannaford introduces Guiding Stars • Confederation of the of the EU (CIAA) commits to voluntary nutrition labeling scheme across EU member states
2007	• Unilever introduces Choices program • U.K. Food Standards Agency implements Traffic Light system • Kellogg's introduces Nutrition-at-a-Glance • General Mills implements Nutrition Highlights to replace Goodness Corner • Keystone Food and Nutrition Roundtable studies the various FOP systems in the United States • FDA public hearing on front-of-package and other nutrition symbols • NuVal system is developed
2008	• ConAgra introduces Start Making Choices symbol using MyPyramid • Smart Choices program is developed • Mars International launches Guideline Daily Amount (GDA) labeling of its foods and snacks in the United States • Nutrient Rich Food Index articles are published in the scientific literature

2009	• Healthy Ideas is launched at Giant Foods and Stop & Shop supermarkets • Sara Lee introduces Nutritional Spotlight; similar to recent efforts by Mars and Kellogg's • FDA releases "Comments on Symbols Public Hearing and Current Plans for Addressing Issues," from the 2007 hearing • Smart Choices is formally launched • FDA issues letter to Smart Choices • Most industry participants suspend use of Smart Choices; program is put on hold • FDA designs and begins to implement a plan to conduct research on FOP nutrition rating systems and symbols • Institute of Medicine Nutrition Rating Systems and Symbols committee is formed
2010	• FDA requests comments and data on front-of-pack labeling • U.K. Food Standards Authority announces that Traffic Light system will not be mandatory

Over the next several years additional manufacturers followed suit. PepsiCo and Kraft Foods developed two separate FOP systems, SmartSpot in 2004 and Sensible Solution in 2005. Both were aimed at guiding health-conscious consumers to the "healthier" versions of their products according to the standards of the time (for example, baked potato chips vs. original potato chips or "low fat" ranch dressing vs. original ranch dressing). In 2005 President's Choice in Canada launched a similar program, Blue Menu, to direct consumers to its "healthier" food products.

In 2006 the first algorithm-based summary symbol indicator was introduced into the marketplace. The Guiding Stars system was developed by Hannaford Supermarkets by a scientific advisory panel convened for this purpose. Using a proprietary algorithm that took into account both positive and negative nutrients, the system gave ratings of zero to three stars to foods that met minimum Hannaford nutrient criteria. The star ratings were then displayed on the shelf tags of participating retail stores. Shortly afterwards, in 2007, the NuVal Nutritional Scoring System was introduced and is part of a joint venture of Topco Associates LLC and Griffin Hospital in Connecticut. Similar to the Guiding Stars system, it was based on a proprietary algorithm (Overall Nutritional Quality Index) that took into account—and weighted—both positive and negative nutrients. The NuVal system presented the end result as a number between 1 and 100 which allowed consumers to gauge the nutritional value of a food product: The higher the value, the "healthier" the choice.

In 2008 and 2009 several new FOP systems entered the marketplace, including ConAgra's Start Making Choices, Giant's Healthy Ideas, and the Keystone Roundtable Smart Choices program. Vastly different in their approaches to rating foods, Start Making Choices was a manufacturer-developed program (based on USDA criteria) designed to illustrate food group contributions; Giant's Healthy Ideas was a retailer-developed system using nutrient criteria; and the Smart Choices Program was a nutrient-criteria-based system developed by a consortium of industry, public health, and academic nutrition leaders.

While each program had its own goal and target consumers in mind and used different criteria and approaches to rate foods, the overarching intent of each was to provide consumers with the ability to quickly determine if a food was a nutritious choice, to compare foods within a category, and to determine if the food met their specific nutrient needs (for instance, if it provided 20% Daily Value [%DV] calcium or was "low" in saturated fat). Manufacturer- and retailer-developed FOP systems tended to focus on providing consumers targeted information regarding more nutritious varieties of their own product lines, while nonprofit and academic

groups comprised of dietitians, physicians, nutritionists, and so forth tended to score many or all food products, regardless of brand, and often, to offset administrative costs, charged manufacturers a fee to participate. Typically, the aim of these systems has been to provide consumers with a method to select more nutritious foods at the grocery store on any brands that choose to participate in the program. Purposes and merits of types of systems are discussed in Chapter 5, and Table 5-1 compares FOP types according to potential to fulfill specific purposes.

REACTION TO FRONT-OF-PACKAGE SYSTEMS

As retailers and manufacturers continued to develop and launch FOP systems, concerns were raised about what a variety of systems might mean to consumers. In 2006 the Center for Science in the Public Interest (CSPI) petitioned the FDA to develop a single, consistent FOP system that would present nutrition information graphically on the front of the package.[2] In response, FDA held public hearings in 2007 and in 2008 issued guidance for industry about FOP systems and implied nutrient content claims. The guidance stated that if a product claims to "provide" or "have a low percent of" a specific nutrient, it must meet the current claim regulations for using terms such as "low" or "good source of," including the use of disclosure statements for products that contain more than a certain amount of total fat, saturated fat, cholesterol, or sodium.[3]

By 2009 FOP systems and symbols were abundant, and concerns increased about consumers being confused or even misled. After much attention was given to a Smart Choices symbol appearing on a popular, sugar-sweetened breakfast cereal, in August 2009 FDA and the USDA's Food Safety and Inspection Service sent a joint letter to Sarah Krol,[4] general manager of the Smart Choices program. The letter stated that the agencies "would be concerned if FOP labeling systems used criteria that were not stringent enough to protect consumers against misleading claims; were inconsistent with the *Dietary Guidelines for Americans*; or had the effect of encouraging consumers to choose highly processed foods and refined grains instead of fruits, vegetables, and whole grains." With increasing criticisms and concerns about consumer confusion, FDA Commissioner Margaret Hamburg and the FDA Office of Nutrition, Labeling and Dietary Supplements followed up with open letters to industry announcing the FDA's plan of action to clear up consumer confusion and propose new standards for nutrient criteria to minimize inconsistencies among FOP systems.[5] FDA also issued guidance to industry regarding FOP labeling.[6]

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[2] Available online: http://www.cspinet.org/new/pdf/healthy_symbol_petition.pdf (accessed June 15, 2010).

[3] Available online: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm120274.htm (accessed June 15, 2010).

[4] Available online http://www.fda.gov/Food/LabelingNutrition/LabelClaims/ucm180146.htm (accessed August 4, 2010).

[5] Available online: http://www.fda.gov/Food/LabelingNutrition/LabelClaims/ucm120274.htm (accessed September 20, 2010).

[6] Available online: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm187208.htm (accessed July 7, 2010).

In 2010, with the inception of the Let's Move campaign[7] and the White House's concern about obesity and health, interest in FOP systems has remained strong. FDA has taken a more active role in assessing consumer response to FOP systems, has initiated consumer testing of possible FOP symbols, and has announced a request for comment, information, and data on FOP labeling.[8] While this Institute of Medicine study was congressionally mandated and initiated prior to the most recent FDA activities, it is considered by FDA as one component of the work the agency is supporting to gain additional perspective from nutrition and consumer experts on how to best proceed in potential regulation of FOP systems.

REFERENCE

Schucker, R. E., A. S. Levy, J. E. Tenney, and O. Mathews. 1992. Nutrition shelf-labeling and consumer purchase behavior. *Journal of Nutrition Education* 24:75–81.

[7] Available online: http://www.whitehouse.gov/the-press-office/first-lady-michelle-obama-launches-lets-move-americas-move-raise-a-healthier-genera (accessed June 16, 2010).
[8] 75 FR 22602.

4
Overview of Health and Diet in America

Most of the goals of front-of-package rating systems and symbols are related to helping consumers make more nutritious food choices, given an environment in which the impact of diet on health is of increasing concern. One of the committee's guiding principles assumes a focus on the nutrients and food components most strongly associated with the diet-related health risks affecting the greatest number of Americans. Given this principle, it was important to consider the current state of the average American's diet as well as the health status of the population.

In the United States, poor diet was once associated with undernutrition. Today it is more often associated with excess, particularly excesses in calories, saturated fats, *trans* fats, added sugars, and sodium (DGAC, 2010). The poor diets and sedentary lifestyles of the American public have led to high rates of obesity, overweight, and diet-related chronic diseases, including cardiovascular disease (CVD), hypertension, dyslipidemia, type 2 diabetes, osteoporosis, and certain types of cancer (HHS/USDA, 2005a). It has been estimated that poor diet quality and physical inactivity contributed to approximately 16.6 percent of U.S. deaths in 2000, compared to 14 percent in 1990 (Mokdad et al., 2004).

As shown in Table 4–1, the three main causes of death in the United States are heart disease, cancer, and stroke.[1] Together with diabetes, the sixth leading cause of death, they are the major contributors to the morbidity, mortality, and healthcare costs in this country. All of these chronic diseases are made more likely by the presence of overweight and obesity. Brief overviews of these conditions and the overconsumption of dietary factors that contribute to them are provided below.

OVERWEIGHT AND OBESITY

According to the National Center for Health Statistics, about two-thirds of U.S. adults and about one-third of children aged 2 through 19 years are overweight or obese (Ogden et al., 2010). While obesity is far from a new problem in our nation, its rise over recent decades and its subsequent impact on rates of chronic disease and premature death are of increasing public health priority.

Obesity, defined in adults as a body mass index (BMI) greater than or equal to 30, has become increasingly prevalent over the past three decades, its prevalence doubling between the 1976–1980 and the 1999-2000 National Health and Nutrition Examination Surveys (NCHS, 2010). Only recently has the rate of obesity in adults leveled off, albeit at record high levels. The rates of overweight (BMI of 25–29.9) have remained fairly constant during this time, but the increased rates of those classified as obese, and the shift of those classified as healthy to overweight status has resulted in Americans weighing much more than they did in the 1960s (NCHS, 2010). Childhood obesity, defined as a BMI at or above the sex- and age-specific 95th

[1] Available online: http://www.cdc.gov/nchs/fastats/lcod.htm (accessed July 27, 2010).

TABLE 4-1 Top 10 Leading Causes of Death in the United States: All Ages, 2007

Cause	Deaths per 100,000 Population
Heart disease	616.1
Cancer	562.9
Stroke	135.9
Chronic lower respiratory disease	128.0
Unintentional Injuries (Accidents)	123.7
Alzheimer's disease	74.6
Diabetes	71.4
Influenza and pneumonia	52.7
Nephritis, nephrotic syndrome and nephrosis	46.5
Septicemia	34.8

SOURCE: http://www.cdc.gov/nchs/fastats/lcod.htm.

percentile BMI cut points from the 2000 CDC Growth Charts, has also recently leveled off after several decades of increase, again at record high levels. These alarming trends have given rise to a major, national public health campaign to reduce obesity rates over the next decade. Obesity and overweight increase the risk for premature death and a host of co-morbidities. Co-morbidities include coronary heart disease (CHD) and stroke, type 2 diabetes, metabolic syndrome, certain types of cancer, sleep apnea, osteoarthritis, gallbladder disease, fatty liver disease, and pregnancy complications.[2] In 2006 three of the most prevalent co-morbidities, heart disease, stroke, and diabetes, together accounted for approximately 34 percent of age-related deaths (NCHS, 2010). Additionally, in a prospectively studied cohort of U.S. adults, Calle, et al. (2003) estimated that 14 percent and 20 percent of cancer deaths among men and women, respectively, were due to overweight and obesity. It has been estimated that $169 billion in annual medical savings could potentially be saved if overweight and obesity problems were eliminated in the United States, and even modest caloric reductions (100 calories per day) across the population could save as much as $58 billion in medical costs (Dall et al., 2009).

Overweight and obesity are the result of excess calorie intake or inadequate energy expenditure or both. While total daily caloric expenditure is difficult to quantify because of limited national surveillance, the increase in caloric consumption has been well documented (DGAC, 2010). According to the loss-adjusted USDA food availability data, daily per capita intake increased by 617 calories between 1970 and 2008 (DGAC, 2010). The three largest contributors to the increased calorie intake were added fats and oils (34 percent); flour and cereal products (31 percent); and caloric sweeteners (9 percent) (DGAC, 2010). Caloric sweeteners, or added sugars, include all refined sugars, corn sweeteners, honey, and edible syrups.

[2] Available online: http://win.niddk.nih.gov/publications/health_risks.htm (accessed July 8, 2010).

In the 2005 *Dietary Guidelines for Americans* (HHS/USDA, 2005b), a new concept regarding excess, non-essential calories was introduced. The term was "discretionary calorie allowance" or the balance of calories remaining in a person's energy allowance after accounting for those consumed when meeting recommended nutrient intakes through healthful foods. Only a relatively small number of discretionary calories remain to be consumed as high-energy, low-nutrient foods (i.e., foods high in added sugars, fats, or alcohol) or as additional high-nutrient foods in excess of the levels needed for a healthy diet (e.g., additional fruit and vegetables or whole grains). For example, a person consuming 1600 calories per day would have 130 discretionary calories, while a person consuming 2000 calories a day would have 265. A high intake of added sugars or fat has the potential to contribute to overconsumption of discretionary calories by Americans. Because the concept of discretionary calories has been difficult to translate into meaningful consumer education (DGAC, 2010), the 2010 Dietary Guidelines Advisory Committee (DGAC) referred to the non-essential or extra calories coming from solid fats (i.e., saturated and *trans* fats) and added sugars as "SoFAS" and estimated that Americans currently consume about 35 percent of their total calories from these sources (DGAC, 2010). The Dietary Guidelines Advisory Committee recommended that no more than 5 to 15 percent of total calories should be derived from SoFAS. This was not broken down separately into guidelines for calories from fats and calories from added sugars.

Calories from Fat

Fat is the most calorically dense macronutrient, with a gram of fat contributing 9 calories, compared to 4 calories for a gram of carbohydrate or protein and 7 calories for a gram of alcohol. For this reason, being attentive to calories from fat as part of total calorie intake can be important for weight control. Unsaturated fats (polyunsaturated and monounsaturated) are beneficial, while most saturated fats and *trans* fats have negative effects on lipid profiles and cardiovascular disease risk (see discussion in later section on cardiovascular disease).

Saturated fats are naturally present in animal fats but can also be made from unsaturated fats through the process of hydrogenation. Using NHANES 2001–2002 data, Bachman et al. (2008) identified the top sources of solid fats (a term used by some nutritionists to describe the combination of saturated and *trans* fats) of in the American diet. As shown in Table 4-2, these include grain-based desserts; regular fat cheese; sausage, franks, ribs, and bacon; pizza; fried white potatoes (French fries); and dairy desserts. Sources for children aged 2 to 18 years are similar except that the number one source for children aged 2 to 8 years is whole milk (DGAC, 2010).

Calories from Added Sugars

Individuals in the United States consume a substantial percentage of their total calories as added sugars (DGAC, 2010). NHANES estimates from 2001 to 2004 indicate that the mean intake of added sugars for all persons was 22 teaspoons per day (355 calories), which far exceeds the allowance for discretionary calories (Johnson et al., 2010). In 2010 new recommendations from the American Heart Association were released that advised consumption of added sugars be only 5 percent of daily calories (Johnson et al., 2010). For adult women, this would be fewer than 100 calories (about 25 g or 6 teaspoons) per day, and for adult men, fewer than 150 calories (about 37.5 g or 9 teaspoons) per day. Based on NHANES 2003–2006 data, 13 percent of the

TABLE 4–2 Top 10 Foods Contributing Solid Fats (i.e., Saturated and *trans* Fats) in the American Diet

Food Category	Total Energy Contribution from Solid Fats (%)
Grain-based desserts	10.9
Regular cheese	7.7
Sausage, franks, ribs, bacon	7.1
Pizza	5.9
Fried white potatoes	5.5
Dairy desserts	5.1
Whole milk	4.6
Mexican mixed dishes	4.4
Pasta and pasta dishes	4.2
Burgers	4.1

SOURCE: Bachman et al., 2008.

American population had an added-sugars intake of more than 25 percent of calories (Marriott et al., 2010).

As shown in Table 4-3, the major contributors of added sugars (comprising roughly 72 percent of added sugars consumed, are regular soft drinks or sodas, grain-based desserts (cakes, cookies, and pies), fruit drinks, dairy desserts, and candy.[3] These top five categories are also low in nutrient density. In 2005–2006 NHANES, soda was the top beverage choice for children and adolescents, 2 to 18 years of age, supplying more calories than any other single beverage (DGAC, 2010). Adolescents consume an average of 300 calories per day from sugar-sweetened beverages, accounting for 13 percent of their daily caloric intake (Wang et al., 2008).

Unlike most other carbohydrates, added sugars contribute no nutrients besides energy. Although calorically there is no difference between added sugars and sugars found naturally in fruits and vegetables, the benefit of fruits and vegetables containing naturally occurring sugars lies in the vitamins, minerals, antioxidants, and phytonutrients they provide. Milk products contain lactose, a naturally occurring sugar, as well as protein, calcium, and other nutrients. Dietary guidance focuses on reducing added sugars because foods high in added sugars often supply calories—as well as saturated fats and sodium—but few essential nutrients other than energy. The IOM Dietary Reference Intakes (DRI) report on macronutrients suggests that "added sugars" should be less than 25 percent of calories per day in order to protect against the dilution of micronutrients in the diet (IOM, 2002/2005). For both genders and most age groups, consumption of 25 percent or more of calories from "added sugars" is associated with a significant decrease in the consumption of micronutrients (IOM, 2002/2005). Recent data from Marriott et al. (2010) support this relation for all age groups. The 2005 *Dietary Guidelines for*

[3] Available online: http://riskfactor.cancer.gov/diet/foodsources/added_sugars (accessed August 3, 2010).

TABLE 4-3 Top 10 Foods Contributing Added Sugars in the American Diet

Food Categories	Percent of total added sugars consumed
Soda/energy/sports drinks	35.7
Grain-based desserts	12.9
Fruit drinks	10.5
Dairy desserts	6.6
Candy	6.1
Pre-sweetened cereals	3.8
Sugars/honey	3.5
Tea	3.5
Yeast breads	2.1
Syrups/toppings	1.9

SOURCE: NCI, 2010.

Americans concluded that the problem with added sugars is not that sugars themselves are detrimental to health but that sugars provide only calories (HHS/USDA, 2005a).

There is, however, evidence that small amounts of added sugars may have a beneficial effect on micronutrient intake by improving the palatability of foods and beverages that otherwise may not be consumed (FAO/WHO, 1998; Frary et al., 2004). Examples, particularly for children and adolescents, include sweetened dairy foods and beverages and presweetened cereals. Individuals who consume low levels of added sugars (5 to 10 percent of calories) tend to have higher micronutrient intake than those for whom added sugars account for less than 5 percent of total calories (IOM, 2002/2005; HHS/USDA, 2005a).

The 2010 Dietary Guidelines Advisory Committee report noted that the role of dietary sugars in the obesity epidemic is controversial, with many opposing views and mixed results. Limited evidence shows that intake of sugar-sweetened beverages is linked to higher energy intake in adults, but the evidence is inconsistent regarding associations with obesity (DGAC, 2010; Johnson et al., 2010). The 2010 Dietary Guidelines Advisory Committee report noted that a moderately sized body of evidence suggests that under isocaloric controlled conditions, added sugars (including sugar-sweetened beverages) are no more likely to cause weight gain in adults than any other source of energy (DGAC, 2010). However, the preponderance of observational data for children and adolescents indicates that sugar-sweetened beverage intake can contribute to excess caloric intake, weight gain, and greater adiposity (DGAC, 2010).

CARDIOVASCULAR DISEASE

Cardiovascular disease (CVD) comprises many conditions, including coronary heart disease (CHD) and cerebrovascular disease which are, respectively, the first and third most common causes of death in the United States. The American Heart Association has estimated that 81

million American adults, or about one in three, have one or more types of CVD (AHA, 2010). Among the modifiable risk factors for CVD are body weight (as discussed previously), dyslipidemia, elevated blood pressure, and diabetes—all of which can be influenced or reduced through dietary factors.

Dyslipidemia

Dyslipidemia (abnormalities of blood lipid levels) is a powerful risk factor for atherosclerotic diseases, particularly CHD. Dyslipidemia is generally defined as including at least one of the following disorders: a high concentration of low-density lipoprotein (LDL) cholesterol, a low concentration of high-density lipoprotein (HDL), or a high triglyceride concentration. The primary focus of prevention and treatment is on reducing LDL cholesterol (NIH, 2001). High LDL concentrations are associated with atherogenesis, or plaque development. Even in early life, the lowering of LDL levels can slow or even prevent atherogenesis and subsequent plaque development (HHS/USDA, 2005a), making dietary factors related to dyslipidemia a lifelong concern. In 2006 approximately 32 percent of the adult population greater than 20 years old had an LDL cholesterol concentration considered to be "borderline high" (greater than 130 mg per deciliter) (AHA, 2010).

The dietary factors most directly related to LDL concentrations are saturated fatty acids (SFA) and *trans* fatty acids. The National Cholesterol Education Program has estimated that a reduction of one percentage point in energy from saturated fat decreases serum LDL concentrations by about 1 to 2 percent (NIH, 2002). Data from NHANES 2005–2006 estimated that the intake of saturated fat in America has remained stable over the last 15 years at 11 to 12 percent of calorie intake despite long standing recommendations for Americans to reduce levels to below 10 percent (DGAC, 2010) or even to below 7 percent of calorie intake (the American Heart Association recommendation) (Lichtenstein et al., 2006).

Trans fat intake has been more difficult to estimate than saturated fat intake. Prior to the introduction of *trans* fat on the Nutrition Facts panel in 2006, it was estimated that *trans* fat comprised approximately 3 percent of calorie intake.[4] However, as a result of this new labeling requirement combined with bans in certain localities on the use of partially-hydrogenated fat plus heightened public awareness, many foods have been reformulated to lower or eliminate their *trans* fat (Eckel et al., 2007; Mozaffarian et al., 2010). Thus determining an accurate current estimate of *trans* fat intake will not be possible until nutrient composition databases are updated and more recent intake surveys are analyzed. Nonetheless, since an ideal diet would be as low in *trans* fat as possible (IOM, 2002/2005), it can be assumed that even at the current (likely reduced) intake levels, *trans* fat consumption remains a concern.

The effect of dietary cholesterol on LDL cholesterol concentrations, within the context of current U.S. intakes, is relatively small compared to that of saturated and *trans* fatty acids (Clarke et al., 1997; Howell et al., 1997). Although cholesterol remains a nutrient that should be limited because of its ability to increase the risk of elevated blood LDL cholesterol concentrations (DGAC, 2010), the overconsumption of cholesterol is less of a public health concern than the overconsumption of saturated and *trans* fats and sodium. A majority of women, children 2 to 13 years of age, and girls 14 to 18 years of age have cholesterol intakes at or below recommended levels (DGAC, 2010). Instead, overconsumption of cholesterol is mainly a problem for men and boys aged 12 to 19 years (ARS, 2010; DGAC, 2010). In addition, dietary

[4] 68 FR 41442.

sources of cholesterol largely track with saturated fat. Hence, if sources of saturated fat intakes (which are higher than recommended for much of the population) are reduced, intakes of dietary cholesterol will be as well.

In contrast, unsaturated fats have a number of health benefits. Some polyunsaturated fatty acids are essential nutrients needed for healthy physiological function (DGAC, 2010). In addition, the 2010 Dietary Guidelines Advisory Committee found strong and consistent evidence that dietary polyunsaturated fats are associated with improved blood lipids related to CVD, in particular when these fats replaced saturated and *trans* fats in the diet (DGAC, 2010). A recent pooling project concluded that diets with higher polyunsaturated fat–to–saturated fat ratios were associated with lower CHD rates (Jakobsen et al., 2009). Omega-3 fatty acids from polyunsaturated fat may have an independent beneficial effect on CVD outcomes. Moderate evidence shows that consumption of two servings of seafood per week providing an average of 250 mg of omega-3 fatty acids is associated with reduced cardiac mortality (DGAC, 2010).

Hypertension

Hypertension, also referred to as high blood pressure, is estimated to affect a third of U.S. adults (Fields et al., 2004; IOM, 2010). An additional third of U.S. adults are considered to have pre-hypertension (Cutler et al., 2008). As with adults, blood pressure levels have increased among U.S. children and adolescents over the past two decades (DGAC, 2010). Elevated blood pressures are associated with serious health conditions, including stroke and cardiovascular disease events. Even in childhood elevated blood pressure is a concern, especially since it may lead to increased cardiovascular disease risk later in life (DGAC, 2010).

Multiple diet-related factors influence the development of elevated blood pressure, including excess weight, inadequate potassium intake (see page 4-10), and high alcohol consumption (IOM, 2005). As previously discussed, the majority of the American population is now overweight or obese and is therefore at greater risk for hypertension. In addition, it is important to note that a large body of evidence indicates that a high intake of sodium adversely affects blood pressure (e.g., IOM 2005, 2010).

Over the past four decades sodium intake in the United States has trended upward across both age and gender groups, and it currently averages 3,400 mg per day (IOM, 2010). This exceeds the Upper Intake (UL) levels of the IOM and the recommendations of the 2005 Dietary Guidelines for a daily sodium intake of less than 2,300 mg in the general population and less than 1,500 mg for higher-risk subpopulations; similarly it exceeds more recent recommendations from the 2010 Dietary Guidelines Advisory Committee that most Americans should consume only 1,500 mg of sodium per day (DGAC, 2010; IOM, 2005; 2010). The top contributors to sodium intake are mixed dishes (e.g., sandwiches, pizza with meat, and hamburgers and cheeseburgers), meat and meat alternates, and grain products (e.g., bread, cold cereal, and rice) (see Table 4-4) (IOM, 2010).

TYPE 2 DIABETES

Type 2 diabetes, one of three main types of glucose intolerance, accounts for 90 to 95 percent of all diagnosed cases of diabetes (NDIC, 2008) It was previously referred to as non-insulin-dependent diabetes mellitus or adult-onset diabetes. The onset of type 2 diabetes is closely associated with excess body weight gain. More than 85 percent of people with type 2 diabetes are overweight. Of the estimated 23.6 million Americans with diabetes, approximately 5.7

million of these cases are undiagnosed (NDIC, 2008). Many more Americans are at high risk for the disease without knowing it.[5]

Complications from diabetes are numerous, and its health care costs are staggering. In 2004 heart disease and stroke were noted on, respectively, 68 percent and 16 percent of diabetes-related death certificates among those 65 years or older.[6] Diabetes is also the leading cause of both nervous system disease, amputations, dental disease, and complications during pregnancy. In 2007 the total direct and indirect cost of diabetes in the United States was estimated to be $174 billion.[7] Weight loss can prevent or delay the onset of type 2 diabetes (Hamman et al., 2006). Diet and physical activity interventions are effective and feasible approaches to reducing the incidence of type 2 diabetes and are often more cost effective than medications.[8]

CANCER

The American Cancer Society estimates that about one-third of cancer deaths expected to occur in 2010 will be related to overweight or obesity, physical inactivity, and poor nutrition (ACS, 2010). In 2007 the World Cancer Research Fund and the American Institute for Cancer Research together published an extensive report on the relationship between food, nutrition, and physical activity and the prevention of cancer (WCRF/AICR, 2007). While numerous dietary factors (e.g., carotenoids, lycopene, fiber, selenium, sugar, fatty acids, etc.) were linked to either decreased or increased risks of specific types of cancer, the evidence is difficult to synthesize, and firm judgments on their relationships generally have not been made. The report did, however, conclude that "maintenance of a healthy weight throughout life may be one of the most important ways to protect against cancer" (WCRF/AICR, 2007).

NUTRIENTS AND FOOD GROUPS TO ENCOURAGE

Shortfall Nutrients

Nutrients known to be beneficial or necessary for humans to sustain health are numerous, but recent analyses have found only a few nutrients for which Americans have an insufficient intake that is linked to clinically important conditions. A review by the Dietary Guidelines Advisory Committee 2010 reported insufficient intakes of vitamin D, calcium, potassium, and fiber among Americans (DGAC, 2010).

Vitamin D

Vitamin D has a long-established role in maintaining bone health and is critical to calcium absorption within the body. Classic deficiencies of vitamin D result in rickets in children and bone mineral loss in adults. A number of benefits from vitamin D beyond bone health have been suggested, including improved immune function, cancer risk reduction, and prevention of diabetes, but evidence-based reviews have been carried out for only some health outcomes (Cranney et al., 2007; Chung et al., 2009). There is currently much discussion about the levels of

[5] Available online: http://www.diabetes.org/diabetes-basics/type-2 (accessed July 12, 2010).
[6] Available online: http://www.diabetes.org/diabetes-basics/type-2 (accessed July 12, 2010).
[7] Available online: http://www.diabetes.org/diabetes-basics/type-2 (accessed July 12, 2010).
[8] Available online: http://www.diabetes.org/diabetes-basics/type-2 (accessed July 12, 2010).

deficiency within the U.S. population, but agreed-upon definitions for deficiency or insufficiency of vitamin D do not currently exist, with those in use varying greatly. A report from the IOM

TABLE 4-4 Top 10 Foods Contributing Sodium to the American Diet

Food Categories	Percent of Total Sodium Consumed
Mixed dishes (sandwiches, pizza with meat, burgers, Mexican entrees, pasta dishes)	44
Meat, meat alternatives (chicken, cheese, eggs, bacon/sausage, beef)	15.5
Grains (bread, cold cereal, rice, pancakes, waffles, French toast, crackers)	11.4
Vegetables (green salads, fried and non-fried potatoes, cooked tomatoes, cooked green beans)	9.3
Sweets (cookies, cakes/cupcakes, ice cream, pies/cobblers, doughnuts)	5.0
Condiments and oils (catsup, mustard, relish, soy sauce, gravy, salad dressing, pickles, olives, margarine)	4.3
Salty snacks (corn-based snacks, popcorn, potato chips, pretzels, party mix)	3.4
Milk (plain 2% milk, plain whole milk, plain skim milk, plain 1% milk, yogurt)	2.9
Beverages (noncarbonated sweetened drink, non-diet soda, diet soda, coffee, beer)	2.2
Beans, nuts, seeds (baked or refried beans, nuts, beans, protein or meal enhancement, peanut or almond butter)	2.1

SOURCE: IOM, 2010.

concerning nutritional requirements for vitamin D and calcium will be released in 2010. Fortified foods remain an important source of vitamin D since it is found naturally only in fatty fish, egg yolks, and liver. In addition, vitamin D can be synthesized endogenously when skin is exposed to sunlight.

Calcium

Adequate intake of calcium is necessary for bone health as well as for basic biological functions such as nerve transmission, vasoconstriction, vasodilation, and muscle contraction. The major sources of calcium in the American diet are also the most bioavailable. Although there are additional sources of calcium, fluid milk and milk products provide more than 70 percent of the calcium in American diets (DGAC, 2010). However, with the exception of boys and girls aged 1

to 3 years, NHANES data from 2003 to 2006 indicate that a majority of people in the United States do not meet the Adequate Intake (AI) level for calcium from consuming foods alone (DGAC, 2010) and that adolescents and adults consume only about half the recommended amount of fluid milk and milk products.

Potassium

Adequate potassium intakes are associated with optimal blood pressure (DGAC, 2010) and may reduce the risk of developing kidney stones and bone loss (HHS/USDA, 2005a). Additionally, many clinical trials show that potassium supplementation reduces blood pressure (IOM, 2005). Diets low in potassium and high in sodium are associated with higher blood pressure levels than diets containing adequate potassium and high sodium intake (IOM, 2005). African Americans and hypertensive individuals may benefit most from an increased potassium intake. Data from NHANES 2007–2008 estimated the mean intake in the United States to be 2,290 mg/day for women and 3,026 mg/day for men (ARS, 2010), substantially lower than the recommended AI of 4,700 mg. The main sources are milk, coffee, poultry and beef and mixed dishes prepared from these meats, orange and grapefruit juice, and many other fruits and vegetables.

Fiber

Fiber may protect against cardiovascular disease, obesity, and type 2 diabetes, and it is essential for digestive health (Lairon et al., 2005; Estruch et al., 2009; DGAC, 2010). It has been reported to promote satiety, leading to reduced energy intake and lowering the risk of overweight and obesity (Heaton et al., 1978). Dietary (total) fiber is listed on the Nutrition Facts panel. From NHANES data it is estimated that usual intakes are 15 g/day and that less than 5 percent of the U.S public consumes 25 g per day (DGAC, 2010). The Adequate Intake for total fiber is 14 g/1000 calories (25 g/d total fiber for women and 38 g/d for men) based on the level observed to protect against coronary heart disease (IOM 2002/2005). Sources of dietary fiber include whole grains, legumes, vegetables, fruits, and nuts. The 2010 Dietary Guidelines Advisory Committee report (DGAC, 2010) recommends that more whole grains be substituted for refined grains in the diet and concludes that there is an urgent need for an international definition of whole grain and for methods to measure its content in foods.

Shortfall Food Groups

The shortfall nutrients in the American diet are an indicator of low intake of certain food groups, namely fruits, vegetables, whole grains, and “fat free” or “low fat” milk and milk products. The 2010 Dietary Guidelines Advisory Committee examined data published by the National Cancer Institute (NCI) regarding usual food intake[9] and identified several shortfall food groups which are “consumed in amounts lower than the minimum levels recommended in the USDA Food Patterns to meet IOM nutrient intake recommendations for each age–sex group” (DGAC, 2010). Vegetable intakes fall below recommended intakes for most Americans, and more than 75 percent of adult men and women and boys and girls aged 9 to 18 years consume less than the recommended amount of fruit per day. Most Americans consume more total grains servings per day than recommended. However, more than 95 percent of all age–sex groups fail to

[9] Available online: http://riskfactor.cancer.gov/diet/usualintakes/pop/#results (accessed August 4, 2010).

consume the recommended amount of whole grains, which is 50 percent of the total grains consumed. The intake of fat free or low fat milk and milk products is also less than the recommended amounts for most adults and for most children and adolescents.

The shortfall food groups discussed above have been targeted for increase by both the 2005 Dietary Guidelines Advisory Committee and the 2010 Dietary Guidelines Advisory Committee. In particular, the 2010 Dietary Guidelines Advisory Committee emphasized a total diet approach that is:

- Energy balanced, limited in total calories, and portion controlled
- Nutrient-dense and includes
  - Vegetables, fruits, "high-fiber" whole grains
  - "Fat free" or "low fat" fluid milk and milk products
  - Seafood, lean meat and poultry, eggs, soy products, nuts, seeds, and oils
- Very low in solid fats (i.e., saturated and *trans* fats) and added sugars

Promotion of healthy dietary patterns and of the consumption of under-consumed food groups has been recommended as the primary approach to increasing the intake of the shortfall nutrients (DGAC, 2010).

FINDINGS

From reviewing diet-related health in the United States, it is clear that the greatest nutritional challenge our nation faces is chronic diseases caused by excess intakes rather than deficiencies. Two key findings from this review include:

Finding 1: Obesity, cardiovascular disease, type 2 diabetes, and certain types of cancers are the health risks affecting the greatest number of Americans that are also most strongly associated with diet.

Finding 2: Americans consume too many calories, saturated fats, *trans* fats, and added sugars; too much sodium; and too little Vitamin D, calcium, potassium, and fiber.

These findings were critical in developing conclusions on the criteria for FOP systems, since one of the committee's guiding principles identified in Chapter 1 states that FOP systems should focus on the nutrients or food components most strongly associated with the diet-related health risks affecting the greatest number of Americans. The remaining chapters of this report consider how FOP systems may best address the diet and health concerns identified in these findings.

REFERENCES

ACS (American Cancer Society). 2010. *Cancer facts and figures 2010.* Atlanta, GA: American Cancer Society.

AHA (American Heart Association). 2010. *Heart disease and stroke statistics: 2010 Update at a glance.* Dallas, TX: American Heart Association.

ARS (Agricultural Research Service, USDA). 2010. What We Eat in America, NHANES 2007-2008. Revised Aug 2010. http://www.ars.usda.gov/SP2UserFiles/Place/12355000/pdf/0708/Table_1_NIN_GEN_07.pdf

Bachman, J. L., J. Reedy, A. F. Subar, and S. M. Krebs-Smith. 2008. Sources of food group intakes among the U.S. population, 2001–2002. *Journal of American Dietetic Association* 108:804–814.

Calle, E. E, C. Rodriguez, K. Walker-Thurmond, M. J. Thun. 2003. Overweight, obesity, and mortality from cancer in a prospectively studied cohort of U.S. adults. *New England Journal of Medicine* 348(17):1625–1638.

Chung, M., E. M. Balk, M. Brendel, S. Ip, J. Lau, J. Lee, A. Lichtenstein, K. Patel, G. Raman, A. Tatsioni, T. Terasawa, and T. A. Trikalinos. 2009. Vitamin D and calcium: Systematic review of health outcomes. Evidence Report/Technology Assessment No. 183. AHRQ Publication No. 09–E015, Rockville, MD: Agency for Healthcare Research and Quality.

Clarke, R., C. Frost, R. Collins, P. Appleby, and R. Peto. 1997. Dietary lipids and blood cholesterol: Quantitative meta-analysis of metabolic ward studies. *BMJ* 314(7074):112–117.

Cranney, A., T. Horsley, S. O'Donnell, H. A. Weiler, L. Puil, D. S. Ooi, S. A. Atkinson, L. M. Ward, D. Moher, D. A. Hanley, M. Fang, F. Yazdi, C. Garritty, M. Sampson, N. Barrowman, A. Tsertsvadze, and V. Mamaladze. Effectiveness and safety of vitamin D in relation to bone health. 2007. Evidence Report/Technology Assessment No. 158. AHRQ Publication No. 07–E013. Rockville, MD: Agency for Healthcare Research and Quality.

Cutler, J. A., P. D. Sorlie, M. Wolz, T. Thom, L. E. Fields, and E. J. Roccella. 2008. Trends in hypertension prevalence, awareness, treatment, and control rates in United States adults between 1988–1994 and 1999–2004. *Hypertension* 52:818–827.

Dall, T. M., V. L. Fulgoni, Y. Zhang, K. J. Reimers, P. T. Packard, and J. D. Astwood. 2009. Potential health benefits and medical cost savings from calorie, sodium and saturated fat reductions in the American diet. *American Journal of Health Promotion* 23:412–422.

DGAC (Dietary Guidelines Advisory Committee). 2010. *Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010.* Washington, DC: U.S. Department of Health and Human Services, U.S. Department of Agriculture.

Eckel, R. H., S. Borra, A. H. Lichtenstein, and S. Y. Yin-Piazza. 2007. Understanding the complexity of *trans* fatty acid reduction in the American diet. *Circulation* 115:2231–2246.

Estruch, R., M. A. Martinez-Gonzalez, D. Corella, J. Basora-Gallisa, V. Ruiz-Gutierezz, M. I. Covas, M. Fiol, E. Gomez-Garcia, M. C. Lopez-Sabater, R. Escoda, M. A. Pena, J. Diez-Espino, C. Lahoz, J. Laptera, G. Saez, and E. Ros. 2009. Effects of dietary fiber intake on risk factors for cardiovascular disease in subjects at high risk. *Journal of Epidemiology & Community Health* 63:582–588.

FAO/WHO (Food and Agriculture Organization/World Health Organization). 1998. *Carbohydrates in human nutrition*. Rome: Food and Agriculture Organization.

Fields, L. E., V. L. Burt, J. A. Cutler, J. Hughes, E. J. Roccella, and P. Sorlie. 2004. The burden of adult hypertension in the United States 1999 to 2000: A rising tide. *Hypertension* 44(4):398–404.

Frary, C. D., R. K. Johnson, and M. Q. Wang. 2004. Children and adolescents' choices of foods and beverages high in added sugars are associated with intakes of key nutrients and food groups. *Journal of Adolescent Health* 34(1):56–63.

Hamman, R. F., R. R. Wing, S. L. Edelstein, J. M. Lachin, G. A. Bray, L. Delahanty, M. Hoskin, A. M. Kriska, E. J. Mayer-Davis, X. Pi-Sunyer, J. Regensteiner, B. Venditti, and J. Wylie-Rosett, J.

2006. Effect of weight loss with lifestyle intervention on risk of diabetes. *Diabetes Care* 29(9):2102–2107.

Heaton, K. W., G. B. Haber, L. Burroughs, and D. Murphy. 1978. How fiber may prevent obesity: Promotion of satiety and prevention of rebound hypoglycemia. *American Journal of Clinical Nutrition* 31:S280.

HHS/USDA (U. S. Department of Health and Human Services/U.S. Department of Agriculture). 2002/2005. *Dietary Guidelines Advisory Committee Report, 2005.* Washington, DC: Government Printing Office.

HHS/USDA (U. S. Department of Health and Human Services/U.S. Department of Agriculture). 2005b. *Dietary guidelines for Americans, 2005.* Washington, DC: Government Printing Office.

Howell, W., D. McNamara, M. Tosca, B. Smith, and J. Gaines. 1997. Plasma lipid and lipoprotein responses to dietary fat and cholesterol: A meta-analysis. *American Journal of Clinical Nutrition* 65(6):1747–1764.

IOM (Institute of Medicine). 2002/2005. *Dietary reference intakes for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein and amino acids.* Washington, DC: The National Academies Press.

IOM. 2005. *Dietary reference intakes for water, potassium, sodium, chloride, and sulfur.* Washington, DC: The National Academies Press.

IOM. 2010. *Strategies to reduce sodium intake in the United States.* Washington, DC: The National Academies Press.

Jakobsen, M. V., E. J. O'Reilly, B. L. Heitmann, M. A. Pereira, K. Balter, G. E. Fraser, U. Goldbourt, G. Hallmans, P. Knekt, S. Liu, P. Pietiren, D. Spiegelman, J. Stevens, J. Virtarmo, W. C. Willett, and A. Ascherio. 2009. Major types of dietary fat and risk of coronary heart disease: A pooled analysis of 11 cohort studies. *American Journal of Clinical Nutrition* 89:1425–1432.

Johnson, R. K., L. J. Appel, M. Brands, B. V. Howard, M. Lefevre, R. H. Lustig, F. Sacks, L. M. Steffen, J. Wylie-Rosett, and on behalf of the American Heart Association Nutrition Committee of the Council on Nutrition, Physical Activity, and Metabolism and the Council on Epidemiology and Prevention. 2010. Dietary sugars intake and cardiovascular health: A scientific statement from the American Heart Association. *Circulation* 120:1011–1020.

Lairon, D., N. Arnault, S. Bertrais, R. Planells, E. Clero, S. Hercberg, and M.–C. Boutron-Ruault. 2005. Dietary fiber intake and risk factors for cardiovascular disease in French adults. *American Journal of Clinical Nutrition* 82:1185–1194.

Lichtenstein, A. H., L. J. Appel, M. Brands, M. Carnethon, S. Daniels, B. Franklin, P. Kris-Etherton, W. S. Harris, B. Howard, N. Karanja, M. Lefevre, L. Rudel, F. Sacks, L. Van Horn, M. Winston, and J. Wylie-Rosett. 2006. Diet and lifestyle recommendations revision 2006: A scientific statement from the American Heart Association Nutrition Committee. *Circulation* 114:82–96.

Marriott, B. P., L. Olsho, L. Hadden, and P. Connor. 2010. Intake of added sugars and selected nutrients in the United States, National Health and Nutrition Examination Survey (NHANES) 2003-2006. *Critical Reviews in Food Science and Nutrition* 50:228–258.

Mokdad, A., J. S. Marks, D. E. Stroup, and J. Gerberding. 2004. Actual causes of death in the United States. *Journal of the American Medical Association* 291(10):1238–1245.

Mozaffarian, D., M. F. Jacobson, and J. S. Greenstein. 2010. Food reformulations to reduce *trans* fatty acids. *New England Journal of Medicine* 362(21):2037–2039.

NCHS (National Center for Health Statistics, Centers for Disease Control and Prevention). 2010. Health, United States, 2009, with special feature on medical technology. PHS Publication No. 2010-1232. Hyattsville, MD: National Center for Health Statistics, Centers for Disease Control and Prevention. Also http://www.cdc.gov/nchs/hus.htm.

NCI (National Cancer Institute). 2010. Sources of calories from added sugars among the U.S. population, 2005–2006. Available at http://riskfactor.cancer.gov/diet/foodsources/added_sugars (accessed August 31, 2010).

NDIC (National Diabetes Information Clearing House. 2008. National diabetes statistics, 2007. NIH Pub. No. 08-3892, June 2008. Also http://diabetes.niddk.nih.gov/dm/pubs/statistics/#allages.

NIH (National Institutes of Health). 2001. Executive summary of the third 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). *Journal of the American Medical Association* 285:2486–2497.

NIH. 2002. Third 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) final report. *Circulation* 106(25):3143–3421.

Ogden, C.L.; M. D. Carroll; L. R. Curtin; M. Lamb; K. M. Flegal. 2010.Prevalence of high Body Mass Index in US children and adolescents, 2007-2008. *JAMA*. 303(3):242-249.

Pi-Sunyer, F. X. 2009. The medical risks of obesity. *Post Graduate Medicine* 121(6):21–33.

Wang, Y. C., S. N. Bleich, and S. L. Gortmaker. 2008. Increasing caloric contribution from sugar-sweetened beverages and 100% fruit juices among U.S. children and adolescents, 1988-2004. *Pediatrics* 121:1604-1614.

WCRF/AICR (World Cancer Research Fund/American Institute for Cancer Research). 2007. *Food, nutrition, physical activity, and the prevention of cancer: A global perspective.* Washington, DC: American Institute for Cancer Research.

5
Purpose and Merits of Front-of-Package Nutrition Rating Systems

Given the prevalence of obesity and chronic disease in the United States, there is a great need to provide the public with tools that can help them adopt healthier lifestyles, including tools to help select a health promoting diet. The goal of the Nutrition Labeling and Education Act and the standardized label format (Nutrition Facts panel) was to provide useful nutrition information to help consumers make better dietary choices. A recent U.S. Department of Agriculture (USDA) study shows that while the majority of Americans still report using the Nutrition Facts panel, there appears to have been a small decline in use over the ten-year period between 1996 and 2006 (Todd and Variyam, 2008). The authors suggest that for many consumers the difficulty of using this information exceeds the perceived benefits. This is consistent with studies that have shown that even those individuals who use the labels have difficulty interpreting the nutrition information correctly, regardless of their numeracy (the ability to use and understand numbers in daily life) and literacy (Cowburn and Stockley, 2005; Rothman et al., 2006).

A study sponsored by the American Dietetic Association reported that 67 percent of consumers said that diet and nutrition were very important to them, but 41 percent of the respondents said that their poor understanding of diet and nutrition was a key reason that they did not do more to achieve a healthy diet. A majority of respondents reported looking for practical tips to help them eat right, and the percentage of consumers actively seeking information about nutrition and healthy eating doubled from 19 percent in 2000 to 40 percent in 2008 (ADA, 2008).

Based on a systematic review of research on consumer understanding of nutrition labels, Cowburn and Stockley (2005) called for improvements in nutrition labeling so as to provide more useful information at the point of purchase and to promote the selection of healthier foods. FOP rating systems and symbols have the potential to provide such an improvement. While many of the healthiest foods in the supermarket, such as fresh fruits and vegetables, do not bear labels, symbols for these foods could be placed on signage or shelf labels.

CATEGORIZATION OF FRONT-OF-PACKAGE NUTRITION RATING SYSTEMS

As described in Chapter 3, there are a variety of reasons for developing and using FOP nutrition rating systems, and the reasons for use and development vary according to the intended end user, the goals of the rating systems, and the interests of the bodies developing the systems. Because there are dozens of systems in use both in the United States and abroad, the committee chose for its review a set of 20 systems representative of those now in the marketplace. To make it easier to compare and contrast them, the various systems were placed into three categories. Descriptions of these categories are provided in Box 5-1.

BOX 5-1
Definition of Front-of-Package System Categories

Nutrient-Specific Systems: Systems with symbols that display the amount per serving of select nutrients from the Nutrition Facts panel on the front of the food package or use symbols based on claim criteria. Percent daily values (%DV) or guideline daily amounts (%GDA) appear on the front of the package, which may also include traffic light colors or words to indicate that a product contains "high," "medium," or "low" amounts of specific nutrients. A declaration of calories per serving may also be on the front of the food package. Systems using symbols based on claim criteria may award multiple symbols indicating that a product is "low fat," "high fiber," etc.

Summary Indicator Systems: Systems with a single symbol, icon, or score that provides summary information about the nutrient content of a product. No specific nutrient content information is given in these systems. Systems may be based on nutrient thresholds or algorithms. Products that meet the criteria are awarded the system's symbol. Systems often use different criteria based on food categories (e.g., type of food or food product). Algorithm systems evaluate food products based on an equation that takes nutrients and other components (positive and/or negative) into account. Products are given a numeric score (i.e., 1–100) or number of symbols (i.e., 0, 1, 2, 3) to indicate the nutritional quality of the product.

Food Group Information Systems: Systems in which symbols are awarded to a food product based on presence of a food group or food ingredient. Some symbols indicate the presence of a serving (or partial serving) of a particular food group; other symbols indicate the presence of ingredients considered to be important dietary components, such as whole grains.

Nutrient-specific systems have been developed largely by food manufacturers and retailers (Wegmans, Harris Teeter, Kellogg's, General Mills), with the exception of the U.K. Food Standards Agency's Traffic Light system. Wegmans' and Harris Teeter's systems feature symbols to indicate nutrient content—e.g., LF for "low fat," HF for "high fiber," etc. —and are based upon Food and Drug Administration (FDA) nutrient content claims. General Mills and Kellogg's present select information from the Nutrition Facts panel, such as calories and fat per serving, usually accompanied by the percentage of Daily Value (%DV)[1] or Guideline Daily Amount (%GDA).[2] The systems are aimed at providing consumers with a snapshot of the nutrient content of a food and what that food contributes to their daily diet. If consumers want to consume a specific amount of fiber or limit their sodium intake, this type of system can help

[1] Daily Values (DVs) were developed by FDA to put the amount of a nutrient in a serving of food in the context of a total daily diet; %DVs are required in the Nutrition Facts panel for those nutrients for which Daily Values were established (21 CFR 101.9(8).

[2] Guideline Daily Amounts (GDAs) are used in Europe on a voluntary basis by food and beverage and retail industries to give context to the energy and nutrient content of foods and beverages. In June 2006 the Confederation of the Food and Drink Industries introduced EU GDAs based on Eurodiet recommendations (available online at http://www.gdalabel.org.uk/gda/background_european.aspx (accessed June 17, 2010). Nutrition at a Glance (from Kellogg's) uses the term "GDA" in system descriptions, and uses Daily Values as the basis for the %GDA presented on products sold in the United States.

them to do so quickly by glancing at a package and selecting or rejecting the product based on its nutrient content. Some of the nutrient-specific systems, such as the UK traffic light characterize the amount of various nutrients by using color, words, or some combination of the two to indicate that the products contains "high," "medium," or "low" amounts of each nutrient of interest.

Summary indicator systems have been developed by independent (nonprofit) organizations or advisory groups, food manufacturers, and consortiums of those groups. No specific nutrient content information is given in these systems. Generally, a single symbol or score is used. Summary indicator systems may be based on nutrient thresholds or algorithms. Threshold-based systems such as Smart Choices or the Heart Check use a single symbol to indicate that the food product upon which it is featured has satisfied that system's nutrient criteria. These systems are aimed at providing consumers with a way to select foods of higher nutritional quality without having to process nutrition information in detail. Summary indicators based on algorithms like Guiding Stars and NuVal use a mathematical equation, which may include a combination of positive and negative values reflecting the various nutrients as well as other factors to score the nutritional quality of a food. A numerical or symbol-based score is used as the summary symbol.

Food group information systems emphasize particular food groups or components in a food product, such as fruits and vegetables or whole grains. ConAgra is the main food manufacturer using this type of system, which it applies in combination with USDA's MyPyramid. ConAgra's target audience is consumers who want the convenience of prepared meals and foods but who are concerned about the healthfulness of those prepared foods (ConAgra, 2010). In addition, the Whole Grains Council developed a Whole Grain Stamp for council members to use on package labels when the product contains at least 8 g of whole grains, the amount that is equivalent to half a serving of whole grains according to MyPyramid guidelines.

GENERAL PURPOSES OF FRONT-OF-PACKAGE SYSTEMS

In 2010, the FDA announced an overarching goal for FOP nutrition rating systems:

> The goal of an FOP nutrition label is to increase the proportion of consumers who readily notice, understand, and use the available information to make more nutritious choices for themselves and their families, and thereby prevent or reduce obesity and other diet-related chronic disease. [3]

FDA also identified a number of other potential purposes of FOP systems, including providing "a more convenient and effective information tool for consumers seeking quick and accurate information about the nutritional quality of the food they are purchasing and accessing," helping to educate consumers and aid them in making healthier food choices,[4] and encouraging industry reformulation of products.[5]

The committee's review of existing systems identified a number of purposes for FOP systems. As described in Chapter 3, some of them were intended to encourage the purchase of

[3] 75 FR 22602.
[4] 75 FR 22602.
[5] 75 FR 22602.

more nutritious products belonging to an individual company's portfolio. Others were introduced specifically to help consumers make choices consistent with reduced CVD risk. Still others were designed to encourage the reformulation of packaged foods. Many other purposes were identified as well.

In addition to examining the purposes of the various FOP rating systems that have been introduced to the marketplace, the committee also found it useful to try to identify as many potential purposes of FOP rating systems as possible, regardless of whether a particular purpose had driven previous system development. In this exercise, the committee identified ten potential purposes of FOP rating systems. Table 5-1 identifies purposes that are currently or could potentially be achieved by the broad categories of FOP system types defined in Box 5-1. The description of the purposes provided below also includes some examples (although not an exhaustive list) of current systems identified by the committee as serving a particular purpose.

Provide Prominent Calorie Content Information

At present, the major health challenge in the United States is overweight and obesity, and energy content is arguably the most important information that should be presented as a component of an FOP system or symbol. Calorie content can be presented in various ways: (1) per serving, (2) percentage of a 2,000-calorie reference total daily intake, (3) calories per package for items that are likely to be consumed for a single meal or snack, or (4) per serving and per package (regardless of size). As an example of the third approach, the beverage industry announced it will declare calories per container as part of an FOP system on packages up to and including 20 fl. oz.[6] It might be possible for all types of FOP systems to include prominent calorie content information if this were incorporated into the FOP symbol.

Provide Prominent Serving Size Information

As with calorie information, FOP nutrition rating systems could also provide descriptive information about serving size in order to reinforce with consumers the actual quantity of food that is associated with the declared calorie content. None of the reviewed FOP systems specifically indicates serving size, but, if found useful through consumer research, serving size could be indicated alongside or incorporated within the system symbol. An additional metric that could help consumers associate calorie content and serving size is the number of servings per package for packages that contain three or more servings.

Provide Targeted Nutrition Information

By design, nutrient-specific systems provide information on targeted nutrients. These systems all include nutrients identified by the system developers as nutrients that should be limited in the diet, but not all of them necessarily include nutrients to encourage. In addition to amount per serving, some U.S. systems provide the percent of the Daily Value (%DV) per serving, and UK systems may provide the percent of the Guideline Daily Amount (%GDA).[7]

[6] Available online: http://www.ameribev.org/news--media/news-releases--statements/more/180 (accessed June 1, 2010).

[7] As stated in footnote 2, Kellogg's Nutrition at a Glance uses the term "GDA" in system descriptions, but actually uses FDA Daily Values for calculating the percentage contribution to a 2,000 calorie daily diet.

TABLE 5-1 Comparison of Front-of-Package Scheme Types According to Attribute or Potential to Fulfill Specific Purposes[a]

	Nutrient Specific Information			Summary Indicator		Food Group Information	
Purpose	Calories per Serving	Nutrient Amount per Serving	Symbol Based on FDA/USDA Claim Criteria	Based on Nutrient Thresholds	Based on Algorithm	Food Groups	Food Ingredient
Provide prominent calorie content information	✓	✓	✓	✓	✓	✓	✓
Provide prominent serving size information	✓	✓	✓	✓	✓	✓	✓
Provide targeted nutrition information	✓	✓					
Indicate whether product is high or low in specific nutrient(s)	✓	✓	✓				
Summarize overall nutritional value of a product				✓	✓		
Facilitate comparisons of nutritional value *within* food categories	✓[b]	✓[b]	✓[b]	✓[c]	✓[c]		
Facilitate comparisons of nutritional value *across* food categories	✓[b]	✓[b]	✓[b]	?[d]	?[d]		
Provide information about contribution to recommended food groups				✓[e]		✓	✓
Provide guidance on products suitable for marketing to children	✓[b]	✓[b]	✓[b]	✓[c]	✓[c]		
Encourage product reformulation	✓	✓	✓	✓	✓	✓	✓

[a]A checkmark indicates a system subtype either currently does or potentially could be developed to fulfill the specified purpose.
[b]Only specific nutrient content can be compared, e.g., sodium, saturated fat, etc.
[c]Only overall nutritional value can be compared.
[d]The ability to compare products across categories would depend on how the nutrient thresholds or algorithm are set.
[e]Some summary indicator systems include criteria for food groups, but food group contribution is not depicted on FOP.

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Indicate Whether a Product Is High or Low in Specific Nutrients

Some systems use symbols that indicate whether a product meets the criteria for a nutrient content or health claim defined by FDA or USDA, e.g. “low fat” cheese or “lean” beef. Similarly the Heart Check symbol (American Heart Association) includes text to indicate that an item is “low” in saturated fat and cholesterol (non-meat items) or “extra lean" (meat and seafood). UK labeling schemes may include a text descriptor of “high,” “medium,” or “low” or a color indicator of “high” (red), “medium” (amber), or “low” (green) for nutrients that should be limited in the diet.

Summarize Overall Nutritional Value of a Product

By definition, summary indicators purport to assess the overall nutritional value of a product. As described in Box 5-1, a food product may be evaluated based upon (1) a specific set of criteria for various nutrients (threshold) or (2) a mathematical equation—commonly referred to as an algorithm—that takes nutrients and other factors (positive or negative or both) into account and generates a score or other symbol to indicate the product’s nutritional quality.

Facilitate Comparisons of Nutritional Value *Within* Food Categories

A merit of systems based on nutrient-specific information—and, to some extent, summary symbols based on nutrient thresholds and algorithms—is that consumers can compare the nutritional value of items within a product category, such as within the category of crackers. For example, the sodium content of crackers can be compared on the basis of weight (expressed in mg) or %DV per serving. These comparisons can also be made with the Nutrition Facts panel, but moving sodium information to a more prominent location on the package may allow for more convenient decision-making. Sodium content could also be evaluated if the products carried a nutrient content claim, such as “low sodium,” or a claim-based FOP symbol for “low sodium.” However, for this comparison to be made accurately, the consumer must be able to assume that products that do not contain the claim do not qualify as “low sodium,” which may not always hold true.

In contrast to focusing on a single nutrient, threshold- and algorithm-based systems attempt to evaluate the overall nutritional value of a given product by considering the content of many different nutrients that should be either limited or encouraged. Thus, a cracker that contains a summary symbol based on nutrient thresholds will have met specific criteria not only for sodium but also for other nutrients and will theoretically have a better overall nutritional value than a cracker that does not have the symbol. Crackers evaluated by an algorithm can be compared by, for example, the number of stars they contain (as in Guiding Stars) or by the numerical value of their scores (as in NuVal).

Facilitate Comparisons of Nutritional Value *Across* Food Categories

All FOP systems based on nutrient-specific information allow consumers to compare the nutritional value of food and beverage items across product categories. Assuming that crackers and cookies would be viewed as two different product categories, for example, consumers could compare the sodium content of crackers to the sodium content of cookies on the basis of amount expressed as mg or %DV per serving. Cookies and crackers can also be compared for sodium content based on the presence of nutrient content claim–based symbols because the criteria for

claims such as "sodium-free," "very low sodium," and "low sodium" are the same for all product categories (except main dishes and meals[8]). For comparisons to be made accurately, the consumer must be able to assume that products that do not contain a claim or symbol indicating "low sodium" are indeed not low in sodium, which is not always true.

FOP systems using summary indicators based on thresholds could allow for comparison of nutritional value *across* product categories if the systems have one set of nutrient criteria for all food categories. However, current threshold systems have different nutrient criteria for different food categories, which are themselves defined differently for each system. For example, the overall nutritional value of a breakfast cereal and yogurt could only be compared in a threshold-based system if the nutrients included and the criteria for evaluating the nutrient content were the same.

The same limitations for comparing products *across* food categories apply to algorithm-based systems. For the general population (i.e., not including infant and toddler foods), Guiding Stars has three broad food categories which differ enough in their algorithms to preclude comparison of a breakfast cereal and a yogurt based on the number of stars assigned. The NuVal system uses one general algorithm but applies many different "universal adjustors," "weighting coefficients," and other adjustors that are category-specific (Katz et al., 2009), and that have the potential to lead to inconsistencies in across-category comparisons. The Nutrient Rich Food Index (NRFI) applies only one algorithm across all product categories (Fulgoni et al., 2009), but consumers would not know how the content of individual nutrients influenced the final score.

Provide Information About Contribution of Recommended Food Groups

The committee reviewed two FOP nutrition rating systems that describe a product's contribution to the intake of specific food groups or food ingredients. The Start Making Choices symbol (ConAgra) shows how much one serving of a given product contributes to the recommended daily intakes of MyPyramid food groups such as fruits, vegetables, dairy, and meat and beans. Similarly, the Whole Grains Council developed a stamp symbol to communicate the whole grain (i.e., a food ingredient) content of products.[9]

While the information is not depicted on the FOP symbol, some summary indicator systems based on nutrient thresholds include criteria for encouraging the inclusion of MyPyramid food groups or a food ingredient such as whole grains. Several product categories in Sensible Solutions (Kraft) and Smart Choices include the criterion that at least a one-half serving of fruits, vegetables, whole grains, or fat-free or "low fat" milk products should be included.

[8] 21 CFR 101.61. Depending on the claim, the sodium criteria for main dishes and meals are expressed per labeled serving or per 100 g. The sodium criteria for all other food s regardless of product category are expressed per reference amount customarily consumed (RACC) for sodium free, very low sodium, and low sodium as well as per labeled serving for low sodium. Special rules apply if the RACC is small, i.e., 30 g or less or 2 tablespoons or less.

[9] Available online: http://www.wholegrainscouncil.org/files/US_StampUsageGuide.pdf (accessed 6/1/10). Products must contain at least 8 g of whole grain per labeled serving to use the basic Whole Grain Stamp. Products that contain at least 16 g of whole grain and in which all the grains are whole grains may use the 100% Whole Grain Stamp.

Provide Guidance on Products Appropriate for Marketing to Children

In response to concerns about the high prevalence of overweight and obesity in children and teens, there are growing efforts to develop nutrition standards for determining which products might appropriately be marketed to children. In 2006 the Council of Better Business Bureaus launched the Children's Food and Beverage Advertising Initiative (CFBAI) to provide companies that advertise foods and beverages to children under age 12 years with a transparent and accountable advertising self-regulation mechanism. Part of a participant's pledge to CFBAI is a guarantee that nutrient criteria are consistent with established scientific and government standards, such as the *Dietary Guidelines for Americans*, MyPyramid food group recommendations, and FDA standards for nutrient content and health claims.[10] The CFBAI pledge approach is similar to FOP systems based on nutrient thresholds, but it does not require products to carry an FOP symbol. Each company participating in this self-regulation program has established a different set of nutrition criteria on which to evaluate its products and marketing practices. Conceivably, an appropriately designed FOP nutrition rating system for the general population might also be useful in advising industry on products that may be appropriate for marketing to children ages 4 years and older and could provide for a more consistent set of nutrient criteria for all companies that participate.

Encourage Product Reformulation

FOP rating systems can encourage food manufacturers to reformulate products or develop new products in order to meet specific nutrient targets. Several supporters of the CFBAI have either reformulated existing products or developed new products to be consistent with their pledged nutrition criteria.[11] However, it should be noted that at times, such as during the "low fat" trend in the 1990s, encouraging product reformulation can have unintended consequences. In addition, for certain nutrient criteria one must consider various issues related to the potential encouragement of overfortification of the food supply.

[10] Available online: http://www.bbb.org/us/children-food-beverage-advertising-initiative (accessed July 8, 2010).

[11] Available online http://www.bbb.org/us/storage/0/Shared%20Documents/finalbbbs.pdf (accessed June, 18, 2010). The Children's Food and Beverage Advertising Initiative: A Report on Compliance and Implementation during 2008 (see Appendix H, page 78).

REFERENCES

ADA (American Dietetic Association). 2008. *Nutrition and you: Trends 2008*. Chicago, IL: ADA.

ConAgra. 2010. MyPyramid Labeling Program. Presented at the Public Information-Open Session for the Committee on Examination of Front-of-Package Nutrition Rating Systems and Symbols. Washington, DC. April 9, 2010.

Cowburn, G., and L. Stockley. 2005. Consumer understanding and use of nutrition labelling: A systematic review. *Public Health Nutrition* 8:21–28.

Ford, E. S., U. A. Ajani, J. B. Croft, J. A. Critchley, D. R. Labarthe, T. E. Kottke, W. H. Giles, and S. Capewell. 2007. Explaining the decrease in U.S. deaths from coronary disease, 1980–2000. *New England Journal of Medicine* 356(23):2388–2398.

Ford, E. S., C. Li, G. Zhao, W. S. Pearson, and A. H. Mokdad. 2008. Prevalence of metabolic syndrome among U.S. adolescents using the definition from the International Diabetes Federation. *Diabetes Care* 31(3):587–589.

Fulgoni, V. L., III, D. R. Keast, and A. Drewnowski, A. 2009. Development and validation of the nutrient-rich foods index: A tool to measure nutritional quality of foods. *Journal of Nutrition* 139:1549–1554.

IOM (Institute of Medicine). 2006. *Food marketing to children and youth: Threat or opportunity?* Washington, DC: The National Academies Press.

Katz, D.L., V.Y. Njike, Z. Faridi, L.Q. Rhee, R.S. Reeves, D.J.A. Jenkins, and K.T. Ayoob. 2009. *The stratification of foods on the basis of overall nutritional quality: The Overall Nutritional Quality Index. American Journal of Health Promotion* 24(2):133-143.

Rothman, R. L., R. Housam, H. Weiss, D. Davis, R. Gregory, T. Gebretsadik, A. Shintani, and T. A. Elasy. 2006. Patient understanding of food labels: The role of literacy and numeracy. *American Journal of Preventive Medicine* 31(5):391–398.

Taylor, C. L., and V. L. Wilkening. 2008. How the nutrition food label was developed, part 1: The nutrition facts panel. *Journal of the American Dietetic Association* 108:437–442.

Todd, J. E., and J. N. Variyam. 2008. The decline in consumer use of food nutrition labels, 1995–2006. *Economic Research Report No. (ERR–63)*. 32 pp.

6
Scientific Basis of Front-of-Package Systems

As discussed in previous chapters, front-of-package (FOP) nutrition rating systems have been developed for different purposes. The systems have also been based on different approaches to setting nutrient criteria. Among the existing FOP nutrition rating systems and symbols, no two have been developed for exactly the same purposes; similarly, no two have the same underlying nutrient criteria. Concerns over the limitations of the nutrient criteria used in developing existing systems as well as concerns over the potential strength of FOP symbols in encouraging purchases have fueled much of the current debate over the use of FOP nutrition rating systems, and they were a motivating factor in the creation of this study.

Given the number of FOP systems in the market today and the potential for future systems to have a variety of attributes, it was not possible for the committee to undertake an exhaustive evaluation of each system. Instead, the committee took a more general approach to discussing the strengths, limitations, and challenges of developing FOP systems. In the following pages, existing systems are sometimes discussed in order to provide specific examples that illustrate a point, but it is important to keep in mind that these are only examples and are not intended to offer a comprehensive list of all systems that exhibit a certain attribute. The first section of this chapter describes various issues associated with developing the nutrient criteria of FOP rating systems, while the second section identifies the general strengths and limitations related to the committee-defined categories of FOP rating systems presented in Chapter 5.

DEVELOPING FRONT-OF-PACKAGE NUTRITION RATING SYSTEMS

The development of FOP nutrition rating systems requires a number of steps: making decisions related to the overall purpose (see Chapter 5); developing nutrient criteria, which includes selecting which nutrients and other components to include and choosing the basis for setting the criteria; determining the role of fortification; deciding whether to use the same criteria across all food categories or to use category-specific criteria; monitoring compliance; updating system criteria; and choosing between placing symbols on food packaging versus on shelf tags. This section addresses issues and challenges associated with each of these decision points.

Determining Nutrients to Include

As shown in Table 6-1, the nutrients and, in some cases, other food components included in the existing systems vary tremendously. Most systems focus solely or primarily on which nutrients to limit, some include certain nutrients or food groups that are to be encouraged, still others pay attention to limiting some nutrients and to encouraging other nutrients and food groups, and a few also include some combination of additional food components, universal adjustors, and weighting coefficients. Most commonly, the nutrients to limit include some combination of calories, total fat, saturated fat, *trans* fats, cholesterol, sodium, and total or added sugars. Nutrients to encourage have usually been based on those required to be declared in the Nutrition Facts panel or the concerns identified by the *Dietary Guidelines for Americans*, (HHS/USDA, 2005b), or both, and typically include one or more of fiber, calcium, potassium,

magnesium, iron, vitamin A, vitamin C, and vitamin E. Systems that focus solely on nutrients that should be limited appear to be primarily concerned with reducing the risk for diet-related chronic diseases. Systems that attempt to assess the overall nutritional value of foods generally include nutrients to limit, nutrients or food groups to encourage, and sometimes other factors.

In determining which nutrients to include in FOP systems, existing systems have used dietary guidance recommendations from domestic and international governments, other authoritative bodies, and the opinions of scientific advisory panels assembled by rating system administrators. Determining which recommendations will serve as the basis both for selecting the nutrients to include and for setting their qualifying levels is a difficult process.

Of particular concern in determining the basis for which nutrients to include are the strength of the scientific basis for setting the criteria and the changing state of the emerging science. Some FOP systems include only nutrients recognized as being of importance by consensus documents such as the *Dietary Guidelines for Americans*, while other systems include nutrients or other food components or attributes that have not been recognized by such groups. The inclusion of nutrients and other food components that have not been recognized by consensus bodies is concerning because it is likely that the reason consensus bodies have not recognized these as nutrients to encourage or discourage is that there is insufficient scientific evidence from which to draw a conclusion. Consensus bodies generally review guidelines and recommendations on a regular basis and modify criteria on the basis of the most recent data. Another factor related to selecting which nutrients to include and which qualifying criteria is whether to use international dietary recommendations. Some criteria for existing FOP systems are based on dietary guidance recommendations from other countries—usually because the criteria themselves were developed abroad. While many nations are experiencing the same diet and health concerns as the United States, it is important to keep in mind that there are various population and food supply differences among countries and thus dietary recommendations from another country may reflect public health concerns in that country that may not be of concern in the United States.

In summary, decisions about nutrients to include in front-of-package rating systems and the underlying nutrient criteria would be most properly grounded in current nutrition science if based on current consensus documents on the dietary needs of the U.S. population.

Establishing the Scientific Basis for Nutrient Criteria

Existing systems vary greatly in the approaches they use for setting criteria once the nutrients and other components to include have been selected. As shown in Table 6-2, some criteria are based on U.S. Food and Drug Administration (FDA) label claims, some on dietary guidance recommendations from domestic or international governments or other authoritative bodies, and still others on the opinions of scientific advisory panels assembled by rating system administrators. Each approach has advantages and limitations. The sections that follow describe the strengths and limitations of setting nutrient criteria based on Daily Values and on existing nutrient content claim criteria versus setting criteria based on other forms of dietary guidance or nutrition expertise.

Nutrient Criteria Based on Daily Values

Nutrient-specific systems and some summary indicator systems in the United States use as their basis FDA and USDA criteria related to nutrition labeling, nutrient content claims, and

TABLE 6-1 Nutrients and Other Components in Existing Front-of-Package Programs.

FOP programs	Nutrients considered in criteria													
	Calories	Total fat	Sat fat	*Trans* fat	Cholest	Sodium	Sugar	Fiber	Protein	Vitamins minerals	Whole grains	Food groups	Other
Nutrient-specific systems														
General Mills Nutrition Highlights	+		+			+	+	+		+				
General Mills Goodness Corner	+	+					+	+	+	+	+			
Harris Teeter Wellness Keys	+	+				+	+	+	+	+				
Kellogg's Nutrition at a Glance	+	+				+	+	+		+				
U.K. FSA Traffic Light		+	+			+	+							
Wegmans Wellness Keys		+	+		+	+	+			+				
Summary Indicator														
AHA Heart Check		+	+		+	+		+	+	+	+			
AU/NZ Heart Foundation Tick Programme	+		+	+		+		+	+	+		+		
Canada Heart & Stroke Foundation Health Check		+	+	+		+	+	+		+				
Choices			+	+		+	+	+						
Giant Food Healthy Ideas		+	+		+	+	+	+	+	+				
Guiding Stars			+	+	+	+	+	+		+	+	+		
Kraft Sensible Solution	+	+	+	+		+	+	+	+	+	+			
Nutrient Rich Foods Index			+			+	+	+	+	+				
NuVal			+	+	+	+	+	+		+				+
Pepsi Co Smart Spot		+	+		+	+	+	+		+				
Smart Choices		+	+	+	+	+	+	+		+				
Sweden NFA Keyhole	+	+	+			+	+	+			+	+		
Food Group Information														
ConAgra Start Making Choices											+	+		
Whole Grain Council Whole Grain Stamp											+			

NOTE: Sources for each system's nutrient criteria are available at the beginning of Appendix C.

health claims. The simplest approach is to provide the amount of nutrient per serving or the amount of nutrient as a percent of the Daily Value, or both. As described in Chapter 2, consumer education efforts have generally characterized 5 percent or less of the Daily Value as a "low" amount and 20 percent or more of the Daily Value as a "high" amount of a nutrient.

Some issues with the use of Daily Values deserve consideration. For example, not all nutrients of primary interest to the public health—such as total calories, *trans* fat, and added

sugars—have a Daily Value. The lack of a Daily Value means not only that there is no basis for developing criteria for a nutrient content claim but also that there is no way to inform consumers whether the amount of a nutrient is "high" or "low." In the absence of a defined Daily Value for calories, some systems have improvised a reference total daily intake of 2000 calories, which is consistent with the basis upon which the Daily Values for total fat and saturated fat were derived. Even for nutrients with already established Daily Values and claim criteria for "low" and "high," there are no regulatory definitions for "medium" amounts of any nutrient, which makes it difficult to design criteria for systems that characterize nutrient contents in this way. Furthermore, many Daily Values based on dietary recommendations made 20 to 30 or more years ago would benefit from a reexamination to better reflect current science.

FOP nutrition rating systems that use symbols (or text) to indicate that a product meets the criteria for a nutrient content or a health claim have additional limitations. For instance, a product that claims to be a "good source of fiber" or an "excellent source of calcium" may not be low in the nutrients that should be limited, e.g., saturated fat and sodium. Even though FDA regulated product labels must include a nutrient disclosure statement immediately adjacent to a claim when certain levels of fat, saturated fat, cholesterol, or sodium are exceeded,[1] consumers may disregard these statements. Another issue is that the criteria for "low" may be too strict for some products that might otherwise be consistent with a healthful diet, such as fatty fish, tree nuts, peanut butter, and most vegetable oils. Or products may qualify for one or more nutrient content claims but not make the claim on the package label. Because consumers most likely do not know the nutrient amounts that qualify products for a nutrient content claims, it may not be easy for them to make comparisons and decisions among products with and without a FOP nutrient-specific symbol.

Overall, despite some limitations, using nutrient criteria based on regularly updated Daily Values or nutrient amounts per RACC holds promise as a method of setting criteria for FOP systems. Using this structure would maintain consistency with other nutrition labeling requirements that are likely to remain in place in the future.

Nutrient Criteria Not Based on Daily Values

When no Daily Value exists or when the criteria for "low" cannot be met by products that system developers want to qualify, alternatives to the Daily Value must be found. In many cases in the past, system developers have looked to dietary guidance recommendations from domestic or international governments or other authoritative bodies as well as to the opinions of scientific advisory panels assembled by rating system administrators to set criteria.

One commonly used approach has been to apply dietary recommendations intended for the total diet to individual products. For example, because there is no Daily Value for total sugars or added sugars, criteria for individual products have been based on the WHO recommendation to limit free sugars intake to less than 10 percent of total energy intake, a recommendation that is based on data related to a low incidence of dental caries (WHO, 2003), or else on the IOM macronutrient report suggestion that added sugars should comprise no more than 25 percent of

[1] 21 CFR 101.13 (h). When levels exceed 13 g fat, 4 g saturated fat, 60 mg cholesterol, and 480 mg sodium per reference amount, per labeled serving, or for foods with small reference amounts, per 50 g, a disclosure is required as part of the claim (e.g., "See nutrition information for ____ content'' with the blank filled in with the identity of the nutrient exceeding the specified level). Main dishes and meals have higher disclosure amounts. (FSIS-regulated meat and poultry products do not have a similar requirement.)

TABLE 6-2 Overview of Existing Front-of-Package Programs

System Icon	Program Name	System Developer	Criteria Publicly Available	Basis for Nutrient Criteria
		Nutrient-Specific Systems		
	General Mills Nutrition Highlights[a]	Food manufacturer	Yes	FDA %DVs
	General Mills Goodness Corner[b]	Food manufacturer	Yes	FDA regulations for nutrient content claims
[Image withheld at the request of the retailer]	Harris Teeter Wellness Keys[c]	Retailer	Yes	FDA regulations for nutrient content claims
	Kellogg's Nutrition at a Glance[d]	Food manufacturer	Yes	FDA %DVs presented as %GDAs
	UK Traffic Light[e]	Government agency	Yes	EC regulation No. 1924/2006 for green/amber boundaries; COMA and SACN advice for amber/red boundaries
	Wegmans Wellness Keys[f]	Retailer	Yes	FDA regulations for nutrient content claims

[a]Reprinted with permission of General Mills.
[b]Reprinted with permission of General Mills.
[c]Image withheld at the request of the retailer
[d] © 2010 Kellogg North America Company used with permission. It is understood that any copyright in and to the images, as well as any trademarks contained with those images, is and shall remain the sole property of Kellogg North America Company.
[e] Reprinted with kind permission of Food Standards Agency, UK.
[f] Used with permission of Wegmans Food Markets, Inc.

System Icon	Program Name	System Developer	Criteria Publicly Available	Basis for Nutrient Criteria
Summary Indicator Systems				
	Choices (EU)[g]	Non-industry experts	Yes	WHO guidelines for saturated and *trans* fats, sodium, sugars; dietary guidelines from 21 countries
	Guiding Stars[h]	Retailer	No	Proprietary algorithm based upon FDA, USDA, USDHHS, IOM, and WHO recommendations and regulations
	Canada's Health Check[i]	Nonprofit organization	Yes	Canada's Food Guide
Reprint permission pending	Giant Food Healthy Ideas[j]	Retailer	Yes	Dietary Guidelines for Americans, implied nutrient content claims, and health claims
	AHA Heart Check[k]	Nonprofit organization	Yes	FDA %DVs, implied nutrient content claims, coronary heart disease health claims

[g] Front-of-Pack device of the Choices Programme. Exact wording on the logo varies with the local language. Image provided by Choices International Foundation.
[h] © & ® Guiding Stars Licensing Company.
[i] Reprinted with permission of Canada's Heart & Stroke Foundation.
[j] Reprint permission pending.
[k] Heart Check Mark is a registered trademark of the American Heart Association.

System Icon	Program Name	System Developer	Criteria Publicly Available	Basis for Nutrient Criteria
No symbol exists at this time	Nutrient Rich Foods Index	Non-industry experts	Yes	FDA %DVs
	NuVal[l]	Non-industry experts	No	Proprietary algorithm based upon Dietary Guidelines for Americans and DRIs, as well as established data in scientific literature
	Kraft Sensible Solution[m]	Food manufacturer	Yes	Dietary Guidelines for Americans, and authoritative statements from NAS and FDA
	Smart Choices[n]	Industry and non-industry consortium	Yes	Dietary Guidelines for Americans, and authoritative statements from NAS and FDA
Reprint permission pending	PepsiCo Smart Spot[o]	Food manufacturer	Yes	Authoritative statements from FDA and NAS
	Sweden National Food Administration Keyhole[p]	Government agency	Yes	National Food Administration Regulation LIVSFS 2005:9

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[m] SENSIBLE SOLUTION and design are registered trademarks of Kraft Foods Holdings, Inc.
[n] The SMART CHOICES PROGRAM Logo is a registered trademark of Smart Choices Program, Inc.
[o] Reprint permission pending.
[p] The Swedish National Food Administration.

System Icon	Program Name	System Developer	Criteria Publicly Available	Basis for Nutrient Criteria
Reprint permission pending	Australia/New Zealand Tick Programme[q]	Industry and non-industry working group	Yes	Working-group determined values
Food Group Information Systems				
	ConAgra Start Making Choices[r]	Food manufacturer	Yes	USDA's MyPyramid
	Whole Grain Council Whole Grain Stamp[s]	Industry and non-industry consortium	Yes	USDA's MyPyramid

[q] Reprint permission pending.
[r] START MAKING CHOICES® is a registered trademark of ConAgra Foods RDM, Inc.
[s] Courtesy Oldways and the Whole Grains Council, wholegrainscouncil.org.

total calories consumed, which was based on data related to decreased intake of some micronutrients of American subpopulations that exceeded this level (IOM, 2002/2005).

Another example is how criteria for fat and saturated fat are sometimes set. When the criteria for "low fat" and "low saturated fat" are difficult to meet, the dietary recommendations to keep total fat to no more than 35 percent of calories and saturated fat to less than 10 percent of calories (HHS/USDA, 2005) are often applied to individual foods. The appropriateness of applying a total diet recommendation to an individual food has not been established, even though this approach was used in the development of criteria for "low fat" and "low saturated fat" claims for main dishes and meals, items which make a significant contribution to total dietary intake.[2]

Another approach used when criteria for "low" cannot be met is to apply nutrient disclosure amounts.[3] These amounts are part of U.S. nutrition labeling regulations concerning the use of claims. If a food qualifies for a claim for one nutrient but exceeds certain prescribed levels for another nutrient, disclosure statements are placed adjacent to claims on food packages to alert consumers that some nutrients in the food may increase the risk of a diet-related disease or health condition.[4] In all cases, disclosure amounts are considerably higher than the amounts required to

[2] 21 CFR 101.62(b) and 21 CFR 101.62(c).
[3] 21 CFR 101.13(h).
[4] Available online: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm064908.htm (accessed June 23, 2010).

meet "low" criteria (by regulation, 20 percent or more of the Daily Value). A main concern about such approaches is whether the criteria they adopt are too lenient.

Determining a Basis for Expressing Nutrient Amounts in Criteria

The Nutrition Facts panel provides nutrient information as an amount (in grams or milligrams) or as a percent of the Daily Value per serving, or both. Criteria for nutrient content and health claims are based on the Reference Amount Customarily Consumed (RACC) and sometimes also per labeled serving size and/or per 50 g or 100 g. As such, FOP systems based on nutrient-specific information are grounded in regulations for nutrition labeling and claims. FOP systems based on nutrient thresholds commonly express nutrient criteria per labeled serving size. The labeled serving size is the appropriate household measure of food or beverage that most closely approximates the RACC.[5] Depending on the product and how it is packaged, individual items can have a labeled serving size as low as 51 percent or as high as 200 percent or more of the RACC.[6] Consequently, some items can be manufactured in such a way as to reduce a labeled serving size to meet a FOP's nutrient criteria.

Algorithm-based FOP rating systems generally evaluate nutrient content per 100 calories in order to take into account the importance of obtaining valuable nutrients within a limited number of calories.[7] One example is the Nutrient Rich Foods Index (NFRI) (Fulgoni et al., 2009). Proponents of this approach emphasize that positive nutritional aspects of foods are given similar weight in the overall score, and scores for individual foods are considered in the context of the overall dietary pattern. One potential negative aspect of this approach is that scores for some lower- and reduced-calorie foods could be biased and difficult to interpret. For example, nutrient values per 100 calories would be higher for lower-calorie versions of some products, which would lead to a bias against the products when scored on the basis of nutrients to limit (e.g., reduced-calorie salad dressing might receive a poorer score than the regular version if the two products had similar levels of sodium) and cause a bias in favor of the products when scored on the basis of nutrients to encourage (e.g., a calcium-fortified, reduced-calorie beverage might have a more favorable score than the full-calorie version if both products contained similar calcium concentrations). Algorithms also tend to result in relatively low scores for foods, such as lean chicken, that are generally considered to be components of an adequate diet but that contain few of the targeted nutrients to encourage.

Another issue specific to FOP systems based on algorithms that calculate a product score using a combination of nutrients to encourage in the numerator and nutrients to encourage in the denominator is the relationship among the ratios used to account for the risk of chronic disease. The merits of including constituents that should be encouraged as well as those to avoid, and the correct relative weighting of the factors in the numerator and denominator, cannot be known with certainty. Some systems allow beneficial nutrients to offset nutrients that should be limited in American diets, a practice that some view as questionable. There are also questions about the wisdom of giving food products good overall scores on the basis of providing vitamins and minerals that are actually not lacking in the U.S. food supply or for which there is some doubt about the level of public health concern.

[5] 21 CFR 101.12.
[6] 21 CFR 101.9(b)(i)(B)(C)(D).
[7] Although not visible to the consumer using a system based on 100 calories may be inconsistent with the regulatory framework for nutrition labeling in which nutrition information is displayed per serving, derived from Reference Amounts Customarily Consumed (RACC).

Developing Criteria Based on Food Groups or Food Categories

Some FOP systems include criteria for a minimum amount of a food group or ingredient that should be encouraged in the diet—such as fruits, vegetables, low- or no-fat dairy products, and whole grains. Other systems require a quantification of the amount of a food group that is contained in a product. Threshold-based systems with food group criteria also include criteria for nutrients to limit, but systems based on food group information do not.

Many threshold-based systems include criteria for product categories like snack foods, sweets, and desserts despite general agreement that consumption of these items should be decreased because of their contributions to intakes of calories, saturated fat, *trans* fat, added sugars, and sodium. While these systems generally contain criteria for nutrients to limit as well as nutrients or food groups to encourage, the qualifying criteria may be viewed by some as too lenient. Furthermore, consumers may perceive foods in these categories that qualify for a symbol as being relatively healthy and not pay attention to the labeled serving size—and thus the amount eaten—when consuming them.

At the same time, replacing regular versions of products with more nutritious versions that meet FOP criteria may still improve total diet quality. Because of resource and time constraints, the committee was unable to carry out the necessary modeling to determine the effect of including products that are generally considered foods to limit in FOP systems. The committee recognized, however, that it would be useful to conduct such studies.

Establishing the Role of Fortification

Fortification is another issue of concern in setting FOP system criteria. Some systems include nutrients to encourage as part of the system criteria. However, this raises questions about how foods will be rated that do not naturally contain nutrients to encourage and whether this situation might give food manufacturers incentives to alter their product formulations.

Not all foods, even those considered to be important in health-promoting diets, are sources of nutrients to encourage, such as vitamin D, calcium, potassium, and dietary fiber. If nutrients to encourage are included in the criteria for FOP rating systems, foods that may otherwise be choices to encourage in the diet could receive less favorable ratings than foods that do contain these components. Alternatively, manufacturers might choose to fortify products in order to improve product ratings. The U.S. government has recognized that fortification "can be an effective way of maintaining and improving the overall nutritional quality of the food supply."[8] However, the government also recognizes that fortification could "result in over- or underfortification in consumer diets and create imbalances in the food supply . . . [and] it could also result in deceptive or misleading claims for certain foods."[9]

In addition, including these dietary components in nutrition rating systems may encourage the addition of these nutrients to food systems in which the nutrient is unstable (because of their chemical compositions or storage conditions) or not biologically available, which would contradict FDA fortification policy. In the case of dietary fiber, fortification may also encourage consumers to eat foods that have had fiber added rather than increasing their consumption of naturally-occurring, plant-based foods that are high in dietary fiber, as recommended by the 2010 Dietary Guidelines Advisory Committee (DGAC, 2010).

[8] 21 CFR 104.20 (a).
[9] 21 CFR 104.20 (a).

In summary, including nutrients to encourage (e.g., fiber and certain vitamins and minerals) in front-of-package systems may encourage overfortification or the addition of these nutrients to food systems in which the nutrient is unstable or not biologically available, which would contradict FDA fortification policy.

Developing the Same Criteria for All Foods Versus Category-Specific Criteria

In developing FOP nutrition rating systems it will be important to consider whether to apply one set of nutrient criteria across all or most product categories or to develop criteria that are specific to individual food product categories.

When one set of criteria is used for all or most foods, federal regulations for nutrition labeling and nutrient content claims often form the basis for the criteria. As mentioned above, claim criteria are based on the RACC[10] as well as on labeled serving sizes and Daily Values for nutrients. Claim criteria are defined so that any claim—such as "free," "low," "good source," or "excellent source"—is the same across all categories of foods and beverages, with modifications for meat, fish, and poultry and for main dishes and meals. Developing FOP systems with the same criteria for all foods creates consistency in how individual products are evaluated, makes it possible to compare foods across all food categories, and makes it easier for consumers to understand the meaning of a claim.

Summary indicator systems typically develop nutrient criteria that are specific to food product categories and to their relative contribution to total intake. For example, because fiber content may be more relevant for fruits, vegetables, and grain products, while calcium is more relevant for dairy products, different nutrient criteria may be set for these different food categories. Developing category-specific criteria requires decisions about which and how many categories to include. Among the threshold-based systems reviewed, Smart Spot (PepsiCo) has nutrient criteria for 3 product categories, Smart Choices for 19 categories, and Healthy Ideas (Giant Food stores) for about 105 categories. Guiding Stars has algorithms for 3 food categories (with qualifying scores ranging from 1 to 3 stars); NuVal has one algorithm with "universal adjustors," "weighting coefficients," and other adjustors that are category-specific (with scores ranging from 1 to 100); and the Nutrient Rich Foods Index has one algorithm with no category-specific factors (most foods' raw scores range from -150 to 300; theoretical raw scores range from -300 to 900) and raw scores are divided into quintiles and assigned a score 1-5 for better comprehension. Decisions must also be made about which nutrients to consider for each category and what scientific basis to use. The summary indicator systems reviewed by the committee differ widely in how these decisions have been made and so influence the final evaluation of products. While tailoring nutrient criteria to specific food categories can be seen as beneficial in certain ways, it limits individual products to being compared only *within* product categories that have the same nutrient criteria and not *across* product categories that have different criteria. An example of product variability among summary indicator systems is shown on Table 6-3 and discussed in greater detail in Box 6–1.

Monitoring Compliance

Another issue that should be considered in developing FOP rating systems is compliance. Analytical detection methods are needed if one is to ensure that the products being evaluated actually contain the levels of nutrients or other components needed to meet FOP system criteria.

[10] 21 CFR 101.12.

Analytical methods are available to monitor compliance for those systems whose criteria are based on nutrients declared in the Nutrition Facts panel. However, there are no simple analytical tests available to ensure compliance for food components like fruit and vegetable content or added sugars.

Analytical methods are also lacking for monitoring compliance of foods that contain a mix of different food groups (e.g., pizza). However, for products that are not a mixture of different food groups, such as canned tomatoes, compliance can be monitored by comparing the declared serving size with the recommended food group servings, and if the product is 100 percent whole grains, compliance can be monitored by reviewing the ingredient list.

Distinguishing between added and naturally occurring sugars in food products has traditionally posed an analytical challenge, especially when food products contain multiple sources of sugars. According to the 2005 *Dietary Guidelines for Americans*, added sugars are sugars and syrups that are added to foods during processing or preparation or at the table (HHS/USDA, 2005a). They include the following: various types of beet and cane sugars (white sugar, brown sugar, and raw sugar), corn syrup, corn-syrup solids, high-fructose corn syrup, malt syrup, maple syrup, pancake syrup, fructose sweetener, liquid fructose, fruit juice concentrate (in some, but not all classifications), honey, molasses, anhydrous dextrose, and crystal dextrose. The most common sources of added sugars are refined beet or cane sugar (sucrose) and high-fructose corn syrups (Haley and Ali, 2007). Sometimes the terms intrinsic and extrinsic sugars are used as synonyms for naturally occurring and added sugars (HHS/USDA, 2005b). Intrinsic sugars are those sugars occur naturally within a food, such as fructose and sucrose in fruits or lactose in milk, and extrinsic sugars are those that are added to foods.

While it is possible to estimate how much added sugar a food might generally contain (e.g., for the purposes of creating databases for dietary surveys such as NHANES), it is not currently possible to determine the exact amount of added sugar in a product. There is no difference between the molecular structure of sugar molecules that occur naturally in the food and the structure of those added to the food (HHS/USDA, 2005b). Analytical methods approved by AOAC International are available for the qualitative and quantitative analysis of mono- and disaccharides in foods (BeMiller, 2003), but the structural equivalence between added and naturally occurring sugars makes it impossible to distinguish between the two types of sugar. A laboratory analysis of a breakfast cereal that contains both raisins and high-fructose corn syrup would, for example, be unable to distinguish the naturally occurring fructose in the raisins from the fructose in high-fructose corn syrup. Without an approved analytical method to make such distinction between types of sugars, it is essentially impossible to independently verify the amount of sugars added to a food product. Thus, the FDA has stated that it would be unable to enforce compliance with the disclosure of added sugars on nutrition labels since analysis only generates the level of total sugars, and historically the agency has maintained the position that it will not promulgate regulations it cannot enforce.[11] Concerns like this one clearly have implications for the development of FOP system criteria.

[11] 58 FR 2079.

BOX 6-1
Case Study—Illustrative Comparison of Cereal and Dairy Products Using Existing System Criteria

The committee compared selected cereal and dairy products with the criteria from the threshold- and algorithm-based systems shown in Table 6-3 to the best of its ability. Information for the products is in Appendix C. The following illustrates the variability among systems**. Note that these estimates are for illustrative purposes only.**

Of note within the six cereal products evaluated:

- Only non-instant and instant oatmeal met the criteria for all threshold systems;
- Six cereal products evaluated met the threshold criteria for Heart Check and Smart Choices;
- Four met criteria for Healthy Ideas, Smart Spot, and Health Check;
- Three met criteria for Sensible Solutions; and
- Two met criteria for Choices.
- Instant oatmeal received 3 Guiding Stars and was scored 87 by NRFI[a] and 39 by NuVal, compared with non-instant oatmeal with 2 Guiding Stars and a score of 22 by NRFI and 57 by NuVal, and a toasted oat cereal with 2 Guiding Stars and a score of 84 by NRFI and 37 by NuVal.

Of note within the eight dairy products evaluated:

- Only fat free milk and fat free plain yogurt passed all criteria from each FOP system; 1% fat milk passed criteria for some programs, but failed for at least 3 programs due to saturated fat content.
- Reduced-fat cheddar cheese and part-skim mozzarella met only the criteria for Choices and Health Check, and did not earn a star rating.
- Fat free milk, 1% fat milk, and fat free plain yogurt received 3 Guiding Stars; fat free milk was scored 56 by NRFI and 91 by NuVal; 1% fat milk was scored 30 by NRFI and 81 by NuVal; and fat free plain yogurt was scored 43 by NRFI and 96 by NuVal.

When comparing across product categories by NRFI scores, fat free milk (57) and fat free plain yogurt (43) scored lower than the toasted oat cereal (84) and instant oatmeal (87) and had scores comparable to crisped rice cereal (50), sweetened toasted oat cereal (49), and apple cinnamon cereal bar (47). It is difficult to interpret what these scores may mean. At face value they seem to imply that the nutritional value of fat free milk and fat free plain yogurt is lower than that of some cereals and comparable to others. It may also reflect that the algorithm is not food-category specific or be an artifact of the assumptions made when hand calculating the estimates.

The NuVal scores for fat free milk (91), 1% fat milk (81), and fat free plain yogurt (96) were higher than the scores for all the cereal products. This may in part reflect the use of categorical adjustors for dairy used in this algorithm (Katz et al., 2009).

[a] All NRFI scores are in raw format and have not been transformed.

TABLE 6-3 Comparison of Selected Products Against Criteria for Various FOP Types Based on Summary Indicators.

	Based on Nutrient Thresholds[a]						Based on Algorithm		
Product	Choices	Healthy Ideas	Heart Check	Sensible Solutions	Smart Choices	Smart Spot	Health Check	Guiding Stars[b]	Nutrient-Rich Foods Index[c]	NuVal[c]
Cereal Products										
Crisped rice cereal			✓		✓	✓		0	50	23
Toasted oat cereal		✓	✓	✓	✓	✓	✓	2	84	37
Sweetened toasted oat cereal			✓		✓			0	49	27
Oatmeal, non-instant	✓	✓	✓	✓	✓	✓	✓	2	22	57
Oatmeal, instant	✓	✓	✓	✓	✓	✓	✓	3	87	39
Apple cinnamon cereal bar		✓	✓		✓		✓	1	47	25
Dairy Products										
Reduced-fat cheddar cheese	✓						✓	0	16	ND[d]
Part-skim mozzarella	✓						✓	0	0	22
Reduced-fat processed cheese product				✓				0	27	26
Fat free milk		✓	✓	NC[e]	✓	✓	✓	3	57	91
1% fat milk				NC	✓		✓	3	31	81
1% fat chocolate milk				NC				0	19	54
Fat free plain yogurt		✓	✓	NC	✓	✓	✓	2	43	96
Low fat fruit yogurt		✓	✓	NC			✓	0	6	23

[a] A checkmark indicates that the product met the systems criteria.
[b] Value indicates number of stars awarded, which range from 1 to 3. Products that are evaluated but do not quality for at least one star are not required to display a zero or no star rating.
[c] Value estimated with a number of assumptions for nutrients not on the Nutrition Facts Panel. Nutrient Rich Food Index Scores generally range from -150 to 300; NuVal scores can range from 1 to 100.
[d] ND, not determined.
[e] NC, no criteria for milk or yogurt.
NOTE: Based on committee calculations using available information and for illustrative purposes only.

Another concern related to monitoring compliance is the fact that algorithms for some summary indicator systems are not publically available. This precludes scientific review and understanding of the algorithm components, and how the nutrients and other factors included in the algorithm are evaluated. Although not necessarily unique to algorithm systems, there is also a concern that even if an algorithm is publicly available, it may include nutrients, food components, or weighting factors that were not analyzed specifically for the product being evaluated, but rather were imputed from the scientific literature or food composition databases.

In summary, to ensure that products actually meet FOP nutrient criteria, it is important that nutrient criteria be publically available and that analytical detection methods be available for the nutrients included in the criteria.

Updating FOP System Criteria

The currency of the Daily Value and of serving and portion sizes is important for FOP systems. One of the committee's guiding principles was that information highlighted in FOP systems be consistent with the Nutrition Facts panel. Nutrient information presented in the Nutrition Facts panel is based on the amount per labeled serving or a percent of the Daily Value or both. The Nutrition Labeling and Education Act (NLEA) of 1990 also requires that nutrients be presented in the context of the daily diet; it also specifies that serving sizes should represent "an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food."

Daily Values

The Daily Values comprise Reference Daily Intakes (RDIs) and Daily Reference Values (DRVs). RDIs were created during the implementation of NLEA when FDA changed the name of the U.S. RDAs to Reference Daily Intakes (RDIs) in order to reduce confusion with the RDAs developed by the National Research Council (NRC) of the NAS. FDA at the same time maintained the values based on the 1968 RDAs (NRC, 1968), rather than the newer 1989 RDAs (NRC, 1989b), as explained in Chapter 2. In addition, FDA established Daily Reference Values (DRVs) for total fat, saturated fatty acids, cholesterol, total carbohydrate, dietary fiber, sodium, and potassium, based largely on recommendations from *The Surgeon General's Report on Nutrition and Health* (HHS, 1988), the NRC's report *Diet and Health: Implications for Reducing Chronic Disease Risk* (NRC, 1989a), and the National Cholesterol Education Program's "Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction" (NIH, 1990). The RDIs and DRVs form the basis for the Daily Values.

When NLEA was implemented in 1993, the scientific basis for the RDIs was already outdated. The Institute of Medicine, the health arm of the NAS, has since issued new Dietary Reference Intakes, but the RDIs and DRVs—and thus the Daily Values—have not been updated in a timely manner to reflect current nutrition science and to be more relevant to public health.

Serving and Portion Sizes

To determine amounts customarily consumed, FDA used dietary intake data from the 1977–1978 Nationwide Food Consumption Survey (NFCS) and, to a lesser extent, the 1987–1988 NFCS, augmented by other sources of information where available.[12] However, Since 1993, it

[12] 58 FR 2229.

is generally recognized that portion sizes as customarily consumed for many foods have increased, contributing to concerns about excess calorie intake and obesity (e.g., Young and Nestle, 2003). Consequently the RACCs used for determining labeled serving sizes may not reflect the larger portions of food actually being consumed today. While the NLEA mandate would suggest that serving sizes may need to be adjusted to reflect the new amounts customarily consumed, concerns about increased portion sizes and obesity have led to questions about whether labeled serving sizes might more appropriately be based on smaller serving sizes rather than the new, larger amounts generally consumed today.

These issues are of concern for nutrition labeling in general, but they affect FOP systems as well, especially if these systems are designed to maintain consistency with other nutrition labeling regulations. FOP systems have an added challenge in that additional dietary guidance recommendations such as the Dietary Guidelines may factor into criteria. These additional recommendations have the potential to change, creating another potential way in which FOP system criteria may become outdated.

In summary, it will be important to consider developing a formalized process that will trigger an automatic reassessment of FOP system nutrient criteria if changes are made in the dietary recommendations or nutrition labeling regulations on which the system is based.

Expressing Nutrition Information on Front-of-Package Versus Shelf Tags

A final issue associated with developing FOP rating systems that the committee identified was whether to use FOP symbols on shelf tags or on product packaging. Shelf tag symbols offer some advantages in that they provide an option for providing FOP symbols on unpackaged foods, such as fresh produce, and they may be more effective in getting consumer attention than the symbols on food packaging in retail stores. Because shelf tags can be used to label all foods in a store, they can potentially provide information on the whole diet and not just packaged foods. However, a limitation of shelf tags is that consumers may have difficulty determining which symbol goes with what product, especially if products get moved around on the shelf. An advantage of using symbols on packaging is that, unlike shelf tags, symbols on packaging stay with the food item once it has been purchased, while shelf tag symbols do not. Having the symbol remain with the product when it is brought into the home may help to reinforce the nutritional quality of the product with consumers and other members of the household besides the shopper. This potential benefit needs to be balanced with the inability to provide symbols on foods, such as fruits and vegetables, whose consumption should be encouraged but that are not traditionally sold in packages.

CATEGORY-SPECIFIC STRENGTHS AND LIMITATIONS OF FOP NUTRITION RATING SYSTEMS

The previous section discussed issues associated with developing FOP nutrition rating systems. This section focuses on the strengths and limitations generally associated with each of types of FOP system. Summaries of the strengths and limitations identified by the committee are provided in Tables 6-4 and 6-5.

Nutrient-Specific Information Systems

Nutrient-specific systems provide information about nutrients and food components to limit or encourage and typically display some combination of (1) calories per serving, (2) targeted nutrients expressed as amount per serving; %DVs; or "high," "medium," or "low" indicators, and (3) symbols or icons based on FDA or USDA nutrient content or health claim criteria. Current systems that provide nutrient amounts per serving include General Mills Nutrition Highlights, Kellogg's Nutrition at a Glance, and the U.K. Traffic Light. Examples of symbols or icons based on FDA or USDA nutrient content or health claim criteria include Harris Teeter and Wegmans Wellness Keys.

Strengths

Nutrient-specific systems all use one approach across all or most categories of foods and beverages: a declaration, description, or evaluation of calories or a nutrient amount per labeled serving. Many U.S. versions highlight nutrients shown on the Nutrition Facts panel that are considered of particular concern for the health of the American public. Highlighting nutrient amounts on the front of the package, putting the amounts into the context of a daily diet as a percent of the Daily Value, and characterizing the amounts as "high," "medium," or "low" can help individuals who want to comply with public health guidance or dietary recommendations from a healthcare provider. The approach is consistent with current regulations for declaring nutrient amounts and criteria for nutrient content claims. An additional strength is that, with the exception of added sugars, analytical methods and procedures for monitoring compliance are defined in regulations.[13]

Limitations

Label space is limited, especially for small packages, which restricts the amount and type of information that can be presented. Including too many nutrients or icons may result in label clutter and interfere with consumers' ability to use the information. Alternatively, consumers may read only the FOP symbol and reduce their use of the Nutrition Facts panel.

One limitation of nutrient-specific systems that characterize the amount of nutrient present is the lack of a Daily Value for some nutrients, and without a Daily Value there is no basis upon which to develop criteria for characterizing the amount of the nutrient. Even for nutrients with Daily Values and already established claim criteria for "low" and "high," no regulatory definition exists for "medium" amounts.

Nutrient-specific systems based on FDA/USDA claim criteria that use symbols or text to indicate that a product meets the criteria for a nutrient content or health claim have additional limitations. Some products that qualify for a nutrient content claim may not have "low" amounts of the nutrients that should be limited in healthful diets. Even though regulations require that information concerning nutrients to limit be disclosed when certain claims are made, consumers may disregard the information. Furthermore, disclosure amounts may be too lenient for some product categories. At the same time, the criteria for "low" may be too strict for some products, especially those that might be consistent with a healthful diet. Finally, some products may qualify for one or more nutrient content claims but not actually make the claims on the package

[13] 21 CFR 101.9(g).

TABLE 6-4 Comparison of FOP System Types According to Potential Strengths.[a]

	Nutrient-Specific Information			Summary Indicator		Food Group Information	
Strength	Calories per Serving	Nutrient Amount per Serving	Symbol Based on FDA/USDA Claim Criteria	Based on Nutrient Thresholds	Based on Algorithm	Food Groups	Food Ingredient
Applies one standard or format across all or most product categories	✓	✓	✓			✓	✓
Addresses product categories according to their relative contribution to total intake				✓	✓		
Targets nutrients of public health concern	✓[b]	✓[b]	✓[b]	✓[c]	✓[c]		
Facilitates compliance with dietary recommendation(s) from healthcare provider	✓[b]	✓[b]	✓[2]				
Helps consumers identify nutrient-dense food				✓[d]	✓[d]		
Provides measure of relative amount of nutrient if %DV, high/medium/low text, and/or color coding is used	✓	✓	✓				
Declares/evaluates nutrient amounts consistent with current regulations	✓	✓	✓				
Analytical methods available for monitoring compliance of nutrients in the Nutrition Facts panel	✓	✓	✓	✓	✓[e]		

[a]A checkmark indicates the strength is specific to that system subtype.
[b]Applies to individual nutrients.
[c]Nutrients of public health concern may be included in threshold criteria and algorithms but are not transparent to consumers.
[d]Nutrients contributing to nutrient density are not transparent to consumers.
[e]However, an algorithm may incorporate parameters such as glycemic load or weighting factors that are not specific to the product evaluated, and the algorithms for NuVal and Guiding Stars are not publically available, thus precluding compliance monitoring.

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TABLE 6-5 Comparison of FOP System Types According to Potential Limitations.[a]

	Nutrient-Specific Information			Summary Indicator		Food Group Information	
Limitation	Calories per Serving	Nutrient Amount per Serving	Symbol Based on FDA/USDA Claim Criteria	Based on Nutrient Thresholds	Based on Algorithm	Food Groups	Food Ingredient
FOP label space limited for small packages		✓	✓			✓	
Too much information may reduce consumer comprehension and use	✓	✓	✓			✓	
Decreased use of Nutrition Facts panel	✓	✓	✓	✓	✓	✓	✓
No Daily Value for some nutrients, thus no basis for nutrient content claims	✓[b]	✓	✓	✓	✓		
No definition for low, medium, and/or high for some nutrients	✓	✓	✓	✓			
Products qualifying for any one claim may not have zero/low amounts of nutrients to limit	✓	✓	✓				
Consumers may disregard disclosure information associated with nutrient claims	✓	✓	✓				
Nutrient disclosure amounts may be too lenient for some product categories			✓	✓			
Low claim criteria may be too strict for some nutrients in some product categories			✓	✓			
Some product nutrient criteria based on recommendations for a total dietary intake				✓			
Nutrient criteria not publically available for some systems					✓		
Nutrients or amounts influencing product evaluation not transparent at point of purchase			✓	✓	✓		

	Nutrient-Specific Information			Summary Indicator		Food Group Information	
Limitation	Calories per Serving	Nutrient Amount per Serving	Symbol Based on FDA/USDA Claim Criteria	Based on Nutrient Thresholds	Based on Algorithm	Food Groups	Food Ingredient
Need to decide how many and which product categories to include				✓	✓		
Need to decide which nutrients to include and basis for evaluation				✓	✓		
May encourage discretionary fortification to meet threshold criteria or improve algorithm score unless rules in place				✓	✓		
May not have criteria for nutrients to limit						✓	✓
May not be able to monitor compliance				✓[c]	✓[c,d]	✓[e]	✓[5]

[a] A check mark indicates the limitation is specific to that system subtype.
[b]Current systems use 2,000 calories as a reference total daily intake.
[c]Nutrient thresholds or algorithms may include nutrients, food components, or weighting factors that are not specific to the product being evaluated and are imputed from food composition databases and literature that may or may not be publically available.
[d]The algorithms for some systems are not publically available.
[e]If the product is not a mixture of different foods, compliance can be monitored by comparing the declared serving size with the recommended food group servings. If the product is 100% whole grains, compliance can be monitored by reviewing the ingredient list.

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label. Because not all eligible products make nutrient content claims and because not all food items carry FOP nutrient-specific text or symbols, it may not be easy for consumers to compare and make decisions among products.

Summary Indicator Systems

Summary indicator systems include both systems based on nutrient thresholds and systems based on algorithms. The two types both attempt to assess the overall healthfulness of a food product, in one case by setting nutrient or food component thresholds and in the other by integrating information about various nutrients to limit, nutrients to encourage, and other factors. Examples of current systems based on nutrient thresholds include Choices (EU), Sensible Solutions (Kraft), and Smart Spot (PepsiCo); examples of those based on algorithms include Guiding Stars and NuVal

Strengths

Summary indicator systems typically develop criteria specific to food categories and their relative contribution to total intake. Both threshold- and algorithm-based systems tend to include nutrients thought to be important to public health concern and also to consider nutrient density. Analytical methods are available for some, but not all, nutrients that make it possible to monitor compliance for those systems whose nutrient thresholds or algorithms are publically available and that are based on nutrients listed in the Nutrition Facts panel.

Limitations

Similar to the case with systems based on nutrient-specific information, a lack of Daily Values can present challenges for setting nutrient criteria for summary indicator systems if the Daily Values are used as the basis for the criteria. For threshold-based systems, challenges for setting the nutrient criteria include a lack of definition for “low,” “medium,” and “high” for some nutrients, criteria for “low” that are too low, and lenient disclosure amount criteria for some nutrients. One approach to dealing with these issues has been to apply dietary recommendations intended for the total diet to individual products, but the appropriateness of this approach has not been established.

Generally, nutrient criteria for summary indicator systems are publicly available on the sponsoring organization’s website or in peer-reviewed journals (see Table 6-2), but two of the algorithm systems reviewed by the committee are not publically available. A lack of transparency makes it impossible to have independent assessment of the scientific basis underlying the algorithm or to monitor compliance. In addition, the analytical methods necessary for compliance monitoring are not available for some nutrients (e.g., added sugars and bioflavanoids) (BeMiller, 2003; Robbins et al., 2006; Kwik-Uribe and Bektash, 2008).

Another limitation for summary indicator systems is that consumers do not know at the point of purchase how individual nutrients in a product contributed to the product’s evaluation. With threshold systems, consumers can assume that nutrient amounts meet specific targets, but with algorithm systems consumers cannot know what led to the final rating or what might comparatively be considered the best and worse ratings within a product category.

For both threshold- and algorithm-based systems, decisions need to be made about how many and which product categories to include, which nutrients to include, and the basis upon which to evaluate each nutrient. While tailoring nutrient criteria to specific food categories can be seen as

a positive, the systems reviewed differ widely in how these decisions have been made and how they influenced the final evaluation of products, which in some cases may have led to the approval of foods that are generally identified as items to limit in the diet. Finally, as discussed previously in this chapter, the way that summary indicator systems are developed may encourage discretionary fortification in order to meet threshold criteria or improve algorithm scores unless rules are put in place to prevent it. Fortification is a particular concern for summary indicator systems; in these systems, more than in other system types, fortification may be likely to improve the rating of a product that contains nutrients of concern.

Food Group Information Systems

This type of FOP rating system provides information about the contribution a product makes to the recommended intake of food groups or ingredients. The food groups to encourage are usually fruits, vegetables, whole grains, and fat free or low fat dairy products. Start Making Choices (Con Agra) is an example of a system based on food groups and the Whole Grain Stamp is an example of a system based on an ingredient.

Strengths

The FOP systems based on food group information that were reviewed by the committee appear to apply a single, consistent approach across all product categories. For example, to carry a Start Making Choices (ConAgra) logo, products must have at least 10 percent of the daily recommended amount of a food group, and the percent daily amounts must be displayed in increments of 5 percent.[14] Likewise, the Whole Grains Council has specific instructions that apply to all products for how to determine the whole grain contents.[15]

Limitations

A limitation of systems based on food groups is the lack of analytical methods for monitoring compliance of foods that contain a mixture of different food groups (e.g., pizza). FOP systems based on food groups and ingredients may have an additional limitation if there are no criteria for evaluating the amounts of nutrients to limit in the diet. Foods that qualify may not, for instance, be low in nutrients to limit such as sodium and saturated fat.

SUMMARY

Developing the nutritional criteria underlying FOP nutrition rating systems requires decisions about a variety of factors: the nutrients and other components to include and the basis for setting the criteria, the role of fortification, whether the same criteria should be used across all food categories or whether category-specific criteria should be developed, how best to monitor compliance, how to update system criteria, and the placement of symbols on food packaging versus on shelf tags. Decisions related to these issues will affect the outcome of product

[14] Available online: http://www.iom.edu/~/media/Files/Activity%20Files/Nutrition/NutritionSymbols/6_%20Mark%20Andon%20-%20Start%20Making%20Choices.pdf [accessed 9/14/10].

[15] Available online: http://www.wholegrainscouncil.org/files/US_StampUsageGuide.pdf [accessed 9/14/10].

evaluations. It may be valuable to use a set of test foods to determine how products fare under evaluation by systems that are based on different types of product categories and nutrient criteria and to see whether ratings and rankings of the test foods are consistent with dietary guidance and useful for informing consumers about the usefulness of products in a health-promoting diet.

Decisions about the nutrients to include in FOP systems and about the underlying nutrient criteria will be most effectively grounded in current nutrition science if they are based on current, government-endorsed, consensus documents on the dietary needs of the U.S. population.

Including nutrients to encourage (e.g., fiber and certain vitamins and minerals) in FOP systems may encourage overfortification or the addition of these nutrients to food systems in which the nutrient is unstable or not biologically available, which would contradict FDA fortification policy.

To ensure that products actually meet FOP nutrient criteria, the criteria need to be publically available, analytical methods need to exist for detecting the nutrients and other components included in the criteria, and products need to be evaluated based on their specific nutrient content and not on values imputed from databases and the literature. In addition, it is important that system developers consider creating a formalized process that would trigger an automatic reassessment of nutrient criteria if changes are made in the dietary recommendations or the nutrition labeling regulations on which the system is based.

Based on the committee's review, several options exist for setting criteria, but these require further testing of consumer use and understanding to assess their overall viability. These options will be further discussed in the next chapter.

REFERENCES

BeMiller, J. N. 2003. Carbohydrate analysis. In *Food Analysis*, 3rd ed., edited by S. S. Nielsen. New York: Kluwer Academic. Pp. 143–174.

DGAC (Dietary Guidelines Advisory Committee). 2010. *The report of the Dietary Guidelines Advisory Committee on Dietary Guidelines for Americans, 2010*. Washington, DC: U.S. Department of Health and Human Services, U.S. Department of Agriculture.

Fulgoni, V. L., D. R. Keast, and A. Drewnowski. 2009. Development and validation of the Nutrient-Rich Foods Index: A tool to measure nutrition quality of foods. *Journal of Nutrition* 139:1549–1554.

Haley, S., and M. Ali. 2007. Sugar backgrounder. *Outlook Report No. (SSS-249).* Washington, DC: U.S. Department of Agriculture Economic Research Service.

HHS (Department of Health and Human Services). 1988. *The Surgeon General's report on nutrition and health.* Washington, DC: U.S. Public Health Service, Office of the Surgeon General.

HHS/USDA (U. S. Department of Health and Human Services/U.S. Department of Agriculture). 2005a. *Dietary Guidelines Advisory Committee Report, 2005.* Washington, DC: Government Printing Office.

HHS/USDA (Health and Human Services/U.S. Department of Agriculture). 2005b. *Dietary guidelines for Americans, 2005.* Washington, DC: Government Printing Office.

IOM. (Institute of Medicine). 2002/2005. *Dietary reference intakes for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein, and amino acids.* Washington, DC: The National Academies Press.

Katz, D. L., V. Y. Njike, Z. Faridi, L. Q. Rhee, R. S. Reeves, D. J. A. Jenkins, and K. T. Ayoob. 2009. *The stratification of foods on the basis of overall nutritional quality: The Overall Nutritional Quality Index. American Journal of Health Promotion* 24(2):133-143.

Kwik-Uribe, C. and R. M. Bektash. 2008. Cocoa flavanols – measurement, bioavailability and bioactivity. *Asia Pacific Journal of Clinical Nutrition* 17(S1):280–283.

NIH (National Institutes of Health). 1990. *National cholesterol education program: Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction*. Washington, DC: U.S. Government Printing Office.

NRC (National Research Council). 1968. *Recommended dietary allowances. Seventh revised edition. Washington, DC: National Academy of Sciences.*

NRC. 1989a. *Diet and health: Implications for reducing chronic disease risk.* Washington, DC: National Academy Press.

NRC. 1989b. *Recommended dietary allowances.* Washington, DC: National Academy Press.

Robbins, R. J., C. Kwik-Uribe, J. F. Hammerstone, and H. H. Schmitz. 2006. Analysis of flavanols in foods: What methods are required to enable meaningful health recommendations? *Journal of Cardiovascular Pharmacology* 47(S2):S110–S118.

WHO (World Health Organization). 2003. Diet, nutrition, and the prevention of chronic diseases; Joint *WHO/FAO Technical Report Series no. 916.* Available online: http://www.who.int/dietphysicalactivity/publications/trs916/download/en/index.html (accessed June 3, 2010).

Young, L. R., and M. Nestle. 2003. Expanding portion sizes in the U.S. marketplace: implications for nutrition counseling. *J Am Diet Assoc* 103(2):231-4.

7
Conclusions and Plans for Phase II

Previous chapters have documented the proliferation of nutrition rating systems and symbols that has taken place in U.S. and international markets in recent years. Each of the systems is intended to promote the purchase and consumption of more nutritious foods and to help consumers make purchasing decisions on the basis of nutrition information quickly and accurately, but these systems vary greatly in the particular details of their purpose, symbols, formats, and criteria used. In this chapter the committee presents its conclusions, made on the basis of available information and its judgment, about how FOP systems might be best structured in the future. For the first phase of the committee's work, the primary focus was the nutrition science underlying these systems. This focus is reflected in the conclusions presented here. This chapter also describes plans for a second phase of work that will consider consumer use and effectiveness of FOP systems and symbols to improve dietary practice and improve health.

TARGET AUDIENCE

Conclusion 1: Front-of-package rating systems and symbols would be best geared toward the general population.

The committee concluded that the target population for FOP rating systems should be the general population, for several reasons. The majority of the U.S. population is now overweight or obese, and the prevalence of chronic diseases and behaviors that increase the risk for chronic diseases are both at high levels (Ford et al., 2007, 2008). Thus there is an urgent need for a majority of the population to make healthier food choices. Furthermore, past nutrition labeling efforts, such as the Nutrition Facts panel, have used the general population as the intended audience (Taylor and Wilkening, 2008), so maintaining the general population as the audience for FOP rating systems will maintain consistency with other nutrition labeling now present on foods.

While FOP criteria and symbols would be best geared toward the general population, the committee recognizes that specific subpopulations (e.g., those with diet-related chronic disease, lower-income populations, minority populations, parents, and primary food purchasers) may benefit from information campaigns on FOP labeling that are specifically designed to address their particular health needs and to capture their attention. Such a campaign would be consistent with the IOM (2006) report suggesting a marketing campaign to educate parents about sound nutritional choices for their families. No such national campaign has been launched since that report. An appropriately designed system might be useful for determining products that may be marketed to children, an issue that can be revisited in Phase II.

PURPOSES

Conclusion 2: The committee supports the goal and purposes of front-of-package systems announced by the Food and Drug Administration in April 2010 and concludes that the most useful primary purpose of front-of-package rating systems and symbols would be to help consumers identify and select foods based on the nutrients most strongly linked to public health concerns for Americans.

An ideal system would allow consumers to identify the amount of calories per serving and the serving size as well to compare and evaluate amounts of targeted nutrients present in different products both *within* and *across* food categories. Such a system may also encourage food and beverage manufacturers to reformulate products to meet nutrient criteria targeted by FOP systems. Two system types could fulfill these purposes—nutrient-specific systems and summary indicator systems based on nutrient thresholds in which all food categories had the same nutrient thresholds.

NUTRITION INFORMATION TO INCLUDE

As discussed above, the variation in FOP systems has led to numerous questions, including how sound the criteria are that are used to determine which products are the more nutritious choices. The committee considered these and a number of other questions in its review of existing systems. In developing conclusions on nutrients that should be included or excluded and options for setting criteria, the committee weighed potential conclusions against the guiding principles in Chapter 1. Conclusions 3 through 5 reflect the committee's assessment of which pieces of nutrition information it would be reasonable to include or exclude from FOP systems at the current time.

Conclusion 3: Regardless of system type, it would be useful to declare calorie and serving size information prominently in front-of-package symbols.

As discussed in Chapter 4, obesity and overweight, which are caused by calorie consumption in excess of energy expenditure, are now a critical public health concern that affects the population. Given that overweight and obesity pose an increased risk for numerous diseases and morbidities, the 2010 Dietary Guidelines Advisory Committee encourages all Americans to know their energy needs as a means of avoiding inappropriate weight gain (DGAC, 2010). Including total calories in nutrition rating system symbols could be one tool for emphasizing the importance of calories in the American diet. In addition, such information might help consumers select lower-calorie foods, consume lower quantities of higher-calorie foods, and track the number of calories consumed per day and the relative contribution of various foods consumed.

Including a more prominent display of calories within nutrition rating symbols would also provide consistency between packaged and restaurant foods. The Patient Protection and Affordable Care Act,[1] signed into law in March 2010, amends the Food, Drug, and Cosmetic Act to require chain restaurants to provide access to nutrition information for standard menu items.

[1] *Patient Protection and Affordable Care Act*, HR 3590, Title IV, Subtitle C, §4205; 111th Cong., 2nd sess., March 2010.

Restaurants with 20 or more outlets are required to post calories on menus, menu boards (including drive-thrus), and food display tags. Similarly, vending machines operated by large distributors are required to have calorie information displayed for vended products. Including calories on FOP systems for packaged foods could complement these new requirements.

Providing serving size information would also give context to the amount of food associated with the calories per serving displayed as part of an FOP symbol. Serving size information in an easy-to-understand format consistent with current dietary practices may help consumers do a better job of visualizing appropriate serving sizes and put their servings into the context of the other foods and beverages they are consuming.

Displaying serving sizes would best be accomplished by using household measures that would be easy for the consumer to understand. U.S. authoritative bodies, consumer research groups, health professionals, and the food industry have long held that nutrient amounts should be expressed per serving rather than per 100 g, as is used in some other countries (Usmanova and Thor, 2003). Furthermore, there is some evidence that consumers find it helpful when a clear definition of a serving is provided. Research conducted during the development of the MyPyramid Food Guidance System found that most focus group participants believed that using household measures (e.g., cups or tablespoons) would be more effective than simply using the word "servings" because the household measures are more commonly understood (Britten et al, 2006). Household measures are also commonly used in the Nutrition Facts panel, so displaying serving size information in household measures would maintain consistency with this other tool for consumers.

In addition, the committee identified several related approaches as being potentially important for enhancing accuracy, comparability, and consumer understanding of the relative contribution a product might provide towards daily caloric intake. These approaches include adding calories per package and the number of servings per package and providing context for how the calories per serving relate to daily caloric needs (e.g., the proportion of a 2000-calorie diet that a serving of a particular product provides). Consumer research may help determine whether one or more pieces of this additional information might be helpful in assisting consumers to visualize serving size and in increasing consumer awareness of the calorie contributions of the products they consume. The committee also recognized that the reference amounts customarily consumed (RACCs) used for defining labeled serving sizes in the Nutrition Facts panel may not reflect the larger portions of food consumed today.

Conclusion 4: The most critical nutritional components to include in front-of-package nutrition rating systems are calories, saturated fat, *trans* fat, and sodium.

As stated in the committee's guiding principles (see Chapter 1), the committee considers it critical that FOP rating systems focus on the nutritional components that are most strongly associated with the diet-related health risks affecting the greatest number of Americans, such as obesity, cardiovascular disease, hypertension, type 2 diabetes, and certain types of cancer. Calories, saturated fat, *trans* fat, and sodium are four of the most critical nutritional components affecting these health risks, and they are also overconsumed in the American diet (see Chapter 4). As previously described, calories are the most critical nutritional component to address in reducing obesity and its various co-morbidities, including coronary heart disease (CHD) and stroke, type 2 diabetes, metabolic syndrome, and certain types of cancer. Reducing sodium intake can reduce blood pressure, which in turn can reduce an individual's risk of stroke and

cardiovascular disease events. Decreasing saturated and *trans* fat intake may decrease the risk of cardiovascular disease. Given the adverse health effects of excess calories, saturated fat, *trans* fat, and sodium intakes, including these components in nutrition rating systems could have important benefits to public health by helping Americans chose foods with lower levels of these nutrients of concern. Calories, saturated fat, *trans* fat, and sodium should not be viewed in isolation, however. It is important to understand not only whether labeling to encourage the choice of similar products with less of these components is effective in meeting that goal, but also whether such labeling encourages alternate food choices and, if so, the relative nutrient profile of those alternate choices.

Conclusion 5: There is insufficient evidence at this time to suggest that including the following nutrients would be useful in all types of front-of-package rating systems or symbols: total fat, cholesterol, total carbohydrate, total or added sugars, protein, fiber, vitamins, and minerals other than sodium.

It may not be essential or useful to include in all types of FOP systems a number of the nutrients that currently appear on the Nutrition Facts panel or in existing FOP system criteria. Many factors led to the conclusion that certain nutrients might not be included in FOP system criteria at this time, including the relative importance of these nutrients to the most pressing diet-related public health concerns, the potential for some nutrients to track with other nutrients that are considered important to include in FOP rating systems, and challenges in measuring compliance for some nutrients. This issue is particularly important considering the limited space available on food labels and shelf tags to present nutrition information, especially for FOP symbols that display information on individual nutrients.

It is important to recognize that even though it might be best to exclude these nutrients from FOP system criteria, monitoring their intake is still important in assembling a diet that is consistent with optimal health outcomes. The point, however, is that other tools may be more appropriate for accomplishing goals for some of these nutrients, freeing up FOP systems to focus on the most critical public health concerns. For example, the Food, Drug and Cosmetic Act requires that information on total fat, cholesterol, total carbohydrate, total sugar, protein, fiber, and many vitamin and mineral contents appear on the Nutrition Facts panel. This information can be used by individuals who want or need to monitor intakes of these nutrients (e.g., individuals who need to monitor iron intake). Mandatory fortification of commonly consumed foods with vitamins or minerals that are lacking in the diet is another tool that is more suited to meeting certain public health needs for particular nutrients, and education campaigns are yet another.

Reasons for excluding each of the nutrients listed above from FOP systems are provided in the sections that follow.

Total Fat

Because of the lack of data supporting an association between fat in the diet and either body weight or health outcomes, it is difficult to conclude that including total fat in FOP systems would be useful. Total fat includes mono- and polyunsaturated fats, which are associated with beneficial health outcomes, as well as saturated and *trans* fats, which are nonessential and associated with adverse health outcomes. The lack of evidence supporting an association with total fat and health and the heterogeneity in the total fat composition of a food product makes it

difficult to characterize total fat content as a positive or negative attribute in many types of nutrition rating systems.

Furthermore, recent dietary guidance encourages the consumption of unsaturated oils in order to displace saturated and *trans* fats in the diet, making it important that Americans not be discouraged from consuming all forms of fat. Yet, there is some evidence that consumers continue to be confused about the various types of fats and that many continue to avoid even beneficial fats. The 2010 IFIC Food and Health Survey found that close to a third of Americans are attempting to decrease their intake of mono- and polyunsaturated fats (IFIC, 2010). Since many consumers have a negative view of all types of fat, it is likely that these consumers may avoid all products showing higher levels of total fat content in FOP systems that include nutrient-specific information, and this may not always be the desired behavior.

Cholesterol

While cholesterol remains a concern for certain subpopulations, overconsumption of cholesterol is not as significant a problem for the general population as overconsumption of saturated fat, *trans* fat, and sodium, so there is less need to include cholesterol in FOP system criteria.

Furthermore, saturated fat criteria may help address most major sources of cholesterol. The major source of cholesterol in the diet is animal products, primarily meat and dairy. These foods are also typically sources of saturated fats. Since saturated fats are important to include in FOP systems, most foods that are "high" in cholesterol would already be rated poorly because of their saturated fat content. Therefore, it may not be necessary to include specific cholesterol criteria in order to help consumers chose lower-cholesterol foods. For some systems, such as those displaying nutrient amounts per serving, excluding cholesterol from the FOP symbol may help to reduce label clutter, leading consumers to focus more on nutrients of greater public health concern.

Total Carbohydrates

Like total fat, total carbohydrates consist of multiple components with various physiological functions. Carbohydrates as a class include a variety of compounds including monosaccharides (e.g., fructose), disaccharides (e.g., sucrose or table sugar), starch, fiber, pectins, and gums. These compounds vary greatly in their physiological function. The consumption of some carbohydrates, such as fiber, is encouraged, while consumption of other carbohydrates, such as added sugars (e.g., sucrose, high-fructose and corn syrup) is discouraged. Because of the varied physiological functions that carbohydrates take on, it would be difficult in many types of nutrition rating systems to characterize the total carbohydrate content of an individual food as either a positive or a negative attribute.

Total Sugars

Consensus about the amount of total sugars that can be consumed in a healthy diet is still lacking. Beyond a role in dental caries and as a contributor to calories, identifying additional potential adverse effects of sugars on health outcomes remains elusive. Furthermore, total sugars include those naturally present in fruits, vegetables, and dairy products, which are generally considered foods to encourage. Thus, it is difficult to conclude that including total sugars in FOP

systems could at this time address issues of public health concern or that such inclusion would not result in adverse dietary pattern outcomes.

Added Sugars

It might be plausible to include added sugars information on FOP labeling, mainly because the consumption of added sugars has increased, and this increase has contributed to the overall increase in total calories in Americans' diets. A number of reports have recommended limits on the intake of added sugars, including *Nutrition Standards for Foods in Schools* (IOM, 2007) and the Report of the Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases (WHO/FAO, 2003). The *Dietary Guidelines for Americans* and other federal nutrition guidance call on Americans to reduce the intake of added sugars, and surveys show that consumers are concerned about added sugars in foods (HHS/USDA, 2005; IFIC, 2009). However, a number of concerns and barriers exist for including added sugars in FOP rating systems.

Based on the literature, there is a lack of scientific evidence and agreement about what adverse effects added sugars have on health outcomes independent of total sugar, with the exceptions that added sugars, whether in solid or liquid form, contribute extra calories which could lead to weight gain and obesity and that current sugar intakes exceed amounts consistent with consuming recommended intakes of essential nutrients. Because of the lack of scientific evidence and agreement on whether added sugars adversely affect health outcomes beyond contributing to calories, the committee concluded that the emphasis should be on calories rather than added sugars *per se*.

A relatively small number of food categories—regular soft drinks, sugar and candy, grain-based desserts (cookies, cakes, and pies), and fruit drinks (fruitades and fruit punch)—provide over 70 percent of the added sugars in the American diet (Guthrie and Morton, 2000). Recommendations to reduce consumption of these specific types of food combined with including calories in FOP rating systems would be one approach to reducing added sugars in the American diet without requiring the inclusion of added sugars in FOP rating systems, and this approach would also maintain the current emphasis on the importance of calories.

Another concern about including only added sugars and not total sugars on FOP systems is that it would under-represent the sugars content of foods high in naturally occurring sugars, thus misleading consumers who may need to be aware of total sugars, such as individuals with diabetes, those trying to control their weight, or parents trying to limit children's sugars intake. For example, 100 percent fruit juice contains naturally occurring sugars but can easily be over-consumed and can contribute to energy imbalance; thus, it has been recommended that such juices be consumed in moderation (AAP, 2001).

Inclusion of added sugars content in FOP systems also raises several challenges and concerns related to maintaining consistency with the Nutrition Facts panel, which was a guiding principle of the committee's decision-making process. The Nutrition Facts panel on foods and beverages currently gives the amount of total sugars in a serving, but it does not distinguish whether the sugars were added to the food or occur naturally. Barriers to including added sugars on the Nutrition Facts panel have included both the state of nutrition science surrounding added sugars and various compliance monitoring concerns. As discussed in Chapter 6, distinguishing between added and naturally occurring sugars in food products presents analytical challenges. Lacking a regulatory compliance method, the only apparent solution to this analytical gap would be for food manufacturing companies to share proprietary product formulations with the Food and Drug

Administration (FDA) or a government-approved third-party auditor in order to differentiate and verify the amount of added sugars. Given the proprietary nature of most food formulations, some food manufacturers may resist sharing such information and oppose the inclusion of added sugars on the Nutrition Facts panel or in FOP information.

In 1999, the Center for Science in the Public Interest, with support from a number of health and consumer organizations, petitioned FDA to require that added sugars be included on the Nutrition Facts panel (CSPI, 1999). Such labeling would make it possible for consumers to know how much has been added to foods such as yogurt, ice cream, puddings, flavored milks, breakfast cereals, and baked goods. It has been suggested that added sugars could be listed in grams in order to be consistent with total sugars (Krebs-Smith, 2001) and that FDA should establish a Daily Reference Value for added sugars and require a mandatory disclosure of added sugars in both grams per serving and percent Daily Value (CSPI, 1999). It will be important in the future to reevaluate whether added sugars content can or should be included in the Nutrition Facts panel. However, given there is no scientific consensus concerning the adverse effects of added sugars (apart from their caloric contributions), and because monitoring levels of added sugars is not feasible, including added sugars on the Nutrition Facts panel may be a difficult task. Until these issues can be resolved and added sugars can be included in the Nutrition Facts panel, it seems premature to include added sugars in FOP systems.

Protein

Protein is currently not a nutrient of public health concern. Given that one of the guiding principles identified by the committee was that FOP systems should focus on those nutrients or food components that are most strongly associated with the diet-related health risks affecting the greatest number of Americans, it does not seem useful to include protein in the criteria of such systems at this time.

Fiber, Vitamins, and Minerals (Other Than Sodium)

While it is widely recognized that a healthful diet contains adequate amounts of various vitamins, minerals, and fiber, deciding whether to include information on them in FOP systems must take into account the lack of critical public health need for many of these nutrients, concerns over fortification, and the limited space for FOP symbols. For example, while the evidence for highlighting specific types of fiber is not as robust as that for the so-called negative nutrients, physiologic benefits and nutrients present in fiber-containing foods are recognized. Thus encouraging consumption of these foods is important, and the committee recognizes that increasing fruit and vegetable intake is a core recommendation of the *Dietary Guidelines for Americans.* Manufacturers also have mechanisms such as nutrient content and, in some cases, health claims to highlight positive nutrients. Thus, given the issues of space, need to focus on public health priorities, and availability of other tools, the committee concluded that including fiber on every type of FOP system was not essential. There are also measurement and definitional issues with fiber that complicate its use on FOP.

For many vitamins and minerals there is no overarching public health need for the general population to increase intake. In fact, the 2010 Dietary Guidelines Advisory Committee found vitamin D, calcium, and potassium to be the only vitamins and minerals for which Americans have insufficient intake and were of public health concern (DGAC, 2010).

Even for those vitamins, minerals, and fiber for which there is a public health need to increase intake, inclusion in FOP systems may not be the best means for achieving this goal. As described in Chapter 6 in the section on the role of fortification, including these nutrients in FOP systems could lead to practices such as excessive or inappropriate uses of fortification that may not be beneficial to consumers, or it could inadvertently drive consumers away from high-quality food choices that do not contain significant amounts of these nutrients. Similar fortification concerns arise for fiber, and, there are also concerns regarding the definition of fiber, the health benefits of novel fibers that have been developed in recent years, and the fact that the 2010 Dietary Guidelines Advisory Committee stressed that fiber in the diet should come from incorporating more whole grains, fruits, vegetables, and legumes into the diet (DGAC, 2010). These potential adverse consequences, coupled with the risk of label clutter for some systems, imply that including these nutrients in FOP rating systems may not be an ideal tool for increasing consumption. This should not be taken to imply that the committee has minimized the importance of addressing public health concerns about shortfall nutrients in the U.S. diet, but it is instead recognition that encouraging consumers to eat a diet rich in shortfall nutrients may require other tools, depending on the type of FOP labeling. For example, there may be the possibility of using nutrient content claims (e.g., good source of calcium) and other claims as tools for calling attention to nutrients on specific products types.

POTENTIAL QUALIFYING AND DISQUALIFYING NUTRIENT CRITERIA

Given the gaps in scientific data noted above, the ongoing consumer research by FDA and others, and the plans for examination of consumer use of FOP labeling in the second half of the committee's work, it is premature at this time to draw conclusions on the exact types of FOP symbols and systems that might be the most useful in informing consumers and facilitating dietary changes. The second phase of this study will consider consumer understanding and use of FOP symbols with the goal of helping to draw additional conclusions concerning which systems and symbols might be most helpful. Because of the diversity of system types, the committee was unable to identify a set of criteria that could be used for all FOP systems. However, the committee did examine how criteria might be set for various system types, and it believes that these considerations might serve as a basis for setting future FOP criteria once consumer research and testing results can determine which formats are most appropriate. Furthermore, the committee notes that future modeling work could help determine if the criteria were set in such a way that the types and quantities of products labeled facilitate recognition of FOP systems by consumers. In addition, modeling could be used to determine if choices made based on the criteria would be likely to improve food choices and lead to diets that are consistent with current dietary guidance.

The sections that follow describe the committee's thoughts on how criteria might be set for various system types. For each of the potential systems, the committee identified ways in which criteria might be set for calories, saturated fat, *trans* fat, and sodium, i.e., the nutrients that the committee concluded were most important to include in FOP systems.

Conclusion 6: Based on the committee's review, several options exist for setting criteria for two types of rating systems (nutrient-specific information and a summary indicator based on nutrient thresholds), but further testing of consumer use and understanding is required to assess their overall viability.

The committee identified multiple options for setting criteria for two of the system types it had defined. For nutrient-specific information systems it identified four options for setting criteria, while two options were identified for a summary indicator based on threshold systems. These options are described in the following sections. Other system types, including food group information systems and summary indicators based on algorithms, did not have readily apparent options for setting criteria. The challenges for setting criteria for these types of systems are also described in the sections that follow.

Nutrient-Specific Information

Several types of nutrient-specific information systems are possible. Some, such as calories per serving and claim-based icons (e.g., "low sodium" symbols), are factual statements, and the claim-based symbols are already subject to labeling regulations. On the other end of the spectrum of nutrient-specific information systems are those systems that use colors or words to indicate that a food is "high," "medium," or "low" in a specific nutrient. These systems require more work to establish criteria because existing labeling regulations do not establish "medium" levels, and "low" and "high" levels have not been established for all nutrients of interest.

The committee identified four options for displaying calories, saturated fat, *trans* fat, sodium, and serving size which depend on the amount of information considered to be of most use to consumers.

Option 1: Amount per Serving

The first option would be a simple, declarative statement (see Box 7–1). This would bring calories, saturated fat, *trans* fat, and sodium to more prominent locations for faster reading of some of the key information that is already part of the Nutrition Facts panel. To maintain consistency with the Nutrition Facts panel, the nutrients would need to be stated in the same units (calories, grams, or milligrams) and based on the same serving size as the Nutrition Facts panel. Because saturated fat and *trans* fat (so-called solid fats) are both fats of concern, these components could be combined to reduce the number of individual components that would need to be understood by consumers and to save valuable space on the front of food labels. The committee recognizes that doing so would be inconsistent with the Nutrition Facts panel and, therefore, would not be in accordance with one of the guiding principles intended to assist the committee in identifying a potential FOP system. Still, the benefits to the consumer and the food industry, in addition to health educators by minimizing one of the complexities in nutrition education programs, make it worth considering (IOM, 2003). The two types of fats are listed one after another and indented under total fat in the Nutrition Facts panel. Consumer research could be conducted to determine how consumers would respond to the summation of the two amounts under a single heading on the FOP label. In addition, to avoid the need for consumers to look at the Nutrition Facts panel in order to determine the serving size, the symbol could include the product serving size in terms of common household measurements.

Option 2: Amount Within the Context of a Daily Diet

The second option would display calories, saturated fat, *trans* fat, and sodium in the context of the daily diet by displaying the %DV provided per serving (See Box 7–2). Daily Values currently exist for some but not all nutrients of interest. A Daily Value for calories does not exist, but the %DV could be based on a 2000-calorie diet, which is consistent with the Nutrition Facts panel and is currently being done by at least one food manufacturer on FOP labeling. Providing a DV for calories was discussed by FDA in its 2004 report entitled *Calories Count: Report of the Working Group on Obesity* (FDA, 2004) and in an April 4, 2005, advance notice of proposed rulemaking.[2] Using this, a 200-calorie serving, for example, would contribute 10 percent of the Daily Value for calories. Like calories, *trans* fat does not have a Daily Value. However, similar to the suggestion in Option 1, grams of *trans* fat could be combined with grams of saturated fat, and the %DV could then be calculated on the basis of the combined quantity, using the Daily Value for saturated fat. This approach was taken for nutrition labeling in Canada.[3] Without new rulemaking to amend current nutrition labeling regulations to provide for a declaration of the %DV of saturated and *trans* fat combined, this option would result in a value that would, when

BOX 7-1
Nutrient-Specific Information Option 1: Nutrient Amounts per Serving

Declaration of:

- Calories
- Saturated fat + *trans* fat (g)
- Sodium (mg)
- Serving size

BOX 7-2
Nutrient-Specific Information Option 2: Nutrient Amounts Within the Context of a Daily Diet

Declaration of:

- %DV of calories based on a 2000-calorie/day diet
- %DV of saturated fat + *trans* fat *(using DV for saturated fat as basis for calculation)*
- %DV of sodium
- Serving size

*Calories, grams of saturated + *trans* fats, and milligrams of sodium could also be displayed.

[2] 70 FR 17008.
[3] Available online: http//www.hc-sc.ca/fn-an/label-etiquet/nutrition/cons/inl_main-eng.php (Accessed September 17, 2010).

trans fats are present, differ from the %DV declared on the Nutrition Facts panel for saturated fat. To address the lack of a Daily Value for *trans* fat and because Daily Values have not been not updated as new DRIs have been established and are considered by some to be out of date, labeling systems based on Daily Values would benefit from updating. This would ensure that the systems are based on the most accurate information known about the nutrient quantities that should be consumed for optimal health. This type of system could also display information on calories, grams of saturated and *trans* fat, and milligrams of sodium if this was found to be useful to consumers.

Option 3: Characterization of the Amount of Nutrients in Foods—"Low" Levels Only

The third option would characterize the amount of various nutrients per serving, identifying whether a serving of food contained "low" amounts of saturated fat, *trans* fat, and sodium (See Box 7–3). The indication of "low" might be displayed as the word "low," as a green light, or some combination of the two. Information on the amounts and %DV of saturated and trans fats and sodium contributed by the food might also be present. For this option, the regulated definitions for "low" could be used as the criteria for saturated fat, again combining saturated and *trans* fats as described in Option 2 *(s*ee Table 7–1). While the regulated criteria for "low" could be used for sodium as well, if FDA adopts the recommendations of the recent IOM report *Strategies to Reduce Sodium Intake* (IOM, 2010), it may be necessary to adjust the criteria for "low." If the IOM recommendations to gradually reduce the amount of sodium in foods are adopted, the criteria for "low" could be adjusted with each stepwise reduction in the level of sodium considered to be Generally Recognized as Safe. If Option 3 is used, it would be useful to display calories and possibly a %DV for calories (based on a 2000-calorie per day diet). However, there was some question about the utility of including an indication of "low calorie." The FDA definition of "low" is 40 calories per RACC. Since few foods, even those considered as part of a healthy diet, contain 40 calories or less per RACC, characterizing calorie levels in this way could have the unintended consequence of discouraging the consumption of otherwise nutritious foods.

TABLE 7-1 FDA-Regulated Criteria for "Low" Calories, Saturated Fat, and Sodium Nutrient Content Claims

	Individual Food	Main Dishes and Meals
Calories	40 calories or less per RACC (and per 50 g if RACC is small)	120 calories or less per 100 g
Saturated Fat	1 g or less per RACC + 15% of less calories from saturated fat	1 g or less per 100 g + less than 10% of calories from saturated fat
Sodium	140 mg or less per RACC (and per 50 g if RACC is small)	140 mg or less per 100 g

BOX 7–3
Nutrient-Specific Information Option 3: Characterization of the Amount of Nutrients in Foods—"Low" Levels Only

- Declaration of calories
- Characterization of saturated fat + *trans* fat as "low" when appropriate
- Characterization of sodium as "low" when appropriate
- Declaration of serving size

* Grams of saturated + *trans* fats and milligrams of sodium as well as %DVs for saturated + *trans* fats, sodium, and calories could also be displayed; %DV for calories is based on 2,000 calories/day.

BOX 7-4
Nutrient-Specific Information Option 4: Characterization of the Amount of Nutrients in Foods—"High," "Medium," and "Low" Levels

- Declaration of calories
- Characterization of saturated fat + *trans* fat as "high"/"medium"/"low"
- Characterization of sodium as "high"/"medium"/"low"
- Declaration of serving size

*Grams of saturated + *trans* fats and milligrams of sodium as well as %DVs for saturated + *trans* fats, sodium, and calories could also be displayed; %DV for calories is based on 2,000 calories/day

Option 4: Characterization of the Amount of Nutrients in Foods—"High," "Medium," and "Low"Levels

The fourth option would be similar to Option 3 but would further characterize the relative amounts of nutrients by including indicators of "medium" and "high" (See Box 7–4). This might be displayed using words or traffic light colors, or both. For saturated and *trans* fats and sodium, the same criteria described in Option 3 could be used to identify "low" contents.

For "high" criteria, it may be possible to use disclosure statement criteria. FDA regulations require that disclosure statements be placed adjacent to claims on food packages when another nutrient in the food exceeds certain prescribed levels. (FSIS regulated meat and poultry product labels are not subject to this requirement.) Disclosure statements are intended to alert consumers

that some nutrients in the food may increase the risk of a disease or health-related condition.[4] For example, a food that is "low" in saturated fat but "high" in sodium is required to have the statement "See nutrition information for sodium content" if a "low saturated fat" claim is made. Table 7-2 displays the current disclosure levels for saturated fat and sodium. These levels could be used for "high" criteria, with "medium" levels being defined as all nutrient levels between "low" and "high" criteria. As described in previous options, *trans* fat content could be added to the saturated fat content, and the combined total could be rated against the saturated fat regulations.

TABLE 7–2 FDA-Regulated Disclosure Levels for Saturated Fat and Sodium

	Individual Food[a]	Main Dish[b]	Meal[b]
Saturated Fat	4 g	6 g	8 g
Sodium	480 mg	720 mg	960 mg

[a] Per RACC, per labeled serving, or for foods with small RACC, per 50g
[b] Per labeled serving

On the other hand, characterizing calorie contents in the same way that saturated fat, *trans* fat, and sodium are characterized under this option could have unintended consequences. Small differences in caloric intake can result in a weight change over time. Thus, even consumers who were trying to consume a healthy diet by consuming most foods within the "medium" range for calories could gain weight, particularly if foods were within the upper range of the "medium" criteria and were consumed multiple times per day. Furthermore, no disclosure statement levels exist for calories, which would create additional complications for setting criteria if an effort was made to characterize calorie levels. Despite these concerns, calories remain important for such labeling systems and could be included by providing the number of calories per serving or a %DV for the calories per serving based on a 2,000-calories-per-day diet.

Summary Indicators Based on Nutrient Thresholds

The committee concluded that two options might be reasonable for developing a nutrient threshold-based summary indicator. As discussed above, these systems would be based on the content of calories, saturated fat, *trans* fat, and sodium and would include a declaration of serving size. The two options would be to (1) set the same criteria across all foods or (2) develop different criteria across food categories in order to make the criteria more or less stringent based on the characteristic attributes of the food category. For either system, the setting of criteria would benefit from modeling studies to ensure that an adequate number of foods qualify within each category and to ensure that the resulting ratings make sense from the perspectives of both nutrition science and dietary guidance.

Option 1: Set Criteria Across All Food Categories

A summary indicator based on the same criteria across all food categories would make it possible to compare foods across the supermarket. For example, apple slices would be rated

[4] Available online: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm064908.htm (accessed June 23, 2010).

against the same criteria as potato chips, as is currently possible using existing nutrient content claims defined by FDA and the U.S. Department of Agriculture.

For FOP systems, products qualifying for the use of a summary indicator (summary symbol) on packaging or shelf tags would need to meet multiple criteria requirements including providing information on calories and serving size and meeting specified levels for saturated fat, *trans* fat, and sodium (see Box 7-5). Criteria could be similar to those proposed in Option 3 for nutrient-specific information systems but result in a single symbol rather than a "low" characterization for each nutrient. However, setting criteria in this manner would likely result in certain food categories having very few foods that qualify for a summary symbol. Since consumers would see a single summary symbol rather than a characterization of the levels of individual nutrients (as in Options 3 and 4 for the nutrient-specific information), there might be some additional flexibility to set less stringent qualifying levels of saturated fat and sodium without having to worry about inconsistencies with criteria for "low" nutrient content claims. The committee did not have sufficient resources or data to propose what these less stringent levels might be. However, the committee expects that parties interested in developing such a system could model the effects that various criteria would have on which foods qualify.

Option 2: Set Separate Criteria by Food Categories

A summary indicator based on separate criteria for various food categories would be valuable for comparing products within a food category (See Box 7–6). For example, breakfast cereals, snack foods, and meats could each be considered separate food categories and thus have their own nutrient criteria. The downside of this option would lie in the difficulty of comparing foods across categories because of differences in qualifying criteria.

To develop this type of summary symbol system, it would be necessary to determine the number of distinct food categories that are reasonable and to determine criteria for saturated fat, *trans* fat, and sodium for each category. The committee assumes that in this type of system, the

BOX 7-5
Summary Indicator Option 1: Same Criteria Across All Food Categories

Set criteria for all foods with requirements for:

- Declaration of calories as part of the symbol
- Declaration of serving size as part of the symbol
- Specified threshold for saturated fat used across all food categories
- Specified threshold for *trans* fat used across all food categories
- Specified threshold for sodium used across all food categories

BOX 7-6
Summary Indicator Option 2: Separate Criteria by Food Categories

Set varied criteria for different food categories with requirements for:

- Declaration of calories as part of the symbol
- Declaration of serving size as part of the symbol
- Category-based thresholds for saturated fat
- Category-based thresholds for *trans* fat
- Category-based thresholds for sodium

criteria for certain nutrients would be less stringent in some categories than in others so that a sufficient number of products would qualify for the symbol in each category. For example, the sodium criteria for a soup category might be more lenient than for a breakfast cereal category. There may be a role for calorie criteria in this type of summary indicator system, but further modeling would be needed to determine the usefulness of such a requirement. Given the complexity of the Phase I task, the importance of a timely Phase I report, and data shortfalls, the committee was unable to develop conclusions on the food categories and category-specific nutrient criteria that would be needed for such a system. However, the committee expects that parties interested in developing such a system could model the effects of various food categories and criteria.

Summary Indicators Based on Algorithms

The committee concluded that algorithm-based ratings would not constitute an ideal system for the purposes of characterizing or rating only calories, saturated fat, *trans* fats, and sodium. This is because an algorithm-based system would need to assume that the effects of saturated fat, *trans* fat, and sodium are additive for overall health outcomes, which is not the case. Furthermore, the use of algorithms to rate the quality of foods based on these nutrients could have adverse effects on the goal of promoting a high-quality diet. For example, a food that is "low" in saturated fat may still contribute a large amount of sodium. But by the nature of an algorithm, the resulting score for this product could be similar to a product with moderate levels of both nutrients, leaving consumers unable to recognize that, by eating the first food, they would need to limit the amount of sodium they consume from other sources. This could result in overconsumption of certain nutrients over the course of the day, particularly if multiple foods were consumed that received better scores due to one nutrient being extremely low when another nutrient content was not as favorable.

Food Group Information

The committee also concluded that FOP symbols based on food group information would not provide sufficient information about nutrients of concern. Such systems generally provide only information on the percentage of recommended food group intake (e.g., 10 percent of daily vegetables or 30 percent of daily dairy needs). Such information could be useful to consumers in terms of the number of servings they need to consume per day, but it does not characterize the nutritional quality of the food. This could make some foods receive good ratings even though

they are not "low" in saturated fat, *trans* fat, or sodium. For example, a pasta dish with a full serving of vegetables might supply a high percentage of daily vegetable needs but also be "high" in sodium and saturated fat because of a heavy cream sauce. Therefore, such systems are most likely insufficient for addressing the major nutrient concerns that exist in the United States.

PLANS FOR PHASE II

During the first phase the committee was challenged by the task of considering advantages and disadvantages of various approaches and the nutrition criteria that underpin the FOP graphic representations without the benefit of an examination of consumer research. Such a focus, however, did enable the committee to focus singularly on the criteria that undergird symbols and to draw conclusions for exploration in the second phase in the context of consumer behavior research.

During the second phase, an ad hoc committee will continue the overall activity to the review and make recommendations about front-of-package nutrition rating systems and symbols by shifting to an emphasis on understanding which systems and symbols are most effective with consumers. The committee will draw on the first phase report as it considers: (1) which systems and symbols are most effective with consumer audiences and best promote health, (2) how to maximize their use, and (3) the potential benefits of a single, standardized front-label food guidance system regulated by the Food and Drug Administration. Thus, in addition to the expertise resident in the first phase committee, the second phase committee will include additional expertise about how consumers make sense of nutrition and other health information.

The committee's approach to its task will be multifaceted and will include gathering information from relevant consumer behavior literature and experts in relevant fields, including research on FOP undertaken by FDA; deliberating on issues relevant to the task; and then drafting its report. As evidenced by the questions below, the committee will be attentive to research related to consumer literacy and numeracy, as well as usability of labels by various subgroups in the population including children and adolescents. The committee will not undertake its own consumer research.

Modeling to understand which foods would receive favorable ratings with various criteria options and to ensure that the resulting ratings encourage a diet that is consistent with dietary guidance is desirable. Ultimately, any system will need to be field tested to ensure that it results in more nutritious food choices among the American public. During Phase II the committee intends to explore available modeling from the literature, and identify questions, target audience, and study designs for such modeling based on understandings from its review of the consumer literature. Given the timeframe and financial resources, the ability to conduct substantial modeling during the study process may be limited.

There are a number of questions whose answers have and will continue to enhance the committee's understanding of FOP system development and use to convey information accurately and affect purchase choices and eating behavior. Some were posed to developers and administrators of FOP systems during preparations for, and as part of, the Phase I workshop, and the committee will reexamine them. These are shown in Chapter 1, Box 1-2. Questions will also be posed as part of the committee's workshop on *Consumer Behavior Research and Front of Package Nutrition Rating Systems and Symbols—What do consumers know, understand, and use?* This workshop is an important component of the committee's information gathering. It is expected that the workshop will be held in conjunction with the initial second phase meeting of the committee in order to best inform the committee's deliberations. The workshop will include

presentations on consumer information on FOP systems and symbols and additional consumer research issues. Time will be made available for public comment on issues in the course of the workshop.

Presenters about recent consumer behavior research will be asked to describe briefly their research methods and samples, including populations and subpopulations studied, and then to address such questions as:

- What are the limitations of your work and how generalizable are your results?
- What does your work show about clutter and other factors that influence attention to and comprehension of FOP?
- What does your work show about differences among demographic or other populations and what are variations in response to the FOP by children, adolescents, people who do not speak English, people with low health literacy and those with low incomes?
- What kinds of diet and health outcomes did you explore and what did you find?
- If your work focused more generally on food labeling, what are implications of your work for FOP?
- What do you think should be on FOP?

Additional issues of particular importance to the committee are consumer literacy and numeracy, population subgroups, new technologies, consumer use of back of panel and relevance for FOP, and relationship of labeling to product reformulation. These topics will be explored at the workshop and subsequently considered by the committee during its deliberations. The committee will seek answers to questions such as the following through the workshop and subsequent literature analysis:

- What is known about health literacy and numeracy and its distribution in the population?
- What are the implications for developing an FOP system?
- What should the committee consider related to the health literacy of the American populations and subgroups as it considers FOP labeling?
- For example, what is the best way to communicate to the consumer using FOP? What factors need to be considered for individuals with low health literacy and numeracy?
- How much information is too much?
- Are there variations in response to the Nutrition Facts panel by subgroups—children, adolescents, non-English speakers, low income?
- What is the vision of the future related to new consumer technologies?
- What does the committee need to consider so that its recommendations are timely and will not be outdated quickly?
- Has nutrition labeling affected product reformulation?
- What should the committee pay particular attention to in considering FOP labeling and its potential for influence on product reformulation?

In addition to the information learned through the workshop, the committee's deliberations will be informed by examination of evidence related to the effects of health information from

product packaging and point of purchase displays on consumer perceptions, decisions, and behaviors. General information and information related to specific nutrients, if available, will be sought. As was the case with the Phase I review of nutrient rating systems, international research on consumer aspects of use of symbols and will be reviewed, including that conducted in the United Kingdom. The report of the second phase is due late summer 2011.

CONCLUDING REMARKS

After reviewing a number of existing systems and examining the roles that FOP nutrition rating systems and symbols have the potential to play, clear conclusions can be drawn in some areas, but questions remain in others. It is clear that no system is perfect—each has strengths and limitations that must be weighed against the primary and secondary purposes of FOP systems. For the most part, systems have not been field tested in order to provide data on whether the stated goals of the system are achieved. Given current public health needs, it was the judgment of this committee that a limited number of nutrition components most closely related to prominent health conditions may have the potential to be of most benefit when reported with an FOP system. Phase II offers an opportunity to explore these conclusions in the context of consumer behavior.

If the options identified by the committee are supported by the consumer research and ultimately adopted, adjustments to nutrition labeling regulations for FDA-defined claim criteria, Daily Values, and/or RACCs may be useful to ensure consistency and allow an appropriate number of products to qualify for FOP symbols. The committee's guiding principles stress the need for maintaining consistency with existing nutrition labeling regulations. To comply with this principle, in many cases it would be best if criteria were continually anchored to the most recent version of the *Dietary Guidelines for Americans* and current consensus reports. The committee recognizes that calls have been made to update nutrition labeling regulations, including Daily Values and RACCs, and that to respond by publishing advance notices of proposed rulemaking on some of the topics. It would be useful if FDA developed a formalized process that would trigger an automatic reassessment of system nutrient criteria when changes are made in the dietary recommendations on which the system is based. This could include updates to FOP system criteria.

Once the scientific integrity of a potential FOP system has been verified, research will be needed to determine the most effective way of presenting the ratings to consumers and evaluating the system after it is adopted. Some such research is being conducted by the FDA, academic institutions, and industry and can factor into future FOP system development and adjustments.

REFERENCES

AAP (American Academy of Pediatrics/Committee on Nutrition). 2001. The use and misuse of fruit juice in pediatrics. *Pediatrics* 107:1210–1213.

Britten, P., J Haven, and C Davis. 2006. Consumer research for development of educational messages for the MyPyramid Food Guidance System. *Journal of Nutrition Education and Behavior* 38:S108-S123.

CSPI (Center for Science in the Public Interest). 1999. Petition for proposed rulemaking to establish a daily reference value for "added sugars" to require nutrition labeling of "added sugars" and to make corresponding changes to nutrient content and health claim regulations. Submitted by CSPI to FDA on August 3, 1999. http://www.cspinet.org/reports/sugar/sugarpet1.pdf (accessed September 11, 2010).

DGAC (Dietary Guidelines Advisory Committee). 2010. *Report of the Dietary Guidelines Advisory Committee on the dietary guidelines for Americans, 2010.* Washington, DC: U.S. Department of Health and Human Services, U.S. Department of Agriculture.

Ford, E. S., U. A. Ajani, J. B. Croft, J. A. Critchley, D. R. Labarthe, T. E. Kottke, W. H. Giles, and S. Capewell. 2007. Explaining the decrease in U.S. deaths from coronary disease, 1980–2000. *New England Journal of Medicine* 356(23):2388–2398.

Ford, E. S., C. Li, G. Zhao, W. S. Pearson, and A. H. Mokdad. 2008. Prevalence of metabolic syndrome among U.S. adolescents using the definition from the International Diabetes Federation. *Diabetes Care* 31(3):587–589.

Guthrie, J. F., and J. F. Morton. 2000. Food sources of added sweeteners in the diets of Americans. *Journal of the American Dietetic Association* 100:43–48.

HHS/USDA (Department of Health and Human Services/U.S. Department of Agriculture). 2005. *Dietary guidelines for Americans, 2005.* Washington, DC: Government Printing Office.

IFIC (International Food Information Council Foundation). 2009. *Food & Health Survey: Consumer attitudes toward food, nutrition, & health.* Washington, DC: IFIC.

IFIC. 2010. *Food & Health Survey: Consumer attitudes toward food safety, nutrition, & health.* Washington, DC: IFIC.

IOM (Institute of Medicine). 2003. *Dietary reference intakes: Guiding principles for nutrition labeling and fortification*. Washington, DC: The National Academies Press.

IOM. 2007. *Nutrition standards for foods in schools: Leading the way toward healthier youth.* Washington, DC: The National Academies Press.

IOM. 2010. *Strategies to reduce sodium intake in the United States.* Washington, DC: The National Academies Press.

Krebs-Smith, S. M. 2001. Choose beverages and foods to moderate your intake of sugars: Measurement requires quantification. *Journal of Nutrition* 131:527S–535S.

Usmanova, N. and E. Thor, E. 2003. Communicating nutritional information to the global consumer: adapting to shifting consumer attitudes toward nutrition. *International Food and Agribusiness Management Review* 6:1–18.

WHO/FAO (World Health Organization/Food and Agriculture Organization). 2003. *Diet, nutrition and the prevention of chronic diseases: Report of a joint WHO/FAO expert consultation*. WHO Technical Report Series, No. 916. Geneva: WHO.

Appendix A

Glossary with Abbreviations and Acronyms

Added sugars

Sugars eaten separately or used as ingredients in processed or prepared foods, such as white sugar, brown sugar, raw sugar, corn syrup, corn syrup solids, high-fructose corn syrup, malt syrup, maple syrup, pancake syrup, fructose sweetener, liquid fructose, honey, molasses, anhydrous dextrose, and crystalline dextrose. May contain oligosaccharides. These do not include naturally occurring sugars such as lactose in milk or fructose in fruits. FDA defines added sugars as sugars or other ingredients added during processing or packaging that functionally substitute for sugars, such as fruit juice concentrates, jams, and jellies, including ingredients that may functionally increase the sugars content of a food, such as enzymes (21 CFR 101.60 (c)(2)).

Adequate intake

A recommended average daily nutrient 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. A Dietary Reference Intake value.

Algorithm

A formula or series of calculations in which a food product's nutrient content is incorporated to produce a value by which the overall value of the product's contribution to the diet can be determined.

Balanced diet

The overall dietary pattern of foods consumed that provide all the essential nutrients in the appropriate amounts to support life processes, including growth and development in children, without promoting excess body fat accumulation and excess weight gain.

Body Mass Index (BMI)

An indirect measure of body fat calculated as the ratio of a person's body weight in kilograms to the square of a person's height in meters. In children and youth, assessment of BMI is based on growth charts for age and gender and is referred to as the BMI for Age.

Caloric sweeteners

Sweeteners consumed directly and as food ingredients (such as sucrose) from refined cane and beet sugars, honey, dextrose, edible syrups, and corn sweeteners (primarily high-fructose corn syrup); contains oligosaccharides.

CDC

Centers for Disease Control and Prevention

COMA/SACN

Committee on Medical Aspects of Food and Nutrition Policy and the Scientific Advisory Committee on Nutrition in the United Kingdom

Competitive foods

Foods and beverages offered at schools other than meals and snacks served through the federally reimbursed National School Lunch Program (NSLP), School Breakfast Program (SBP), and the after-school snack programs. Competitive foods include food and beverage items sold through a la carte lines, snack bars, student stores, vending machines, and school fundraisers.

Daily Reference Value (DRV)

Value used in nutrition labeling for food components of public health concern for which there were no RDAs in 1993. In conjunction with RDIs, are known as Daily Values (DVs) in Nutrition Facts panel and specified in 21 CFR 101.9(c)(9).

Daily Value (DV)

Dietary reference values established by FDA and used in nutrition labeling that are based on recommended daily intake levels of nutrients needed for good health. DV comprises RDIs and DRVs.

DGAC

Dietary Guidelines Advisory Committee

***Dietary Guidelines for Americans* (DGA)**

A federal summary of the latest dietary guidance for the American public based on current scientific evidence and medical knowledge. The Guidelines are issued jointly by the U.S. Department of Health and Human Services and U.S. Department of Agriculture and revised every 5 years.

Dietary Reference Intakes (DRI)

A set of four distinct nutrient-based reference values established by the Institute of Medicine of the National Academy of Sciences that replaced the former Recommended Dietary Allowances in the United States. They include Estimated Average Requirements (EARs), Recommended Dietary Allowances (RDAs), Adequate Intakes (AIs), and Tolerable Upper Intake Level (UL).

Disclosure level

The level of total fat, saturated fat, cholesterol or sodium that, when exceeded, triggers the need for a disclosure statement when a nutrient content claim is used on labels of FDA-regulated food products. The disclosure statement (i.e., “See nutrition information for ___ content” with the blank filled in by the name of the nutrient exceeding the specified level) must be placed adjacent to the claim and is intended to alert consumers to levels of nutrients that may increase the risk of disease or health-related condition. Levels are specified in 21 CFR 101.13(h).

Discretionary calories

The balance of calories remaining in a person's “energy allowance” after consuming sufficient nutrient-dense forms of foods to meet all nutrient needs for a day. Discretionary calories may be used in selecting forms of foods that are not the most nutrient dense (e.g., whole milk rather than fat-free milk) or may be additions to foods (e.g., salad dressing, sugar, butter). A person's energy allowance is the calorie intake at which weight maintenance occurs.

Energy balance

A state where calorie intake is equivalent to energy expenditure, resulting in no net weight gain or loss. In this report, energy balance in children is used to indicate equality

between energy intake and energy expenditure that supports normal growth and development without promoting excess weight gain.

Energy expenditure

Calories used to support the body's basal metabolic needs plus those used for thermogenesis, growth, and physical activity.

Energy intake

Calories ingested as food and beverages.

Fast food

Foods and meals designed for ready availability, use, or consumption and sold at eating establishments for quick availability or take-out.

FDA

U.S. Food and Drug Administration

FD&C Act

Federal Food, Drug, and Cosmetic Act

Food category

A way of characterizing foods according to either the type of food product, such as meals, main dishes, or individual food items, or by type of food, such as cereals, dairy, and soups.

Food Guide Pyramid

An educational tool designed for the public that translates and graphically illustrates recommendations from the Dietary Guidelines for Americans and nutrient standards such the Dietary Reference Intakes into food group–based advice that promotes a healthful diet for the U.S. population. In 2005 it was replaced by an interactive food guidance system, *MyPyramid.*

Front-of-package (FOP) nutrition rating systems and symbols

Systems that use nutrient criteria and symbols to indicate that a product has certain nutritional characteristics Symbols are often placed on the principal display panel of the product, but may also be found on the side, top, or back panels or on self tags.

Guideline Daily Amounts (GDA)

GDAs are nutrient intake levels that most people are guided to consume daily for a healthy diet. They provide a voluntary benchmark against which the contribution from specific nutrients per portion of a food product can be assessed. The food and beverage and retail industries derive their GDA values from international, EU and government guidelines. GDAs were first seen in the United Kingdom and are increasingly being used in the European Union (EU). The Confederation of the Food and Drink Industries of the EU (CIAA) proposed a harmonized industry approach to nutrition labeling across the EU, including the use of standardized GDA values.

Health claims

Claims that describe a relationship between a food, food component, or dietary supplement ingredient and a reduction in the risk of developing a disease or health-related condition.

Health promotion

The process of enabling people to increase control over and to improve their health through networks and initiatives that create healthy environments. To reach a state of complete physical, mental, and social well-being, an individual or group must be able to identify and to realize aspirations, to satisfy needs, and to change or cope with the

environment. Health is a resource for everyday life, not the objective of living, and is a positive concept emphasizing social and personal resources, as well as physical capacities.

Healthful diet

For children and adolescents, a healthful diet provides recommended amounts of nutrients and other food components within estimated energy requirements (EER) to promote normal growth and development, a healthy weight trajectory, and energy balance. A healthful diet also reduces the long-term risk for obesity and related chronic diseases associated with aging, including type 2 diabetes, and metabolic syndrome.

HHS

U.S. Department of Health and Human Services

Intrinsic sugars

Sugars that are naturally occurring within a food, such as fructose and sucrose in fruits or lactose in milk.

IOM

Institute of Medicine

Labeled serving size

Serving size as determined by the product manufacturer; based on the RACC and regulations for determining serving size.

Marketing

An organizational function and a set of processes for creating, communicating, and delivering value to customers and for managing customer relationships in ways that benefit an organization and its stakeholders. Marketing encompasses a wide range of activities, including market research, analyzing the competition, positioning a new product, pricing products and services, and promoting them through advertising, consumer promotion, trade promotions, public relations, and sales.

MyPyramid

USDA-developed system by which Americans can determine how much of each food group to eat in order to meet daily nutritional requirements.

NAS

National Academy of Sciences

NCI

National Cancer Institute

NLEA

Nutrition Labeling and Education Act

NRC

National Research Council

Nutrient amount per serving on FOP

Systems with symbols that display the amount per serving of select nutrients from the Nutrition Facts panel on the front of the food package or use symbols based on claim criteria. They provide information on percent daily values (%DV) or guideline daily amounts (%GDA) and may also include traffic-light colors or words to indicate that a product contains “high,” “medium,” or “low" amounts of specific nutrients. A declaration of calories per serving may also be on the front of the food package. Systems using

symbols based on claim criteria (FDA or USDA) may award multiple symbols indicating that a product is “low fat,” “high fiber,” etc.

Nutrient content claim

Label claim that characterizes the level of a nutrient in a food (i.e., nutrient content claim) made in accordance with FDA's authorizing regulations. Nutrient content claims describe the level of a nutrient or dietary substance in the product, using terms such as “free,” “high,” and “low,” or they compare the level of a nutrient in a food to that of another food, using terms such as “more,” “reduced,” and “light.”

Nutrient density

The amount of nutrients that a food contains per unit volume or mass. Nutrient density is independent of energy density, although in practice the nutrient density of a food is often described in relationship to the food’s energy density. Fruits and vegetables are nutrient dense but not energy dense. Compared to foods of high fat content, carbonated soft drinks are not particularly energy dense because they are made up primarily of water and carbohydrate, but because they are otherwise low in nutrients, their energy density is high with respect to their nutrient content.

Nutrient profiling

The science of categorizing foods according to their nutritional composition and the categorization of foods for specific purposes on the basis of their nutrient composition, according to scientific principles.

Obesity

An excess amount of subcutaneous body fat in proportion to lean body mass. In adults, a BMI of 30 or greater is considered obese. In this report, obesity in children and youth refers to the age- and gender specific BMI that is equal to or greater than the 95th percentile of the Centers for Disease Control and Prevention BMI charts.

Percent Daily Value (%DV)

Percentages found in the Nutrition Facts panel on food labels that describe the nutrient contribution of the food to a 2,000-calorie diet for most nutrients. A high percentage means a serving of the food contains a lot of the nutrient, and a low percentage means it contains a little. The goal is to choose foods that together give close to 100 percent of each nutrient per day. Vitamins and minerals are based upon highest RDA values established by NRC in 1968 and 1989.

Portion size

Represents the amount of food an individual chooses to consume for a meal or snack. Portions can be larger or smaller than the serving sizes listed on the food label or the Food Guide Pyramid.

Prevention

With regard to obesity, primary prevention represents avoiding the occurrence of obesity in a population; secondary prevention represents early detection of disease through screening with the purpose of limiting its occurrence; and tertiary prevention involves preventing the sequelae of obesity in childhood and adulthood.

Proprietary

Privately owned and operated; something that is held under patent, trademark, or copyright by a private person or company.

Recommended dietary allowance (RDA)

Daily intake level of a nutrient that was considered to be adequate to meet the requirements of almost all healthy individuals in each life-stage and for each sex at the time the requirements were developed.

Reference Amount Customarily Consumed (RACC)

Amount of food customarily consumed per eating occasion by persons in a population group as determined by FDA; used as the regulatory basis for determining labeled serving sizes on the Nutrition Facts panel. Are specified in 21 CFR 101.12

Reference daily intake (RDI)

Nutrient reference values for protein, vitamins and minerals established by FDA. In conjunction with DRVs, are known as Daily Values (DVs) on Nutrition Facts panel and are specified in 21 CFR 101.9(c)(7)(iii) and (8)(iv).

Shelf tag nutrition labeling

Nutrition labeling present on the shelf tag of retail stores indicating that a product contains nutrient contents that make the product a more nutritious choice. Nutrition symbols or scores or both are displayed alongside the product price and bar code.

Structure/function claims

Structure/function claims describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans, such as "Calcium builds strong bones." Such claims may also characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function, for example, "Fiber maintains bowel regularity," or "Antioxidants maintain cell integrity," or else they may describe general well-being from consumption of a nutrient or dietary ingredient.

Summary symbol based on nutrient criteria thresholds per category

A system in which food products are grouped by categories (e.g., type of food or food product) and evaluated based upon that system's criteria. Products that meet the criteria are awarded the system's symbol.

Summary symbol/score based on algorithm

A system in which food products are evaluated based on an equation that takes nutrients (positive or negative) into account. Products are given a numeric score (i.e., 1–100) or number of symbols (i.e., 0, 1, 2, 3) to indicate the nutrition quality of the product.

Symbol

A characteristic graphic shape on a food label or in labeling, which may enclose words, numbers or other graphic shapes, and which may utilize characteristic colors, the intent of which, as a whole, is to represent the nutritional properties of a food.

Symbol based on claim criteria (FDA, USDA or other organization)

A system in which a symbol is awarded to food products that meet FDA, USDA, or other organization requirements for claims, such as "low fat" or "high fiber." Multiple symbols can be awarded for a single product for many programs.

Symbol based on food group or food component (food-based symbol)

A system in which a symbol is awarded to food products based on the presence of a food group or food component, such as whole grains. An example of this type of system is ConAgra's Start Making Choices.

Total sugars

The amount of naturally occurring sugar in a food product plus any sugar added during processing. It is defined for nutrition labeling purposes as the sum of all free mono- and disaccharides. Oligosaccharides are not included.

USDA

U.S. Department of Agriculture

WHO

World Health Organization

Appendix B
FDA Regulatory Requirements for Nutrient Content Claims[1]

FREE	
Calories	• Less than 5 calories per RACC and per labeled serving.
Total fat	• Less than 0.5 g per RACC and per labeled serving (or, for meals and main dishes, less than 0.5 g per labeled serving). • Contains no ingredient that is fat or understood to contain fat, except as noted below.* • "__% Fat Free" may be used if food meets the requirements for "low fat" and the % declared is in same type size as "fat free." • 100% Fat Free: Food must be "fat free" and contain less than 0.5 g fat per 100 g
Saturated fat	• Less than 0.5 g saturated fat and less than 0.5 g *trans* fatty acids per RACC and per labeled serving (or, for meals and main dishes, less than 0.5 g saturated fat and less than 0.5 g *trans* fatty acids per labeled serving). • Contains no ingredient that is understood to contain saturated fat except as noted below.* • Must declare the amount of cholesterol if 2 mg or more per RACC, and the amount of total fat if 0.5 g or more per RACC (or for meals and main dishes the amount of cholesterol, if 2 mg or more per labeled serving and the amount of total fat if 0.5 g or more per labeling serving).
Cholesterol	• Less than 2 mg per RACC and per labeled serving (or, for meals and main dishes, less than 2 mg per labeled serving). • Contains no ingredient that contains cholesterol except as noted below.* • Cholesterol claims only allowed when food contains 2 g or less saturated fat per RACC, or, for meals and main dish products, 2 g or less saturated fat per labeled serving size. • Must declare the amount of total fat per serving next to claim when fat exceeds 13 g per RACC and per labeled serving (or per 50 g if RACC is small), or when fat exceeds 19.5 g per labeled serving for main dishes or 26 g for meal products.
Sodium	• Less than 5 mg per RACC and per labeled serving (or, for meals and main dishes, less than 5 mg per labeled serving). • Contains no ingredient that is sodium chloride or generally understood to contain sodium except as noted below.* • "Salt Free" must meet criterion for "sodium free." • "No Salt Added" and "Unsalted" are allowed if no salt is added during processing. Must declare "This is not a sodium-free food" on information panel if food is not "sodium free."

[1] These are requirements for most nutrient content claims.

Sugars	• "Sugar Free": Less than 0.5 g sugars per RACC and per labeled serving (or, for meals and main dishes, less than 0.5 g per labeled serving). • Contains no ingredient that is a sugar or generally understood to contain sugars except as noted below.* • Disclose calorie profile (e.g., "low calorie" or "not a low calorie food"). • "No added sugars" and "Without added sugars" are allowed if no sugar or sugar containing ingredient such as jam, jelly, or concentrated fruit juice is added during processing. Must state if food is not "low" or "reduced calorie."
LOW	
Calories	• 40 calories or less per RACC (and per 50 g if RACC is small). • Meals and main dishes: 120 calories or less per 100 g.
Total fat	• 3 g or less per RACC (and per 50 g if RACC is small). • Meals and main dishes: 3 g or less per 100 g and not more than 30% of calories from fat.
Saturated fat	• 1 g or less per RACC and 15% or less of calories from saturated fat. • Meals and main dishes: 1 g or less per 100 g and less than 10% of calories from saturated fat. • Must declare the amount of cholesterol if 2 mg or more per RACC, and the amount of total fat if more than 3 g per RACC (or for meals and main dishes, the amount of cholesterol if 2 mg or more per labeled serving, and the amount of total fat if more than 3 g per 100 g or more than 30% of calories from fat).
Cholesterol	• 20 mg or less per RACC (and per 50 g of food if RACC is small). • Meals and main dishes: 20 mg or less per 100 g. • Cholesterol claims only allowed when food contains 2 g or less saturated fat per RACC, or for meals and main dish products, per 100 g • Must declare the amount of total fat next to claim when fat exceeds 13 g per RACC and per labeled serving (or per 50 g if RACC is small), or when fat exceeds 19.5 g per labeled serving for main dishes or 26 g for meal products.
Sodium	• 140 mg or less per RACC (and per 50 g if RACC is small). • Meals and main dishes: 140 mg or less per 100g. • "Very Low Sodium": 35 mg or less per RACC (and per 50 g if RACC is small); for meals and main dishes: 35 mg or less per 100 g.
Sugars	• Not defined.

REDUCED/LESS

To bear a relative claim about the level or a nutrient, the amount of that nutrient must be compared to an amount in an appropriate reference food. For "reduced" claims, the reference food must be (1) an established regular product or average representative product or (2) a similar food. For "less" claims, it must be either of the above or a dissimilar food in the same product category which may generally be substituted for the labeled food (e.g., potato chips for pretzels).

Calories	• At least 25% fewer calories per RACC than appropriate reference food (or, for meals and main dishes, at least 25% fewer calories per 100 g). • Reference food may not be "low calorie." • Uses term "fewer" rather than "less."
Total fat	• At least 25% less fat per RACC than an appropriate reference food (or, for meals and main dishes, at least 25% less fat per 100 g). • Reference food may not be "low fat."
Saturated fat	• At least 25% less saturated fat per RACC than an appropriate reference food (or, for meals and main dishes, at least 25% less saturated fat per 100 g). • Reference food may not be "low saturated fat." • Must declare the amount of cholesterol if 2 mg or more per RACC and the amount of total fat if more than 3 g per RACC (or, for meals and main dishes the amount of cholesterol if 2 mg or more per labeled serving and the amount of fat if more than 3 g per 100 g or more than 30% of calories from fat).
Cholesterol	• At least 25% less cholesterol per RACC than an appropriate reference food (or, for meals and main dishes, at least 25% less cholesterol per 100 g). • Reference food may not be "low cholesterol." • Cholesterol claims only allowed when food contains 2 g or less saturated fat per RACC, or, for meals and main dishes, per 100 g. • Must declare the amount of total fat next to cholesterol claim when fat exceeds 13 g per RACC and labeled serving (or per 50 g of food if RACC is small), or when the fat exceeds 19.5 g per labeled serving for main dishes or 26 g for meal products.
Sodium	• At least 25% less sodium per RACC than an appropriate reference food (or, for meals and main dishes, at least 25% less sodium per 100 g). • Reference food may not be "low sodium."
Sugars	• At least 25% less sugars per RACC than an appropriate reference food (or, for meals and main dishes, at least 25% less sugars per 100 g).

HEALTHY	
Individual Food	• Low fat (i.e., 3 g or less fat per RACC). • Low saturated fat (i.e., 1 g or less per RACC and 15% or less of calories from saturated fat • Sodium: 480 mg or less per RACC and 480 mg or less per labeled serving, except foods with a RACC less than or equal to 30 g or 2 Tbsp. must contain 480 mg or less per 50 g. • Cholesterol: 60 mg or less per RACC and 60 mg or less per labeled serving, except foods with a RACC less than or equal to 30 g. or 2 Tbsp. must contain 60 mg or less per 50 g. • Beneficial nutrients: At least 10% of Daily Value for vitamin A, vitamin C, calcium, iron, protein or fiber per RACC, except for raw fruits and vegetables, single ingredient or a mixture of canned or frozen fruits and vegetables, or enriched cereal grain products that conform to a standard of identity. • Fortification in accordance with Fortification Policy in 21 CFR 104.20.
Seafood/ Game Meat	• Total fat: Less than 5 g fat per RACC and per 100 g. • Saturated fat: Less than 2 g per RACC and per 100 g. • Sodium: Same as for individual food. • Cholesterol: Less than 95 mg per RACC and per 100 g. • Beneficial nutrients: Same as for individual food. • Fortification in accordance with Fortification Policy in 21 CFR 104.20.
Meal or Main Dish	• Low fat (i.e., 3 g or less per 100 g and not more than 30% of calories from fat). • Low saturated fat (i.e., 1 g or less per 100 g and less than 10% of calories from saturated fat). • Sodium: 600 mg or less per labeled serving. • Cholesterol: 90 mg or less per labeled serving. • Beneficial nutrients: At least 10% of Daily Value per labeled serving of two of the following nutrients for a main dish and three of the nutrients for a meal: vitamin A, vitamin C, calcium, iron, protein or fiber per labeled serving. • Fortification in accordance with Fortification Policy in 21 CFR 104.20.
LIGHT	
	• If 50% or more of the calories are from fat, fat must be reduced by at least 50% per RACC. If less than 50% of calories are from fat, fat must be reduced at least 50% or calories reduced at least 1/3 per RACC. Reference food may not be “low calorie” and “low fat.” • For sodium reduced products, if sodium is reduced by 50% or more and the food does not meet the definition of “low calorie” or “low fat”, claim must say “light in sodium. If sodium is reduced by 50% or more and the food meets the definition of “low calories” and “low fat”, the claim “light” may be used without further qualification. • Meals or main dishes must meet the definition for “low calorie” or “low fat” meal and be labeled to indicate which definition is met.

	• "Light in sodium": sodium is reduced by at least 50% per RACC and, except for meals and main dishes, the reference food may not meet the definition of "low in sodium." For meals and main dishes, "light in sodium" must meet definition for "low in sodium." • "Lightly salted": 50% less sodium than normally added to reference food and if food does not meet definition for "low sodium", it must state that on the information panel, i.e. "not a low sodium food." • The reference food must be representative of the type of food bearing the claim (e.g., average value of top three brands or representative value from valid data base), or a similar food (e.g., potato chips for potato chips).
OTHER NUTRIENT CONTENT CLAIMS	
High	• Contains 20% or more of the DV per RACC. • May be used on meals or main dishes to indicate that the product contains a food that meets the definition.
Good Source	• Contains 10–19% of the DV per RACC. • May be used on meals or main dishes to indicate that the product contains a food that meets the definition.
More	• Contains at least 10% more of the DV per RACC than appropriate reference food. • May only be used for vitamins, minerals, protein, dietary fiber, and potassium.
Lean	• On seafood or game meat products: less than 10 g total fat, 4.5 g or less saturated fat, and less than 95 mg cholesterol per RACC and per 100 g (for meals and main dishes, meets criteria per 100 g and per labeled serving). • On mixed dishes not measurable with a cup (as defined in 21 CFR 101.12(b) in Table 2): less than 8 g total fat, 3.5 g or less saturated fat, and less than 80 mg cholesterol per RACC.
Extra Lean	• On seafood or game meat products: less than 5 g total fat, less than 2 g saturated fat, and less than 95 mg cholesterol per RACC and per 100 g (for meals and main dishes, meets criteria per 100 g and per labeled serving).
High Potency	• On foods to describe individual vitamins or minerals that are present at 100% or more of the RDI per RACC or on a multi-ingredient food product that contains 100% or more of the RDI for at least 2/3 of the vitamins and minerals with RDIs and that are present in the product at 2% or more of the RDI (e.g., "High-potency multivitamin, multimineral dietary supplement tablets").
Modified	• May be used in statement of identity of a food that bears a relative claim (e.g., "Modified fat cheesecake, contains 35% less fat than our regular cheesecake").

Fiber Source	• If a fiber claim is made and the food is not low in total fat, then the label must disclose the level of total fat per labeled serving.
Antioxidants	• An RDI must be established for each of the nutrients that are the subject of the claim. • Each nutrient must have existing scientific evidence of antioxidant activity. • The level of each nutrient must be sufficient to meet the definition for "high," "good source," or "more." • Beta-carotene may be the subject of an antioxidant claim when the level of vitamin A present as beta-carotene in the food is sufficient to qualify for the claim.

NOTES: * Except if the ingredient listed in the ingredient statement has an asterisk that refers to footnote (e.g., "* adds a trivial amount of fat").

RACC = Reference Amounts Customarily Consumed.

Small RACC = Reference Amounts Customarily Consumed of 30 g or less or 2 tablespoons or less. (For dehydrated foods that are typically consumed when rehydrated with water or a diluent containing an insignificant amount, as defined in 21 CFR 101.9(f)(1), of all nutrients per RACC, the per 50 g criterion refers to the prepared form of the food.)

When a claim is made on a food that contains more than 13 g total fat, 4 g saturated fat, 60 mg cholesterol, or 480 mg sodium per RACC, per labeled serving, or, for foods with small RACC, per 50 g, a disclosure statement is required as part of claim (i.e., "See nutrition information for___content" with the blank filled in with nutrient(s) that exceed the prescribed levels). The disclosure statement is required on meal products that exceed 26 g total fat, 8 g saturated fat, 120 mg cholesterol, or 960 mg sodium, and on main dish products that exceed 19.5 g total fat, 6 g saturated fat, 90 mg cholesterol, or 720 mg sodium per labeled serving.

For "free", "very low", or "low" claims, must indicate if food meets a definition without benefit of special processing, alteration, formulation or reformulation; e.g., "broccoli, a fat-free food" or "celery, a low calorie food."
SOURCE: 21 CFR Part 101. Food Labeling Guide: Guidance for Industry. September 1994; revised April 2008. Food and Drug Administration See Appendixes A and B. (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/default.htm [accessed September 11, 2010].

Appendix C

Sources of Criteria and Program Information and Sample Product Evaluations

Criteria and Program Information for Nutrition Rating Systems and Symbols

Choices Program
Accessed: January 28, 2010
Website: http://choicesprogramme.org/en/about_the_choices_programme/product_criteria

Goodness Corner
Accessed March 18, 2010
Website: http://www.mycereal.com/corporate/health_wellness/your_health_detail.aspx?CatID=7780&Select-CatID=7780&section=yourhealth

Guiding Stars
Accessed March 18, 2010
Criteria are not publicly available; scores were obtained from Hannaford website and Guiding Stars program staff.
Website: http://www.hannaford.com/Contents/Healthy_Living/Guiding_Stars/index.shtml

Health Check
Accessed January 28, 2010
Website: http://www.healthcheck.org/page/program-critieria

Healthy Ideas
Accessed January 28, 2010
Website: http://images.giantfood.com/static/full/GNTL/media/living_well/healthy-ideas-criteria.pdf

Heart Check
Accessed March 18, 2010
Website: http://www.heart.org/HEARTORG/GettingHealthy/NutritionCenter/HeartSmart Shopping/Heart-Check-Mark_UCM_300914_Article.jsp

New Zealand Tick Programme
Accessed July 19, 2010
Website:
http://www.heartfoundation.org.au/sites/tick/Health_Professionals/Pages/TickCriteria.aspx

Nutrient Rich Food Index (NRFI)
Accessed January 28, 2010
Website: http://www.nutrientrichfoods.org/for_health_professionals/scientific_background.html

NuVal
Accessed March 18, 2010
Criteria are not publicly available; scores were obtained from NuVal website and NuVal program staff.
Website: http://www.nuval.com/Science/origins

Criteria and Program Information for Nutrition Rating Systems and Symbols

Sensible Solution
Accessed September 25, 2009
Website:
http://www.kraftfoods.com/kf/healthyliving/sensiblesolution/sensiblesolution_landing.aspx

Smart Choices
Accessed January 28, 2010
Website: http://www.smartchoicesprogram.com/professionals.html

Smart Spot
Accessed September 25, 2009
Website: http://www.pepsico.com/Purpose/Health-and-Wellness/Smart-Spot.html

Start Making Choices
Accessed March 18, 2010
Website: http://www.startmakingchoices.com/tools/pyramid.jsp

Swedish Keyhole
Accessed July 19, 2010
Website: http://www.slv.se/en-gb/Group1/Food-and-Nutrition/Keyhole-symbol/

UK Traffic Light
Accessed March 18, 2010
Website: http://www.eatwell.gov.uk/foodlabels/trafficlights

Wellness Keys (Harris Teeter)
Accessed March 18, 2010
Website: http://www.harristeeter.com/yourwellness/wellness_keys.aspx

Wellness Keys (Wegmans)
Accessed March 18, 2010
Website: http://www.wegmans.com/webapp/wcs/stores/servlet/CategoryDisplay?langId=
1&storeId=10052&catalogId=10002&categoryId=280946

Whole Grain Stamp
Accessed January 28, 2010
Website: http://wholegrainscouncil.org/whole-grain-stamp

Calculations for NRFI scores:

The NRFI scores were calculated using NRFI 6.3 formula (Fulgoni et al., 2009), which includes 6 nutrients to encourage (protein, fiber, vitamins A, C, iron, and calcium) and 3 nutrients to limit (saturated fat, sodium, and added sugars). To calculate scores for illustrative purposes, IOM staff used the information available on the Nutrition Facts panel. As per the published algorithm, a reference value of 125 grams was used for total sugars because added sugars is not available on the Nutrition Facts panel; also protein was not adjusted for protein quality. NRFI scores can theoretically range from -300 to 900, but the majority of foods score in the -150 to 300 range. NRFI raw scores are often divided into quintiles and assigned a score 1-5 for simplicity. Raw scores are more precise for comparing foods and therefore those were used for our comparison tables.

Crisped Rice Cereal

Serving Size	Calories	Total Fat	Sat. Fat	Chol.	Sodium	Total Carbs	Dietary Fiber	Sugars	Protein	Vit. A	Vit. C	Iron	Calcium
1-1/4 cup	130	0 g	0 g	0 mg	220 mg	29 g	< 1 g	4 g	2 g	25%	25%	20%	0%
Choices	NC	NC	+	+	limit 500 mg per 100 g	NC	min 1.3 g per 100 kcal	+	NC	NC	NC	NC	NC
Healthy Ideas	NC	+	+	+	+	NC	min 2.5 g per 30 g	max 35% sugar by weight	NC	+	+	+	+ vit
Heart Check	NC	+	+	+	+	NC	+	NC	+	+	+	+	+
Sensible Solution	+	+	+	NC	+	NC	min 10% DV	+	NC	+	+	+	+ vit
Smart Choices	NC	+	+	NC	+	NC	+ vit	+	NC	+	+	+	+ vit
Smart Spot	NC	+	+	+	+	NC	+ sug	+	+	+	+	+	+ vit
Canada's Health Check	NC	+	NC	NC	+	NC	min 2 g per serving	+	NC	NC	NC	NC	NC
GM Goodness Corner	130 cal label	low-fat label	low-sat. fat label	low-chol. label	NC	net carbs given	min 10% DV for GSL	grams given	min 10% DV for GSL	ESL	ESL	ESL	min 10% DV for GSL
HT Wellness Keys	max 40 cal for low-cal label	fat free and heart-healthy label	heart-healthy label	heart-healthy label	heart-healthy label	NC	min 10% DV for GSL	NC	min 10% DV for GSL	ESL and heart-healthy label	ESL and heart-healthy label	ESL and heart-healthy label	min 10% DV for GSL
Start Making Choices	NC	NC	NC	NC	NC	NC	min 10% DV	NC	min 10% DV	+	+	+	min 10% DV
Wegmans' Wellness Keys	max 40 cal for low-cal label	fat-free and heart-healthy label	heart-healthy label	heart-healthy label	heart-healthy label	NC	min 5 g for high-fiber label	max 0.5 g for sugar-free label	NC	heart-healthy label	heart-healthy label	heart-healthy label	min 20% DV for high calcium
UK Traffic Light	NC	green	green	NC	amber	NC	NC	amber	NC	NC	NC	NC	NC
Guiding Stars	0 stars (0 to 3 stars)												
NRFI	50 (-300 to 900)												
NuVal	23 (1-100)												

NOTE: + = meets criteria, DNQ = does not qualify, NC = no criteria, +vit, +prot, +sug, +fiber, etc. = nutrient in header of column is acceptable due to level of nutrient with +, GSL = good source label, ESL = excellent source label, min _%DV = must provide _% DV to meet criteria.

Toasted Oat Cereal

Serving Size	Calories	Total Fat	Sat. Fat	Chol.	Sodium	Total Carbs	Dietary Fiber	Sugars	Protein	Vit. A	Vit. C	Iron	Calcium
1 cup	100	2 g	0 g	0 mg	190 mg	20 g	3 g	1 g	3 g	10%	10%	10%	45%
Choices	NC	NC	+	NC	limit 500.mg per 100.g	NC	+	+	NC	NC	NC	NC	NC
Healthy Ideas	NC	+	+	+	+	NC	+	+	NC	+	+	+	+
Heart Check	NC	+	+	+	+	NC	+	NC	+	+	+	+	+
Sensible Solution	+	+	+	NC	+	NC	+	+	NC	+	+	+	+
Smart Choices	NC	+	+	NC	+	NC	+	+	NC	+	+	+	+
Smart Spot	NC	+	+	+	+	NC	+	+	+	+	+	+	+
Canada's Health Check	NC	+	NC	NC	+	NC	+	+	NC	NC	NC	NC	NC
GM Goodness Corner	100 cal label	max 3 g per 50 g for low-fat label	low sat. fat	low chol.	NC	net carbs given	GSL	grams given	min 5 g for GSL	GSL	GSL	GSL	ESL
HT Wellness Keys	max 40 cal for low-cal label	low-fat and heart-healthy label	heart-healthy label	heart-healthy label	heart-healthy label	NC	+	NC	min 10% DV for GSL	GSL	GSL	GSL	ESL
Start Making Choices	NC	NC	NC	NC	NC	NC	+	NC	min 10% DV	+	+	+	+
Wegmans' Wellness Keys	max 40 cal for low-cal label	low-fat and heart-healthy label	heart-healthy label	heart-healthy label	heart-healthy label	NC	min 5 g for high-fiber label	max 0.5 g for sugar-free label	NC	heart-healthy label	heart-healthy label	heart-healthy label	high-calcium and heart-healthy label
UK Traffic Light	NC	amber	green	NC	amber	NC	NC	green	NC	NC	NC	NC	NC
Guiding Stars	2 stars (0 to 3 stars)												
NRFI	84 (-300 to 900)												
NuVal	37 (1-100)												

NOTE: + = meets criteria, DNQ = does not qualify, NC = no criteria, +vit, +prot, +sug, +fiber, etc. = nutrient in header of column is acceptable due to level of nutrient with +, GSL = good source label, ESL = excellent source label, min _%DV = must provide _% DV to meet criteria.

Sweetened Toasted Oat Cereal

Serving Size	Calories	Total Fat	Sat. Fat	Chol.	Sodium	Total Carbs	Dietary Fiber	Sugars	Protein	Vit. A	Vit. C	Iron	Calcium
3/4 cup	110	1.5 g	0 g	0 g	190 mg	22 g	2 g	9 g	3 g	10%	10%	25%	10%
Choices	NC	NC	+	NC	max 500 mg per 100 g	NC	+	limit 28 g per 100 g	NC	NC	NC	NC	NC
Healthy Ideas	NC	+	+	+	+	NC	min 10% DV	+	NC	+	+	+	+
Heart Check	NC	+	+	+	+	NC	+	NC	+	+	+	+	+
Sensible Solution	+	+	+	NC	+	NC	min 10% DV	max 30% cal from sugar	NC	+	+	+	+
Smart Choices	NC	+	+	NC	+	NC	+ vit	+	NC	+	+	+	+
Smart Spot	NC	+	+	+	+	NC	min 10% DV	max 25% cal from sugar	min 10% DV	+	+	+	+
Canada's Health Check	NC	+	NC	NC	+	NC	+	max 6g	NC	NC	NC	NC	NC
GM Goodness Corner	110 cal label	low-fat label	low-sat .fat label	low-chol. label	NC	net carbs given	min 10% DV for GSL	grams given	min 5 g for good source label	GSL	GSL	ESL	GSL
HT Wellness Keys	max 40 cal for low-cal label	low-fat and heart-healthy label	heart-healthy label	heart-healthy label	heart-healthy label	NC	min 10% DV for GSL	NC	min 10% DV for GSL	GSL and heart-healthy label	GSL and heart-healthy label	ESL and heart-healthy label	GSL and heart-healthy label
Start Making Choices	NC	NC	NC	NC	NC	NC	min 10% DV	NC	min 10% DV	+	+	+	+
Wegmans' Wellness Keys	max 40 cal for low-cal label	low-fat and heart-healthy label	heart-healthy label	heart-healthy label	heart-healthy label	NC	min 5 g for high fiber label	max 0.5 g for sugar-free label	min 10% DV for GSL	heart-healthy label	heart-healthy label	heart-healthy label	heart-healthy label
UK Traffic Light	NC	amber	green	NC	amber	NC	NC	red	NC	NC	NC	NC	NC
Guiding Stars	1 star (0 to 3 stars)												
NRFI	49 (-300 to 900)												
NuVal	27 (1-100)												

NOTE: + = meets criteria, DNQ = does not qualify, NC = no criteria, +vit, +prot, +sug, +fiber, etc. = nutrient in header of column is acceptable due to level of nutrient with +, GSL = good source label, ESL = excellent source label, min _%DV = must provide _% DV to meet criteria.

Old-Fashioned Oatmeal

Serving Size	Calories	Total Fat	Sat. Fat	Chol.	Sodium	Total Carbs	Dietary Fiber	Sugars	Protein	Vit. A	Vit. C	Iron	Calcium
1/2 cup	150	3 g	.5 g	0 mg	0 mg	27 g	4 g/2 g/2 g	1 g	5 g	0%	0%	10%	0%
Choices	NC	NC	+	+	+	NC	+	+	NC	NC	NC	NC	NC
Healthy Ideas	NC	+	+	+	+	NC	+	+	NC	+ fiber	+ fiber	+	+ fiber
Heart Check	NC	+	+	+	+	NC	+	NC	+	+	+	+	+
Sensible Solution	+	+	+	NC	+	NC	+	+	NC	+ vit	+ vit	+	+ vit
Smart Choices	NC	+	+	NC	+	NC	+	+	NC	+ vit	+ vit	+	+ vit
Smart Spot	NC	+	+	+	+	NC	+	+	+	+ vit	+ vit	+	+ vit
Canada's Health Check	NC	+	NC	NC	+	NC	+	+	NC	NC	NC	NC	NC
GM Goodness Corner	150-cal label	low-fat label	low–sat. fat label	low-chol. label	NC	net carbs given	GSL	grams given	GSL	min 10% DV for GSL	min 10% DV for GSL	min 10% DV for GSL	min 10% DV for GSL
HT Wellness Keys	max 40 cal for low-cal label	low-fat and heart-healthy label	heart-healthy label	heart-healthy label	low-sodium and heart-healthy label	NC	GSL	NC	GSL	min 10% DV for GSL	min 10% DV for GSL	GSL	min 10% DV for GSL
Start Making Choices	NC	NC	NC	NC	NC	NC	+	NC	+	min 10% DV	min 10% DV	+	min 10% DV
Wegmans' Wellness Keys	max 40 cal for low-cal label	low-fat and heart-healthy label	heart-healthy label	heart-healthy label	low-sodium and heart-healthy label	NC	min 5g for high-fiber label	max 0.5g for sugar-free label	heart-healthy label	min 10% DV	min 10% DV	heart healthy label	min 20% DV for high calcium
UK Traffic Light	NC	amber	green	NC	green	NC	NC	green	NC	NC	NC	NC	NC
Guiding Stars	3 stars (0 to 3 stars)												
NRFI	22 (-300 to 900)												
NuVal	57 (1-100)												

NOTE: + = meets criteria, DNQ = does not qualify, NC = no criteria, +vit, +prot, +sug, +fiber, etc. = nutrient in header of column is acceptable due to level of nutrient with +, GSL = good source label, ESL = excellent source label, min _%DV = must provide _% DV to meet criteria.

Instant Plain Oatmeal

Serving Size	Calories	Total Fat	Sat. Fat	Chol.	Sodium	Total Carbs	Dietary Fiber	Sugars	Protein	Vit. A	Vit. C	Iron	Calcium
1 packet	100	2 g	0 g	0 mg	80 mg	19 g	3 g/1 g	0 g	4 g	20%	0%	40%	10%
Choices	NC	NC	+	+	+	NC	+	+	NC	NC	NC	NC	NC
Healthy Ideas	NC	+	+	+	+	NC	+	+	NC	+	+ vit	+	+
Heart Check	NC	+	+	+	+	NC	+	NC	+	+	+ vit	+	+
Sensible Solution	+	+	+	NC	+	NC	+	+	NC	+	+ vit	+	+
Smart Choices	NC	+	+	NC	+	NC	+	+	NC	+	+ vit	+	+
Smart Spot	NC	+	+	+	+	NC	+	+	+ sug	+	+ vit	+	+
Canada's Health Check	NC	+	NC	NC	+	NC	+	+	NC	NC	NC	NC	NC
GM Goodness Corner	100 cal label	max 3 g per 50 g for low-fat label	low-sat. fat label	low-chol. label	NC	net carbs given	GSL	grams given	min 5 g for GSL	ESL	min 10% DV for GSL	ESL	GSL
HT Wellness Keys	max 40 cal for low-cal label	low-fat and heart-healthy label	heart-healthy label	heart-healthy label	low-sodium and heart-healthy label	NC	GSL	NC	min 10% DV for GSL	+	min 10% DV for GSL	+	+
Start Making Choices	NC	NC	NC	NC	NC	NC	+	+	+	+	min 10% DV	+	+
Wegmans' Wellness Keys	max 40 cal for low-cal label	low-fat and heart-healthy label	heart-healthy label	heart-healthy label	low-sodium and heart-healthy label	NC	min 5 g for high-fiber label	sugar-free label	min 10% DV	heart-healthy label	min 10% DV	heart healthy label	heart healthy label
UK Traffic Light	NC	amber	green	NC	green	NC	NC	green	NC	NC	NC	NC	NC
Guiding Stars	3 stars (0 to 3 stars)												
NRFI	87 (-300 to 900)												
NuVal	39 (1-100)												

NOTE: + = meets criteria, DNQ = does not qualify, NC = no criteria, +vit, +prot, +sug, +fiber, etc. = nutrient in header of column is acceptable due to level of nutrient with +, GSL = good source label, ESL = excellent source label, min _%DV = must provide _% DV to meet criteria.

Apple Cinnamon Cereal Breakfast Bar

Serving Size	Calories	Total Fat	Sat. Fat	Chol.	Sodium	Total Carbs	Dietary Fiber	Sugars	Protein	Vit. A	Vit. C	Iron	Calcium
1 Bar	130	3 g	.5 g	0 mg	105 mg	24 g	2 g	12 g	2 g	15%	20%	10%	20%
Choices	NC	NC	+	+	+	NC	+	max 28g per 100g	NC	NC	NC	NC	NC
Healthy Ideas	NC	+	+	+	+	NC	+ vit	+	NC	+	+	+	+
Heart Check	NC	+	+	+	+	NC	+ vit	NC	+ vit	+	+	+	+
Sensible Solution	+	+	+	NC	+	NC	min 10% DV	max 25% cal from sugar	min 10% DV	+	+	+	+
Smart Choices	NC	+	+	NC	+	NC	+ vit	+	NC	+	+	+	+
Smart Spot	NC	+	+	+	+	NC	min 10% DV	max 25% cal from sugar	min 10% DV	+	+	+	+
Canada's Health Check	NC	+	+	NC	+	NC	+	+	NC	NC	NC	NC	NC
GM Goodness Corner	130 cal label	low-fat label	low–sat. fat label	low-chol. label	NC	net carbs given	min 10% DV for GSL	grams given	min 10% DV for GSL	GSL	ESL	GSL	ESL
HT Wellness Keys	max 40 cal for low-cal label	low-fat and heart-healthy label	heart-healthy label	heart-healthy label	low-sodium and heart-healthy label	NC	min 10% DV for GSL	NC	min 10% DV for GSL	GSL and heart-healthy label	ESL and heart-healthy label	GSL and heart-healthy label	ESL and heart-healthy label
Start Making Choices	NC	NC	NC	NC	NC	NC	min 10% DV	NC	min 10% DV	+	+	+	+
Wegmans' Wellness Keys	max 40 cal for low-cal label	low-fat and heart-healthy label	heart-healthy label	heart-healthy label	low-sodium and heart-healthy label	NC	min 10% DV for high-fiber label	max 0.5 g for sugar-free label	NC	heart-healthy label	heart-healthy label	heart-healthy label	heart-healthy label
UK Traffic Light	NC	amber	green	NC	green	NC	NC	red	NC	NC	NC	NC	NC
Guiding Stars	1 star (0 to 3 stars)												
NRFI	47 (-300 to 900)												
NuVal	25 (1-100)												

NOTE: + = meets criteria, DNQ = does not qualify, NC = no criteria, +vit, +prot, +sug, +fiber, etc. = nutrient in header of column is acceptable due to level of nutrient with +, GSL = good source label, ESL = excellent source label, min _%DV = must provide _% DV to meet criteria.

Reduced Fat Cheddar Cheese

Serving Size	Calories	Total Fat	Sat. Fat	Chol.	Sodium	Total Carbs	Dietary Fiber	Sugars	Protein	Vit. A	Vit. C	Iron	Calcium
1 oz.	90	6 g	4 g	20 mg	230 mg	0 g	0 g	0g	7 g	10%	0%	0%	20%
Choices	NC	NC	+	NC	+	NC	NC	+	NC	NC	NC	NC	NC
Healthy Ideas	NC	max 3 g	max 1 g	+	+	NC	+ vit	NC	+	+	+ vit	+ vit	+
Heart Check	NC	max 3 g	max 1 g	+	+	NC	+ prot, vit	+	+	+	+	+	+
Sensible Solution	+	max 3 g	max 2 g	+	+	NC	min 10% DV	+	+	+	+ vit	+ vit	+
Smart Choices	NC	max 3 g	max 2 g	+	+	NC	NC	+	NC	+	+ vit	+ vit	+
Smart Spot	NC	max 30% cal from fat	max 1 g	+	+	NC	+ sug	+	+	+	+ vit	+ vit	+
Canada's Health Check	NC	+	NC	NC	+	NC	NC	NC	NC	NC	NC	NC	+
GM Goodness Corner	90-cal label	max 3 g	max 1 g	sat. fat too high	NC	net carbs given	min 10% DV for GSL	grams listed	GSL	min 20% for ESL	min 10% DV for GSL	min 10% DV for GSL	ESL
HT Wellness Keys	max 40 cal for low-cal label	max 3 g	max 1 g	sat. fat too high	max 140 mg for low-sodium label	NC	min 10% DV for GSL	NC	GSL	GSL	min 10% DV for GSL	min 10% DV for GSL	ESL
Start Making Choices	NC	NC	NC	NC	NC	NC	NC	NC	+	+	min 10% DV	min 10% DV	+
Wegmans' Wellness Keys	max 40 cal for low-cal label	max 3 g	max 1 g	sat. fat too high	max 140 mg for low-sodium label	NC	min 5 g for high-fiber label	sugar-free label	NC	NC	NC	NC	NC
UK Traffic Light	NC	red	red	NC	amber	NC	NC	green	NC	NC	NC	NC	NC
Guiding Stars	0 stars (0 to 3 stars)												
NRFI	16 (-300 to 900)												
NuVal	Not determined (1-100)												

NOTE: + = meets criteria, DNQ = does not qualify, NC = no criteria, +vit, +prot, +sug, +fiber, etc. = nutrient in header of column is acceptable due to level of nutrient with +, GSL = good source label, ESL = excellent source label, min _%DV = must provide _% DV to meet criteria.

Part-Skim Mozzarella Cheese

Serving Size	Calories	Total Fat	Sat. Fat	Chol.	Sodium	Total Carbs	Dietary Fiber	Sugars	Protein	Vit. A	Vit. C	Iron	Calcium
1 oz.	70	5 g	3 g	15 mg	200 mg	< 1 g	0	< 1 g	6 g	2%	0%	0%	10%
Choices	NC	NC	+	NC	+	NC	NC	+	NC	NC	NC	NC	NC
Healthy Ideas	NC	max 3 g	max 1 g	+	+	NC	+ prot	NC	+	+ vit	+ vit	+ vit	+
Heart Check	NC	max 3g	max 1 g	+	+	NC	+	NC	+	+ vit	+ vit	+ vit	+
Sensible Solution	+	max 3 g	max 2g	+	+	NC	min 10% DV	+	NC	+ vit	+ vit	+ vit	+
Smart Choices	NC	max 3 g	max 2 g	+		NC	+ vit	+	NC	+ vit	+ vit	+ vit	+
Smart Spot	NC	max 35% cal from fat	max 1 g	+	+	NC	+ sug	+	+	+ vit	+ vit	+ vit	+
Canada's Health Check	NC	+	NC	NC	+	NC	NC	NC	NC	NC	NC	NC	min 15% DV
GM Goodness Corner	70-cal label	max 3 g	max 1 g	DNQ due to sat. fat	NC	net cabs given	min 10% DV for GSL	grams given	GSL	min 20% DV for ESL	min 10% DV for GSL	min 10% DV for GSL	ESL
HT Wellness Keys	max 40 cal for low-cal label	max 3 g	max 1g	DNQ due to sat. fat	max 140 mg for low–sodium label	NC	min 10% DV for GSL	NC	+	min 10% DV for GSL	min 10% DV for GSL	min 10% DV for GSL	+
Start Making Choices	NC	NC	NC	NC	NC	NC	min 10% DV	NC	+	min 10% DV	min 10% DV	min 10% DV	+
Wegmans' Wellness Keys	max 40 cal for low-cal label	max 3 g	max 0.5 g	DNQ due to sat. fat	max 140 mg for low-sodium label	NC	min 5 g for high-fiber label	sugar-free label	NC	NC	NC	NC	min 20% DV
UK Traffic Light	NC	amber	red	NC	amber	NC	NC	green	NC	NC	NC	NC	NC
Guiding Stars	0 stars (0 to 3 stars)												
NRFI	0 (-300 to 900)												
NuVal	22 (1-100)												

NOTE: + = meets criteria, DNQ = does not qualify, NC = no criteria, +vit, +prot, +sug, +fiber, etc. = nutrient in header of column is acceptable due to level of nutrient with +, GSL = good source label, ESL = excellent source label, min _%DV = must provide _% DV to meet criteria.

Reduced Fat Processed Cheese Slices

Serving Size	Calories	Total fat	Sat. fat	Chol.	Sodium	Total Carbs	Dietary Fiber	Sugars	Protein	Vit. A	Vit. C	Iron	Calcium
1 slice	45	2.5 g	1.5 g	10 mg	280 mg	2 g	0 g	1 g	4 g	4%	0%	0%	20%
Choices	NC	NC	+	NC	max 900 mg per 100 g	NC	NC	+	NC	NC	NC	NC	NC
Healthy Ideas	NC	+	max 1 g	+	+	NC	+ vit	NC	+ vit	+ vit	+ vit	+ vit	+
Heart Check	NC	+	max 1 g	+	+	NC	+	NC	+	+	+	+	+
Sensible Solution	+	+	+	+	+	NC	+	+	+	+ vit	+ vit	+ vit	+
Smart Choices	NC	+	+	+	max 240 mg	NC	+ vit	+	NC	+ vit	+ vit	+ vit	+
Smart Spot	NC	max 35% cal from fat	max 1 g	+	+	NC	+ sug	+	+ sug	+ vit	+ vit	+ vit	+
Canada's Health Check	NC	+	NC	NC	max 240 mg	NC	NC	NC	NC	NC	NC	NC	+
GM Goodness Corner	45-cal label	low-fat label	max 1 g	low-chol. label	NC	net carbs given	min 10% for GSL	grams given	min 10% for GSL	min 10% for GSL	min 10% for GSL	min 10% for GSL	ESL
HT Wellness Keys	max 40 cal for low cal	low-fat label	max 1 g	+	max 140 mg for low-sodium label	NC	min 10% for GSL	NC	min 10% for GSL	min 10% for GSL	min 10% for GSL	min 10% for GSL	+
Start Making Choices	NC	NC	NC	NC	NC	NC	min 10% DV	NC	min 10% DV	min 10% DV	min 10% DV	min 10% DV	+
Wegmans' Wellness Keys	max 40 cal for low cal	low-fat label	max 1 g	sat. fat too high	max 140 mg for low-sodium label	NC	min 5 g for high-fiber	max 0.5 g	NC	NC	NC	NC	+
UK Traffic Light	NC	amber	red	NC	amber	NC	NC	amber	NC	NC	NC	NC	NC
Guiding Stars	0 stars (0 to 3 stars)												
NRFI	27 (-300 to 900)												
NuVal	26 (1-100)												

NOTE: + = meets criteria, DNQ = does not qualify, NC = no criteria, +vit, +prot, +sug, +fiber, etc. = nutrient in header of column is acceptable due to level of nutrient with +, GSL = good source label, ESL = excellent source label, min _%DV = must provide _% DV to meet criteria.

Fat Free Milk

Serving Size	Calories	Total Fat	Sat. Fat	Chol.	Sodium	Total Carbs	Dietary Fiber	Sugars	Protein	Vit. A	Vit. C	Iron	Calcium
1 cup	80	0 g	0 g	4 mg	125 mg	12 g	0 g	11 g	8 g	10%	4%	0%	30%
Choices	NC	NC	+	NC	+	NC	NC	+	NC	NC	NC	NC	NC
Healthy Ideas	NC	+	+	+	+	NC	+ prot	+	+	+	+ vit	+ vit	+
Heart Check	NC	+	+	+	+	NC	+ prot, vit	NC	+	+	+ vit	+ vit	+
Sensible Solution	No category for milk or yogurt												
Smart Choices	NC	+	+	+	+	NC	+ vit	+	NC	+	+ vit	+ vit	+
Smart Spot	NC	+	+	+	+	NC	+ sug	+	+ sug	+	+ vit	+ vit	+
Canada's Health Check	NC	+	NC	NC	+	NC	NC	NC	NC	NC	NC	NC	+
GM Goodness Corner	80-cal label	low–fat label	low-sat. .fat label	low-chol. label.	NC	net carbs given	min 10% DV	grams given	GSL	GSL	min 10% DV	min 10% DV	ESL
HT Wellness Keys	max 40 cal	low-fat, heart-healthy label	heart–healthy label	heart–healthy label	low-sodium, heart-healthy label	NC	min 10% DV	NC	GSL	GSL	min 10% DV	min 10% DV	ESL
Start Making Choices	NC	NC	NC	NC	NC	NC	min 10% DV	NC	min 10% DV	+	min 10% DV	min 10% DV	+
Wegmans' Wellness Keys	max 40 cal	low-fat, heart-healthy label	heart–healthy label	heart–healthy label	low-sodium, heart-healthy label	NC	min 5 g	NC	NC	NC	NC	NC	high calcium
UK Traffic Light	NC	green	green	NC	green	NC	NC	amber	NC	NC	NC	NC	NC
Guiding Stars	3 stars (0 to 3 stars)												
NRFI	57 (-300 to 900)												
NuVal	91 (1-100)												

NOTE: + = meets criteria, DNQ = does not qualify, NC = no criteria, +vit, +prot, +sug, +fiber, etc. = nutrient in header of column is acceptable due to level of nutrient with +, GSL = good source label, ESL = excellent source label, min _%DV = must provide _% DV to meet criteria.

1% Fat Plain Milk

Serving Size	Calories	Total Fat	Sat. Fat	Chol.	Sodium	Total Carbs	Dietary Fiber	Sugars	Protein	Vit. A	Vit. C	Iron	Calcium
1 cup	110	2.5 g	1.5 g	15 mg	125 g	13 g	0 g	12 g	8 g	10%	0%	0%	30%
Choices	NC	NC	+	NC	+	NC	NC	+	NC	NC	NC	NC	NC
Healthy Ideas	NC	+	max 1 g	+	+	NC	+ prot, vit	+	+	+	+ vit	+ vit	+
Heart Check	NC	+	max 1 g	+	+	NC	+ prot, vit	NC	+	+	+ vit	+ vit	+
Sensible Solution	No category for milk or yogurt												
Smart Choices	NC	+	+	+	+	NC	+ vit	+	NC	+	+ vit	+ vit	+
Smart Spot	NC	+	max 1 g	+	+	NC	+ sug	+	+ sug	+	+ vit	+ vit	+
Canada's Health Check	NC	+	NC	NC	+	NC	NC	NC	NC	NC	NC	NC	+
GM Goodness Corner	110-cal label	low–fat label	max 1 g	low–chol. label	NC	net carbs given	min 10% DV	grams given	GSL	GSL	min 10% DV	min 10% DV	ESL
HT Wellness Keys	max 40 cal	low–fat label	max 1 g	DNQ due to sat. fat	low-sodium label	NC	min 10% DV	NC	GSL	GSL	min 10% DV	min 10% DV	ESL
Start Making Choices	NC	NC	NC	NC	NC	NC	min 10% DV	NC	+	+	min 10% DV	min 10% DV	+
Wegmans' Wellness Keys	max 40 cal	low-fat label	max 1 g	DNQ due to sat. fat	low-sodium label	NC	min 5 g	NC	NC	NC	NC	NC	high calcium
UK Traffic Light	NC	green	green	NC	green	NC	NC	amber	NC	NC	NC	NC	NC
Guiding Stars	3 stars (0 to 3 stars)												
NRFI	31 (-300 to 900)												
NuVal	81 (1-100)												

NOTE: + = meets criteria, DNQ = does not qualify, NC = no criteria, +vit, +prot, +sug, +fiber, etc. = nutrient in header of column is acceptable due to level of nutrient with +, GSL = good source label, ESL = excellent source label, min _%DV = must provide _% DV to meet criteria.

1% Fat Chocolate Milk

Serving Size	Calories	Total Fat	Sat. Fat	Chol.	Sodium	Total Carbs	Dietary Fiber	Sugars	Protein	Vit. A	Vit. C	Iron	Calcium
8oz	150	2.5 g	1.5 g	15 mg	290mg	25 g	1 g	22 g	9 g	10%	0%	4%	30%
Choices	NC	NC	+	NC	max 100 mg per 100 g	NC	NC	max 5 g added per 100 g	NC	NC	NC	NC	NC
Healthy Ideas	NC	+	max 1 g	+	+	NC	+ prot, vit	+	+	+	+ vit	+ vit	+
Heart Check	NC	+	max 1 g	+	+	NC	+ prot, vit	NC	+	+	+ vit	+ vit	+
Sensible Solution	No category for milk or yogurt												
Smart Choices	NC	+	+	+	max 240 mg	NC	+ vit	+	NC	+	+ vit	+ vit	+
Smart Spot	NC	+	max 1 g	+	+	NC	DNQ due to sugar	max 25% cal from sugar	DNQ due to sugar	+	+ vit	+ vit	+
Canada's Health Check	NC	+	NC	NC	max 240 mg	NC	NC	NC	NC	NC	NC	NC	+
GM Goodness Corner	150-cal label	low–fat label	max 1 g	low-chol. label	NC	net carbs given	min 10% DV	grams given	GSL	GSL	min 10% DV	min 10% DV	ESL
HT Wellness Keys	max 40 cal	low-fat label	max 1 g	DNQ due to sat. fat	max 140 mg	NC	min 10% DV	NC	GSL	GSL	min 10% DV	min 10% DV	ESL
Start Making Choices	NC	NC	NC	NC	NC	NC	min 10% DV	NC	min 10% DV	+	min 10% DV	min 10% DV	+
Wegmans' Wellness Keys	max 40 cal	low–fat label	max 1 g	DNQ due to sat. fat	max 140 mg	NC	min 5 g	NC	NC	NC	NC	NC	high calcium
UK Traffic Light	NC	green	green	NC	green	NC	NC	amber	NC	NC	NC	NC	NC
Guiding Stars	0 stars (0 to 3 stars)												
NRFI	19 (-300 to 900)												
NuVal	54 (1-100)												

NOTE: + = meets criteria, DNQ = does not qualify, NC = no criteria, +vit, +prot, +sug, +fiber, etc. = nutrient in header of column is acceptable due to level of nutrient with +, GSL = good source label, ESL = excellent source label, min _%DV = must provide _% DV to meet criteria.

Fat Free Plain Yogurt

Serving Size	Calories	Total Fat	Sat. Fat	Chol.	Sodium	Total Carbs	Dietary Fiber	Sugars	Protein	Vit. A	Vit. C	Iron	Calcium
227g	110	0 g	0 g	5 mg	150 mg	16 g	0 g	15 g	11 g	0%	4%	0%	40%
Choices	NC	NC	+	NC	+	NC	NC	+	NC	NC	NC	NC	NC
Healthy Ideas	NC	+	+	+	+	NC	+ prot, vit	+	+	+ vit	+ vit	+ vit	+
Heart Check	NC	+	+	+	+	NC	+ prot, vit	NC	+	+ vit	+ vit	+ vit	+
Sensible Solution	No category for milk or yogurt												
Smart Choices	NC	+	+	+	+	NC	+ vit	+	NC	+ vit	+ vit	+ vit	+
Smart Spot	NC	+	+	+	+	NC	+ sugar	+	+ sugar	+ vit	+ vit	+ vit	+
Canada's Health Check	NC	+	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	+
GM Goodness Corner	110-cal label	low-fat label	low-sat. fat label	low–chol. label	NC	net carbs given	min 10% DV	grams given	ESL	min 10% DV	min 10% DV	min 10% DV	ESL
HT Wellness Keys	max 40 cal	low-fat, heart-healthy label	heart-healthy label	heart-healthy label	max 140 mg for low-sodium label, heart- healthy label	NC	min 10% DV	NC	ESL	min 10% DV	min 10% DV	min 10% DV	ESL
Start Making Choices	NC	NC	NC	NC	NC	NC	min 10% DV	NC	+	min 10% DV	min 10% DV	min 10% DV	+
Wegmans' Wellness Keys	max 40 cal	low-fat, heart-healthy label	heart-healthy label	heart-healthy label	max 140 mg for low-sodium label, heart-healthy label	NC	min 5 g	NC	NC	NC	NC	NC	high calcium
UK Traffic Light	NC	green	green	NC	green	NC	NC	amber	NC	NC	NC	NC	NC
Guiding Stars	3 stars (0 to 3 stars)												
NRFI	43 (-300 to 900)												
NuVal	96 (1-100)												

NOTE: + = meets criteria, DNQ = does not qualify, NC = no criteria, +vit, +prot, +sug, +fiber, etc. = nutrient in header of column is acceptable due to level of nutrient with +, GSL = good source label, ESL = excellent source label, min _%DV = must provide _% DV to meet criteria.

Low Fat Fruit Yogurt

Serving Size	Calories	Total Fat	Sat. Fat	Chol.	Sodium	Total Carbs	Dietary Fiber	Sugars	Protein	Vit. A	Vit. C	Iron	Calcium
6oz	150	1.5 g	1 g	5 mg	110 mg	28 g	< 1 g	26 g	6 g	0%	4%	0%	20%
Choices	NC	NC	+	NC	+	NC	NC	max 5 g added per 100 g	NC	NC	NC	NC	NC
Healthy Ideas	NC	+	+	+	+	NC	+ prot, vit	+	+	+ vit	+ vit	+ vit	+
Heart Check	NC	+	+	+	+	NC	+ prot, vit	NC	+	+ vit	+ vit	+ vit	+
Sensible Solution	No category for yogurt												
Smart Spot	NC	+	+	+	+	NC	DNQ due to sugar	max 25% cal from added sugar	DNQ due to sugar	min 10% DV	min 10% DV	min 10% DV	+
Smart Choices	NC	+	+	+	+	NC	+ vit	max 12 g added per 8 oz	NC	+ vit	+ vit	+ vit	+
Canada's Health Check	NC	+	NC	NC	+	NC	NC	NC	NC	NC	NC	NC	+
GM Goodness Corner	150-cal label	low-fat label	low–sat. fat label	low-chol. label	NC	net carbs given	min 10% DV	grams given	GSL	min 10% DV	min 10% DV	min 10% DV	ESL
HT Wellness Keys	max 40 cal	low-fat, heart-healthy label	heart-healthy label	heart-healthy label	low-sodium, heart-healthy label	NC	min 10% DV	NC	GSL	min 10% DV	min 10% DV	min 10% DV	ESL
Start Making Choices	NC	NC	NC	NC	NC	NC	min 10% DV	NC	+	min 10% DV	min 10% DV	min 10% DV	+
Wegmans' Wellness Keys	max 40 cal	low-fat, heart-healthy label	heart-healthy label	heart-healthy label	low-sodium, heart-healthy label	NC	min 5 g	NC	NC	NC	NC	NC	high calcium
UK Traffic Light	NC	green	green	NC	green	NC	NC	amber	NC	NC	NC	NC	NC
Guiding Stars	0 stars (0 to 3 stars)												
NRFI	6 (-300 to 900)												
NuVal	23 (1-100)												

NOTE: + = meets criteria, DNQ = does not qualify, NC = no criteria, +vit, +prot, +sug, +fiber, etc. = nutrient in header of column is acceptable due to level of nutrient with +, GSL = good source label, ESL = excellent source label, min _%DV = must provide _% DV to meet criteria.

Appendix D
Workshop Agenda

Committee on
Examination of Front-of-Package Nutrition Rating Systems and Symbols

April 9, 2010

The National Academy of Sciences Building
2101 Constitution Avenue, NW, Washington, DC 20418
NAS Lecture Room, 9:00 a.m.–4:00 p.m.

9:00 a.m. Welcome
Ellen Wartella, *Committee Chair*

SESSION 1: INTERNATIONAL NUTRITION RATING SYSTEMS AND SYMBOLS

9:15 a.m. Front-of-Pack Systems in the United Kingdom
Claire Boville, M.B.A., M.Sc., B.Sc. (by telephone)
Deputy head of Food Composition and Labelling Division
Head of Labeling, Promotions and Dietetic Foods Unit
Food Standards Agency

9:45 a.m. The Choices Program
Jacob C. Seidell, Ph.D.
Chairman, International Scientific Program for Choices
Professor of Nutrition and Health
VU University Medical Center, Amsterdam, The Netherlands

9:55 a.m. Committee Discussion with Presenters

10:30 a.m. Break

SESSION 2: DOMESTIC NUTRITION RATING SYSTEMS AND SYMBOLS

10:45 a.m. The Heart Check Program
Kim Stitzel, M.S., R.D.
Director, Nutrition and Obesity
Consumer Health Division
The American Heart Association

10:55 a.m. The Smart Choices Program
Joanne Lupton, Ph.D.
Distinguished Professor
University Faculty Fellow
William W. Allen Endowed Chair in Human Nutrition
Department of Nutrition and Food Science
Texas A&M University

11:05 a.m. The General Mills Nutrition Highlights and Goodness Corner Programs
Kathy Wiemer, M.S., R.D.
Director/Fellow, Regulatory Affairs
General Mills Bell Institute of Health & Nutrition

11:15 a.m. The ConAgra Start Making Choices Program
Mark Andon, Ph.D.
Vice President, Nutrition Research, Quality, and Innovation
ConAgra Foods

11:25 a.m. The NuVal System
David Katz, M.D., M.P.H., FACPM, FACP
Adjunct Associate Professor of Public Health Practice
Director of the Yale Prevention Research Center
Yale University School of Medicine
Chief Science Officer, NuVal LLC

11:35 a.m. The Nutrient Rich Foods Index
Adam Drewnowski, Ph.D.
Director
Center for Obesity Research
University of Washington

11:45 a.m. The Guiding Stars Program
Mark Kantor, Ph.D.
Associate Professor and Extension Specialist
Department of Nutrition and Food Science
University of Maryland

11:55 a.m. Committee Discussion with Presenters

1:00 p.m. Lunch on Your Own

SESSION 3: CONCERNS ABOUT NUTRITION RATING SYSTEMS AND SYMBOLS

2:00 p.m. Perspectives on Front of Package Labeling

Marion Nestle, Ph.D., M.P.H.
Paulette Goddard Professor
Department of Nutrition, Food Studies and Public Health
New York University

2:15 p.m. Committee Discussion with Presenter

2:25 p.m. Break

SESSION 4: FDA SPONSOR PERSPECTIVES

2:30 p.m. Update on FDA Front-of-Pack Efforts

Jessica Leighton, Ph.D.
Senior Science Advisor
Office of the Commissioner
Food and Drug Administration

Barbara Schneeman, Ph.D.
Director
Office of Nutrition, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration

SESSION 5: PUBLIC COMMENTS

3:00 p.m. Public Comments

4:00 p.m. Adjourn

Appendix E
Committee Member Biographical Sketches

Ellen A. Wartella, Ph.D., is professor of communication and psychology at Northwestern University and the former executive vice chancellor and provost at the University of California, Riverside. Prior to that, she was dean of the College of Communication and professor in the Department of Radio-Television Film at the University of Texas in Austin. Dr. Wartella is a co-principal investigator on a 5-year, multi-site research project entitled IRADS Collaborative Research: Influence of Digital Media on Very Young Children, funded by the National Science Foundation. She was a co-principal investigator on the National TV Violence Study and a co-principal investigator of the Children's Digital Media Center project funded by the National Science Foundation. She serves on the National Educational Advisory Board of the Children's Advertising Review Unit of the Council of Better Business Bureaus, the Board of Directors for the World Summit on Media for Children Foundation, PBS KIDS Next Generation Media Advisory Board, the Board of Trustees for Sesame Workshop, and advisory boards for the Center on Media and Child Health and the Rudd Center for Food Policy and Obesity. She has served on the National Research Council/Institute of Medicine Board on Children, Youth, and Families and the Committee on Food Marketing and the Diets of Children and Youth. She is a member of the American Psychological Association and the Society for Research in Child Development and is the past president of the International Communication Association. Recent honors include election as fellow of the American Association for the Advancement of Science and the Steven H. Chaffee Career Productivity Award from the International Communication Association. Dr. Wartella received a B.A. with honors in economics from the University of Pittsburgh, M.A. and Ph.D. degrees in mass communications from the University of Minnesota, and completed postdoctoral research in developmental psychology at the University of Kansas.

Alice H. Lichtenstein, D.Sc., is Stanley N. Gershoff Professor of Nutrition Science and Policy in the Friedman School and director and senior scientist of the Cardiovascular Nutrition Laboratory at the U.S. Department of Agriculture's Jean Mayer Human Nutrition Research Center on Aging, both at Tufts University. She holds secondary appointments as an associated faculty member in the Institute for Clinical Research and Health Policy Studies at Tufts Medical Center and as a professor of medicine at Tufts University School of Medicine. Dr. Lichtenstein's research group focuses on assessing the interplay between diet and heart disease risk factors. Recent and current work includes addressing in postmenopausal females and older males issues related to *trans* fatty acids, soy protein and isoflavones, sterol/stanol esters, and novel vegetable oils differing in fatty acid profile and glycemic index. Selected issues are investigated in animal models and cell systems with the aim of determining the mechanisms by which dietary factors alter cardiovascular disease risk. Additional work is focused on population-based studies to address the relationship of cholesterol homeostasis and nutrient biomarkers on cardiovascular disease risk and on the application of systematic review methods to the field of nutrition. Dr. Lichtenstein is a member of the American Society for Nutrition; the Arteriosclerosis, Thrombosis, and Vascular Biology Council; and the Nutrition, Physical Activity, and Metabolism Council of the American Heart Association. She is a past-chair of the American Heart Association Committee on Nutrition and served on the Department of Health and Human

Services/U.S. Department of Agriculture 2000 Dietary Guidelines Advisory Committee, the Institute of Medicine (IOM) Dietary Reference Intake macronutrient panel, and the IOM Food Forum. Dr. Lichtenstein completed her undergraduate work at Cornell University, holds a masters degree from the Pennsylvania State University, and masters and doctoral degrees from Harvard University. She received her postdoctoral training in the field of lipid metabolism at the Cardiovascular Institute at Boston University School of Medicine.

Lindsay H. Allen, Ph.D., is director of the U.S. Department of Agriculture's Western Human Nutrition Research Center located on the University of California, Davis campus. The center's primary focus is prevention of obesity, inflammation, and related chronic diseases through nutrition interventions. She is an expert on the prevalence, causes, and consequences of micronutrient deficiencies in developing countries and has conducted numerous interventions to assess the efficacy of micronutrient supplements and food-based approaches for improving nutritional status, pregnancy outcome, and child development. Dr. Allen has served on ten committees of the Institute of Medicine, including the Food and Nutrition Board and the Standing Committee for the Scientific Evaluation of Dietary Reference Intakes. She has been an adviser to many bilateral and international agencies, including the World Health Organization, UNICEF, the Asian Development Bank, the World Bank, the Pan American Health Organization, the Food and Agriculture Organization of the United Nations, and she was president of the American Society for Nutrition and the Society for International Nutrition Research. She is vice president of the International Union of Nutritional Sciences. Dr. Allen was awarded the American Society for Nutrition's Kellogg International Nutrition Prize in 1997 and the Conrad Elvejhem Award for Public Service in Nutrition in 2009. She received her doctorate from the University of California, Davis.

Tracy A. Fox, M.P.H., R.D., is the founder of Food, Nutrition and Policy Consultants, LLC, an organization in Washington, DC, specializing in food and nutrition policy and programs at the federal, state, and local levels. She has assisted government, schools, and nonprofit and for-profit organizations in policy and program enhancements to promote positive environmental change. Ms. Fox worked with the Centers for Disease Control and Prevention to collect, analyze, document and publicize success stories of school and district-based nutrition and physical activity initiatives and to evaluate promising childhood obesity prevention projects across the country in Head Start and day care programs, school districts, after-school programs, and farmers' markets. She was a member of the IOM Committee on Nutrition Standards for Foods in School and the Institute of Medicine and National Research Council's Committee on Local Government Actions to Prevent Childhood Obesity. She is president-elect of the Society for Nutrition Education and is a member of the Action for Healthy Kids' Strategic Advisory Committee. Prior to forming her consulting company, Ms. Fox was with the government relations office of the American Dietetic Association and at the Food and Nutrition Service in the U.S. Department of Agriculture. Ms. Fox received her M.P.H. from the University of Pittsburgh Graduate School of Public Health and a B.S. in dietetics from Hood College.

Matthew W. Kreuter, Ph.D., M.P.H., is professor of social work and medicine at Washington University in St. Louis, and founding director of the Health Communication Research Laboratory, one of five National Cancer Institute–designated Centers of Excellence in Cancer Communication Research. He is also a member of the Washington University Institute for Public

Health and co-leader of the Cancer Prevention and Control Program at the Siteman Cancer Center. His research explores strategies to increase the reach and effectiveness of health information in low-income and minority populations to help eliminate health disparities. Dr. Kreuter has served as a member of the Institute of Medicine's Board on Population Health and Public Health Practices. He received his Ph.D. and M.P.H. in health behavior and health education from the School of Public Health at the University of North Carolina, Chapel Hill.

Anusree Mitra, Ph.D., is associate professor of marketing at the Kogod School of Business at American University. In this role, Dr. Mitra teaches marketing management, consumer behavior, and marketing research. Her research focuses on consumer perceptions of marketing information, such as advertising, nutritional labeling, and other mandatory disclosures, and their public policy implications. She has published scholarly articles in the *Journal of Consumer Research*, *International Journal of Research in Marketing*, *Journal of Public Policy and Marketing*, *Marketing Letters*, and *Journal of Business Research*. Two of her articles in the *Journal of Consumer Research* won awards from the Association of Consumer Research. Dr. Mitra has a Ph.D. in Business from the University of Florida, an M.B.A. from the Indian Institute of Management, and a B.S. in economics from the University of Calcutta.

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 at Pennsylvania State University. She is retired from the Hershey Company where she was associate director for nutrition. She earlier worked for the Procter and Gamble Company and was assistant professor of nutrition at the University of North Carolina, Chapel Hill. Dr. Seligson's professional memberships include the American Society for Nutrition and the American Dietetic Association. She has held leadership positions on committees and activities at such associations as the American Society for Nutrition, the International Food Information Council, the International Life Sciences Institute, and the National Food Processors Association. She was a member of the Institute of Medicine (IOM) Committee on Food Marketing to Children and Youth and the IOM Committee on Dietary Reference Intakes in Nutrition Labeling. Dr. Seligson has published extensively in the areas of nutrition and food consumption. She is an advisor on nutrition, scientific, and regulatory issues for the Hershey Company, the Coca-Cola Company, Burger King Corporation, the Children's Food and Beverage Advertising Initiative, and Children's Advertising Review Unit. She received her Ph.D. from the University of California, Berkeley.

Mary T. Story, Ph.D., R.D., is professor in the Division of Epidemiology and Community Health and associate dean for student life in the School of Public Health at the University of Minnesota, Minneapolis. She is also an adjunct professor in the Department of Pediatrics, School of Medicine at the University of Minnesota. Dr. Story received her Ph.D. in nutrition, and her interests are in the area of child and adolescent nutrition, obesity prevention, and environmental and policy approaches to improve healthful eating. Her research focuses on understanding the multiple factors related to eating behaviors of youth and on environmental, community, and school-based interventions for obesity prevention and healthful eating. She has written over 300 journal articles and publications in the area of child and adolescent nutrition and obesity. She is the director of the National Program Office for the Robert Wood Johnson Foundation Healthy Eating Research program. She is on editorial boards for the Journal of the *American Dietetic Association*, *Journal of Adolescent Health*, and *Nutrition Today*. She was a member of the

Institute of Medicine (IOM) Committee on Food Marketing to Children and Youth, the IOM Committee on Nutrition Standards for Foods in Schools, and the IOM/National Research Council Committee on Local Government Actions to Prevent Childhood Obesity. She is a current member of the IOM Standing Committee on Childhood Obesity Prevention.

Virginia Wilkening, M.S., R.D., is a former U.S. Food and Drug Administration (FDA) career nutrition scientist. She joined FDA in 1983 and retired in 2004. At retirement she was deputy director of the Office of Nutritional Products, Labeling, and Dietary Supplements in the Center for Food Safety and Applied Nutrition. In that position, Ms. Wilkening shared responsibility for developing policy and regulations for dietary supplements, nutrition labeling, food standards, infant formula, and medical foods as well as for compliance and enforcement actions and scientific evaluation to support such regulations and related policy development and analytical database research. Prior to holding this position, she served as team leader for a multidisciplinary group responsible for implementing that part of the Nutrition Labeling and Education Act of 1990 that pertained to nutrition labeling, Reference Daily Intakes (RDIs), Daily Reference Values (DRVs), serving sizes, and format for the nutrition label. She had a similar role in implementing the Dietary Supplement Health and Education Act of 1994. In 2007 Ms. Wilkening joined the EAS Consulting Group as a senior consultant on a contract basis. She also worked for 12 years as a nutritionist with the Nutrition and Technical Services Staff in the Food and Nutrition Service at USDA. Her work included developing nutrition standards and goals and evaluating the effectiveness of such goals for the National School Lunch Program and other child nutrition programs. She was also chief dietitian at Mather Memorial Hospital in Port Jefferson, New York. Ms. Wilkening earned B.S. and M.S. degrees in nutrition at the University of California, Davis.