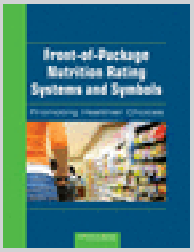


# Front-of-Package Nutrition Rating Systems and Symbols: Promoting Healthier Choices

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Ellen A. Wartella, Alice H. Lichtenstein, Ann Yaktine, and Romy Nathan, Editors; Committee on Examination of Front-of-Package Nutrition Rating Systems and Symbols (Phase II); Institute of Medicine

# Front-of-Package Nutrition Rating Systems and Symbols

## Promoting Healthier Choices

Committee on Examination of Front-of-Package Nutrition Rating Systems and Symbols (Phase II)

Food and Nutrition Board

Ellen A. Wartella, Alice H. Lichtenstein, Ann Yaktine, and Romy Nathan, *Editors*

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

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the 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:

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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 **Diana Birt,** Iowa State University, and **Elena O. Nightingale,** Washington, DC. Appointed by the National Research Council and 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

American consumers today enjoy a wide array of food products from which to choose, but they also face a daunting challenge when trying to make healthful food choices. This challenge is exacerbated by the proliferation of front-of-package and shelf tag nutrition rating symbols and systems intended to communicate information about the healthfulness of the food. Not surprising, consumers trying to make choices in a short amount of time among packages cluttered with information and with different nutrition rating systems may have difficulty choosing more healthful products.

During Phase I of the study to examine front-of-package nutrition rating symbols and systems, the committee found that the health risks most strongly associated with diet and affecting the greatest number of Americans are obesity and its associated chronic diseases. The committee also found that Americans consume too many calories, saturated and *trans* fats, and added sugars, and too much sodium; leaving other important nutrients at risk for inadequacy. Given these findings, the Centers for Disease Control and Prevention (CDC) with additional support from the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services and the Center for Nutrition Policy and Promotion (CNPP) of the U.S. Department of Agriculture asked the committee to carry out Phase II of the study to consider the benefits of a single, standardized front-label food guidance system; assess which icons or symbols would be most effective with consumers; and develop recommendations about the systems and icons that best promote health and ways to maximize their use.

The Phase II committee consisted of the Phase I committee members and three new members, Jim Crimmins, Brian Elbel, and Elizabeth Howlett. The committee conducted an extensive review of both peer-reviewed and non-reviewed evidence. It also conducted a public workshop to gather information from experts outside the committee and to hear from stakeholders. Invited speakers included Chung-Tung Jordan Lin and Alan Levy from the FDA; Kelly Brownell from the Yale University Rudd Center; Regina Hildwine from the Grocery Manufacturer's Association and Marianne Smith-Edge from the International Food Information Council; Christina Zaradoolas from Mount Sinai School of Medicine; John Kozup from Villanova University; and Christine Johnson from the New York Department of Health. In addition, interviews with representatives from the food manufacturing industry were carried out, and the committee engaged several consultants. Kelly Brownell, Marlene Schwartz, and Lila Rutten served as unpaid consultants to assist the committee in interpreting the evidence. Christopher Casey and Amy Scott developed exemplar graphic representations of front-of-package symbol systems. The contributions of the workshop speakers, industry representatives, and the consultants were invaluable to the committee in guiding its discussions and developing recommendations. On behalf of the committee, I would like to thank them for their excellent work.

I would also like to express my gratitude to the committee members, whose tireless efforts and determination made this report possible. The committee is also grateful to the Institute of Medicine study team: Ann Yaktine, study director; Romy Nathan, senior program officer; Janet Mulligan, Research Associate; Samantha Robotham, senior program assistant; Geraldine Kennedo, administrative assistant; and Anton Bandy, financial officer. I am especially grateful to Linda Meyers, director of the Food and Nutrition Board, who provided guidance to the committee throughout both study phases.

The committee's findings about the current food package environment, together with evidence that consumer food choice behavior has not changed in spite of a myriad of front-of-package nutrition rating systems, clearly suggest that the time has come for a paradigm shift from information-based nutrition rating systems to one that encourages consumers to make more healthful food choices and purchasing decisions. The committee's recommendations are presented as guidance to the study sponsors in developing a front-of-package symbol system that is easily understood and maximizes the opportunity to better inform and guide consumers' toward more healthful food choices.

Ellen A. Wartella, *Chair*
Alice H. Lichtenstein, *Vice-Chair*
Committee on Examination of Front-of-Package
Nutrition Rating Systems and Symbols (Phase II)

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# Summary[1]

There is a long and rich history of government public health efforts to educate and inform the public about nutrition and healthy eating. The first daily food guide, published in 1916, paved the way for a host of scientific documents, reports, brochures, symbols, and educational campaigns, including the *Basic Seven Foods,* the *Food Guide Pyramid,* and the *Nutrition Facts panel*. As a result of efforts such as these, Americans today have access to more information about nutrition than any previous generation. And yet the nation is facing a crisis of obesity and diet-related chronic diseases. Although there are many factors that influence what and how Americans eat, it is clear that there is a disconnect between dietary recommendations and actual consumption.

Most of the front-of-package (FOP) systems that have been developed to date follow in the tradition of providing consumers with nutrition information. The use of such systems implicitly assumes that consumers are receiving appropriate nutrition information, whose impact can be enhanced by making it more prominent (i.e., putting it on the front of packages) and by delivering it more concisely. After reviewing evidence and perspectives from a wide range of disciplines, the committee came to a different conclusion. Rather than refining existing informational approaches to communicating with the public about nutrition, the committee believes there is sufficient evidence to recommend that the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) consider a fundamental shift in strategy. A new FOP symbol system should move beyond simply informing consumers about nutrition facts.

The committee concluded that for a government-sponsored FOP symbol system to help achieve population health benefits, it must not only inform consumers about detailed nutrition content, but also, more importantly, encourage healthier food choices and purchase behaviors. The committee determined that these goals can be better achieved by a simple FOP symbol that serves as a signal or cue to consumers rather than by detailed information about nutrient content on the front of food packages or beverages. Similar approaches, such as the Environmental Protection Agency (EPA) and Department of Energy's (DoE's) *Energy Star*® program, have been highly successful in changing consumer purchase patterns for household appliances and electronics. Some nongovernmental organizations as well as food manufacturers have already developed simple FOP symbols. The committee's recommended approach builds on this foundation, is transparent, and uses the same regulatory criteria consistently across food categories.

[1] This summary does not include references. Citations for the findings presented in the Summary appear in the subsequent chapters.

**BOX S-1**
**Phase I Guiding Principles**

In evaluating the nutrition science of front-of-package (FOP) systems and symbols, the committee adopted four guiding principles to set the stage for the nutritional assessment of FOP systems and symbols. These guiding principles were intended to assist the committee in identifying the systems and elements of systems most important to assisting American consumers in making healthier food choices and the system criteria that could be implemented in the current food environment. The guiding principles are:

1. A well-balanced, high-quality diet consistent with the recommendations of the *Dietary Guidelines for Americans* is essential for the health of Americans, and FOP labeling is one tool among many geared toward helping Americans make healthful choices. Other such tools include MyPyramid,[a] the Nutrition Facts panel (NFP), and health and nutrient content claims.
2. FOP systems will focus on nutrients or food components that are most strongly associated with diet-related health risks affecting the greatest number of Americans.
3. The information highlighted in FOP systems will be consistent with the NFP.
4. FOP systems will apply to as many foods as possible.

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[a]MyPlate replaces MyPyramid as the primary federal government food group symbol and directs consumers to Choose MyPlate.gov to learn how to apply the *Dietary Guidelines*.

## THE COMMITTEE'S TASK AND APPROACH

At the direction of Congress, the Centers for Disease Control and Prevention (CDC) asked the Institute of Medicine (IOM) to undertake a study to examine and provide recommendations regarding FOP nutrition rating systems and symbols. The FDA, and later the USDA Center for Nutrition Policy and Promotion, provided support. The study comprised two phases. The Phase I committee focused on evaluating current systems and nutritional criteria and resulted in a report in 2010. The Phase II committee was tasked to:

- consider the potential benefits of a single, standardized, front-label food guidance system regulated by the FDA,
- assess which icons are most effective with consumer audiences, and
- develop conclusions about the systems and icons that best promote health and how to maximize their use.

The committee drew on the guiding principles (Box S-1), assessment, findings, and conclusions from Phase I (shown in Box S-1) as a starting point. The committee conducted a comprehensive review and analysis of evidence from several sources directly relevant to its charge. In order to be comprehensive, the committee considered a wide range of material from academic peer-reviewed literature and publicly available industry, government, and marketing sources as well as evidence and perspectives from a wide range of disciplines. The committee acknowledged the potential shortcomings of any FOP system that were identified during Phase I, and explored whether and how consumers might use the information provided by an FOP symbol system. Although not tasked with making recommendations about food preparation and consumption practices after purchase, the committee recognized that these practices have implications for health. Finally, the committee evaluated only the potential benefits of a single, standardized, front-label, food guidance system regulated by FDA and not the regulatory or related considerations of universally implementing such a system.

## DEVELOPING A MODEL FOP SYMBOL SYSTEM

The committee's review and analysis of the available evidence (described in Chapters 4 through 6) led to the finding that the various FOP systems in the marketplace predominantly focus on provision of nutrient information at the point of purchase. The evidence about consumer understanding of FOP labeling systems, consumer use of nutrition information, and the effects of food package information on consumer choices suggests that an approach that provides nutrition information only and is not interpretive would have limited success in encouraging healthier consumer food choices and purchase decisions (also discussed in Chapter 6).

Thus, the committee concluded that a shift from an informational approach to an interpretive one that quickly and easily provides guidance would encourage healthier food choices. In addition, an effective FOP symbol system would encourage food and beverage companies to provide healthier choices through reformulation or development of new products, and would encourage retailers to highlight healthier products.

Given the goal of encouraging healthier food choices, the committee evaluated FOP and shelf-tag nutrition rating systems that have demonstrated some success in the marketplace, but concluded that no FOP symbol system is superior to all others. Furthermore, no FOP systems as currently developed show consistent evidence of dramatically influencing consumer choice. However, there is some limited evidence that simple and easy-to-understand FOP systems encourage healthier food selections, particularly in settings where consumers make quick decisions such as in grocery stores with many product choices.

Consumers with limited resources are more likely to be concerned about cost instead of nutrition, and consumers who find the label difficult to understand are less likely to use the nutrition information. Therefore, it is not surprising that the cognitive approach to providing more nutrition information on labels has not been consistently effective across consumer groups. Placing special emphasis on nutritionally at-risk subpopulations such as those with low incomes, low literacy/numeracy skills, or low levels of education, is an important component of the evaluation process. However, the committee recognizes that any FOP system is likely to have a narrow influence on the food purchase decisions of consumers whose access or resources to purchase healthier foods is impacted by economic and/or geographic limitations.

Among consumers with low literacy skills, the evidence reviewed indicates that a simple rating system diminishes the differences in choosing the healthier product between high- and low-literacy adults. FOP labeling, especially using a simple symbol, might serve as a cue or signal for consumers, helping them distinguish between products of greater and lesser nutritional quality. These findings indicate that using simple symbols to summarize complex information about product quality may be especially valuable to low-literacy populations. From its review of existing FOP systems, the committee identified four attributes that are common to most successful FOP systems:

1. simple, understanding does not require specific or sophisticated nutritional knowledge;
2. interpretive, nutrition information is provided as guidance rather than as specific facts;
3. ordinal, nutritional guidance is offered through a scaled or ranked approach; and
4. supported by communication with readily remembered names or identifiable symbols.

The EPA/DoE *Energy Star*® program provides an example of a successful government labeling system. For many consumers, the *Energy Star*® label signals products that deliver high-quality performance while saving energy and reducing operating costs. Consumer awareness of the label is high, and it appears to be effective in informing consumer purchases. Along with the attributes listed above, key factors that have contributed to the *Energy Star*® program's success include partnerships with key stakeholders, widespread market penetration, a dynamic and evolving program, and ongoing and multi-faceted promotions. Each of these factors has relevance for designing and implementing a successful FOP nutrition rating system and, when considered with the totality of the available evidence, informed the committee's assessment of the characteristics of a successful FOP nutrition rating system.

The committee developed a set of eight characteristics that are necessary to the success of an FOP nutrition rating system. Furthermore, the committee determined that the system should carry an identifiable "health meaning," that is, an indication of the extent to which a product contains reasonable amounts of saturated and *trans* fats, sodium, and added sugars, which are considered harmful when consumed in excess or above a certain threshold. The eight characteristics are incorporated into its recommendation for an FOP symbol system.

## RECOMMENDATIONS FOR FRONT-OF-PACKAGE SYSTEMS AND SYMBOLS

From its review of the available evidence, the committee concluded that no flawless FOP symbol systems exist in the marketplace—each has strengths and limitations that must be weighed against the system's intended purposes. The committee also concluded that a single, standardized system that is easily understood by most age groups and appears on all food products would best maximize the effectiveness in encouraging consumers to make healthier food choice and purchase decisions. Such a system would:

- Prominently provide in one symbol system information about calorie content and serving size and targeted information related to nutrients that are strongly associated with public health concerns for Americans and foods with added sugars that the *Dietary Guidelines* recommends reducing or eliminating;
- Facilitate comparisons of nutritional value *within* and *across* food categories; and
- Encourage product reformulation.

The approach and criteria for evaluating nutrients to limit in a FOP symbol system should be transparent and nonproprietary, that is, based on and/or consistent with FDA's labeling regulations.

After reviewing and analyzing the totality of the available evidence and weighing the benefits of and limitations to a single, standardized FOP system, the committee developed the following recommendation for a system that incorporates the characteristics described above:

*Recommendation 1*

**FDA and USDA should develop, test, and implement a single, standardized FOP system to appear on all food and beverage products. The system should have the following eight characteristics:**

- **One simple, standard symbol translating information from the Nutrition Facts panel (NFP) on each product into a quickly and easily grasped health meaning, making healthier options unmistakable;**
- **Displaying:**
  - o **Calories in common household measure serving sizes** (shelf tags to be used on bulk items such as fruits and vegetables as well as packaged goods), and
  - o **Zero to three nutritional "points"** (for saturated and *trans* fats, sodium, and added sugars);
- **Appearing on all grocery products, allowing consumers to compare food choices across and within categories** (universal implementation must be preceded by consumer testing and conducted in conjunction with an education and promotion program);
- **Appearing in a consistent location across products;**
- **Practical to implement by being consistent with nutrition labeling regulations;**
- **Integrated with the NFP so that the FOP symbol system and the NFP are mutually reinforcing;**
- **Providing a nonproprietary, transparent translation of nutrition information into health meaning; and**
- **Made prominent and useful to consumers through an ongoing and frequently refreshed program of promotion integrating the efforts of all concerned parties.**

Implementation of this system will require modifications of and/or exemptions to current FDA regulations and development of both new regulations and food group specifications, for establishing evaluative criteria. Because the NFP does not declare added sugars, the total sugars declaration could be footnoted with a statement such as "Contains no added sugars" or "Contains a qualifying amount of added sugars." A single, standardized FOP symbol system should be the only system appearing on products. For products not meeting the evaluative criteria for an ordinal indicator symbol, the FOP system should still display calorie and serving size information. Examples of symbol systems that are consistent with these recommendations are presented in Chapter 7. An approach to determining the number of points displayed on the FOP system is described in the following section.

## APPROACH TO EVALUATING PRODUCTS AND SETTING CRITERIA FOR NUTRIENT LIMITS

As a critical component of the FOP symbol system, all products would display calories per serving size in common household measures and points[2] for saturated and *trans* fats, sodium, and added sugars. The Phase I committee concluded that added sugars should not be a component of an FOP nutrition rating system because of insufficient evidence about the contribution of added sugars beyond calories to the most pressing diet-related health concerns among Americans; the inability to distinguish analytically between added and naturally occurring sugars in foods without obtaining proprietary product information and including that information on the NFP; and the relatively small number of food categories with high amounts of added sugars. This committee reconsidered this Phase I conclusion in light of events occurring after the release of the Phase I report, specifically the release of the 2010 *Dietary Guidelines for Americans* and the development of an approach to evaluating added sugars content. The 2010 *Dietary Guidelines for Americans*, which is the federal government's nutrition policy document, strongly recommends reducing intakes of calories from added sugars and consumption of foods containing added sugars. These products contribute to energy intake; generally contain no or low amounts of saturated and *trans* fats and sodium; and provide little or no essential nutrients unless fortified, which is not consistent with FDA fortification policy.[3] A relatively small number of food and beverage categories contribute more than half the added sugars in the American diet.

The committee developed an approach to evaluating added sugars based on products categorized as Sugars, Sweets, and Beverages in the USDA *Food and Nutrient Database for Dietary Studies* that addresses previous concerns about analyzing foods for added sugars content. Simply stated, any product that is categorized as Sugars, Sweets, and Beverages in the USDA *Food and Nutrient Database for Dietary Studies* and contains added sugars would not be eligible to earn FOP points. As a consequence, major contributors of added sugars to diets, such as sugars, sweets, and beverages, would erroneously appear as being healthy because they are low in saturated and *trans* fats and sodium.

The strong recommendation from the 2010 *Dietary Guidelines for Americans*, along with the development of this approach to evaluating added sugars, led the committee to conclude that added sugars are an important component that should be included in a FOP nutrition rating system. This conclusion is consistent with the principle that an FOP symbol system should not inadvertently promote products that are inconsistent with current federal dietary guidance.

### Evaluation of Nutrients for FOP Points

The process to evaluate saturated and *trans* fats, sodium, and added sugars in a product occurs in two steps. In the first step, determining *eligibility* for inclusion in the FOP system (for earning any points), a food or beverage is excluded from earning FOP points if it does not meet specified eligibility criteria (see Chapter 7 for details). In the second step, a product that meets the eligibility criteria is evaluated for FOP points for saturated and *trans* fats, sodium, and/or added sugars based on *qualifying* criteria that assess acceptable amounts. The more points displayed, the more the food or beverage helps the consumer avoid less healthy levels of those nutrients identified as being associated with diet-related health risks. For example, a food or beverage product could earn one point for an acceptable level of sodium, one for an acceptable level of saturated and *trans* fats, and/or one point for an acceptable level of added sugars. Saturated and *trans* fats are considered together to facilitate communication about limiting consumption of foods containing solid fats, as recommended in the 2010 *Dietary Guidelines for Americans*. Points for a nutrient component would be displayed using a ranked or scaled (ordinal indicator) symbol

[2] The term "points" is used to indicate that a critical component nutrient met its defined criteria.
[3] 21 CFR 104.20.

as discussed above in the Model for a Symbol System and illustrated in Chapter 7 with hypothetical examples. If a food or beverage product contains any one of the nutrient components of concern in amounts exceeding specified criteria limits, then the product would not be eligible for points and its label would display only calories per serving (examples are illustrated in Chapter 7). Labels of products that do not meet the eligibility and qualifying criteria for points would display only calorie and serving size information. A similar system could be developed for shelf tags for unpackaged or bulk items such as fruits and vegetables as well as packaged goods.

From a nutrient perspective, this two-step process would mean that for each nutrient there are potentially two levels of evaluation, one to determine if the product is eligible to earn any points at all (*eligibility criteria*) and, if so, one to determine how many points the product can earn (*qualifying criteria*). For example, 100 percent whole wheat bread would earn three FOP points, graham crackers two points (one each for saturated and *trans* fats and sodium), oat and peanut butter bars one point (for sodium), and soup crackers no points (because it exceeds the disclosure/disqualifying level for sodium).

The determination of threshold values for a product to earn FOP points, based on regulations for nutrition labeling and nutrient content claims, is explained in Chapter 7. The committee evaluated the nutrient content of a limited number of example foods and beverages in consideration of developing eligibility and qualifying criteria based on current regulations for nutrition labeling and nutrient content claims; these products are shown in Appendix E.

### Alignment with the Regulatory Environment

The committee recognized that there should be alignment between eligibility and qualifying criteria for an FOP symbol system and federal regulations for nutrient content claims. However, the eligibility and qualifying criteria for the FOP symbol system described in this report are not entirely consistent with current regulations for nutrient content claims. As part of developing and testing an FOP symbol system, inconsistencies between potential criteria and current regulations will need to be addressed. The committee views the described criteria as starting points for extensive computer modeling to determine if the criteria are consistent with appropriate ratings for saturated and *trans* fats, sodium, and added sugars across a wide variety of foods and beverages. The committee recognized that the criteria must balance restrictiveness with practicality to allow products to earn FOP system points appropriately. As with all regulatory actions, public input will be required for implementation of a new FOP symbol system and its criteria.

## PROMOTION, EVALUATION, AND RESEARCH

### Promotion

There are a number of ways in which social marketing strategies and theory can be applied to FOP labeling to influence nutrition-related awareness, knowledge, attitudes, and behaviors. Based on its review of existing public health campaigns, the committee concluded that implementation of an effective FOP system must be a well-funded, sustained effort that is dynamic, refreshed on a regular basis, and carried out by a public-private partnership. Campaigns should carefully attend to specific behavioral goals that are effective and actionable. Comprehensive, multi-level approaches that attend to pertinent environmental and policy constraints, socio-cultural influences, and individual-level factors relevant to dietary behavior change in the target population are encouraged.

### Monitoring, Evaluation, and Research

The committee acknowledges that certain federal agencies will incur costs to implement the recommendations for an FOP symbol system and that an additional investment will be needed to support an education and promotion campaign, along with evaluation of the campaign and research to test and refine educational messages. Nevertheless, the committee concluded that implementation of its recommendations offers the best option to maximize the effectiveness of an FOP symbol system in encouraging consumers to make healthier food choices and purchase decisions. There should be ongoing monitoring and periodic evaluation of a new FOP symbol system. This program should include the following components:

- Identifying the steps toward reaching the goal of making healthier choices;
- Conducting research designed to assess success in reaching each step; and
- Enhancing system components and taking corrective action where necessary.

Research should be conducted to assess the needs and preferences of target audiences to better understand factors that influence consumer food choice and purchase behavior. In addition, formative research is necessary to test and refine messages and to determine the best approaches and channels to promote an FOP symbol system. Monitoring through both process and outcome evaluation is needed to assess the effectiveness and impact and to refine and strengthen program components. An evaluation of the impact of the FOP symbol system on product reformulation is also necessary. Ongoing research will help to guide and strengthen implementation efforts and help inform corrective actions where necessary. Placing special emphasis on nutritionally at-risk subpopulations, such as those with low incomes, low literacy/numeracy skills, or low levels of education, is an important component of these processes. Based on these conclusions the committee makes the following recommendation:

*Recommendation 2*

**Implementation of a new FOP symbol system should include a multi-stakeholder, multi-faceted awareness and promotion campaign that includes ongoing monitoring, research, and evaluation.**

## CLOSING REMARKS

After reviewing the available evidence, the committee determined that there is a need for an FOP symbol system designed to encourage consumers to make healthier food choices and that a single, simple FOP symbol system, aligned with current dietary guidance and consistently applied across food product categories, would be most useful to achieving that goal.

# 1

# Introduction

Over the past decade, tremendous growth has occurred in the use of nutrition rating systems and symbols designed to summarize the key nutritional aspects and characteristics of food products. These symbols and the systems that underlie them have become known as front-of-package (FOP) nutrition rating systems, even though the symbols or ratings themselves can be found anywhere on the front of a food package or on a retail shelf tag. The systems are part of a constellation of efforts targeted at encouraging healthier consumer food choices. However, the proliferation of various FOP systems with different nutrition criteria by manufacturers, retailers, health organizations, and others with the intention of helping consumers make healthier choices, or of enhancing marketing/sales, along with other packaging attributes, may have contributed to consumer confusion. In addition, despite this proliferation of FOP systems, there is little evidence to indicate that they have contributed positively to consumer food choices or purchase behaviors.

The Nutrition Labeling and Education Act of 1990 (NLEA) requires that manufacturers of most packaged food products regulated by the U.S. Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services disclose certain nutrition information on a standardized nutrition label, the Nutrition Facts panel (NFP), usually on the back or side of the package. The NLEA does not apply to meat and poultry products regulated by the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA), but parallel regulations, to the extent possible, exist for these products (see Chapter 3).

Although inconsistent in format, content, and criteria, current FOP systems and symbols have the potential to provide useful guidance to consumers as well as to maximize their effectiveness in reaching consumers. Consequently, FDA and USDA have undertaken consumer research to identify an FOP nutrition label that is "driven by sound nutrition criteria, consumer research, and design expertise."[1] 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."

In fiscal year (FY) 2009 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 FOP nutrition

[1] 75 FR 22602.

**BOX 1-1**
**Statements of Task for Phase I and II**

The committee was charged with the following tasks:

Phase I

- 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 nutrition 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 (to be executed as a separate activity) that would consider the potential benefits of a single, standardized front-of-package food guidance system regulated by the Food and Drug Administration and would develop conclusions about which system(s) are most effective in promoting health and how to maximize the use and effectiveness of the system(s).

Phase II

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

rating systems and symbols.[2] In FY 2010, Congress directed CDC to continue the study,[3] for which FDA and later the USDA Center for Nutrition Policy and Promotion provided support.

An ad hoc committee was convened to review systems being used in the United States and abroad and to determine advantages and disadvantages of various approaches as well as the potential benefits of a single, standardized, front-label food guidance system regulated by FDA. The study was conducted in two phases. Phase I focused primarily on the nutrition criteria underlying FOP systems. Phase II, the subject of this report, built on the results of Phase I while focusing on the aspects of consumer understanding and behavior related to the development of a standardized FOP system. Box 1-1 shows the statement of task for both Phases I and II.

The Phase I and II committees reviewed information on packages as well as on shelf tags, and the use of the term FOP symbol systems throughout this report encompasses both methods of conveying information. In addition, for the purposes of this report, the broad statement "making healthier choices" refers to consumers' meeting guidelines of qualifying criteria for saturated and *trans* fats, sodium, and added sugars. The committee's adopted definitions for common terms used throughout the report are provided in Appendix A. This chapter will review the main findings and conclusions from the Phase I report and describe the study goals and process for this report.

[2] Omnibus Appropriations Act, 2009. Division F—Labor, Health and Human Services and Education, and Related Agencies Appropriations Act, 2009 on Public Law No. 111-8, House Appropriations Committee Print, p. 1398.

[3] Consolidated Appropriations Act, 2010. Division D—Departments of Labor, Health and Human Services, and Education, and Related Agencies. Appropriations Act, 2010 on Public Law 111-17. House Conference Report 111-366, p. 1021.

## SUMMARY OF PHASE I REPORT

### Approach to the Study

For its approach to meeting the Phase I goals, the Phase I committee developed four guiding principles to assist in identifying systems and their elements most important to improving the health of the American people and the nutritional criteria that could be realistically implemented. The four guiding principles were as follows:

- A well-balanced, high-quality diet consistent with the recommendations of the 2010 *Dietary Guidelines for Americans* is essential for the health of Americans, and FOP labeling is one tool among many geared toward helping Americans make healthy choices. Other such tools include MyPyramid,[4] the NFP, and health and nutrient content claims.
- FOP 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 NFP.
- FOP systems will apply to as many foods as possible.

The committee identified 20 systems, representative of those already in the marketplace (described in the Phase I report). These systems were grouped into three broad categories based on general characteristics:

- **Nutrient-specific systems** display the amount per serving of selected nutrients from the NFP or use symbols based on claim criteria;
- **Summary indicator systems** use a single symbol, icon, or score to provide summary information about the nutrient content of the product in the package; and
- **Food group information systems** use symbols awarded to a product based on the presence of a certain food group or ingredient.

Although the systems used different criteria to rate foods, their primary purpose was to provide consumers with easy-to-use information that would help them to quickly determine if a food was a healthier choice and to compare foods in a category.

### Findings and Conclusions from Phase I

The Phase I report presented the following two findings regarding the nutrient and diet-related health concerns that FOP systems should target (Box 1-2), which strongly shaped this report:

1. Obesity, cardiovascular disease, type 2 diabetes, and certain types of cancers are the health risks affecting the greatest number of Americans that are most strongly associated with diet, and
2. Americans consume too many calories, saturated and *trans* fats, and added sugars; too much sodium; and too little vitamin D,[5] calcium, potassium, and fiber.

These findings are consistent with the two overarching concepts of the 2010 *Dietary Guidelines for Americans* (USDA, 2010), that is, maintaining calorie balance to achieve a healthy weight while focusing on consuming nutrient-dense foods and beverages, and informed the committee's identification of the FOP system options, consideration of the potential benefits of a single, standardized FOP system, and conclusions about the systems and icons that best promote human health.

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[4] MyPlate replaces MyPyramid as the primary federal government food group symbol and directs consumers to the ChooseMyPlate.gov website to learn how to apply the *Dietary Guidelines*.

[5] A subsequent IOM report, *Dietary Reference Intakes for Calcium and Vitamin D* (IOM, 2011), on vitamin D concluded that vitamin D intake in Americans is not deficient.

**BOX 1-2**
**Obesity and Diet-Related Health Concerns in America**

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). Although obesity is far from a new problem in our nation, its increased prevalence over recent decades and its subsequent negative impacts on rates of chronic disease and premature death and health care costs make its reduction a national health priority for the 21st century. The prevalance of obesity, defined in adults as a body mass index (BMI) greater than or equal to 30, doubled 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 25.0-29.9) have remained fairly constant over the past 30 years, but the increased rates of those classified as obese, and the shift of those classified as healthy to overweight, 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 percentile cut points from the 2000 Centers for Disease Control and Prevention (CDC) Growth Charts, has also recently leveled off after several decades of increase, but 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 comorbidities. Comorbidities 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 (NIH, 2004). In 2006 three of the most prevalent comorbidities, 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).

The committee reached the following conclusions regarding the nutrition science underlying its review of FOP systems:

1. FOP rating systems and symbols would be best geared toward the general population.
2. Consistent with FDA's goals and purposes for FOP systems announced in April 2010, the most useful primary purpose of FOP rating systems would be to help consumers identify and select foods by providing information about the nutrients most strongly linked to public health concerns for Americans.
3. Regardless of system type, it would be useful to prominently declare calorie and serving size information with FOP symbols.
4. The most critical nutritional components to include in FOP nutrition rating systems are calories, saturated fat and *trans* fats, and sodium.
5. There is insufficient evidence at this time to suggest that inclusion of the following nutrients in all types of FOP systems would be useful: total fat, cholesterol, total carbohydrate, total or added sugars, protein, fiber, vitamins, and minerals other than sodium.
6. 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's decision to not include positive nutrients in FOP systems was based on several reasons including (1) the lack of an identified critical public health need, (2) concerns about over-fortification, (3) limited space for FOP symbols on food packages, and (4) the use of nutrient content claims (e.g., good source of calcium) to call attention to specific products. Lastly, vitamins, minerals, and fiber, for which there is a public health need to increase intake, tend to be food-category specific (e.g., calcium in dairy products and fiber in legumes and whole grains), which complicates the development of nutritional criteria.

## STATEMENT OF TASK AND GUIDING PRICIPLES FOR PHASE II

The second phase of *Examination of Front-of-Package Nutrition Rating Systems and Symbols* draws on the work completed in the first phase and considers the potential benefits of a single, standardized FOP symbol system regulated by the FDA. For this second phase of the study, the CDC, with additional support from the FDA and the Center for Nutrition Policy and Promotion (CNPP) of the USDA, requested the IOM Phase II committee to:

- Consider the potential benefits of a single, standardized front-label food guidance system regulated by the FDA,
- Assess which icons are most effective with consumer audiences, and
- Develop conclusions about the systems and icons that best promote health and how to maximize their use.

## APPROACH TO THE PHASE II TASK

Using the Phase I guiding principles, findings, and conclusions as a baseline, the committee turned its focus to assessment of consumer use and understanding of FOP symbols. The Phase I findings about diet-related health concerns, including obesity and related chronic diseases, and food consumption patterns served to underpin the committee's understanding of the effectiveness of FOP systems and symbols relative to consumer behavior.

The Phase I committee concluded that added sugars should not be a component of an FOP nutrition rating system because of insufficient evidence about the contribution of added sugars beyond calories to the most pressing diet-related health concerns among Americans, the inability to distinguish analytically between added and naturally occurring sugars in foods without obtaining proprietary product information and including that information on the NFP, and the relatively small number of food categories with high amounts of added sugars.

This committee reconsidered the Phase I conclusions in light of events occurring after the release of the Phase I report, specifically the release of the 2010 *Dietary Guidelines for Americans* and the development of an approach to evaluating added sugars content. The 2010 *Dietary Guidelines for Americans*, which is the federal government's nutrition policy document, strongly recommends reducing intakes of calories from added sugars and consumption of foods containing added sugars. The committee also determined that failure to address added sugars would result in major contributors of added sugars to diets, such as sugar-sweetened beverages, erroneously appearing to be "healthful" because they are low in saturated and *trans* fats and sodium (see Chapter 7 for details).

The committee conducted a comprehensive review of peer-reviewed published evidence, as well as of non-peer reviewed evidence submitted by industry and government and non-government stakeholders. The committee also reviewed commissioned data collection and analyses of the prevalence of FOP systems and package clutter (discussed in Chapter 6), information obtained from presentations made in a public workshop, and new evidence on consumer use of FOP labeling information at the point-of-purchase compared to the point of consumption. Consultants provided the committee with non-published evidence and assisted with creating examples of simple symbols that would convey clear meaning to consumers. The committee's process for reviewing evidence is further described in Appendix D.

In its reviews and analyses, the committee gave consideration to the multi-disciplinary approach needed to fairly and objectively assess the totality of the evidence. The range of disciplines considered included:

- Marketing and social marketing,
- Public health,

- Health literacy,
- Health communication,
- Nutrition science/nutrition education,
- Information processing,
- Visual/package design,
- Behavioral economics, and
- Nutrition labeling policy.

Finally, the committee considered the components necessary to the effective development, design, and testing of model FOP systems, recognizing that, at the current rate of technology proliferation, in the future there may be additional ways to convey information to help consumers make healthier choices.

## ORGANIZATION OF THE REPORT

The report is organized into nine chapters. This chapter provides background for the study, summarizes the Phase I conclusions, and describes the committee's task and approach. Chapters 2 and 3 describe FOP food package labeling and the regulatory environment for FOP labeling, respectively. Chapter 4 examines consumer use of FOP systems, and Chapter 5 examines the evidence related to consumer understanding of FOP systems. Chapter 6 discusses the current food package environment, how consumers process food package information, and how this knowledge can be applied to designing an effective FOP nutrition labeling system. The characteristics of model FOP systems and an approach to developing criteria to evaluate saturated and *trans* fats, sodium, and added sugars in food and beverage products consistent with a successful FOP system are discussed in Chapter 7. Chapter 8 discusses the promotion of FOP labeling in the context of social marketing. Lastly, the committee's overall conclusions and recommendations are found in Chapter 9.

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# 2

# The Food Package Environment

## INTRODUCTION

The statement of task asks the committee to consider the potential benefits and effectiveness of a single, standardized front-of-package (FOP) symbol system. Any response to this task would be incomplete without considering the context in which such a system would be implemented. The committee identified two important contextual factors for this report, the food package environment and the regulatory environment. This chapter focuses on the food package environment, in particular the types and amount of information currently on food packages. By better understanding what consumers already encounter on food packages, insights can be gained into the requirements of an FOP nutrition rating system capable of achieving the goals of healthy consumer choices and population health benefits.

## FOOD PACKAGING

The basic functions of food packaging include protecting and preserving the product, providing consumers with product information, including ingredient and nutrient content, and marketing (Coles, 2003; Hawkes, 2010). The marketing function involves determining the structure of a package to make it easy to transport and display, easy for consumers to access and serve its contents, and distinctive in size, shape, or texture. It also includes exterior graphic design—using colors, typography, images, and messages to attract consumer attention and make the product and brand appealing to potential buyers (Teng, 1991; Nancarrow et al., 1998; Underwood et al., 2001). Understanding package design and its role in food marketing is critical to understanding the context in which an FOP nutrition rating system would be implemented.

## PACKAGE DESIGN

Package design is a $1 trillion industry (Horovitz, 2011). Even a small change in sales can mean the difference between profit and loss for many products, and packaging can influence consumer purchase decisions. When shopping for food, consumers face aisle after aisle of shelves filled with very similar products. Information from food industry reports and leaders indicates that consumers are spending less time on food shopping, making quick decisions at the shelf and placing great value on being able to get in and out of a store quickly (Park et al., 1989; Inman and Winer, 1998; IRI, 2009). Product packaging is designed to influence those decisions. It is the one aspect of marketing that is present at the moment of choice and reaches nearly all consumers who are purchasing from a given product category (Behaeghel, 1991; Peters, 1994). Effective package design helps products stand out amidst the competition for consumers' attention and conveys information about the qualities of the product and/or brand (Nancarrow et al., 1998; Underwood et al., 2001).

## PACKAGE INFORMATION

Food packages today contain a wide array of information, including branding, product images, product claims, and promotions (see Table 2-1). *Branding* seeks to build, reinforce, and convey a product's identity. Brands that are familiar, easily recognizable, and associated with positive attributes such as quality, value, health, or enjoyment generally have a competitive advantage over less recognizable brands (Aaker, 1991). On food packages, product images, names, slogans, symbols, logos, and licensed characters are all used to build, reinforce, or convey brand identity to consumers. Many packages also include *product images* or photographs that show the appearance of the food inside. *Product claims* include a wide range of messages, from descriptions of the product (e.g., "crispy toasted rice") or how it is made (e.g., "organic") to subjective evaluations (e.g., "delicious") and nutrition-related claims. Nutrition claims can be structure/function claims (e.g., "calcium builds strong bones"), nutrient content claims (e.g., "zero calories" or "good source of vitamin C"), or health claims (e.g., "While many factors affect heart

**TABLE 2-1** Selected Types of Information Commonly Found on Front of Food Packages

| Type | Description *(example)* |
|---|---|
| Branding | Name, logos, slogans, characters associated with brand |
| Product images | Photographs or illustrations of the product<br>*(e.g., bowl or spoonful of steaming soup)* |
| Product claims | |
| *Product description* | What is the product<br>*(e.g., non-dairy creamer)* |
| *Subjective evaluation* | Selected product attributes<br>*(e.g., now crunchier)* |
| *How product is made* | Process used in selecting ingredients, manufacturing, packaging<br>*(e.g., organic, eco-friendly, recycled paper)* |
| *Structure/function claims* | Linking a product ingredient to a known function in humans<br>*(e.g., calcium builds strong bones)* |
| *Nutrient content claims* | Characterizing the level of a nutrient listed in the Nutrition Facts panel<br>*(e.g., "low fat" or "reduced sugar")* |
| *Health claims* | Characterizing the relationship of a substance to a disease or health-related condition<br>*(e.g., "Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.")* |
| Promotions | |
| *Special offers* | Purchase of the product confers access to other benefits<br>*(e.g., instant savings coupon, $1 coupon inside)* |
| *Sponsorships* | Formal affiliation with an issue or organization<br>*(e.g., pink ribbons, official soft drink of...)* |
| *Partnerships* | Cross marketing with other products<br>*(e.g., characters from popular cartoons or movies)* |
| *Giveaways* | Package contents include free novelties<br>*(e.g., toys, games)* |

disease, diets low in saturated fats and cholesterol may reduce the risk of heart disease"). Chapter 3 of this report describes the regulatory criteria for making such claims. *Promotions* can include special offers (e.g., discounts, coupons), giveaways (e.g., toys, games), endorsements (e.g., from celebrities), partnerships (e.g., with professional sports leagues, hit movies), and sponsorships (e.g., of an event or for a cause) designed to increase product appeal to consumers. When evaluating the possible benefits of an FOP nutrition rating system, it is important to recognize that these other types of package information may also be present.

### Prevalence of Product Claims and Other Information on Food Packages

Data collected periodically by the U.S. Food and Drug Administration (FDA) through the Food Label and Package Survey[1] (FLAPS) indicate that the use of product claims on food packages is widespread. This recurring survey collects data on processed, packaged food labels in the U.S. food supply and monitors the food industry's response to FDA labeling regulations. The most recent FLAPS (2006-2007) included a representative sample of 1,227 products from 57 product groups (e.g., baby food, beverages, bread), with the number of sampled products within a group set in proportion to sales for that group. An analysis of the data in aggregate revealed that more than half of product packages (53.2 percent) included nutrient content claims, the majority of which focused on fat (22.4 percent), calories (10.3 percent), or sodium (7.5 percent) (Brandt et al., 2010).

Within a food category, particularly breakfast cereals, the use of certain types of package information and product claims occurs with greater frequency than others. To illustrate, a study by Page et al. (2008), discussed in detail below, found that nearly all cereal packages studied (93 percent) contained a picture of the product, 81 percent included health or nutrient content claims, and 64 percent included other product claims. In addition, half of the products reviewed included cartoon characters, and 30 percent included images of other merchandise or toys on the package.

### Amount of Information on Packages

The committee considered not only the variety of packaging information, but also the total amount of information on a package. Data sought by the committee and provided by consultants included an examination of the number of promotions and product, health, and ingredient claims on the packages of 20 top-selling brands of crackers, yogurt, and frozen pizza in the United States. The average package of yogurt contained 5.4 instances of such information, followed by crackers (3.0), and frozen pizza (1.6). Cumulatively, these types of package marketing accounted for 12.7 percent of package surface area. By comparison, FOP nutrition symbols on these products accounted for 2-3 percent of surface area. The study did not count or measure instances of branding or product images appearing on the packages.

In a study of cereal packages aimed to appeal to children, Page et al. (2008) conducted a content analysis of 122 cereal packages available in the United States and created an index of total package promotions that summed across the different promotion strategies measured. Applying this index to the total package surface area, the investigators were able to identify an average of 6.4 promotions per cereal package. The FLAPS study and its data analysis and the data submitted to the committee together describe a significant amount of information on food packages that contributes to an overall "busy" food package environment.

### Nutritional Quality of Foods Bearing Product Claims and Promotions

The committee also identified evidence suggesting that a high percentage of food products bearing nutrition claims and other product information used in marketing are likely to be high in undesirable nutrients such as saturated and *trans* fats, sodium, and added sugars. Findings from these studies do not suggest that product packaging includes false claims that are in violation of food labeling regulations (see Chapter 3), rather that many packages containing foods high in undesirable nutrients include *other* claims about positive nutrient-related characteristics of

[1] Available online: http://www.fda.gov/Food/LabelingNutrition/ConsumerInformation/ucm122084.htm (accessed July 19, 2011).

the product. In other words, the package of a food high in fat would not claim it is low in fat, but might highlight that it is high in vitamin A.

In one example, a community-wide study reviewed all packaged food products (n = 56,900) in six grocery stores in a small Midwestern city to ascertain the prevalence of four types of claims—statements of fact, structure/function claims, nutrient content claims, and health claims—and to determine the frequency of such claims on food products high in saturated fat, sodium, and sugars. Nearly half (49 percent) of all food products in the stores used nutrition claims in marketing. Nutrient content claims were most common, appearing on 76 percent of packages that contained nutrition claims. Among those products that used nutrition claims in marketing, about half (48 percent) were found to be high in saturated fats or sodium (based on the standard of >20 percent Daily Value (%DV) per serving from the Nutrition Facts panel) or sugar (based on standards for sugars developed by Colby et al., 2010). In total 23 percent of all products contained nutrition marketing and were also high in saturated fats, sodium, and/or sugars (Colby et al., 2010).

In a web-based analysis, Schwartz et al. (2008) examined differences in nutritional quality of cereals marketed to children, defined as having a licensed character, television or movie theme, or other child-oriented promotion on the package, compared to cereals not marketed to children. The cereals were also analyzed for nutrient content claims and health claims. Data analysis showed that cereals marketed to children were not significantly different from those not marketed to children for saturated fat, sugar, or cholesterol per serving, as reported on the Nutrition Facts panel. However on a per gram basis, cereals marketed to children were significantly higher in energy, sodium, carbohydrate, and sugar and significantly lower in fiber and protein compared to cereals not marketed to children. When the overall nutritional quality of cereals bearing nutrient content claims or health claims was compared to those without claims, there was no difference for fat, sodium, fiber, or energy. In other words, the presence or absence of nutrient content claims and health claims did not distinguish between cereals of greater and lesser nutritional quality, suggesting that such information might not be especially useful to consumers trying to make a choice on the basis of these claims.

In Australia, Chapman et al. (2006) examined two product promotion strategies—premium offers (e.g., giveaways, competitions) and cartoon and movie character promotions—on food packages in seven categories targeted to children. This study found that these marketing strategies were used on a range of 9 to 35 percent of packages across the seven categories. Additionally, three-quarters of all promotions involved cartoon or movie characters, and the promotions were more likely to appear on less healthy food products. These results suggest that products bearing promotions, particularly those aimed at children, are likely to have a poor nutritional profile.

## Value-Based Labeling

New types of package labeling are also coming into the marketplace. The most common of these is "value-based labeling," a marketing strategy that positions products as satisfying consumer concerns about social, environmental, or food safety issues (Basu and Hicks, 2008) and reflects industry efforts to make changes that respond to these values. Labels for "fair trade" coffee or "dolphin-safe" tuna, for foods that are "organic," "locally grown," "free-range," or "farm-raised," and for packaging materials that are "recycled" or "biodegradable" are all examples of value-based labeling used on food packages (De Pelsmacker et al., 2005; Anders and Moser, 2008; Hustvedt et al., 2008; Jacquet and Pauly, 2008; McEachern and Warnaby, 2008; Carlsson et al., 2010). "Eco-labeling" is one of the fastest-growing segments of value-based marketing. In the 1990s there were only a handful of eco-labeling programs worldwide; today there are more than 415, including 78 different "green" labels for food products alone (Woolverton and Dimitri, 2010). In 1995, 23 states had programs for branding and promoting agricultural products, e.g., "locally grown"; by 2006, 43 states had such programs (Patterson, 2006). Consumer understanding of these terms and labels is generally low, and studies suggest that the growing number of eco-labeling programs may contribute to consumer misunderstanding and misinterpretation of labeled products (Conner and Christy, 2004; Henryks and Pearson, 2010).

To be effective, FOP nutrition labels must compete in a very busy and ever changing package environment with an array of messages designed to capture consumer attention and promote products. When present, FOP symbols account for a very small proportion of package surface area relative to other food package marketing icons, promotions, and images and may have the most "competition" from the least healthy products. Moreover, food packages frequently include nutrition-related claims that might be seen by consumers as suggesting positive nutritional value despite information provided in an FOP symbol system that shows high levels of saturated fat, sodium, added sugars, or calories. Such a package environment could weaken the impact of an FOP nutrition rating system intended to guide consumers toward healthier food choices.

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# 3

# The Regulatory Environment

As discussed in Chapter 2, food labels contain a wide array of information and are used to capture consumers' attention and promote products. The federal government's responsibility is to see that the information on food labels is not false or misleading and that labels contain information that is material with respect to consequences that may result from consumption of the food.[1] To accomplish this, both the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) and the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) have established regulations concerning mandatory labeling components. In addition, the Federal Trade Commission (FTC) has jurisdiction over advertising and takes action to prohibit unfair and deceptive practices.

## MANDATORY LABELING COMPONENTS

### Foods Regulated by the Food and Drug Administration

The Federal Food, Drug, and Cosmetic Act[2] (FD&C Act) governs the labeling of foods regulated by FDA (see Agency Jurisdiction Over Labeling, below). The FD&C Act mandates the inclusion of certain information on labels of packaged foods to promote honesty and fair dealing in the interest of consumers. The mandatory components include the common or usual name of the food (i.e., the statement of identity); the common or usual name of each ingredient when the food is fabricated from two or more ingredients; the name and place of business of the manufacturer, packer, or distributor; an accurate statement of the quantity of contents in terms of weight, measure, or numerical count; allergen information; and nutrition information.[3] The FD&C Act specifies that the nutrition information must include the serving size that is appropriate for the food; the number of servings per container; the total number of calories; and the amounts of total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, protein, and any vitamin and mineral when such information is determined to assist consumers in maintaining healthy dietary practices.[4] The act then provides for nutrients to be added or deleted when such actions are determined to assist consumers in maintaining such practices. Required

[1] FD&C Act, Sec. 201 and 403.
[2] FD&C Act, Sec. 403.
[3] FD&C Act, Sec. 403.
[4] FD&C Act, Sec. 403(q).

nutrition information for foods sold from bulk containers should be available at the point of purchase,[5] and vendors of raw fruit, vegetables, and fish can utilize a voluntary nutrition labeling program.[6]

The Food Allergen Labeling and Consumer Protection Act of 2004 amended the FD&C Act to help consumers avoid health risks posed by food allergens.[7] To do this, the act requires labels of FDA-regulated foods to clearly identify the food source names of all ingredients that are, or contain any protein derived from, the eight most common food allergens,[8] i.e., milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans. A label meets this requirement when the common or usual name of an ingredient that is a major allergen already identifies the allergen's food source (e.g., milk, in the case of condensed milk) or when it lists the name of the food source of a major allergen (1) in parentheses following the name of the ingredient (i.e., "flour (wheat)") or (2) immediately after or next to the list of ingredients in a "contains" statement (i.e., "Contains Milk and Eggs").[9]

In addition to the above mandatory labeling components for all foods, FDA regulations sometimes require label statements such as warnings, notices, or safe handling instructions for specific commodities. For example, shell eggs must bear the safe handling instruction "SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly."[10] Also, regulations of the USDA's Agricultural Marketing Service (AMS) require country-of-origin labeling on perishable agricultural commodities (fresh and frozen fruits and vegetables), fish and shellfish, macadamia nuts, pecans, peanuts, and ginseng when sold by full-line grocers (fish markets are exempt from this requirement).[11]

FDA's implementing regulations require that the common or usual name of the food be placed on the principal display panel, which is that part of the label that is most likely to be presented or examined under customary conditions of display for retail sale.[12] Likewise, the net weight (or other unit of measure) must be present on the principal display panel, specifically on the bottom 30 percent of the panel.[13] The remaining mandatory labeling components may be placed on either the principal display panel or the information panel, which is that part of the label immediately contiguous and to the right of the principal display panel.[14] When there is insufficient space on these two panels, regulations allow for some of the mandatory information to move to other panels.

### Foods Regulated by the Food Safety and Inspection Service, U.S. Department of Agriculture

FSIS is responsible for the labeling of meat, poultry, and some egg products under the authority of the Federal Meat Inspection Act (FMIA),[15] the Poultry Products Inspection Act (PPIA),[16] and the Egg Products Inspection Act (EPIA). These acts require inspection programs designed to insure that meat and poultry products are, among other things, properly labeled.[17] Retail package labels must include the components required for FDA-regulated foods, except for allergen information, and components specific to meat, poultry, or egg products.[18] Containers of federally inspected meat and poultry products must bear a USDA inspection legend (i.e., shield) and establishment or plant number.[19] The inspection legend must be placed on the principal display panel, while the establishment number may be placed within the legend or elsewhere on the container or its labeling (e.g., the lid of the can). Labels of meat and poultry products that require special handling to maintain their wholesome condition must

[5] FD&C Act, Sec. 403(q)(3); 21 CFR § 101.9(j)(16).
[6] FD&C Act, Sec. 403(q)(4); 21 CFR § 101.9(j)(10).
[7] Title 11, Public Law 108-282, Title II.
[8] FD&C Act, Sec 403(w), 21 USC § 343 et seq.
[9] Available online: http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm079311.htm (accessed February 25, 2011).
[10] 21 CFR § 101.17(h).
[11] 74 FR 2658 and avalable at: http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5074846 (accessed February 25, 2011).
[12] 21 CFR §101.1 and §101.2.
[13] 21 CFR §101.105.
[14] 21 CFR §101.2.
[15] 21 U.S.C. 601 *et seq.*
[16] 21 U.S.C. 451 *et seq.*
[17] 58 FR 632 at 634.
[18] 9 CFR 317 [meat] and 9 DFR 381 [poultry].
[19] 9 CFR § 317(c)(5) [meat] and 9 CFR § 381.123 [poultry].

**TABLE 3-1** Mandatory Labeling Components on Retail Packages

| | Foods Regulated by FSIS, USDA | |
|---|---|---|
| Foods Regulated by FDA | Meat and poultry products | Egg products |
| 1. Name of food | 1. Name of food | 1. Name of food |
| 2. Ingredient list | 2. Ingredient list | 2. Ingredient list |
| 3. Manufacturer, packer, or distributor's name and place of business | 3. Manufacturer, packer, or distributor's name and place of business | 3. Manufacturer, packer, or distributor's name and place of business |
| 4. Net weight statement | 4. Net weight statement | 4. Net weight statement |
| 5. Nutrition information | 5. Nutrition information | 5. Nutrition information |
| 6. Allergen information | 6. Inspection legend and establishment number | 6. USDA shield and plant number[a] |
| 7. Country of origin on specified imported products | 7. Handling statement | 7. Notice of required refrigeration on shell eggs |
| 8. Safe handling instructions on certain products | 8. Safe handling instructions on certain products | 8. USDA label approval number on egg products[a] |
| | 9. Country of origin on specified imported products | |

[a] Applies to egg products that go through the USDA inspection system.

also prominently display an applicable handling statement, such as "keep refrigerated" or "keep frozen" on the principal display panel.[20] In addition, safe handling instructions are required if the meat or poultry in a product is raw or only partially cooked and if the product is intended for household consumers or institutional users.[21] The safe handling instructions can be placed anywhere on the label but must be set off by a border and appear in one color type on a contrasting background of one color.

Similar to FDA regulations of country-of-origin labeling on specified food products, AMS regulations require muscle cuts of beef (including veal), lamb, pork, chicken, and goat, and ground products of the same species, to bear the name of the country of origin when sold by full-line grocers (butcher shops are exempt from the requirement).[22] Retailers are allowed a variety of options for marking containers, from labels to placards, signs, stickers, or other formats.

Labeling requirements for egg products are found in regulations of the FDA, FSIS, and AMS. In addition to the five basic mandatory labeling components set forth for FDA-regulated foods, egg products that go through the USDA inspection system are required to include an official USDA shield on the principal display panel. The official plant number of the egg processing plant where inspection took place must be printed within the shield or elsewhere on the container preceded by the letter "P" or the word "Plant."[23] Shell eggs must be labeled to indicate that refrigeration is required, e.g., "Keep Refrigerated,"[24] and FSIS-regulated products that require premarket label approval must display the label approval number.[25] Table 3-1 identifies the mandatory labeling components for food products regulated by FDA, FSIS, and USDA.

## AGENCY JURISDICTION OVER LABELING

As a general rule, FSIS has jurisdictional authority over food labeling for meat, poultry, and egg products and FDA for all other food products. However, the FMIA, PPIA, and EPIA authorize USDA (by delegation, FSIS) to

[20] 9 CFR § 317.2(k) [meat] and 9 CFR § 381.125(a) [poultry].
[21] 9 CFR § 317.2(l) [meat] and 9 CFR § 381.125(b) [poultry].
[22] 74 FR 2658 and available online: http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5074846 (accessed February 25, 2011).
[23] 9 CFR § 590.412.
[24] 9 CFR § 590.410.
[25] Available online: www.fsis.usda.gov/pdf/Labeling_Requirements_Guide.pdf (accessed February 25, 2011).

exempt from its regulatory coverage food products that contain meat, poultry, or egg products "only in a relative small proportion or historically have not been considered by consumers as products of the meat/poultry/egg food industry."[26] As a result, USDA has determined that food products are not subject to FSIS inspection and labeling regulations if, in part, they contain 3 percent or less raw meat; less than 2 percent cooked meat or poultry; or less than 10 percent cooked poultry skins, giblets, fat, and meat in combination (FSIS, 2007). Decisions about the jurisdictional coverage (i.e., "amenability") are based on how a food is formulated rather than on the composition of the final product. The end result is a complex system by which regulatory authority for labeling is determined. Lines between regulatory authority for FDA and FSIS can be complicated; for example, FDA is responsible for labeling of cheese and vegetarian pizzas, while FSIS is responsible for meat pizzas; likewise FDA is responsible for labeling of closed-faced sandwiches, FSIS, for open-faced sandwiches. These and other examples are summarized in Table 3-2 outlining the jurisdictional overlap for labeling of meat, poultry, and egg products (FDA, 2010).[27]

## ADDITIONAL COMPONENTS OF NUTRITION LABELING

### Background

Mandatory inclusion of the Nutrition Facts panel (NFP) on labels of most packaged foods represents only a portion of the possible nutrition-related components on food labels that fall under federal jurisdiction. Other forms of nutrition labeling ascribed to FDA-regulated food products in the FD&C Act include nutrient content claims, health claims, and the voluntary nutrition labeling program provided for raw fruits, vegetables, and fish.[28] In addition, FDA allows the use of structure/function claims and dietary guidance statements. These regulations apply to claims made on both food labels and labeling (i.e., information made available in close proximity to the food item, such as shelf tags).

A historical review of nutrition labeling was included in the Phase I report (IOM, 2010) and is found in Appendix B of this report. It describes the proliferation of nutrition-related claims used in food labeling in the 1970s and 1980s as scientific knowledge about the relationship between diet and health grew rapidly and, with it, consumers' interest in more information about the nutritional content of foods. Many of the claims being made were new and undefined, creating consumer confusion about their meanings. To respond to growing concerns, Congress included in the Nutrition Labeling and Education Act of 1990 (NLEA), which amended the FD&C Act, a requirement that claims that characterize the level of a nutrient, i.e., nutrient content claims, may only be made if they use terms that are defined in regulations promulgated by FDA[29] (see Appendix C for a list of nutrient content claims defined by FDA). Congress also required that if a claim is made on a food that contains another nutrient at a level that increases the risk of a diet-related disease or health condition then that fact must be disclosed adjacent to the claim by the statement "See nutrition information for ___ content" with the blank filled in with the name of the nutrient.[30]

In addition to nutrient content claims, some food manufacturers were interested in making claims about the health benefits of food products. However, at that time FDA's regulations prohibited such claims on food labeling, stating that a food would be considered 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."[31] In 1984, FDA's position was challenged by the Kellogg Company when it worked cooperatively with the National Cancer Institute to begin 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 some cancers. Soon after, other companies began making similar claims, and FDA was faced with the need to reconsider its policies. In response, FDA initiated rulemaking to change its policy by permitting health claims to be made

[26] 21 U.S.C. § 601(j) [meat], 21 U.S.C. § 453(f) [poultry], and 21 U.S.C. § 1033(f) [egg].
[27] Available online: http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM123506.pdf (accessed February 27, 2011).
[28] FD&C Act, Sec. 403(q) and (r).
[29] FD&C Act, Sec. 403(r)(2)
[30] FD&C Act, Sec. 403(r)(2)(B); 21 CFR § 101.13(h).
[31] 21 CFR § 101.9(i), prior to 1993.

under specified conditions, and Congressional hearings were held. The issues were not settled until Congress included provisions in the NLEA to authorize health claims, defined as claims characterizing the relationship of a nutrient to a disease or health-related condition, if the Secretary (and, by delegation, FDA) determined "based on the totality of publicly available scientific evidence … that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence."[32] Although FDA issued regulations providing for health claims that met this "significant scientific agreement" standard, reaching such agreement about additional diet and health relationships proved difficult (Taylor and Wilkening, 2008). In an effort to provide for more health claims, Congress expanded on the "significant scientific agreement" standard in 1997 to allow for health claims based on "authoritative statements" about the relationship between a nutrient and a disease or health-related condition made by certain other scientific bodies of the U.S. government and the National Academy of Sciences.[33]

FDA was subsequently petitioned to allow additional health claims. When the agency denied petitions on the grounds that the claims did not meet the significant scientific agreement standard and were not based on an authoritative statement, a lawsuit claiming that the denial impaired the petitioner's First Amendment rights was filed.[34] The issue was whether the government could prohibit speech about a diet/disease relationship if the basis for the speech does not meet the standard of significant scientific agreement. In its decision, the Court affirmed the First Amendment's protection of commercial speech and hence the need for FDA to provide for additional health claims based on less scientific evidence as long as the claims do not mislead consumers, thereby allowing claims that are accompanied by "qualifying" language to inform consumers about the relative strength of the science[35] (McColl and Bump, 2005). FDA began to consider such claims, known as "qualified health claims," in 2003.[36]

As noted above, other types of nutrition-related statements that are allowed on labels of FDA-regulated foods include (1) structure/function claims that describe the effect that a nutrient or dietary ingredient has on the structure or function of the body but do not make reference to a disease (e.g., calcium builds strong bones and teeth)[37] and (2) dietary guidance statements that focus on general dietary recommendations and practices[38] (e.g., "Fruits and Veggies—More Matters," the National Cancer Institute's initiative to encourage greater consumption of fruits and vegetables for better health[39]). These two types of label statements may be made without prior authorization from FDA but must be truthful and non-misleading.

In addition to claims, the FD&C Act addresses labeling of raw commodities and fish through a voluntary nutrition labeling program for the 20 most frequently consumed raw fruits, vegetables, and fish.[40] The act required FDA to establish guidelines for the voluntary program and then to periodically survey food retailers to see if they are in substantial compliance with the guidelines. If there is not substantial compliance, then FDA is to initiate rulemaking to make such labeling mandatory. In accordance with the act, FDA established guidelines, identified the 20 most frequently consumed fruits, the 20 most frequently consumed vegetables, and the 20 most frequently consumed fish[41] and provided food retailers with the nutrient values to be used in the nutrition labeling of those food items.[42] The required nutrition labeling information can be provided to consumers in a variety of ways. The

[32] FD&C Act, Sec. 403(r)(3).
[33] FD&C Act, Sec. 403(r)(3)(C) .
[34] *Pearson v. Shalala*, United States District Court of Appeals for the District of Columbia, No. 98-053 (January 15, 1999).
[35] 67 FR 78002, December 20, 2002.
[36] Available online: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm053843.htm (accessed August 30, 2011).
[37] Available online: http://www.fda.gov/Food/LabelingNutrition/LabelClaims/StructureFunctionClaims/default.htm (accessed August 30, 2011).
[38] Available online: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm053425.htm (accessed August 30.2011).
[39] Available online: http://www.fruitsandveggiesmatter.gov (accessed September 1, 2011).
[40] FD&C Act, Sec. 403(q)(4).
[41] 21 CFR § 101.42-§ 101.45.
[42] 21 CFR § 101, Appendix C.

**TABLE 3-2** Summary of Jurisdiction Overlap for Commercial Products Regulated by the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA)

| FDA Jurisdiction | USDA Jurisdiction | USDA Jurisdiction | USDA Jurisdiction |
|---|---|---|---|
| 21 U.S.C. 392(b) Meats and meat food products shall be exempt from the provisions of this Act to the extent of the application or the extension thereto of the Meat Inspection Act. FDA responsible for all non-specified red meats (bison, rabbit, game animals, zoo animals, and all members of the deer family including elk [wapiti] and moose). FDA responsible for all non-specified birds, including wild turkeys, wild ducks, and geese. | The Federal Meat Inspection Act (FMIA) regulates the inspection of the following amenable species: cattle, sheep, swine, goats, horses, mules, or other equines, including their carcasses and parts. It also covers any additional species of livestock that the Secretary of Agriculture considers appropriate. Mandatory inspection of Ratites and Squab (including emu) announced by USDA/FSIS April 2001. | The Poultry Products Inspection Act (PPIA) defines the term poultry as any domesticated bird. USDA has interpreted this to include domestic chickens, turkeys, ducks, geese, and guineas. The PPIA states poultry and poultry products shall be exempt from the provisions of the FD&C Act to the extent they are covered by the PPIA. Mandatory inspection of Ratites and Squab announced by USDA/FSIS April 2001. | The Egg Products Inspection Act (EPIA) defines egg to mean the shell egg of domesticated chicken, turkey, duck, goose, or guinea. Voluntary grading of shell eggs is done under USDA supervision. (FDA enforces labels/labeling of shell eggs; USDA signs off on shell egg labels often in consultation with FDA.) |
| Products with 3% or less raw meat; less than 2% cooked meat or other portions of the carcass; or less than 30% fat, tallow, or meat extract, alone or in combination. | Products containing greater than 3% raw meat, 2% or more cooked meat or other portions or the carcass; or 30% or more fat, tallow, or meat extract, alone or in combination.[a] | Products containing 2% or more cooked poultry; more than 10% cooked poultry skins, giblets, fat, and poultry meat in any combination.[a] | Egg products processing plants (egg breaking and pasteurizing operations) are under USDA jurisdiction. |
| Products containing less than 2% cooked poultry meat; less than 10% cooked poultry skins, giblets, fat, and poultry meat (limited to less than 2%) in any combination.[a] | | | |
| Closed-face sandwiches. | Open-faced sandwiches. | | |

| | | | |
|---|---|---|---|
| FDA is responsible for shell eggs and egg-containing products that do not meet USDA's definition of "egg product." FDA also has jurisdiction in establishments not covered by USDA; e.g., restaurants, bakeries, cake mix plants, etc.<br><br>Egg processing plants (egg washing, sorting, and packing) are under FDA jurisdiction. | | | Products that meet USDA's definition of "egg product" are under USDA jurisdiction. The definition includes dried, frozen, or liquid eggs, with or without added ingredients, but mentions many exceptions. The following products, among others, are exempted as not being egg products: freeze-dried products, imitation egg products, egg substitutes, dietary foods, dried no-bake custard mixes, egg nog mixes, acidic dressings, noodles, milk and egg dip, cake mixes, French toast, sandwiches containing eggs or egg products, and balut and other similar ethnic delicacies. Products that do not fall under the definition, such as egg substitutes and cooked products, are under FDA jurisdiction. |
| Cheese pizza, onion and mushroom pizza, meat-flavored spaghetti sauce (less than 3% red meat), meat-flavored spaghetti sauce with mushrooms (2% meat), pork and beans, sliced egg sandwich (closed-face), frozen fish dinner, rabbit stew, shrimp-flavored instant noodles, venison jerky, buffalo burgers, alligator nuggets, noodle soup chicken flavor. | Pepperoni pizza, meat-lovers stuffed crust pizza, meat sauces (3% red meat or more), spaghetti sauce with meat balls, open-faced roast beef sandwich, hot dogs, corn dogs, beef/vegetable pot pie. | Chicken sandwich (open face), chicken noodle soup. | |

NOTE: Jurisdiction for products produced under the School Lunch Program, for military use, etc. is determined via the same algorithm although the purchases are made under strict specifications so that the burden of compliance falls on the contractor. Compliance Policy Guide 565.100, 567.200, and 567.300 provide additional examples of jurisdiction. IOM 3.2.1 and 2.7.1 provide more information on our interactions with USDA and Detention Authority.

[a] Percentages are based on the amount of meat or poultry product used in the product formulation.

SOURCE: U.S. Food and Drug Administration.

information can be displayed at the point of purchase through labeling, such as posters, shelf tags, signs, brochures, notebooks, or leaflets, or on labels affixed to the food.[43]

As noted in Appendix B, although the FD&C Act pertains only to FDA-regulated food products, FSIS made the decision to apply requirements for nutrition labeling to meat and poultry products it regulates so that all foods would provide consistent nutrition information to the extent possible (McCutcheon, 1995). Accordingly, FSIS has issued regulations that require similar nutrition labeling on meat and poultry products and provides for nutrient content claims in a similar manner.[44] However, FSIS has not issued regulations for the use of health claims, although it permits claims that have been authorized by FDA or that are in accordance with a third-party certification program to be used on a case-by-case basis.[45]

In keeping with statutory requirements for the voluntary nutrition labeling program for raw commodities and fish, FSIS issued regulations for a voluntary nutrition labeling program for single-ingredient raw meat and poultry products, including single-ingredient, raw, ground or chopped products.[46] In accordance with provisions of the FD&C Act, these regulations required periodic surveys of food retailers to see if they were in substantial compliance with the voluntary program. When FSIS failed to find significant participation in the voluntary nutrition labeling program, it became obligated to institute rulemaking to require such labeling. In response, FSIS issued final regulations on December 29, 2010, requiring nutrition labeling of the major cuts of single-ingredient raw meat and poultry products and single-ingredient, raw, ground, or chopped products. In the case of major cuts of raw meat and poultry that are not ground or chopped, the required nutrition information may be provided on the label or at point of purchase.[47]

### Front-of-Package Symbols in Conjunction with Claims

Although front-of-package (FOP) rating systems and symbols were not envisioned in 1990 when the NLEA was passed, some of the current programs (see Phase I report, Table S-1) bear similarities to nutrient content and health claims as defined in that act.[48] Acknowledging this, FDA issued guidance for industry in 2008 pointing out that "FDA will proceed with enforcement action against products that bear FOP labeling that are explicit or implied nutrient content claims and that are not consistent with current nutrient content claim requirements."[49] As noted above, nutrient content claims are defined as "claims that characterize the level of a nutrient," and they must be defined in regulations in order to be used. Such claims can be made expressly or implicitly. An expressed nutrient content claim is a direct statement about the level of a nutrient, whereas an implicit claim is one that describes the food in a manner that suggests that a nutrient is present or absent in a certain amount (e.g., "high in oat bran" suggests that the food is high in fiber). Accordingly, when an FOP symbol is used that meets the definition of a nutrient content claim, it must meet all requirements for such claims, including disclosure statements if the food exceeds disclosure levels (more than 20 percent of the Daily Value for individual foods) for total fat, saturated fat, cholesterol, or sodium.

In addition to nutrient content claims, some FOP symbols may be considered to be health claims. As stated above, a health claim is any claim that expressly or by implication characterizes the relationship of any substance to a disease or health condition. This includes third-party endorsements, symbols, and vignettes. As such, the American Heart Association's Heart Check[50] symbol is considered to be a health claim in that its heart shape characterizes the relationship between the food whose label it is on and heart disease. Unlike food labels that must

[43] 21 CFR § 101.45.

[44] 58 FR 632, January 6, 1993.

[45] 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 August 31, 2011).

[46] 58 FR 632, January 6, 1993.

[47] 75 FR 82148, December 29, 2010.

[48] Available online: http://www.regulations.gov/search/Regs/home.html#documentDetail?R=09000064809623e8 (accessed July 3, 2011).

[49] Available online: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm120274.htm (accessed August 30, 2011).

[50] Heart Check Mark is a registered trademark of the American Heart Association.

include disclosure statements if they bear nutrient content claims and contain more than 20 percent of the Daily Value for total fat, saturated fat, cholesterol, or sodium, foods are disqualified from bearing health claims if they contain those same levels (known as disqualifying levels in the case of health claims) of total fat, saturated fat, cholesterol, or sodium.[51]

## REGULATORY ACTIONS REGARDING FRONT-OF-PACKAGE NUTRITION RATING SYSTEMS

In response to actions taken by food manufacturers and retailers to include symbols that indicate nutritional quality on the label or labeling of a food, FDA held a public hearing in 2007 to solicit information about the systems being used, the nutrient thresholds or algorithms used to determine which foods carry the symbol, and consumer and economic issues concerning use of the symbols.[52] In a summary of comments received, FDA revealed plans to evaluate the symbol systems for compliance with labeling statutes and to plan additional research into consumer use and understanding of nutrition symbols.[53] As FOP symbols continued to proliferate on food labels, FDA and USDA jointly wrote a letter of concern in 2009 to the General Manager of the Smart Choices Program,[54] a nutrient-criteria-based FOP system developed by a consortium of industry, public health, and academic nutrition leaders. 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 2010 *Dietary Guidelines for Americans* (USDA, 2010); or had the effect of encouraging consumers to choose highly processed foods and refined grains instead of fruits, vegetables, and whole grains." FDA followed by issuing guidance for the industry regarding point-of-purchase food labeling including FOP labeling.[55] In its guidance, FDA noted the different nutritional criteria used by various systems and expressed concern that some FOP labels may be misleading or not in compliance with regulatory criteria for nutrient content claims (i.e., claiming a food is high in a nutrient in the FOP label, but not meeting FDA criteria for that claim). However, the agency also noted its belief that FOP labeling "can be a way of promoting informed food choices and helping consumers construct healthier diets in accordance with the *Dietary Guidelines for Americans*." To that end, FDA stated that it wanted to work with the food industry, nutrition and design experts, and the IOM to develop an approach to FOP labeling that would help Americans build better diets and improve health. FDA then issued a request for comment, information, and data on consumer use and understanding of possible approaches to FOP labeling of food packages or on shelf tags in retail stores.[56]

To help determine how FOP systems should be used as a nutrition education tool, Congress directed the Centers for Disease Control and Prevention (CDC) to undertake a study with the IOM to examine and provide recommendations regarding FOP labeling systems and symbols.[57] This study has also been supported by FDA and the USDA's Center for Nutrition Policy and Promotion. In addition, FDA also undertook experimental studies to assess quantitatively consumer reactions to various FOP labeling schemes[58] in anticipation of future rulemaking on this issue.

## NEED FOR PERIODIC REASSESSMENT OF THE NUTRITION FACTS PANEL

Congressional intent when passing the NLEA was that the food label should become a more effective public health tool (Kessler et al., 2003). To this end, one of the primary purposes of the implementing regulations was to

[51] FD&C Act, Sec. 403(r)(3)(A); 21 CFR § 101.14(a)(4).
[52] 72 FR 39815, July 20, 2007.
[53] Available online: http://www.regulations.gov/search/Regs/home.html#documentDetail?R=09000064809623e8 (accessed July 3, 2011).
[54] Available online: http://fda/gov/Food/Labeling Nutrition/LabelClaims/ucm180146.htm (accessed July 3, 2011).
[55] Available online: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm187208.htm (accessed July 3, 2011).
[56] 75 FR 22602, April 29, 2010.
[57] HR 1105; in 2010 Congress directed CDC to continue the study (HR 111-366, Conference Report to accompany HR 3288, ordered to be printed December 8, 2009).
[58] 74 FR 62786, December 1, 2009. Also see Chapter 5.

help consumers choose healthier diets (Kessler, 1995). Although research conducted since the implementation of mandatory nutrition labeling indicates that reading food labels is correlated with better dietary patterns (Ollberding et al., 2010), maintaining such results is dependent on maintaining the scientific basis that supports the nutrition information on the label.

Nutrition science is a continually evolving field. In acknowledgment of this, the *Dietary Guidelines for Americans* are required by law to be reviewed, updated if necessary, and published every 5 years.[59] Once an external scientific Dietary Guidelines Advisory Committee conducts an analysis of new scientific information on diet and health and writes a report summarizing its findings, HHS and USDA develop a policy document, the 2010 *Dietary Guidelines for Americans*, and educational materials for the public (USDA, 2010). The committee believes that it would be helpful if FDA and FSIS would likewise develop a formalized process that triggers an automatic reassessment of those aspects of the NFP that are subject to change over time. These include the list of required nutrients; the Daily Value (DV), i.e., reference intake levels; the Reference Amounts Customarily Consumed (RACC), which are used to determine serving sizes; and criteria used to define nutrient content claims and to provide for health claims.

One of this committee's guiding principles is the need to maintain consistency between FOP labeling and existing nutrition labeling regulations. To maximize the health benefits to consumers of any resulting FOP labeling system or symbol, criteria for development and the content of such labeling must be anchored to the most recent version of the *Dietary Guidelines for Americans* and current consensus reports. This can only happen when there is continued reassessment and updates for all aspects of the food label, i.e., FOP labeling, the NFP, and claims.

## FINDINGS AND CONCLUSIONS

### Findings

In order to ensure that food packages are truthful and not misleading, federal statutes have given FDA and FSIS regulatory oversight over food labeling. To fulfill this responsibility, the two agencies have set forth mandatory labeling components, including statements of identity; ingredient lists on products composed of two or more ingredients; statements of the net quantity of contents; identification of the name and place of business of the manufacturer, packer, or distributor; allergen labeling; and nutrition information. In addition, some labels may be required to include additional information such as warning statements, safe handling instructions, country-of-origin notifications, inspection legends, and plant or establishment numbers.

### Conclusions

One of the goals of nutrition labeling, to help consumers choose healthier diets, requires that nutrition information on the food label be based on the most recent *Dietary Guidelines for Americans* and current dietary guidance. To accomplish this, a formalized process should be developed within FDA and FSIS that triggers an automatic reassessment of the scientific basis behind all aspects of nutrition labeling, i.e., the NFP, nutrient content and health claims, and any future FOP labeling system, so that they remain anchored to the most recent version of the *Dietary Guidelines for Americans* and current consensus reports.

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[59] 56 FR 60366.

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# 4

# Consumers' Use of Nutrition Information and Product Choices

## BACKGROUND

Chronic diseases, such as heart disease, cancer, stroke, and diabetes, are among the leading causes of death in the United States, accounting for at least 6 out of every 10 deaths each year (Kochanek et al., 2011) and placing a substantial burden on the nation's healthcare spending (Schoenberg et al., 2007; Vogeli et al., 2007; Cunningham, 2009). The literature on epidemiological, clinical, and laboratory studies linking behavioral risk factors and mortality suggests that poor diet and lack of physical activity are strongly associated with mortality and may soon replace tobacco as a leading cause of death (Mokdad et al., 2004). Poor dietary practices include excess energy intake (Wright et al., 2004), high intakes of saturated fat and sodium (USDA, 2008), and low intakes of fruits, vegetables, and fiber (Serdula et al. 2004; Guenther et al., 2006). Because many risk factors that contribute to the development of chronic diseases, such as poor diet and physical inactivity, are preventable (USDA, 2010b), federal and state agencies have undertaken several initiatives to educate the public about nutrition and health, with the objectives of preventing disease and promoting health. Underlying these efforts is the rationale that an educated public will select healthier diets to reduce the likelihood of premature onset of diet-related chronic disease. This chapter reviews evidence on consumer food choice and barriers to using front-of-package (FOP) nutrition rating systems and symbols, as well as approaches to developing FOP systems by food manufacturers as well as by the U.S. Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS). This chapter discusses the recent proliferation of FOP systems and the impact that multiple types of systems has had on consumer food choice and purchasing decisions. Finally, this chapter concludes by drawing on lessons learned from existing FOP nutrition rating systems and how they can be applied to the development of a more effective system.

## PROVISION OF NUTRITION INFORMATION AT THE POINT OF PURCHASE

Since the passage of the Nutrition Labeling and Education Act (NLEA) in 1990, nutrition labeling has become an important policy tool to provide consumers with nutrition information that will assist them in making nutritionally appropriate food choices and in maintaining sound dietary practices.[1] The cornerstone of labeling regulations under the NLEA's mandate is the Nutrition Facts panel (NFP), an important source of nutrition information that almost all packaged food products are required to carry. By providing information about the nutritional attributes

[1] Nutrition Labeling and Education Act of 1990. Public Law 101-535, 104 Stat 2353.

of a food in a credible, distinctive, standardized, and easy-to-read format at the point of purchase, the NFP was anticipated to help consumers choose healthier and more nutritious diets (Guthrie et al., 1995).

The committee identified several studies suggesting a correlation between reading the NFP and engaging in desired behaviors. Kreuter et al. (1997), for example, showed that label readers have diets that are higher in fruit, vegetables, and fiber and lower in fat compared to non-label readers. Moreover, among label readers, those with lower fat diets report looking for fat information more often than those with higher fat diets. Similarly, those with higher fiber diets report looking for fiber information more often than those with lower fiber diets. Similar results have been reported by other studies (Kim et al., 2000; Lin and Lee, 2003; Macon et al., 2004; Satia et al., 2005; Neuhauser et al., 2007). It has also been shown that label users have diets that are lower in cholesterol relative to non-users (Guthrie et al., 1995). In a review of existing evidence, Kim et al. (2000) concluded that food labels are indeed useful tools for individuals to make healthier food choices, resulting in better health outcomes. The committee noted, however, that the studies employed correlative data, which cannot be used to demonstrate a cause-and-effect relationship between label use and food intake. In particular, because the studies did not account for selection bias, unobserved individual difference variables might have affected both label use and food intake. For example, using a quasi-experimental approach to control for unobserved selection effects, Variyam (2008) found that label use has only a modest association with diet quality. In contrast to Kim et al. (2000), this study found no evidence that label use is associated with a lower intake of total fat, saturated fat, or cholesterol.

The NFP provides a lot of detailed nutrition information that is likely to be crucial for individuals with dietary restrictions due to health conditions such as diabetes, hypertension, heart disease, etc. In fact, label readers frequently reported using nutrition labels for the purposes of avoiding certain nutrients and assessing the nutrition profile (Cowburn and Stockley, 2005). More generally, research on nutrition labeling showed that consumers report high levels of label use. However, studies that employed verbal protocols (as opposed to self-reports) showed that consumers simply look at the NFP without processing the information (Higginson et al., 2002; Cowburn and Stockley, 2005).

A necessary precondition for the NFP's effectiveness is that consumers use and comprehend the information on food labels. Evidence reviewed by the committee, however, revealed that actual label use is much less than what is reported, and that consumers are often confused by the information on the food label and have difficulty understanding serving sizes (Cowburn and Stockley, 2005). Systematic reviews of studies conducted in the European Union (Grunert and Wills, 2007; Wills et al., 2009) and in Australia and New Zealand (Mhurchu and Gorton, 2007) reached the same conclusions.

Taken together, these studies suggest that consumers may have difficulty understanding the role of various nutrients and may not interpret the information from the perspective of how nutrients in foods may impact their daily diet. The literature offers a number of reasons for why nutrition labels are not used by consumers, including lack of time (Barreiro-Hurle et al., 2010), difficulty with the presentation of information, and lack of understanding of food label information (Cowburn and Stockley, 2005). In addition, consumers may not understand which nutrients are important, attending solely to fat or calorie information (Higginson et al., 2002). A study by Cowburn and Stockley (2005) indicated that consumers use numerical information on labels to perform simple calculations, but their ability to accurately interpret the label declines as the complexity of the task increases, especially consumers with lower levels of educational attainment.

### The Role of Consumer Education Campaigns

Nutrition labeling alone is likely to offer limited success as a strategy to improve the population's dietary health. Poor nutrition knowledge may reduce the ability of some consumers to interpret and use the nutrition information provided. When the NLEA was implemented, the federal government, along with other public- and private-sector groups, initiated a major multi-year education campaign to help consumers use the new label (Kulakow, 1995). The goal was to educate consumers about the availability of nutrition information on the food label and about the importance of using that information to maintain healthy dietary practices. However, the campaign stopped after the initial years, and nutrition labeling efforts have not been supplemented by other education strategies, which has resulted in adverse consequences for consumer use of the NFP.

A study by Todd and Variyam (2008) showed that label use declined between 1995-1996 and 2005-2006 for all population groups, particularly among consumers aged 20-29 years and new residents of the country, who likely did not benefit from the public awareness and education campaigns that occurred when the new labels were introduced. Even for the other groups, some depreciation in the value or salience of the information could have occurred, which highlights the need for new campaigns.

The importance of public education as a supplement to regulation was reinforced when *trans* fat was added as a mandatory NFP declaration in 2006. Kozup et al. (2006) stated that without education efforts to increase consumer understanding of *trans* fat levels, the new requirement's effects would be limited. However, FDA had little funding for education, and the resulting education gap hindered at-risk consumers' ability to correctly interpret *trans* fat levels in terms of their daily diet. Howlett et al. (2008) noted, "[M]aximizing the effectiveness of incremental additions to the panel depends on a coordinated attempt at educating consumers about the dangers and levels of a high-*trans* fat diet." However, funding for public education efforts to accompany the labeling regulation has been almost nonexistent.

## Barriers to Nutrition Label Use

There are a number of barriers to consumers' use of nutrition labels. First, a lack of nutrition knowledge is a major barrier to effective use of the NFP (Barreiro-Hurle et al., 2010) and may actually lower the motivation of some consumers to use the nutrition information on the food label. In real-world purchase situations, when consumers are pressed for time, the motivation to process and use nutrition information is even more adversely affected (Grunert and Wills, 2007). This finding has led some investigators to conclude that restrictions in the amount of time consumers' have to process nutrition information on the food label limits its effectiveness (Berning et al., 2010).

Other studies reported that some racial groups, e.g., African-Americans, Asians, and Hispanics, are less likely than Whites to use and understand nutrition labels (Lang et al., 2000; Sullivan, 2003; Satia et al., 2005), primarily because of lack of time to read labels and lack of understanding of the nutrition information. Low numeracy and literacy skills have also been identified as factors related to poorer understanding of food labels, even after adjusting for age, gender, education, race, and income (Rothman et al., 2006). A estimated 90 million U.S. adults have literacy and numeracy skills that are inadequate to function in the current health care environment, so this is not a trivial problem (IOM, 2004). Adults with low health literacy skills are less inclined to use nutrition labels and are at greater risk for diet-related health outcomes. Therefore, the nutrition label is not serving the needs of those who would benefit most from it.

These findings have led to calls to improve nutrition labeling at the point of purchase to encourage selection of healthier products by consumers (Rothman et al., 2006). Researchers have suggested that interpretational aids that make the nutrition label easier to use and enhance the ability to compare products may help consumers better understand how a food product fits into their overall diet (Vishwanathan and Hastak, 2002; Cowburn and Stockley, 2005). A recent systematic review of 58 studies conducted in the European Union showed that consumers favor simplified information on the front of the package that supplements the more complex nutrition table on the back (Grunert and Wills, 2007) for the following reasons: (1) they generally do not have time to process detailed nutrition information; and (2) they lack the cognitive skills needed to use the nutrition information to compare products and interpret the nutrients in the context of their total diet.

In the supermarket shopping environment, consumers often have limited time to process nutrition information, so they do so in a cursory manner (Higginson et al., 2002). Time constraints highlight the need for a simplified FOP label that summarizes key aspects of the nutritional profile, is relevant to consumer concerns about diet-related chronic disease risk, and facilitates product comparisons and healthier food choices. Moreover, understanding such a label would not require substantial nutritional knowledge, time, and cognitive effort to process, compared to the NFP, for example. Such a nutrition rating system would be most effective in the supermarket, where consumers make quick purchasing decisions and must choose from a wide array of products.

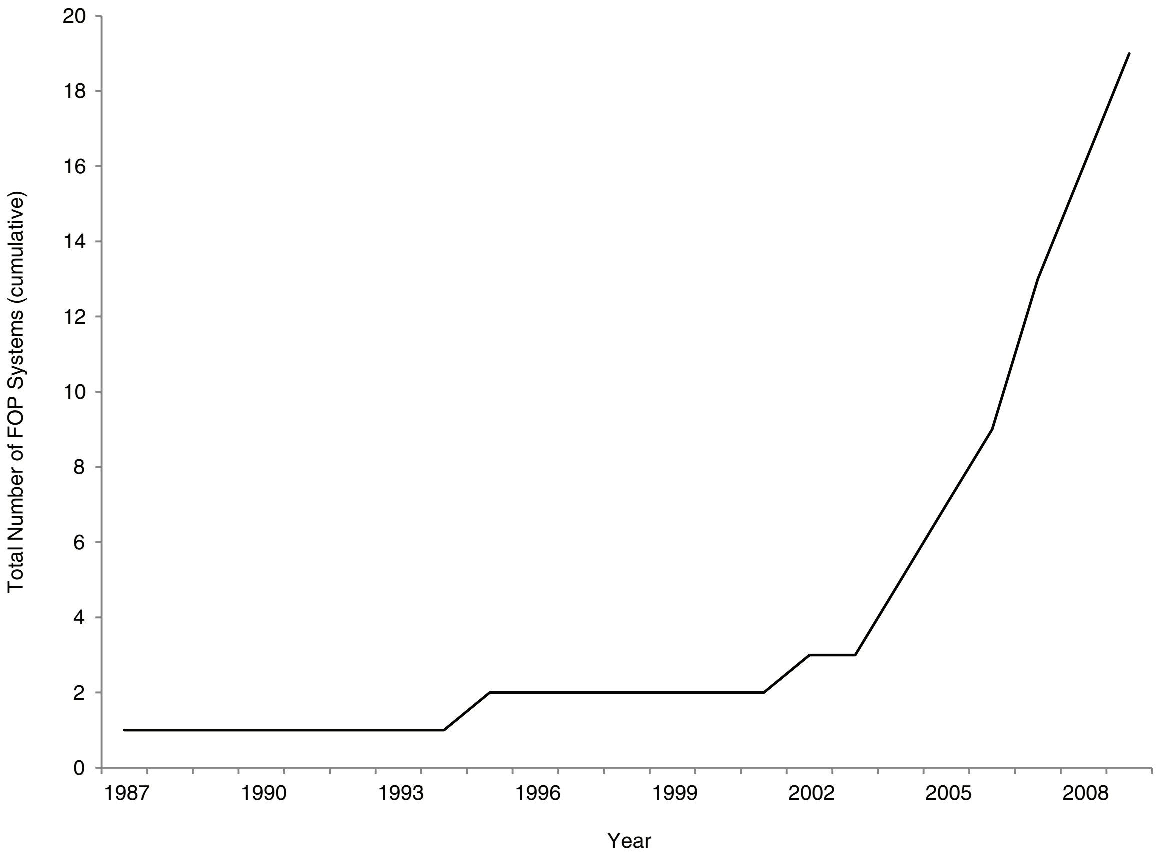


**FIGURE 4-1** Cumulative increase in the total number of front-of-package symbol systems during the past three decades in the United States.

## SIMPLIFYING CONSUMER DECISIONS WITH FRONT-OF-PACKAGE NUTRITION INFORMATION LABELS

During the past three decades, there has been substantial growth in the number of FOP symbols and rating systems designed to summarize the nutritional profiles of food products. All of these systems attempt to make the nutrition information on packages easier to understand and thereby simplify the decision-making process. They utilize a range of strategies—from simple symbols to more complex and detailed information on key nutrients in an easier-to-use format than the NFP. They have been developed by food manufacturers and retailers, governments and nonprofit organizations, industry consortia, and non-industry experts (IOM, 2010). Manufacturers placed their rating systems on the front of the food package; food retailers placed them on their own store brands or on grocery store shelves and display cases. The Phase I report provided a timeline for the development of these FOP systems (IOM, 2010; Chapter 3). Figure 4-1 depicts the proliferation of FOP nutrition rating systems over the past three decades.

The first FOP nutrition rating systems to appear (during the late 1980s and early 1990s) were largely developed by nonprofit organizations. In 1987 the American Heart Association (AHA) created the Heart Guide symbol to signal to the consumer that a food was "heart friendly." The Keyhole symbol was developed in Sweden in 1989, and then expanded to Denmark and Norway. In 1995 the AHA developed a new version of its FOP system, the Heart Check program. The Canadian Heart and Stroke Foundation created the Health Check program in 1999. All these programs used a single symbol that appeared on qualifying products. At that time, food manufacturers were not yet involved in the creation of these programs or in the development of the criteria used by them.

Since 2004 the food industry has attempted to respond to the growing consumer interest in nutrition and to increase the visibility of FDA-approved health and nutrition claims in product packaging and marketing (Kunkel and McKinley, 2007). Manufacturers and retailers developed FOP nutrition rating systems to provide consumers with easy-to-use summaries of the nutrition profile of the product and thereby help them make healthier choices. For example, in 2002 Wegman's supermarkets developed a series of symbols based on FDA and U.S. Department of Agriculture (USDA) nutrient content and health claims that were featured only on the store brand products, effectively differentiating the store brand from competing brands. From 2002 to 2007 other manufacturers, e.g., Kraft, General Mills, Unilever, Kellogg's, and PepsiCo, developed their own FOP systems with the goal of directing consumers to their healthier food products.

In 2006 the UK Food Standards Agency (FSA) recommended that UK food manufacturers and retailers place traffic light (TL) labels on the front of food packages to help consumers to make healthier food choices. The labeling format consists of four, separate, color-coded lights indicating the level of fat, saturated fat, sugar, and sodium in the product. Reflecting criteria determined by FSA, a red light indicates a high level of a specified nutrient, an amber light indicates a medium level, and a green light indicates a low level.

In 2006 algorithm-based summary symbols were introduced into the marketplace. Hannaford Supermarkets' Guiding Stars system uses a proprietary algorithm; based on both positive and negative nutrients, it gives ratings of zero to three stars, which are displayed on shelf tags, to foods that meet the minimum nutrient standards. The NuVal Nutrition scoring system, introduced in 2007, is also based on a proprietary algorithm that considers and weights both positive and negative nutrients, and presents the final score as a number between 1 and 100.

In 2008 ConAgra introduced the Start Making Choices program, an FOP nutrition rating system based on USDA's MyPyramid, which illustrates the contribution of various food groups to a healthier diet. Also in 2008 a consortium of industry, public health, and academic nutrition leaders developed the Smart Choice program, a summary indicator system. In 2009 the retailer Giant Food introduced the Healthy Ideas program in its Giant and Stop & Shop stores.

In January 2011 America's leading food and beverage manufacturers and retailers announced the launch of a new system, Nutrition Keys,[2] which summarizes important nutrition information (calories, saturated fat, sodium, and total sugars content) on the front of food packages. For some products, the Nutrition Keys icon also displays information about "nutrients to encourage," such as potassium, fiber, vitamin A, vitamin C, vitamin D, calcium, iron, and protein.

In summary, FOP nutrition rating systems and symbols have proliferated since the AHA created the Heart Guide symbol in 1987. The Phase I committee reviewed 20 systems that were representative of systems that had been introduced into the marketplace. They fall into three categories: (1) nutrient-specific systems, (2) summary indicator systems, and (3) food group information systems (IOM, 2010; Chapter 6). Although the systems use different criteria to rate foods, their primary goal is to provide consumers with easy-to-use information that enables them to quickly determine if a food is a healthy choice and to compare foods within a category. Some systems, particularly within the food group information category, were found to be more helpful in enabling consumers to make healthier food choices.

### Consumer Research Underpinning the Development of Front-of-Package Systems

As part of its exploratory research into the background of FOP systems, the Phase I committee contacted several FOP system developers, with the goal of better understanding the (1) rationale behind the FOP systems; (2) benefits that the FOP systems have provided to consumers; (3) consumer research that preceded and followed introduction of the FOP systems; and (4) outcomes of these FOP systems. The Phase I committee also conducted telephone interviews with several representatives from nongovernmental organizations and the food industry. One of the themes to emerge from these interviews was that food manufacturers were responding to consumer inter-

[2] Now called "Facts up Front."

est in information. In addition, food manufacturers worked from the hypothesis that consumers shop under time constraints, and, therefore, designed their FOP nutrition rating systems to provide consumers with information that they considered to be easily identifiable, accessible, and relevant to making healthier food choices.

The telephone interviews also revealed that most FOP system developers conducted qualitative and quantitative research to test various versions before choosing the FOP system that performed best with consumers. Importantly, however, most did not test their systems with non-English speaking or with low health literacy populations. Moreover, they did not conduct follow-up research to determine whether the FOP systems were being used by those segments of the consumer population. Regardless of the benefits or limitations of individual FOP nutrition rating systems, spokespersons for the industry groups and other organizations believed that the type of system they developed offered the greatest benefit to the consumer. Developers of summary indicator systems focused on the simplicity of their systems when making comparisons, while developers of nutrient-specific systems considered fact-based systems to be superior to symbol-based systems. In contrast, developers of food group information systems asserted that their type of system was best designed to help consumers eat a more balanced diet by making it easier to track consumption of specific food groups.

## Consumer Confusion from Divergent Front-of-Package Systems

FOP systems were developed with the goal of making it easier for consumers to assess information on the nutritional qualities of a food and thereby facilitate healthier choices. However, in the absence of any consistent guiding standards, the outcome has been a proliferation of systems based on varying underlying criteria. The report *Food Marketing to Children and Youth* (IOM, 2006) expressed concern about the likelihood of consumer confusion surrounding the variety of food rating approaches and recommended that FDA issue guidance on the future development of FOP labeling and grocery shelf signage systems. Public interest groups have also called on FDA to develop standards to ensure more consistency across the various voluntary rating approaches, or to mandate the use of a standard nutrition rating system.

Studies conducted in countries outside the United States provide support for the argument that multiple rating systems actually confuse the consumer. A review of studies from Australia and New Zealand, for example, concluded that multiple labeling systems are likely to cause rather than alleviate consumer confusion (Mhurchu and Gorton, 2007). Research conducted in the United Kingdom also suggested that the presence of multiple FOP systems causes problems for consumers trying to interpret nutrition information from a label (Clegg and Lawless, 2008; Malam et al., 2009) and called for further research on this topic. In 2009, a study conducted for the UK Food Standards Agency examined how the existence of a range of FOP label formats impacts accurate interpretation of FOP labels. Results showed that the coexistence of various FOP labels makes it more difficult and time consuming for consumers to understand the labels and compare products. This report concluded that a standardized FOP labeling system would enhance consumer comprehension and use of FOP labels (BMRB, 2009).

## FDA's Perspective

FDA shared with the committee information resulting from activities they conducted to improve understanding of consumer response to FOP nutrition rating systems, including a request for comment, information, and data on FOP labeling.[3] In the committee's judgment, FOP labeling or corresponding shelf labeling concerning the nutritional attributes of a food product can be an effective way to promote healthier choices and to help consumers to make food choices that are more consistent with the recommendations of the *Dietary Guidelines for Americans*. In its analysis of evidence the committee considered FDA's appraisal that an FOP or shelf labeling system that is consistent with the NFP responds to the needs of the market and provides usable nutrition information at the point of purchase. FDA strongly believes that "the criteria and symbols used in FOP and shelf-labeling systems be nutritionally sound, well-designed to help consumers make informed and healthy food choices, and not be false

[3] 75 FR 22602.

or misleading."[4] Finally, FDA expressed concern that the proliferation of competing FOP symbols and systems could result in consumer confusion and thus be counterproductive.

## LIMITATIONS TO A COGNITIVE APPROACH TO FOP SYMBOL SYSTEMS

Over the past several decades, the chief policy response to the problem of poor dietary intake patterns has been to increase access to information to encourage people to eat a more healthful diet; the NFP and the *Dietary Guidelines for Americans* are examples of such efforts. Many of these nutritional strategies have adopted a "cognitive" approach (Petty et al., 2002), which assumes that the consumer is highly motivated to eat a healthful diet and that access to nutrition information is the main barrier to dietary improvement. Hence, policy initiatives have focused on providing information to increase consumers' nutrition knowledge, with the expectation that this will lead them to select healthier diets.

The results of such an approach have been mixed. On the one hand, there is evidence that some aspects of the American diet have improved during this period. For example, the percentage of calories from total and saturated fat has decreased (CDC, 2004), suggesting that the cognitive approach of providing more information has been somewhat successful. However, during the same period, the average calorie intake has increased significantly (CDC, 2004), and the sodium intake exceeds the maximum level established by the 2005 *Dietary Guidelines* (IOM, 2010). In addition, further improvements are needed even for many dietary aspects that have moved in the desired direction since the 1970s. An examination of some of the factors underlying food choice provides insights into the reasons why simply increasing access to information may have only a limited association with dietary improvement in the population.

"Nutrition knowledge" is only one of the many environmental and individual variables that can affect an individual's food choices (Worsley, 2002). In addition to nutrition, taste, cost, and convenience are also significant predictors of an individual's food choices. Additionally, different population subgroups can vary in terms of the importance placed on each of these factors (Glanz et al., 1998; French et al., 1999). For example, individuals in lower socioeconomic groups and those living in areas without access to a variety of foods may place greater importance on the availability and cost of food, whereas those who have fewer resource constraints may place greater importance on the nutritional quality of foods. However, in general, the majority of studies indicate that taste is a stronger predictor of food choice than health and nutrition; and consumers are most likely to choose foods that they consider tasty (Aikman et al., 2006; Drichoutis et al., 2006). Additionally, cost may outweigh nutrition in times of economic hardship, especially for consumers with limited resources. In other words, they may choose the tastier and cheaper, but less nutritious, food, even though they are knowledgeable about healthy food choices. This finding is consistent with research by Darmon at al. (2002), who showed that when food selection is constrained by economic considerations, healthy eating patterns will necessarily be compromised.

In light of this evidence, it is not surprising that the cognitive approach of providing more information about the nutrition characteristics of a food has not been consistently effective across consumer groups (Baltas, 2001). As discussed above, certain factors might compromise consumers' ability to use nutrition information in food selection, assuming that they are motivated to do so. But motivation is crucial, for without it, nutrition knowledge has minimal impact on consumers' food choice and purchasing decisions. Also as discussed above, nutrition information on food labels is more likely to be read by consumers who are motivated by health concerns, so the label may indeed assist this group in making healthier food choices. In contrast, cognitive approaches are unlikely to motivate the use of nutrition information on the food label by consumers who find the label difficult to understand. This is precisely the group that might benefit from an effective FOP system and whose needs are not being served by the NFP. However, the committee recognizes that any FOP system is likely to have a narrow influence on the food purchase decisions of consumers whose access or resources to purchase healthier foods are impacted by economic and/or geographic limitations.

[4] Available online: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm187208.htm (accessed May 23, 2011).

## FINDINGS AND CONCLUSIONS

### Findings

For the past 20 years, food labels have provided nutrition information through a variety of formats at the point of purchase, with the goal of helping consumers to make healthier food choices. However, concerns remain about whether nutrition rating systems are actually furthering the NLEA's goals of encouraging healthier food choice and purchase behavior. Studies suggest that many consumers have difficulty understanding the NFP and, therefore, would prefer a simplified FOP label that provides information that will help them to assess the nutritional characteristics of the food product.

### Conclusions

In response to the perceived need for a better way to convey nutrition information about a food product, food manufacturers and retailers have developed various FOP nutrition rating systems. However, there is scant evidence to support that the proliferation of FOP nutrition rating systems has encouraged healthier food choices and purchase decisions. In fact, one UK study of the use of FOP labeling found that the coexistence of a number of label formats in the market caused consumer confusion about the levels of key nutrients (BMRB, 2009). Thus, there is a need for a standardized FOP nutrition rating system that moves beyond providing information to encouraging product comparison and healthier food choices by consumers at the point of purchase. Such an FOP symbol system could not only help consumers with food choice and purchase decisions, but also serve as a catalyst for product reformulation, a further benefit to consumers.

Because many consumers have difficulty evaluating product healthfulness based on the NFP, a well-designed FOP symbol system could be a more effective indicator of product healthfulness. Such an indicator is more likely to be used by consumers who are less able or less motivated to use the NFP to evaluate the nutritional qualities of a food product (Zeithaml, 1988; Srivastava and Mitra, 1998). For example, qualitative research in four European countries has shown that consumers have a preference for a simple FOP symbol system, standardized across food products (van Kleef et al., 2007). Too much detailed information on food package labels is not useful for consumers who lack nutrition knowledge or have low literacy and numeracy skills (Fuenkes et al., 2008). The need for a simple FOP symbol system is especially relevant in the grocery store environment, where consumers spend little time in deciding what to buy (USDA, 2008). Research on consumer use of the NFP and on the recent *trans* fat regulation (Kozup et al., 2006; Howlett et al., 2008; Todd and Variyam, 2008) indicate that an FOP system can only reach its full potential and avoid unintended consequences if it is accompanied by an ongoing public education and communication campaign to keep its relevance fresh in the minds of consumers.

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# 5

# Consumer Use and Understanding of Front-of-Package Labeling Systems

## INTRODUCTION

This chapter reviews the studies that have examined front-of-package (FOP) labeling systems in applied and experimental settings. This chapter provides a general overview of the types of studies in the current literature and the methodological strengths and limitations of each. It also distinguishes the literature that has been published in peer-reviewed journals from information from industry, marketing, and government sources, i.e., applied and other settings of marketing research. This primarily includes recent consumer research conducted by the U.S. Food and Drug Administration (FDA), the UK government, and the Grocery Manufacturer's Association and International Food Information Council (GMA-IFIC). The committee noted that while there are a number of theoretical, purchase intent studies, studies examining consumer purchase behavior in the grocery store setting are quite limited in both number and scope. In assessing the evidence and deriving its conclusions about consumer use and understanding of FOP systems the committee included information from applied marketing research, which provided insight into various nutrition rating systems and symbols that was not available in the peer-reviewed literature, particularly into what type of FOP symbols consumers might use. Information provided by FDA, GMA-IFIC, and other industry sources (discussed below) also provided such insight and, along with the committee's expert judgment, served to complement the interpretation of the peer-reviewed evidence. The following discussion describes in further detail the committee's approach to prioritizing and interpreting the available evidence.

### Types of FOP Systems

The committee reviewed the literature for a number of FOP systems described in *Front-of-Package Nutrition Rating Systems and Symbols: Phase I Report* (IOM, 2010), placing an emphasis on published field experimental studies (described below). When reviewing these studies, the committee paid particular attention to the influence of various FOP systems on consumer choice of products and additional outcomes, such as perceptions of the healthfulness of products. The studies either indirectly or directly provided evidence on other factors important to examining FOP systems, including: (a) the extent to which simpler compared to more complex systems are more influential, and (b) the relative influence of FOP systems that highlight or frame nutrition content in only positive terms (e.g., an indicator for being high in nutrients). In general, the data do not exist to compare the effects of every potential FOP system against all other possible options. However, the committee determined that a number of important conclusions could still be drawn.

## LITERATURE REVIEW METHODOLOGY

### Approach to Literature Review

The following section discusses the literature on consumer use of and preferences for FOP symbol systems. The committee limited its review to literature that directly examined FOP symbol systems, was published in the United States and Europe, and covered a search period from January 2000 to June 2011. The committee included studies published prior to 2000 at its discretion. Chapter 4 discusses the literature on use of the Nutrition Facts panel (NFP), and Chapter 6 discusses the literature on consumer response to aspects of labeling, including health claims, package clutter, and related themes. Appendix D provides a complete description of the committee's approach to its review of peer-reviewed published literature.

### Types of Front-of-Package Symbol System Studies Examined

The committee used a hierarchy to categorize studies of FOP symbol systems, ranging from studies that are most likely to provide the best insight into how consumers might respond to a particular FOP symbol system to those that provide a lesser quality of evidence or are associated with greater uncertainty. Studies published in the peer-reviewed literature are at the top of the hierarchy. Within this group, field or natural experiments were given the greatest weighting. Field experiments examined implementation of an FOP symbol system in "real-world" settings and assessed their effects with objective outcomes such as changes in sales data. Although these studies are limited in number, their results are most likely to reveal how FOP systems might influence consumer choice if implemented.

Peer-reviewed studies reporting randomized designs provided the next level of evidence. These studies randomized subjects to view one (or several) variants of a FOP label, either in a research space, outside a supermarket, or online, and compared reactions across the experimental conditions on a variety of outcomes, including consumer choices, perceptions of product healthfulness, and overall preferences for FOP systems. Table 5-1 summarizes examples of field experiments and randomized design studies.

The committee then considered the applied marketing research literature that was either sought out or provided to the committee. Because it had not been subjected to a peer-review process, this work, positioned at the lower tier of the hierarchy, was given substantially less weight in the committee's deliberations.

#### *Peer-Reviewed Field Experiments*

The strongest evidence to demonstrate how an FOP system will operate in a real-world shopping environment comes from actually implementing the system on supermarket shelf tags or products, and observing via sales data the impact that it has on consumer food choice and purchase decisions. As the name implies, field experiments are conducted in natural settings, which may not allow for full control of the environment, but allow for a full examination of how consumers make choices in a natural or real-world setting, with all of the inherent time, cost, and other pressures. They also provide a realistic sample—consumers go to the grocery store as part of their usual shopping routine. The outcome of interest in field experiments is sales, which is a key outcome under examination by the committee. Whether there are correlations between food product sales and patterns of total food consumption and subsequent outcomes such as levels of obesity has yet to be determined. As such, studies of this type are needed to better understand the scale and scope of the effects of FOP systems on consumer behavior.

The committee identified four studies that examined differences in sales after introduction of shelf tag–based FOP systems. In the first study, Levy et al. (1985) examined whether the prominent but relatively simple display of low/reduced dietary components (according to current dietary guidance: sodium, calories, fat, and cholesterol) on a shelf tag would increase sales as a result of "shelf salience." This program was aimed to be "more promotional than rationally persuasive." Ten comparison stores were matched with 10 control stores. Although the results were inconsistent across product categories, the investigators found that on average sales of the labeled products were 4 to 8 percent higher than sales of unlabeled products in comparison stores. The outcome showed an impact of the system on sales and by implication consumer appeal.

In the second study, Sacks et al. (2009) examined the impact of the UK-based traffic light (TL) system on a small subset of products in a store. Red, yellow, or green TLs were posted on “ready meals” (already packaged and chilled meals) and freshly made but pre-packaged sandwiches. Four weeks after the introduction of the labeling system, sales of the sandwiches had not changed. Sales of “ready meals” increased by a small amount, but there was no differential increase in the sales of healthier versus less healthy items. A major limitation of the study is the examination of a very small subset of products with only one FOP system. But, the system as implemented did not encourage consumers to choose healthier products for these product categories. The system was more complex than that of Levy et al. (1985) and included both positive (green for low) and negative (red for high) valence. The study did not provide evidence that allowed the committee to differentially examine the influence of these various factors.

The third study examined the sales of a single product, popcorn, in a field experiment in five grocery stores in the East Bay area of California. Berning et al. (2011) labeled popcorn products differently in the stores, but, if applicable, labels indicated whether the products were low in nutrients to avoid, e.g., “low fat” or “low calorie.” Popcorn products not meeting FDA standards for being low in a nutrient were not labeled with nutrition information, and “control stores” did not label any of the popcorn products with nutrition information. Compared to the “no nutrition labels” condition, when the labels were present there was a decrease in overall sales of the labeled, healthier products and a non-significant but similar in magnitude increase in the sales of the less healthy products. Again, this study was conducted on a single product category, and the findings differ from those of Levy et al. (1985), who found that a similar labeling system was effective for a variety of product categories. In addition, the product tested by Berning et al. (2011) is considered a “treat” or luxury rather than a necessity, which may have influenced how the shelf tag information was perceived by consumers.

In the fourth study, Sutherland et al. (2010) examined the change in sales for all products after the Guiding Stars system was implemented in Hannaford stores (see Chapter 4 for additional details). Looking at sales for the 8-month period after the system was introduced and comparing to the previous year’s sales to control for seasonality, the investigators found no change in the number of products labeled with stars over time, but there was a slight increase in the purchases of products labeled with stars. The greatest increase in sales appeared to be for 1-star products, although there was some increase for 2- or 3-star products. The study did not report changes in overall sales, so the committee was unable to ascertain the relative importance of an overall increase in sales and/or substitutions between the starred (healthier) and non-starred (less healthy) products. An exception is additional data about ready-to-eat cereals, for which there was no evidence that healthier products were substituted for less healthy products. Unfortunately, there was no control group in this study, so it was not possible to ascertain whether sales changed in stores that did not introduce nutrition labeling. This study was funded by Guiding Stars program, and the investigators received compensation from Guiding Stars.

In summary, the evidence from field experiments is limited and inconsistent. The studies were not set up to truly test one FOP symbol system over another, and there is no evidence from the four studies to show one system as being superior to others. However, there is evidence that FOP and shelf tag systems can have some influence on consumer purchases. Of the systems studied, the TL-based system, which was the most complex, appears to have been the least effective in influencing consumer choices. Levy et al. (1985) reported consumer response to a simple shelf tag system, and Sutherland et al. (2010) reported consumer response to a simple and ordinal FOP system. However, the latter’s conclusions cannot be validated because the study was not controlled.

### *Overview of Peer-Reviewed Studies That Are Not Field Experiments*

Non-field experiments do not allow for drawing conclusions about consumer behavior as easily as do field experiments, but they have their advantages. Because they are easier to undertake, non-field experiments can simultaneously examine various FOP systems and can easily control external factors, which allows for focusing on the actual variables of interest. The many issues inherent in non-field experimental studies are discussed below.

Non-field experiments are generally performed in one of three distinct settings. Common approaches are to

**TABLE 5-1** Examples of Peer-Reviewed Studies Evaluating Front-of-Package (FOP) Systems

| Source | Peer-Reviewed Field Experiments | | | | |
|---|---|---|---|---|---|
| | Study Questions | Study Design | Intervention or Conditions | Outcomes Assessed | Summary of Results |
| Levy et al., 1985 | What is the effect of a nutrition information program on market shares of selected shelf-labeled food products low in sodium, calories, cholesterol, and fat? | Quasi-experimental study using matched comparison grocery stores in two metropolitan cities | A media campaign introduced the nutrition program to consumers, and informational guides were available in stores and 1,600 selected products in 23 categories were labeled with shelf tags | Food products by category were subdivided into brands with and without a low/reduced dietary component shelf tag<br><br>Sales were tracked in each participating store for 2 years<br><br>Sales-based market shares were measured as the percentage of store unit sales by category | Overall, the nutrition information program had a positive effect on purchases of products included in the program. The size of the effect varied widely between food categories but generally followed the same order of magnitude as that due to price level or trend effects during the study period. Shoppers, especially those on special diets, reported using the shelf tags to choose products. |
| Sacks et al., 2009 | What impact has the Food Standards Authority-recommended TL labeling format had on food sales in a major UK supermarket chain? | Comparison of weekly product sales as a percentage of total sales by food product category before and after TL labeling | Introduction of TL labeling to ready meals and sandwiches in the United Kingdom | Change in sales compared in the 4 weeks before and after introduction of TL labels<br><br>Percentage change in sales by product category after introduction of TL labeling was compared with the relative healthiness of the products | A small sample of products over a short period of time showed that sales of ready meals increased following introduction of TL labeling.<br><br>Sales of sandwiches did not change significantly after TL labels were introduced.<br><br>There was no association between the healthiness of the products and change in sales. |
| Berning et al., 2011 | What is the effect of nutrition labels that highlight specific positive nutrition standards on microwave popcorn sales? | Comparison of product sales of popcorn with nutrition shelf tag labeling compared to a dummy variable | Positive nutrition labels affixed to grocery store shelves below boxes of microwave popcorn in five chain stores in California | Sales of labeled vs. unlabeled popcorn were analyzed from scanner data | During the intervention period, sales for healthy popcorn decreased while sales for unhealthy popcorn increased (only significant at the 80 percent confidence level). |

| | | | | | |
|---|---|---|---|---|---|
| Sutherland et al., 2010 | What is the effect of a comprehensive storewide supermarket point-of-purchase nutrition intervention using shelf-label 3-tier star icons (Guiding Stars) on food and beverage choices? | Natural experiment from a cross-sectional sample of higher socioeconomic shoppers at a major grocery chain; no comparison group | Purchasing data was collected and assessed for a 2-year period from the study population | Data on purchase changes was reported for ready-to-eat cereals | The Guiding Stars program was found to be effective at bringing about changes in food purchasing behavior immediately after intervention with incremental improvement up to 2 years later. |
| | Peer-Reviewed Non-Field Experiments | | | | |
| Borgmeier and Westenhoefer, 2009 | 1. Which signpost label format enables consumers to identify healthier from less healthy products?<br><br>2. What is the impact of food labels on food choice and quality of diet? | Choice experiment of a convenience sample in Germany | Task 1: Pairwise comparison of foods to identify healthier choices<br><br>Task 2: Simulated shopping trip to test food choice<br><br>Experimental conditions consisted of four different label formats:<br>–simple healthier choice tick<br>–MTL<br>–% GDA<br>–color % GDA<br>Control = no label | Consumers' ability to differentiate healthier from less healthy products by food label format<br><br>Influence of food labels on food choice and quality of diet | Signpost labels were more helpful than no labels for identifying healthier foods and the MTL performed better than the %GDA and simple tick systems. However, even if a food's perceived healthiness is influenced by signpost labeling, it is unlikely to have a major impact on actual food choice.<br><br>Higher sodium intake was associated with higher education in the TL and colored GDA conditions, while the simple tick was associated with lower education.<br><br>For all conditions, the average daily intake for fat, saturated fat, sugar, and sodium was above recommended amounts. |

*continued*

**TABLE 5-1** Continued

| Source | Peer-Reviewed Field Experiments: Study Questions | Study Design | Intervention or Conditions | Outcomes Assessed | Summary of Results |
|---|---|---|---|---|---|
| Feunekes et al., 2008 | 1. How do different FOP labeling formats differ in helping consumers differentiate between healthier and less healthy options?<br><br>2. What effect does labeling format have on decision-making when taking into account the shopping environment? | Choice experiment in geographically and culturally diverse European populations | Participants randomly assigned to three of six labeling formats rated them on liking, comprehension, credibility, and perceived healthiness<br><br>Labeling formats:<br>Study: 1 Checkmark; summary (1-7); stars, smiley faces; TL with words (no numbers); circle, with numbers and colors<br><br>Study 2: Checkmark; stars; multiple checkmarks; % GDA with and without additional information | Perceived differences in healthiness between healthier and less healthy products<br><br>Purchase intentions | Stars and smiley faces showed the greatest differences in perceived healthiness, followed by TL.<br><br>Summary information was not as trusted as other formats.<br><br>No differences were found in purchase intent between labeling formats.<br><br>Less time was spent making decisions with simpler information formats.<br><br>Official endorsements tend to increase the credibility of a labeling format. |
| Kelly et al., 2009 | Which FOP labeling system is most effective in assisting consumers to make healthier, more informed food choices? | Choice experiment of a convenience sample in Australia<br><br>Face-to-face shopping center interviews with randomly selected shoppers | Participants responded to questions about mock packages representing healthier and less healthy options using three food product categories (cereal, savory snacks, frozen meals) and four label conditions (TL; TL + overall rating; monochrome % GDA; color % DI) | Ability to discriminate healthier from less healthy products by label condition and food product category<br><br>Food choice preferences | The TL system was the most effective for assisting consumers to identify healthier products and make comparisons quickly and easily.<br><br>There is a disjuncture between FOP systems initially perceived to be easiest to use and consumers' actual ability to interpret the systems. |

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|---|---|---|---|---|---|
| Gorton et al., 2009 | 1. What is the ability of shoppers from different racial/ ethnic groups to use nutrition labels?<br><br>2. What are shoppers' preferences from among four different label formats? | Intercept survey of shoppers recruited from supermarkets in New Zealand | Participants were randomly selected and geo-coded. Survey questions included nutrition label information, special dietary requirements, and socio-demographic data | Survey responses were analyzed to determine participants' use of nutrition labels, reasons for non-use of labels, basic understanding and interpretation of label information, and preference from among four label formats (nutrition information panel, TL, MTL, and % DI). Responses were assessed by racial/ethnic group, i.e., Maori, Pacific Islander, Asian, or New Zealand European | The ability to estimate nutrient content using the nutrition label was similar across ethnic and income groups, but the ability to use nutrition information to determine healthfulness of a food showed wide variation among ethnic groups. |
| Balcombe et al., 2010 | Are consumers willing to pay for reductions in the various nutrients as indicated by the TL system, i.e., fat, saturates, sugar, and salt, in terms of a basket of shopping? | Choice experiment based on a factorial design<br><br>Randomly distributed questionnaire mailed to UK households | Survey instrument designed with 24 choice sets (4 six-choice stets)<br><br>Nutrients were characterized by TL labels | Consumers' WTP for products chosen from a mix of goods in a virtual shopping basket | Respondents were strongly averse to red TL labels.<br><br>Price estimates for moving from red to green were greater than moving from amber to green.<br><br>Men showed overall lower WTP than women.<br><br>Households with children and respondents with higher education showed higher WTP than those without those attributes. |

*continued*

**TABLE 5-1** Continued

| Source | Study Questions | Study Design | Intervention or Conditions | Outcomes Assessed | Summary of Results |
|---|---|---|---|---|---|
| | Peer-Reviewed Field Experiments | | | | |
| Dunbar, 2010 | 1. What is the ability of consumers to choose between alternate products in the context of composing a meal?<br>2. What is the quality of consumer choices and the efficiency with which choices are made? | Choice experiment in a city marketplace in the UK | Study 1: Food choice based on food product name only or food name with GDA label<br>Study 2: –Defined task (select a meal with <1 gram of salt) using a label tuned to GDA label<br>–Select the healthiest food product using the GDA label | Consumers' ability to select a healthy food product;<br>Efficiency of product choice;<br>Consumers' ability to compose a meal using label information;<br>Quality of consumer food product selection based on nutrition label information | Participants given a food product name only made the quickest selections; however, when either a task-based interface or GDA information was introduced they made healthier choices. Only the task-based interface allowed participants to make selections as quickly as the food name only. |
| | Research on Consumer Preference | | | | |
| van Kleef et al., 2005 | 1. What is the extent to which consumers perceive health claims appropriate with specific food products?<br>2. How are consumer responses to health claims affected by alternative communication formats? | Analysis of previously collected data from a choice experiment using Dutch shoppers selected on the basis of their consideration of health aspects of food when shopping<br>Data was collected in a market research facility | Varied functional food concepts were offered as a set of 100 claim-carrier "mini-concepts" | Participants rated all mini-concepts on four dependent measures: uniqueness, attractiveness, credibility, and intention to try | Participants preferred physiology-based health benefits over psychology/behavior-based benefits. Claims were best received when attached to products with a positive health image and health claim history. No evidence was found to support the superiority of enhanced function claims over disease risk-reduction claim formats. |

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| Berning et al., 2010 | What are shoppers' preferences for nutrition information provided on grocery store shelf labels? | Choice experiment using an intercept survey of shoppers outside a national grocery store chain in three different locations | Color images of shelf labels displayed beneath a picture of a food product<br>Images included variations in price information, unit price, and nutrition information | Analyses of survey responses estimated shoppers' preferences for three sources of nutrition information: price, unit price, (displayed from low to high prominence), and nutrition information (not present or low to high prominence) | Preference for high prominence nutrition information correlated with high prominence unit price and high prominence price information.<br><br>Preference for low prominence nutrition information correlated with low prominence unit price and high prominence price information.<br><br>Positive consumer preferences for provision of nutrition information on grocery store shelves suggest that stores and shoppers can benefit from provision of shelf-label information. |

engage participants in person, as they leave an actual supermarket, or to bring them into a laboratory-based setting. In both cases, participants are shown the FOP labels in person—either in a picture or on an actual product. The third setting is online, i.e., over the Internet, in which case participants view FOP labels via a computer monitor. A limitation to all of these approaches is that participants may not make the choice that they would in an actual in-store shopping environment. In fact, they likely take more time to choose than they would in an actual environment, are not considering price, and are aware that their responses are being examined as part of a research study.

The studies reviewed below employed a large range of FOP symbol systems. This variability provides insight into differences among FOP symbol types but makes comparisons across studies more difficult. Moreover, the simulated food packages are often much simpler than the actual food packages, that is, the FOP symbol is often shown on a plain package stripped of all other information and marketing normally found on products.

Several sample-based considerations could influence the committee's interpretation of the results. First, the samples are often "convenience samples," or individuals who are not randomly or otherwise selected. Often, such samples consist of individuals who are leaving supermarkets, arguably the individuals from whom investigators would be most likely to gather data on responses to FOP systems. However, it is possible that not all stores in a geographic area are sampled or not all consumers consent to a survey, which may exclude a large cross-section of the population, spanning children and other vulnerable groups, such as low-income and certain racial/ethnic groups.

Non-field studies utilize several distinct outcome measures. Of the studies examined, the outcomes most relevant to how consumers might respond to an FOP symbol system are those where consumers make an actual hypothetical choice among products or note their intent to purchase a particular product. However, when Wansink and Ray (1992) compared measures of brand attitude and consumption intention, they found that attitude toward a product was a weak predictor of consumption. Aikman et al. (2006) examined relationships between perception of healthfulness of foods, attitudes, and eating behavior and found that consumers are either not aware or do not use nutrition information when making decisions about the healthfulness of foods, and beliefs about the healthfulness of foods are not related to the frequency of consumption.

Less telling, but also potentially important, are consumers' abilities to choose the healthier product from two or more products. The committee examined consumer preferences for various FOP symbol systems. Chocarro et al. (2009) and Barreiro-Hurle et al. (2010) determined from their studies of consumer label use, nutrition knowledge, and consumer food choices that knowledgeable consumers are more likely than other consumers, particularly price-conscious consumers, to choose healthier foods from among a variety of product options.

### *Analysis of Evidence from Peer-Reviewed Studies That Are Not Field Experiments*

Several experimental laboratory studies were initiated to provide evidence regarding which FOP label format is best understood by consumers. Borgmeier and Westenhoefer (2009) conducted a randomized experimental study of 420 consumers to determine how well different FOP nutrition labels worked. The researchers considered four label formats: simple tick, TL format, monochrome Guideline Daily Amount (GDA), and color-coded GDA. There was also a control condition for which no nutrition information was provided. The simple tick was similar to the Smart Choices™ icon (see Phase I report, Table S-1) that was used briefly in the United States. Participants were asked to complete two tasks. First, they were asked to select the most healthful product in each pair from 28 pairs of food products. Then, in a simulated shopping experience, they were asked to select all the foods and drinks that they would consume during the next day.

Results from the paired comparison task indicate that the TL format was associated with the highest percentage of correct choices. That is, consumers correctly identified the most healthful product (24.8 out of 28 pairs) when nutrition information was presented via a TL system. However, the different food label formats did not influence consumers' ultimate choice of foods. In all experimental groups, the average daily intakes for fat, saturated fat, sugar, and sodium were above the recommended daily amounts. Thus, although the TL system helped consumers identify the most healthy food options, it did not influence consumers' actual choices. The results of both tasks were consistent across different demographic segments (Borgmeier and Westenhoefer, 2009).

Feunekes et al. (2008) conducted a similar study. This two-part study examined the influence of eight FOP nutrition labeling formats that differed in complexity, from relatively simple to more complex, in terms of the amount and type of information provided. Whereas the simpler formats provided an interpretation of the overall healthfulness of the product, the more detailed formats provided judgments of the healthfulness of each nutrient. Participants, selected from four European countries, evaluated healthy and less healthy foods from the same product category.

In the first part of the study, six labeling formats were used: Healthier Choice Tick, Health Protection Factor, smiley faces, stars, Multiple Traffic Light (MTL), and Wheel of Health. The Healthier Choice Tick was a single tick and was only present on the healthier product in the pair. Stars, smiley faces, and the Health Protection Factor provided "grades" for the products. A product could be awarded one to five stars or smiley faces. The Health Protection Factor was derived from the system used to rate sunscreen lotions; products were assigned a number from 1 to 7, with higher numbers indicating a healthier product. The MTL presented information on five key nutrients (energy, total fat, saturated fatty acids, sugar, and salt). Like other iterations of the MTL, each nutrient was given a score of low (green), medium (amber), or high (red), which was indicated by both color and text. The Wheel of Health was based on a system used by the UK retailer Sainsbury's. The label provided the exact amount of the five key nutrients in a pie-chart format, with each slice of the pie colored green (low), amber (medium), or red (high). Participants evaluated the different labeling formats for their ease of understanding. Results indicated that participants found all the formats easy to understand, relatively credible, and likeable and that participants were significantly better able to differentiate between the healthy and unhealthy products when the simpler, graded smiley faces and stars formats were used. Also of interest were the effects of label endorsement: Participants reported that the labels were significantly more credible when endorsed by international or national organizations (Feunekes et al., 2008).

In a second study in the same paper, the investigators introduced two additional different label formats, a multiple choice tick and a GDA format. As in the first study, they found that all formats helped consumers better differentiate between healthy and unhealthy products. However, consumers took the longest time to evaluate the products when the GDA format was presented. Consequently, the investigators concluded that simpler FOP labeling formats such as Healthier Choice Tick or stars may be more effective in helping consumers make healthier choices (Feunekes et al. 2008).

Kelly et al. (2009) conducted a similar study in Australia to examine the effects of format on consumers' evaluations of FOP labeling systems, by examining a TL system and a variation of the TL system in which an overall rating of the product was also included. They also tested a monochrome Percent Daily Intake (% DI) and a modified % DI (M-% DI) labeling format. In these formats, the percentage dietary contribution from energy, protein, total fat, saturated fat, total carbohydrate, sugar, fiber, and sodium for an average adult was presented. In the modified % DI format, the indicator color for each nutrient (green, amber, or red) was presented in addition to the number. Most participants (90 percent) believed that consistent FOP labeling across all food products would be the easiest to understand. Furthermore, they were best able to identify the healthier product when presented with the TL system ranking levels of total fat, saturated fat, sugar, and sodium as either high, medium, or low and assigned a red, amber, or green color-code, respectively. Participants had the most difficulty differentiating products when the M-% DI format was used; 64 percent identified the healthier option, compared to 81 percent with the TL system.

Although the above studies focus on hypothetical choices of products, their findings are similar to those of other research examining outcomes such as understanding the various FOP labels. For example, Gorton et al. (2009) surveyed consumers shopping in a supermarket in New Zealand to assess their understanding of different FOP labeling schemes. In this study, shoppers were presented with a series of questions that assessed preference for and understanding of four nutrition label formats: MTL, simple traffic light (STL), the mandatory Nutrition Information Panel (NIP), and % DI. Consumers were best able to understand the STL and the MTL formats. This study, however, did not examine the influence of consumer preference for purchasing one food over the other in response to labeling format.

Balcombe et al. (2010) conducted a survey-based choice experiment to examine consumer response to the UK TL system. The investigators used as an outcome willingness to pay (WTP) for reductions in fat, saturated fat, sugar, and salt in food products. They found that participants had a very strong preference, reflected in their WTP, for avoiding a market basket containing foods with "red" lights.

Dunbar (2010), in a two-part study, examined consumers' ability to choose between alternative products in the context of composing a meal and assessed the quality of consumers' food choices as well as the efficiency with which choices are made. In the first study, participants recruited from a city marketplace in the UK were asked to choose the healthiest product from among a selection of products displaying either product name only or the GDA panel plus the product name. In the second study, participants were given additional instructions for a specific task and a new condition using a label that also included a task (called a task-based interface). They were asked to choose a product that (1) could be used to make a meal that was low in salt and (2) was the overall healthiest choice. The participants in the first study made faster decisions when given the product name only but made better overall choices when given the GDA label with nutrition information. Interestingly, participants given the GDA label did not significantly reduce the levels of salt chosen in the "pick the healthiest" task. Participants in the second study made faster decisions when given a simplified rather than a more complex GDA text label. Furthermore, they were significantly better able to reduce the amount of salt in their selections with the simplified text label compared to the product name only. There was, however, no significant improvement in making healthier choices with the simplified text label when the label included the "pick the healthiest" task.

*Research on Consumer Preference*

One study examined factors that influence consumers' preference for labeling formats. Using a face-to-face interview of shoppers outside a national grocery store chain, Berning et al. (2010) examined shoppers' preferences for nutrition information provided on grocery store shelf labels. In the choice experiments, color images of shelf labels were displayed below a picture of a food product. The images presented variations of price information, unit price, and nutrition information (total fat, saturated fat, calories, cholesterol, sugar, and sodium either with "low" or "high" prominence). The results showed positive consumer preferences for the provision of nutrition information on grocery store shelf labels and suggested benefits for both stores and shoppers from the provision of shelf-label nutrition information. These benefits include alignment of incentives between stores (providing nutrition information may increase sales) and shoppers (seeking nutrition information on products) and identification of shopper product preferences following the introduction of shelf tag information for certain products in stores.

## Applied Marketing Information

As noted previously, the committee gave only minimal weight to information from applied marketing sources, the type of research at the lowest level of the evidence hierarchy. However, the committee determined that including this type of evidence as a component of the totality of evidence to consider was important because it provided additional insight into how consumers perceive and may use FOP labeling. The Phase I report outlined plans for Phase II by describing a multifaceted approach that would include information from relevant consumer behavior literature, experts from relevant fields, and research on FOP undertaken by FDA (IOM, 2010). In lieu of undertaking its own research, the committee could use already existing research on the usability of labels by population subgroups. Information provided the committee in a public workshop (see Appendix F) as well as applied research identified by the committee formed the core of this evidence.

*Research from FDA*

The committee reviewed research performed by FDA that directly examined FOP food labeling using an approach similar to the laboratory-based experiments described above (Lin and Levy, 2010). In the first of two studies, 2,424 subjects in an online convenience panel were randomized to see a number of different FOP systems—the National Facts panel (NFP), the Smart Choices symbol, a TL system, and a Nutrition Highlights system, similar to the *Nutrition Keys*[1] program developed by the Grocery Manufacturers' Association (GMA). The selection of healthier products was the key outcome, and the results varied depending on which food category was examined. There were no statistically significant differences for snacks, and for meals the NFP had the highest percentage

[1] Now called "Facts up Front."

of correct responses. For cereals, the NFP and TL system tended to perform better, although results were not consistently statistically significant across all comparisons. The committee concluded, therefore, that differences in results by product category call into question the extent to which these findings can be generalized.

Study 2 examined 4,901 participants, also from an online convenience sample. In this study, a larger number of FOP systems were examined, and the outcome was the consumer choice between two products—either the healthier or less healthy product. Decisions among product categories were broken down into hard versus easy choice, with and without the presence of a health cue. When the choices were easy, there were no differences among the FOP systems in choosing a healthy product when the health cue was present, and only small differences without this prompt. For more difficult choices, in general the NFP was most helpful to consumers in choosing a healthy product, which the authors attributed partially to its overall familiarity. No statistically significant differences emerged with the other FOP system.

### *Research from the United Kingdom*

In a study initiated by the Food Standards Agency comparing different TL systems, the British Market Research Bureau (BMRB, 2009) found that consumers' levels of comprehension of different FOP labels were generally high. Of the two labels with the highest overall levels of comprehension, one combined text (the words high, medium, and low), TL colors, and a % GDA and the other combined text and TL colors. The investigators concluded that the coexistence of a variety of different FOP label formats in the marketplace can be confusing to consumers.

### *Research from Industry or Stakeholder Groups*

Industry and stakeholder groups provided the committee with information about sales data that directly related to testing of various FOP systems and that addressed key questions. This information included shelf tag as well as FOP systems data. The American Heart Association provided data from a field-based study that highlighted the Heart Check program on shelf tags of products participating in the program.[2] The Heart Check logo on the shelf tag was as large as or even larger than the original shelf tag in the provided pictures. Sales of products participating in the program increased by 5 percent compared to a control store of similar products not participating in the Heart Check program. The NuVal Corporation, which labels products with an ordinal scale from 1-100, also provided data on changes in sales after the label appeared on some, but not all, products within a product category.[3] Sales of products with high NuVal scores of 50 and above increased compared to those with scores of less than 50 in the year after the labels were in place, when compared to purchases from the previous year, for categories including cold cereal, fresh bread and rolls, and yogurt. The FOP systems information on both FOP labels and shelf tags obtained from industry representatives is reviewed in more detail in Chapter 4.

The GMA-IFIC used an online survey to test comprehension, communication, and interpretation of a potential FOP nutrition information system (Smith-Edge and Hildewine, 2010). The key findings identified from this survey were that increasing the amount of nutrition information on the front of packages strengthened consumers' comprehension and comfort level with the information; consumers viewed the NFP less often when they were asked to find specific information that was available on the FOP; consumers who were provided with calories plus negative and positive nutrients were more likely to agree that the FOP nutrition information was helpful with decision-making and understanding than those provided with calories only; and across all labeling systems tested and for all product categories, a majority of consumers were able to select products considered to be healthier.

[2] Consumer Marketing Research, Heart-Check Mark. Submitted by Dennis Milne, American Heart Association, October 15, 2010.

[3] Information Research, Inc., Letter to the Committee on Examination of Front-of-Package Nutrition Rating Systems and Symbols. Submitted by Annette Maggi, NuVal, March 2010.

## FINDINGS AND CONCLUSIONS

### Findings

Overall, the evidence regarding the effects of FOP systems is not comprehensive. From the limited set of real-world studies reviewed, no single system emerged as the absolute “best.” Looking at the evidence more broadly, when comparing across studies or when comparing multiple systems within the same study, some limited evidence emerges that shows the simpler systems to be more effective in encouraging healthier choices. The lack of research on children and vulnerable populations is noteworthy. In addition, as noted in Chapter 4, when food choice is constrained by economic considerations, healthier food choices will likely receive little attention if they are not affordable.

Given the paucity of evidence from the peer-reviewed literature, the additional evidence obtained from applied market research, including that of FDA as well as the British Market Research Bureau and food manufactures, provided additional insight, not available from other sources, into how consumers perceive and use FOP labeling.

### Conclusions

The committee concluded that research on FOP symbol systems is limited. No single FOP symbol system is supported by evidence of its superiority to all others, and FOP systems alone as currently developed do not show consistent evidence of dramatically influencing consumer choice. However, there is some limited evidence that FOP systems that are simple and easy to understand more effectively encourage choices of healthier products, particularly in the real-world settings where consumers make decisions quickly in a larger context of choices.

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# 6

# Effects of Food Package Information on Consumer Preferences, Choices, and Processing

## INTRODUCTION

Chapter 2 of this report describes the various types and amounts of product and nutrition information currently found on food packages, including branding, images, claims, and promotions. This chapter examines the effects of such information on consumer preferences and choices, and describes how consumers process information about products when faced with multiple competing stimuli, as found on many food packages today. Findings from this research informed the committee's recommendations for designing an effective front-of-package (FOP) nutrition labeling system.

## DOES FOOD PACKAGE INFORMATION INFLUENCE CONSUMERS?

Many studies have examined the effects of food package information and marketing on consumer beliefs, preferences, and choices. These studies often use an experimental design in which some element of package labeling is manipulated by the investigators (e.g., present vs. absent). Participants are then exposed to one or several versions of the package, after which they respond in some way to the product(s) they saw. Responses are measured in a host of ways, from survey-based self-reports, to tracking eye movements, to tracking brain activity in neuromarketing studies. Most studies use simulated or computer-generated package stimuli, although some use actual packages, and most occur in controlled settings. Nearly all types of food package information and marketing described in Chapter 2 have been examined in these types of studies.

### Nutrition-Related Claims

As Chapters 2 and 3 describe, nutrition-related claims are fairly common on food packages and must adhere to regulatory standards. Such claims therefore provide accurate information about the contents of a product and could conceivably influence some consumers' attitudes and choices. Manufacturers choose which claims, if any, to make, and presumably this selection process is purposeful, not random. Thus a manufacturer's choice of claims might influence consumer judgments. For most foods, no single claim would provide a complete characterization of the product as a whole. For example, knowing that a food is a good source of vitamins and iron does not tell consumers whether it is also high or low in saturated fat, sodium, sugar, or calories. Thus when evaluating consumer effects of package claims, it is important to consider not just claim-specific outcomes, but also how claims might affect broader judgments about a product.

In a randomized experiment, Kozup et al. (2003) (Study 1) examined consumer reactions to adding heart-healthy claims to packages of frozen lasagna dinner. Participants were 147 primary food shoppers who completed the study protocol online. Findings showed that those exposed to packages containing the claim reported significantly more favorable nutrition attitudes about the product than those who saw the same package without the label. These attitudes included judging the product to be "nutritious," "good for your heart," and "part of a healthy diet."

Labiner-Wolfe et al. (2010) examined consumer reactions to simulated bread or frozen dinner packages that varied in the presence or absence of nutrition-related claims ("low-carb") and showing or not showing the Nutrition Facts panel (NFP). Participants in the experiment (n = 4,320) were part of a national online consumer panel. Among participants who saw packages that did not show the NFP, those exposed to packages with "low-carb" claims rated the products as more helpful for weight management and lower in calories than those seeing the identical product with no "low-carb" claim (Labiner-Wolfe et al., 2010). However, when the NFP was present, consumers rated products with and without a "low-carb" claim the same in terms of weight management benefits and calories. This apparent benefit of NFP exposure may have less practical value, though, as the majority of Americans—and an even higher proportion of individuals—do not use the NFP (Guthrie et al., 1995; Morton and Guthrie, 1997; Satia et al., 2005; Blitstein and Evans, 2006; Todd and Variyam, 2008) and thus might be more influenced by claims.

In a study of 320 adults from an online consumer panel, Drewnowski et al. (2010) used conjoint analysis to evaluate reactions to 48 nutrient content and product claims. Claims addressed six nutrients to encourage (protein, vitamin C, vitamin A, fiber, calcium, iron) and five nutrients to avoid (fat, saturated fat, cholesterol, sugar, sodium), and either stated the presence or absence of the nutrient (e.g., "contains calcium" vs. "is rich in calcium") or the amount of the nutrient (e.g., "good source of vitamin C" vs. "excellent source of vitamin C"). After exposure to each different claim (or group of claims) about a hypothetical product, consumers rated the healthfulness of the product from 1 (least healthy) to 9 (most healthy). Perceptions of healthfulness (ratings of 7-9) were influenced most by claims about the presence of protein and fiber, followed by claims about the absence of saturated fat and sodium, then by claims about the presence of vitamin C and calcium. Claims about nutrients to encourage were more influential on ratings of healthfulness among women than men. The investigators noted the healthfulness ratings were strongly influenced by claims about protein, a nutrient for which there is no shortfall in the American diet, while claims about low or no sugar did little to enhance healthfulness ratings.

Gorton et al. (2010) conducted intercept interviews with 1,525 food shoppers in 25 grocery stores in New Zealand to assess consumer understanding of two package claims—"97 percent fat free" and "no sugar added"—on simulated food packages. Although a large majority of shoppers (72 percent) interpreted these claims correctly, many shoppers also inferred from the claims that the product was healthy. Nearly half of all shoppers (47 percent) said that a food carrying a "97 percent fat free" claim on the package was "definitely a healthy food." This inference was significantly more likely among shoppers from racial or ethnic minority groups and among low-income shoppers. The same pattern was found for "no sugar added" claims. U.S. studies of responses to nutrition-related claims in food advertising have also found that consumers tend to over-generalize a product's healthfulness based on narrower claims (Andrews et al., 1998).

In European studies, food products whose packages contain health-related product claims are preferred by consumers over products without such claims (e.g., chosen from a set of options with and without nutrition claims), are viewed as more attractive and elicit greater purchase intentions (e.g., Verbeke et al., 2009; Aschemann-Witzel and Hamm, 2010). The likelihood of choosing a product with a package claim is reduced when consumers have an established habit or history of buying a certain product (Aschemann-Witzel and Hamm, 2010), suggesting that in such instances, the effects of branding and brand loyalty may trump those of nutrition-related claims. Collectively, these findings suggest that (1) nutrition-related claims can influence consumers' perceptions of a product; (2) these perceptions sometimes exceed the bounds of the claim, extending to generalized beliefs about the healthfulness of the product; and (3) these over-generalizations may be more common among certain subgroups of consumers, including minorities and those with lower income.

The findings of Labiner-Wolfe et al. (2010) suggest that when consumers see not only a label claim, but also a standardized and comprehensive nutrition statement (i.e., the NFP), over-generalizations of a product's healthfulness can be reduced or eliminated. Similarly, Andrews et al. (1998) found that, although consumers over-generalize the healthfulness of products based on specific claims contained in advertising, these over-generalizations can be significantly reduced using evaluative disclosures that specify whether the per serving amount of a nutrient is "high" according to Food and Drug Administration (FDA) criteria. These evaluative disclosures outperformed three other disclosure conditions (no disclosure, absolute disclosure, and relative disclosure) in reducing over-generalizations about a product's healthfulness, fat content, and benefits for reducing the risks of cancer and heart disease.

It is not clear whether a FOP nutrition label could reduce over-generalizations in the same way that the NFP and evaluative disclosures on advertising did, but evidence of such an effect would provide compelling support for such a system (Schofield and Mullainathan, 2008). In particular, the findings of Andrews et al. (1998) suggest that FOP label formats should evaluate, not just report, amount of key nutrients in a product.

### Other Package Information

In addition to nutrition-related claims, food packages can also contain branding, promotions, and other product information (see Chapter 2). *Product branding* used on food packages may also influence consumer preferences. Robinson et al. (2007) examined the effects of marketing and brand exposure on taste preferences of 3- to 5-year-old children from Head Start centers. The children were asked to taste five pairs of identical foods and beverages in various packaging schemes (e.g., boxes, bags, cups) that were either unbranded or branded as "McDonald's." Children were significantly more likely to report that the "McDonald's"-branded food tasted better (Robinson et al., 2007).

*Promotional marketing* on food packages may also influence consumer preferences and decisions. For example, research shows that a large majority (85 percent) of packaging targeting children uses cartoon-like graphics and typology (Elliott, 2008). To examine the effects of such on-package marketing, Roberto et al. (2010) had children ages 4-6 years taste and rate identical pairs of gummy fruit snacks, graham crackers, and carrots presented in packaging that did or did not include popular cartoon characters. After tasting both, children were also asked to select the product they would choose for a snack. Children preferred the taste of products that came in packages containing a cartoon character (Roberto et al., 2010).

Many studies have examined consumer reactions to *value-based labeling*. In a large choice experiment, i.e., where participants were asked to choose among products that differ on pre-determined attributes, James et al. (2009) examined consumer preferences for applesauce that varied in label claims and price. Consumers (n = 1,521) recruited from 65 counties in Pennsylvania viewed four sets of four different applesauce labels and were asked to select the one they would choose from each set. All labels included the word "applesauce" and a sales price (that varied by product and set). Some labels also included claims indicating the product was locally grown, organic, low-sugar, or low fat; some labels included combinations of these. Controlling for price, claims that the applesauce was locally grown ("Pennsylvania Preferred"), organic, or low-sugar all increased the likelihood that consumers would choose them (James et al., 2009). Of these, locally grown was by far the strongest predictor of choice. Unexpectedly, applesauce labeled as low fat was significantly *less* likely to be selected, perhaps because consumers inferred compromised taste, or because applesauce is a fat-free food, so a "low-fat" claim is meaningless. Analyzing these consumer choices based on variations in product price showed that consumers were willing to pay more for locally grown applesauce than for applesauce labeled as organic, low-fat, or low in sugar.

Studies using different methods have come to similar conclusions—that value-labeled foods are generally preferred to those without such labels. Loureiro et al. (2001) used in-store intercept interviews to examine preferences for organic, eco-labeled, or regular apples in a random sample of shoppers (n = 285) in a grocery store produce section. Their findings showed that when offered at equal prices, consumers preferred organic apples to eco-labeled or regular apples.

### New Methods for Studying Consumer Responses

The emerging fields of consumer neuroscience and neuromarketing bring new tools to understanding consumer reactions to products, packaging, and advertising (Kenning and Linzmajer, 2011; Morin, 2011). Using a variety of methods like functional magnetic resonance imaging (fMRI), marketers and researchers can now examine how the brain processes product and advertising stimuli, and draw inferences based on the location and extent of heightened neural activity in the brain. Although there are no published studies to date using these methods to examine consumer reactions to FOP nutrition labels, several studies have examined other food package labels and claims, food package design, and food advertising.

Linder et al. (2010) showed participants (15 men, 15 women) images of 40 everyday foods that are routinely available in organic or non-organic forms. Participants viewed two versions of every image while inside the scanner, one with a widely used organic food symbol and one with an artificial symbol indicating conventional production (i.e., non-organic). When viewing images with the organic food label, neural activity increased in the ventral striatum, a part of the brain shown in previous research to be involved in anticipating pleasant taste rewards.

Stoll et al. (2008) tested reactions to attractive and unattractive packaging on actual food products widely available in Germany. In a preliminary study, 131 packages were rated on attractiveness and 30 were selected for use in an fMRI experiment: the 10 most attractive, the 10 least attractive, and 10 that were neutral (neither highly attractive nor unattractive). Attractive package designs triggered more activity in areas of the brain associated with attention and processing visual stimuli, while exposure to unattractive package designs triggered increased activity in areas of the brain associated with processing aversive stimuli.

In other studies, exposure to aesthetic (compared to standardized) beverage container designs increased activity in areas of the brain that are also activated by smiling faces (Reimann et al., 2010). Providing consumers with product information like claims that a food has "rich and delicious taste" or that a bottle of wine is very expensive has been associated with increased activity in an area of the brain associated with experiencing pleasantness when consumers received this information (vs. not receiving it) prior to tasting a product (Grabenhorst et al., 2008; Plassman et al., 2008).

Although these studies provide no direct evidence about how consumers might process FOP food labels, they reinforce findings from traditional marketing studies that indicate certain messages, designs, and labels on food products and packages can influence consumers' reactions to and experiences with a product.

## Effects Vary Among Sub-Groups of Consumers

Although the findings described above focus on overall main effects of package label information, it is clear across many studies that these effects can vary among different sub-groups of consumers and across food categories. For example, in the Robinson et al. (2007) study of consumer preferences and "McDonald's" branding on food packaging, the effects of branding were greatest among children with a television in their home and those who ate at a McDonald's restaurant more frequently. In James et al. (2009), a choice study of applesauce, consumers with more knowledge about agriculture were less willing to pay more for organically and locally grown applesauce. In Loureiro et al. (2001), the preference for organic apples was strongest among consumers with children and those with greater concerns about food safety and the environment. And while the majority of children in Roberto et al. (2010) chose a snack that had a cartoon on the package, this effect was weaker for carrots than gummy fruit snacks or graham crackers.

These subgroup effects are highly consistent with well-established theoretical and empirical literature on information processing and persuasion. *Previous experience* (e.g., eating at branded fast-food restaurants), *familiarity* (e.g., seeing television advertisements for branded restaurants, knowing cartoon characters), *issue involvement* (e.g., concern about food safety and the environment), and *personal relevance* (e.g., having children that might be affected) all influence individuals' attention, receptivity, and reactions to information in predicable ways (Petty and Cacioppo, 1979; Petty et al., 1981; Wu and Shaffer, 1987; Johnson and Eagly, 1989; Garcia-Marques and Mackie, 2001). Applied to FOP food labeling, care should be taken to design an approach that maximizes the impact of nutrition information for the greatest number of people, especially population sub-groups that historically have not used this information.

In summary, many elements of food packaging, including nutrition-related claims, branding, promotions, and other product information, have been shown to influence consumers' product attitudes, preferences, and choices, at least in controlled and experimental settings.

## HOW DO CONSUMERS PROCESS PRODUCT INFORMATION IN A CLUTTERED PACKAGE ENVIRONMENT?

Chapter 2 described the context in which consumers today would likely encounter FOP nutrition labels. In short, consumers are in a hurry, spending less time shopping for food and making very quick decisions at the point of purchase about individual products. These decisions are made in the face of a wide array of products, each of which comes in a unique package that may be decorated with some combination of branding, images, promotions, and claims about the product, how it is made, and its healthfulness. As described above, many of these package design features and product claims have been shown to influence consumer attitudes, preferences, and choices, at least in controlled settings and for some groups of consumers. These findings beg the question: *What would make an FOP nutrition label stand out enough to have an impact in this environment?*

### Insights from Visual Design

All visual design relies on the idea of contrast (Dondis, 1974). To a large extent, manipulations in contrast between an object and background or among objects in a field determine what people pay attention to and how they understand its meaning. Contrast can be achieved by variations in color, size, shape, position, and other design features. For example, elements that are bigger, bolder, have more color contrast with the space around them, or are shaped differently generally will be noticed before smaller, lighter, commonly shaped, or subtle elements (Schiffman and Kanuk, 1983). Designers purposefully create, select, and arrange elements to be more or less prominent, calling attention to those they deem most important. This is true of food package design, too, and therefore relevant for FOP nutrition labeling. Both aim to capture consumer attention amidst many competing stimuli in a busy retail environment.

Theories and explanations of visual attention reinforce this design perspective, proposing that people attend to different features of a complex scene serially, starting with the most salient features (Treisman and Gelade, 1980; Koch and Ullman, 1985; Itti et al., 1998). In consumer studies, several researchers have tested this phenomenon empirically by examining consumer reactions to different stimuli in a cluttered information environment. Although none of these studies has directly examined attention to FOP nutrition labels on food packages, some pose information processing tasks that are roughly analogous to finding information on a busy food package.

### Capturing Consumer Attention in a Cluttered Environment

Pieters et al. (2007) studied consumer attention to multi-component feature advertising for grocery stores. A newspaper advertisement showing a set of 10 to 20 "featured" products (e.g., sale items) on a single page is an example of this type of advertisement, and is considered by the researchers to be a "cluttered" environment. There are two key attributes of this type of advertisement. "Set size" refers to the number of different "components" (e.g., products) that make up the advertisement. "Set structure" refers to similarities or dissimilarities in the design or arrangement of the different components. In general, a larger set size and heterogeneous structure add to competitive clutter, making it harder for any individual component of the advertisement to stand out and attract attention (Rosenholtz et al., 2005). Thus the salience of any one advertisement component is likely determined by not only its own attributes, but also its contrast with the other components around it.

The study tested this proposition by analyzing eye-tracking data from consumer responses to 1,100 such advertisements. Eye tracking captures consumers' visual attention to advertisements—where they looked, in what order, and for how long. This study focused on consumer attention to brand, text, images, price, and promotion information. Findings showed that consumer attention was greatest for components of the advertisements that were distinctive in some way from other components in the set (Pieters et al., 2007). The distinctiveness attribute with the greatest effect on attention was size—the larger a component of the advertisement, the more attention consumers paid to it. Other, similarly designed, eye-tracking analyses have compared consumer attention to pictures, brand, and text in print advertisements, finding that, among them, pictures are superior at capturing attention, regardless of size (Pieters and Wedel, 2004).

Lohse (1997) studied consumer responses to advertising in a different type of cluttered environment, *Yellow Pages* listings. Study participants (n = 32) were given a task of choosing a certain type of business in the *Yellow Pages*. Eye-tracking equipment was used to assess which listings and advertisements attracted the most attention. Color advertisements were noticed sooner than those without color and viewed longer than those without color, and overall more color ads were noticed than those without color (Lohse, 1997). Because most listings and advertisements use only black ink, the use of color enhances contrast with surroundings on the page. Size also captured attention. Consumers noticed nearly all (93 percent) of the quarter-page advertisements, but only 26 percent of the plain (i.e., text only) listings. Among plain listings, those using bold text were more likely to be viewed than those using normal text. Findings also showed that consumers spent 54 percent more time viewing businesses that they ended up choosing, therefore establishing a link between attention and choices.

Applied to food packages, these findings suggest that through visual design, some types of package information—branding, images, product claims, and even FOP nutrition labeling—can be made more prominent than others. It is possible, as Woolverton and Dimitri (2010) propose, that as the amount of package information increases, some consumers will be overwhelmed and unable (or unwilling) to process it all (Woolverton and Dimitri, 2010). Instead they will rely on simple cues, like branding or label claims, to make judgments about and comparisons among products.

## Cues and Signals

Cue Utilization Theory and Signaling Theory suggest that under certain circumstances, consumers rely on extrinsic cues or signals as surrogate indicators of product quality (Richardson et al., 1994). The theories explain how consumers use product information to distinguish between better and lesser quality products when they have no direct experience with the products. For example, sellers of a high-quality product might use price, brand, or a warrantee to "signal" the higher quality of their product to consumers (Boulding and Kirmani, 1993; Nancarrow et al., 1998; Brucks et al., 2000). Food package claims and FOP labels might act as signals of quality or healthfulness for consumers. Signaling studies indicate that consumers are most likely to rely on signals for purchase decisions involving new or unfamiliar products (Richardson et al., 1994) when they are time stressed and need to make fast judgments about a product (Pieters and Warlop, 1999) and when their ability or motivation to process more complex information is limited (Jae and DelVecchio, 2004).

In a randomized experiment, Jae and DelVecchio (2004; Study 2) examined the effects of packaging cues on household consumer products among high- and low-literacy adults. All participants (n = 80) viewed a pair of identically priced paper towel products that varied in quality. By random assignment, packaging for the paper towels used either a plain or interesting design, and described product quality using either an informational approach (a bulleted list of product characteristics) or a simple symbol (a star-rating system). In every pair, the paper towel in plain packaging was of higher quality (i.e., the better choice, given equivalence in price). When the pair of products both described quality using a bulleted list, high-literacy adults chose the better paper towel in plain packaging, while low-literacy adults chose the inferior product in nice packaging. However, when the simpler star-rating system was used, there were no differences between high- and low-literacy adults choosing the better paper towel. These findings indicate that using simple symbols to summarize complex information about product quality may be especially valuable to low-literacy populations.

The strength of simple visual communication also has been demonstrated in consumer studies of reactions to certain types of food labels. Kapsak et al. (2008) conducted a web-based study of 5,642 U.S. adults to evaluate a possible FDA label system that graded the strength of scientific evidence behind health claims made on food packages. Participants viewed packages of orange juice, pasta sauce, or breakfast cereal containing health claims that were well known (orange juice—calcium), moderately well known (pasta sauce—lycopene) or fictitious (cereal—trilinium). Each package also contained one of four versions of a label that rated the strength of the evidence behind the health claim: report card graphic, report card text, embedded claim text, or point-counterpoint claim text. Finally, the strength of evidence was varied within each label format for each product. Participants viewed two-dimensional color images of each food package and could toggle between front, back, and side views of the product.

The simplest format—a report card graphic using letter grades (A-D) to reflect strength of evidence—performed best. It was the only format tested in which consumers did not have difficulty distinguishing between the four levels of evidence. Although FDA never implemented this labeling system, the investigators summarized their findings as suggesting "the strength of visual communication over text on food labels" and the value of "simple, direct, and positive messaging to consumers about the health benefits of foods" (p. 255).

FOP food labeling, especially using a simple symbol, might serve as a cue or signal for consumers. Although there are some label claims that could be made by any food product regardless of its nutritional quality (e.g., "Moms love it"), fact-based claims about a standard set of nutrients could be made only by those that meet some predetermined nutritional standard. Thus consumers might view an objective, uniform FOP nutrition label as a kind of signal, helping distinguish between products of greater and lesser nutritional quality.

Another labeling system, *Energy Star®*, already uses this approach to help consumers judge the energy efficiency and energy costs of durable goods such as consumer electronics and household appliances (Box 6-1). *Energy Star®* is a U.S. government–based program jointly led by the Environmental Protection Agency (EPA) and Department of Energy (DoE). Products that meet energy efficiency standards set by EPA and DoE can carry the *Energy Star®* label—a simple blue square bearing the program name—and manufacturers and retailers can use *Energy Star®* branding to advertise and market approved products. In a 2003 review of eco-labeling programs for energy efficiency, Banerjee and Solomon (2003) singled out *Energy Star®* as particularly successful, and concluded that one reason for its impact was the clarity and simplicity of its label. They asserted that across all programs, simpler labels like the *Energy Star®* logo were more useful to consumers. Citing repeated consumer complaints about other types of labels that focused on information disclosure, they observed that "the proportion of informed consumers who are willing and able to use technical information effectively is low" (p. 120).

There might also be unintended effects of nutrition cues or signals on food packages. One of the most consistent findings in studies of consumer reactions to package claims is the tendency of consumers to over-generalize the healthfulness of a product based on claims about a specific nutrient (e.g., Andrews et al., 1998; Kozup et al., 2003; Gorton et al., 2010; Labiner-Wolfe, 2010). A study by Horgen and Brownell (2002) suggested that consumers might interpret a favorable rating on an FOP nutrition label as a signal that the food does not taste good. It is also possible that different labels on a product package could signal conflicting information to consumers, in which case effectiveness of both may be diminished. For example, the FOP nutrition label for a particular food might indicate it is a less healthful choice while the manufacturer's nutrient content claim on the same package announces that the food is "a good source of vitamin A." Because nutrition-related claims are fairly common—even on products that exceed FDA-recommended levels of fat and sodium (Harris et al., 2009; Colby et al., 2010)—the effects of any new FOP-package labeling system should be evaluated in this specific context.

## Location of Information on Packages

The location of an FOP nutrition label may also influence the likelihood that consumers attend to and use it. Visual search studies suggest that when viewing certain types of stimuli, humans rely on familiar "scan paths" or "saliency maps" that are encoded in memory from similar visual search situations in the past (Koch and Ullman, 1985; Itti et al., 1998; Rybak et al., 2005). These paths or maps reflect established patterns of knowing "where" to look to find "what" information in a particular context. As an example, when regular shoppers view items on a grocery store shelf, they know to look at shelf tags to find product prices. If FOP nutrition symbols were located in the same place on every food package (e.g., upper right-hand corner), then it would be expected that some consumers might develop a scan path in which they always looked in this place for nutrition information. When they encountered a new package, cognitive processes would select and follow this established path for processing package information.

These scan paths can be influenced by training (Itti, 2005). So-called "pre-attentive" prompts can help individuals locate information in a busy or complex landscape (Wolfe, 2005). At the simplest level, such prompts might tell consumers *where* to look to find a FOP nutrition label (e.g., upper right-hand corner). More specific prompts that also indicate *what* to look for should have an even greater impact on attention (Wolfe, 1994). In 2005, Wolfe proposed a typology of probable, possible, and unlikely sources of pre-attentive guidance. The list of probable

**BOX 6-1**
**Energy Guide and *Energy Star*® Programs**

Created in 1992 by the U.S. Environmental Protection Agency (EPA), the *Energy Star*® program aims to reduce energy use and greenhouse gas emission by helping consumers and businesses identify energy efficient products. Products that meet energy efficiency standards set by EPA and the Department of Energy (DoE) can carry the *Energy Star*® label, and manufacturers and retailers can use *Energy Star*® branding to advertise and market approved products. Qualified products include a wide range of appliances, consumer electronics, lighting fixtures, heating and cooling equipment, office equipment, and items from more than 50 other product categories.

For consumers, the *Energy Star*® label signals products that deliver the same or better performance as comparable models while using less energy and saving money. Consumer awareness of *Energy Star* is high, and the program appears to influence purchase behavior. The *Energy Star*® label is recognized by 80 percent of the American public. In 2010, Americans bought 200 million *Energy Star*®–qualified products from more than 60 different product categories. One-third of U.S. households have purchased an *Energy Star*® labeled appliance, and of these purchases, 75 percent of consumers report that the *Energy Star*® label was an important factor in their decision. Both consumers and the environment benefit from these purchases. EPA reports that in 2010, *Energy Star*® helped save households and businesses $18 billion on utility bills and prevented 170 million metric tons of greenhouse gas emissions.

In a 2003 review of eco-labeling programs for energy efficiency, Banerjee and Solomon (2003) singled out *Energy Star*® as particularly successful, and concluded that one reason for its impact was the clarity and simplicity of its label. They asserted that across all programs, simpler labels such as the *Energy Star*® logo were more useful to consumers. Citing repeated consumer complaints about other types of labels that focused on information disclosure, they observed that *"the proportion of informed consumers who are willing and able to use technical information effectively is low"* (p. 120).

At least five other factors have contributed to the success of the *Energy Star*® program, and each has relevance for designing and implementing a FOP nutrition labeling program for foods:

- *Partnerships* with key stakeholders, including thousands of public- and private-sector organizations that manufacture, sell, or use qualified products.
- *Widespread* market penetration for *Energy Star*®, with more than 40,000 individual products now carrying the program label.
- A *dynamic* and evolving program that in less than 20 years has grown from a few personal electronics products, to near ubiquity among household electronics and appliances, to buildings and homes and the materials used to make them. It also constantly reviews its energy efficiency guidelines to make sure qualifying standards are sufficiently demanding and reflect advances in technology.
- Ongoing and multi-faceted *promotions* are used to assure that *Energy Star*® remains prominent and attractive to consumers, manufacturers, and retailers. These include awareness campaigns, tax incentives, and rebates for consumers, an online presence, and public recognition of partner organizations and highly compliant manufacturers. Finally, *funding* is dedicated to support these activities. In FY 2010, EPA appropriated $55.5 million for *Energy Star*®.

SOURCE: http://www.energystar.gov/index.cfm?c=about.ab_history.

ENERGY STAR

sources included color, size, shape, and number. Applied to FOP nutrition labeling, telling consumers to look for "three yellow stars in the upper right hand corner" could increase the likelihood that they will find and attend to this information.

A recent and comprehensive study of FOP nutrition rating systems lends strong empirical support to these propositions. Bialkova and van Trijp (2010) assessed consumer response time and accuracy and ability to distinguish between single and multiple nutrition labels on pictures of actual food packages currently on the market. Each participant (n = 24) viewed 193 packages on a computer screen. Packages varied systematically based on the type of nutrition label ("*Choices*" logo, monochrome Guideline Daily Amount [GDA], multi-colored GDA), its size and location, and whether the package included both a "*Choices*" and GDA label, or only one. Participants were asked to indicate as fast as possible whether or not any nutrition label was present (Task 1) and whether one or two labels were present (Task 2). Responses were timed and checked for accuracy.

Findings showed that participants' responses were significantly faster when the nutrition label appeared in the same location as the previous trial (i.e., consistency of location across multiple successive exposures). It follows that if nutrition labels were located in different positions on different food packages, then it would take consumers longer to find and use them. Reactions were fastest when the label was in the top right position.

Other findings from the study were equally applicable to the design and implementation of an FOP nutrition labeling system. For example, participants were able to identify the "*Choices*" label faster than the GDA label. In contrast to the data-laden GDA label, the "*Choices*" label is a simple check mark logo. This finding reinforces those of previous consumer studies showing simpler labels have advantages over more complex ones (e.g., Banerjee and Solomon, 2003; Jae and DelVecchio, 2004; Kapsak et al., 2008). Among the two GDA labels, reaction time was faster for the monochromatic vs. multi-color version, and for all labels, larger size led to faster response time. The investigators hypothesize that the physical features of a nutrition label—its size, color, shape, and location are key determinants of consumer attention to the label.

## SUMMARY AND CONCLUSIONS

### Summary

Many studies have examined effects of different types of food package information on consumer preferences, choices, and behavior. These studies demonstrate that such information can influence consumers, and likely affects some groups more than others, including those with less knowledge about or interest in nutrition. One limitation of this research is its low external validity. Many studies are conducted in controlled or online settings and use simulated packages and labels rather than actual products. Such studies afford researchers the opportunity to easily manipulate and test different package labeling features, but ignore the complexity of the shopping environment. This complexity exists at both a macro level (e.g., many similar products side by side in a store aisle) and at a micro level (e.g., many instances of branding, promotion, labeling, claims, and other information on a single package). In order to design an optimal FOP nutrition labeling system, it is essential to understand how consumers process information in a busy, cluttered environment.

To succeed, FOP nutrition labels would need to stand out and capture attention in this busy and competitive food package environment. Principles of visual design, theories of visual search and empirical evidence from well-designed studies suggest that a label would need to be distinctive and contrast with other information around it. Distinctiveness might be achieved through a label's design features including its size, shape, color, and/or location. Moreover, if consumers can be conditioned to look in certain places for a certain type of label, the repetition in location and appearance could help them find nutrition labels faster.

Labels conveying information via a simple symbol may also be beneficial to consumers. Studies of food package labels and other consumer product labeling indicate that compared to other types of labels, simpler symbols may be easier for consumers to find, may be more useful to them, help them distinguish between levels on an ordinal scale, and may influence their product choices. Some of these advantages may be particularly beneficial to disadvantaged populations. In one study, a simple symbol improved decision-making about consumer products in low-literacy populations.

Still unclear is how FOP nutrition symbols might perform in the presence of other nutrition-related label claims, especially those highlighting a nutrient that is not addressed by the FOP system. Findings from several studies indicate this is likely to be a common occurrence, and theories suggest it could diminish or negate possible benefits of a nutrition label. Future research should explore this possibility.

## Conclusions

This chapter examined effects of package information on consumer preferences and choices, and explored how consumers process package information in the face of multiple competing stimuli. Because literature that addressed these topics and was also specific to FOP nutrition labels was relatively sparse, the committee also considered literature from related domains. These included studies examining other consumer products (i.e., non-food), other information stimuli (e.g., advertising), and theories and findings from a range of disciplines including visual design, marketing, information search and retrieval, and attention and information processing.

Although no definitive, proven best FOP strategy was identified, in the committee's judgment, the collective literature reviewed in this chapter strongly suggest a certain approach. Consumers are making point-of-purchase decisions about food products in very little time and in the face of a diverse and growing number of stimuli on food packages. The characteristics of an FOP nutrition labeling system that would cause it to stand out in this environment, capture consumers' attention, and be accessible and useful to a diverse cross-section of American consumers are:

1. A simple symbol, signal, or cue that instantly conveys meaning without written information, percentages, or other nutrition data or statistics;
2. Placement of the symbol in the same location on all food packages;
3. A design that maximizes the symbol's visual contrast with existing elements of packaging;
4. Assurance that the symbol is sufficiently prominent in size to compete effectively with other package elements and attract consumer attention; and
5. A complementary campaign that guides consumers to look in a specific location for the specific symbol.

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# 7

# A Model Front-of-Package Symbol System Including Criteria for Evaluating Nutrients

## INTRODUCTION

This chapter describes the characteristics of a model front-of-package (FOP) symbol system and presents an approach for evaluating food and beverage products for the amount of saturated and *trans* fats, sodium, and added sugars. This chapter also presents evaluation criteria for products using the term "points" to indicate that a critical component nutrient met its defined criteria, discusses how nutritional criteria might be based on current Food and Drug Administration (FDA) regulations for labeling nutrient content and health claims, and highlights the strengths, limitations, and regulatory issues pertaining to such a system. The assessment is based on a convenience sample of food and beverage products whose relevant nutrition information is provided in Appendix E.

The Phase I committee concluded that added sugars should not be a component of an FOP nutrition rating system because of insufficient evidence about the contribution of added sugars beyond calories to the most pressing diet-related health concerns among Americans; the inability to distinguish analytically between added and naturally occurring sugars in foods without obtaining proprietary product information and including that information on the Nutrition Facts panel (NFP); and the relatively small number of food categories with high amounts of added sugars. This committee reconsidered this Phase I conclusion in light of events occurring after the release of the Phase I report, specifically the release of the 2010 *Dietary Guidelines for Americans* and the development of an approach to evaluating added sugars content. The 2010 *Dietary Guidelines for Americans*, which is the federal government's nutrition policy document, strongly recommends reducing intakes of calories from added sugars and consumption of foods containing added sugars. These products contribute to energy intake; generally contain no or low amounts of saturated and *trans* fats and sodium; and provide little or no essential nutrients unless fortified, which is not consistent with FDA fortification policy.[1] A relatively small number of food and beverage categories contribute more than half the added sugars in the American diet.

The development of criteria, discussed in this chapter, to evaluate foods with added sugars makes it possible to give no FOP points to such foods while allowing some foods that contain small amounts of added sugars to earn FOP points. The committee's approach addressed previous logistical issues around determining added sugars content that would allow some foods that are major contributors of added sugars to the diet, i.e., beverages and sweets, to erroneously appear to be healthy because they are low in saturated and *trans* fats and sodium.

The strong recommendation from the 2010 *Dietary Guidelines for Americans*, along with the development of

[1] 21 CFR 104.20.

this approach to evaluating added sugars, led the committee to conclude that added sugars are an important component that should be included in an FOP nutrition rating system. This conclusion is consistent with the principle that an FOP symbol system should not inadvertently promote products that are inconsistent with current federal dietary guidance.

## FRONT-OF-PACKAGE MODEL SYSTEM

The committee reviewed published evidence and data submitted by stakeholders and consultants and developed conclusions about FOP systems that will be effective in attracting consumer attention and encouraging them to make healthier food choices. Specifically, the committee's examination of the totality of the available evidence led to the following conclusions:

- To be effective, FOP nutrition labels must compete in a very busy and ever-changing package environment that includes an array of messages designed to capture consumer attention and promote products.
- Nutrition information provided in an FOP symbol system should be based on the most recent *Dietary Guidelines for Americans* and current consensus reports.
- There is a need for a standardized FOP nutrition rating system that moves beyond providing information to one that encourages product comparison and healthier food choices by consumers at the point of purchase.
- FOP systems that are simple and easy to understand more effectively encourage consumers to choose healthier products.
- Consumers are making point-of-purchase decisions about food products in very little time and in the face of a diverse and growing number of stimuli on food packages.
- Campaigns that guide consumers to look in a specific location for the specific symbol would maximize the use and benefit of an FOP system.

Furthermore, the committee identified three outcomes that an FOP system should produce in order to be successful among a broad range of consumers. The system must:

- encourage consumers to make healthier choices at the point of purchase,
- encourage food and beverage companies to provide healthier offerings by reformulating products or developing new ones, and promoting those healthier offerings, and
- encourage retailers to highlight those healthier offerings.

## POTENTIAL FOR SUCCESS

Given the goal of increasing healthier choices, the committee looked closely at a number of FOP and shelf tag systems that have demonstrated some success in the marketplace. The committee focused less on what consumers said and more on what they did, as measured by in-market retail sales. The committee also focused on consumers' processing and use of nutrition rating symbols in a cluttered on-package environment. Based on the evidence reviewed in the preceding chapters, the committee determined that the type of nutrition rating symbol system most likely to be successful in enabling healthier food choice and purchase decisions will be:

- simple, understanding does not require specific or sophisticated nutritional knowledge;
- interpretive, nutrition information is provided as guidance rather than as specific facts;
- ordinal, nutritional guidance is offered through a scaled or ranked approach; and
- supported by communication with readily remembered names or identifiable symbols.

## CHARACTERISTICS OF A MODEL FOP SYMBOL SYSTEM

In addition to the three outcomes of an effective FOP system, the committee identified eight characteristics that are essential to the success of an FOP system. These characteristics are:

1. **One simple, standard symbol translating information from the NFP on each product into a quickly and easily grasped health meaning, making healthier options unmistakable.** "Health meaning" refers to the extent to which a product contains reasonable amounts of three nutrient components (saturated and *trans* fats, sodium, and added sugars) considered harmful to health when consumed in excess or above a certain threshold. All information currently on the NFP would remain on the NFP. The committee suggested adding, on the FOP, a simple summary symbol offering nutritional guidance on that information.
2. **Displaying:**
   a. **Calories in common household measure serving sizes, and**
   b. **Zero to three nutritional "points."** The more points, the more the food or beverage helps consumers avoid less healthy levels of nutrients identified as being associated with diet-related health risks. Specifically, a food or beverage product could earn one point for an acceptable level of sodium, one for an acceptable level of saturated and *trans* fats, and/or one point for an acceptable level of added sugars. Saturated and *trans* fats are considered together to facilitate communication about limiting consumption of foods containing solid fats (USDA, 2010). If a food or beverage product contains any one of the nutrient components of concern in amounts exceeding specified criteria limits, then the product would not be eligible for points (see examples and discussion of points below). A similar system could be developed for shelf tags for unpackaged or bulk items such as fruits and vegetables as well as packaged goods.
3. **Appearing on all grocery products allowing consumers to compare food choices across and within categories.** If all products displayed the FOP symbol system, then it would be easier for consumers to make healthier food choices both within and across food categories. If, however, consumers come to perceive products not displaying the FOP symbol system as less healthy alternatives, then they would in essence "use" the system even if it did not appear on all products;
4. **Appearing in a consistent location across products.** Chapter 4 discusses the benefits of minimizing processing time. Chapter 6 discusses the benefits of characteristics that capture consumer attention, including color and contrast. If symbols are placed on a consistent, as opposed to unpredictable, FOP location, then it will take less time for consumers to process the information;
5. **Practical to implement because the FOP symbol system is consistent with nutrition labeling regulations.** FDA and the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service have developed extensive regulations for nutrition labeling, determining labeled serving sizes and explicit and implied nutrient content claims, and declaring ingredient content. These regulations were developed based on science and with public input from an array of interested parties through a formal rulemaking process and are publicly available;
6. **Integrated with the NFP so that the FOP symbol system and the NFP are mutually reinforcing.** A FOP symbol system and the NFP can be integrated by placing a check, star, or other indicator inside or next to the NFP adjacent to the nutrition component earning the point. In this way, those who are interested can easily see what component(s) earned a point. When the NFP is displayed in the basic vertical format,[2] it is possible to place the check or other indicator just outside the box (see examples in Figures 7-1 through 7-3). However, when the NFP is displayed in a tabular format[3] or linear format[4] it is not possible to place the check or other indicator just outside the box and adjacent to the name of the nutrient earning the point. Accordingly, it would be preferable to consistently have the check or other indicator inside the box for all NFP formats. The committee recognizes that current regulations would need to be modified to allow a

[2] 21 CFR 101.9(d)(12).
[3] 21 CFR 101.9(j)(13)(iii) or 101.9(j)(13)(ii)(A)(*1*).
[4] 21 CFR 101.9(j)(13)(ii)(A)(*2*).

check or other indicator within the NFP. Rulemaking to provide for such a modification could accompany rulemaking to establish an FOP system;

7. **Providing a nonproprietary, transparent translation of nutrition information into health meaning.** Ease of compliance and enforcement requires publicly available and standardized nutrition criteria. An FOP nutrition rating symbol system that displays earned nutrient points based on criteria consistent with labeling regulations is nonproprietary, transparent, and can easily be monitored for compliance; and
8. **Made prominent and useful to consumers through an ongoing and a frequently refreshed program of promotion integrating the efforts of all concerned parties.**

Brands invest in frequent consumer communications that maintain the power and salience of their brand symbols. Without that continual, frequent communication, any symbol can fade from interest and exert less and less influence on choice (Hasher and Zacks, 1984; Romaniuk and Sharp, 2004; Wixted, 2004). Similarly, without frequent communication from the brand to the consumer, any FOP symbol system will fade from interest and become less and less useful in helping consumers make healthier choices. A readily remembered name or "brand" for the FOP symbol would facilitate communication to consumers by increasing its salience and encouraging its use. This need for the FOP system dovetails with the objectives of many governmental and nongovernmental organizations and food manufacturers that are interested in helping consumers make healthier choices and reduce diet-related chronic disease risk—USDA, FDA, the Centers for Disease Control and Prevention (CDC), the American Heart Association, the American Diabetes Association, the American Dietetic Association, and the Grocery Manufacturer's Association, among others. Integrating the efforts of these concerned parties behind the FOP system can contribute dramatically to its ability to increase healthier food choices by consumers.

In addition, a well-designed FOP symbol system would also stimulate competition among food and beverage companies to provide the consumer with the most desirable options that do not lead to or contribute to diet-related chronic disease. A well-designed FOP symbol system should be a competitive opportunity.

### Examples of FOP Symbols

The committee commissioned two graphic designers to produce examples of FOP symbols that incorporate to varying degrees the communication and design concepts discussed above. The examples in Figures 7-1 through 7-3 illustrate different visual interpretations of FOP symbol systems for food product packages. Each figure displays a series of four hypothetical food product packages showing the two-component symbol system of calories per serving (expressed in household measures) and a nutrient component rating symbol. Each system is also displayed in three "usage" samples: the FOP symbol, a shelf tag, and the NFP with a tie-in to the FOP symbol. It is important to note that the committee does not endorse any particular design or product; these examples are presented for illustrative purposes only. The committee encourages regulators and industry stakeholders to engage in a process of selecting and designing an effective FOP symbol system based on the committee's recommendations, and incorporating effective design elements such as color and contrast (see Chapters 6 and 9 for additional information).

## APPROACH TO EVALUATING PRODUCTS FOR FOP POINTS

When developing the approach to evaluating food products the committee considered the eight characteristics described in the previous section for a model FOP system as well as factors that would influence its assessment of food products. This section describes the approach and discusses the overall strengths and limitations of potential nutritional criteria as well as of each nutrient category.

A model FOP symbol system displays calories and serving size information, as described by characteristic 2a, and indicates acceptable levels of saturated and *trans* fats, sodium, and added sugars in food and beverage products. It also excludes products from earning points for acceptable amounts of these nutrient components if any one component exceeds a specified limit (described by characteristic 2b). Products are ineligible for FOP points if one (or more) of the nutrient components is present in an amount that exceeds a specified limit. Additionally, a model FOP symbol system must be consistent with nutrition labeling regulations as described by characteristics

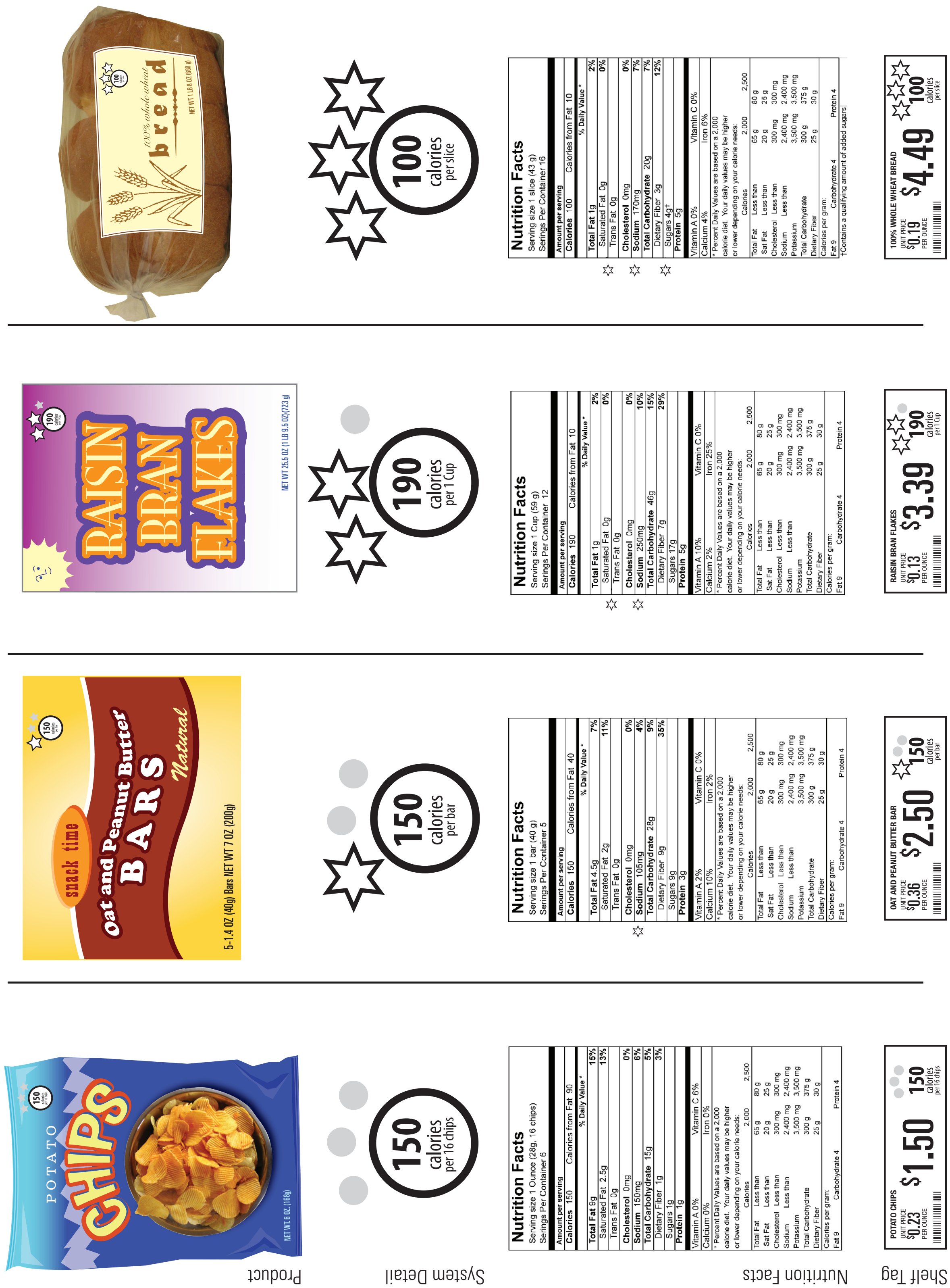


FIGURE 7-1 Front-of-package symbol system example 1.

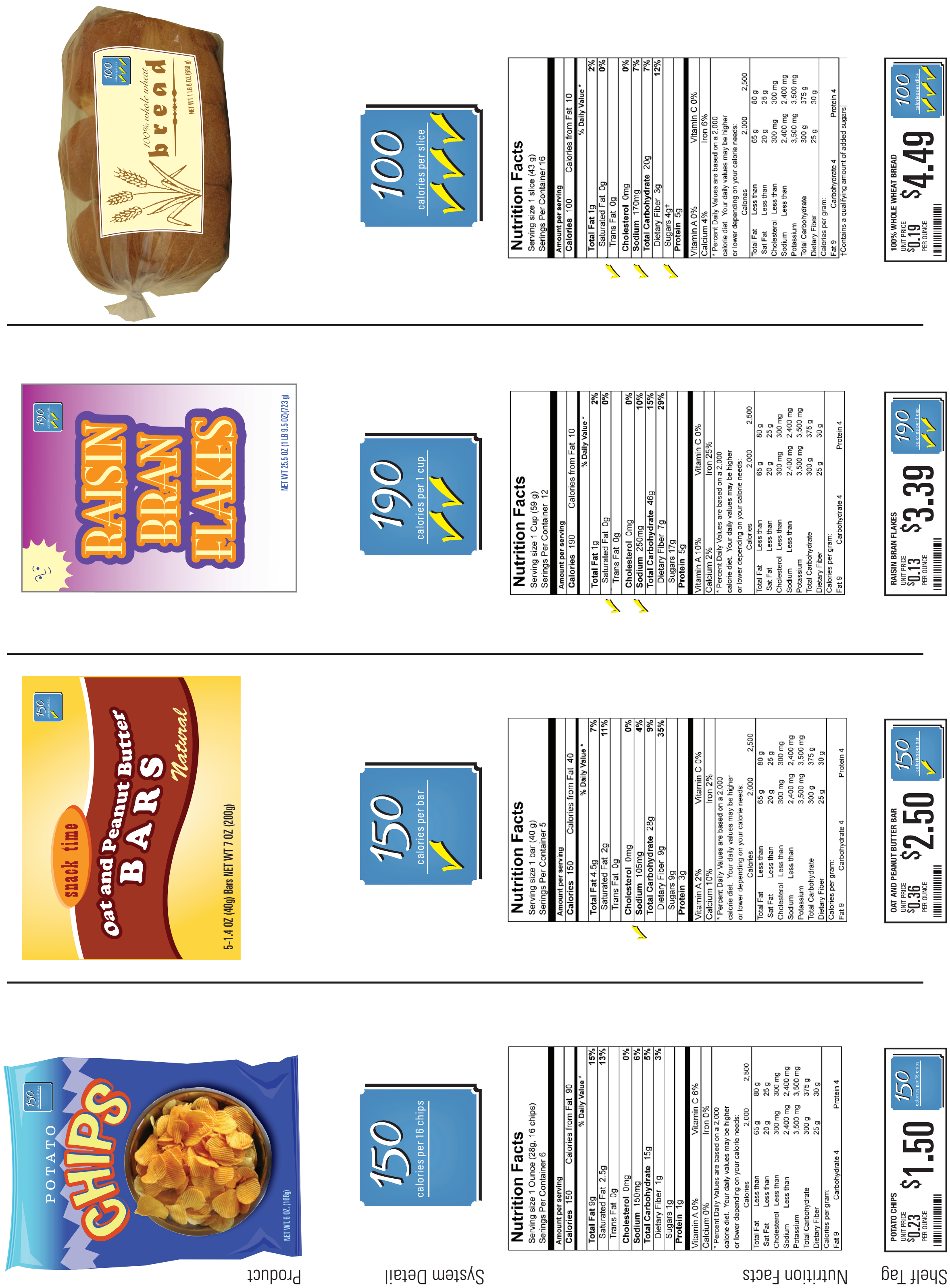


FIGURE 7-2 Front-of-package symbol system example 2.

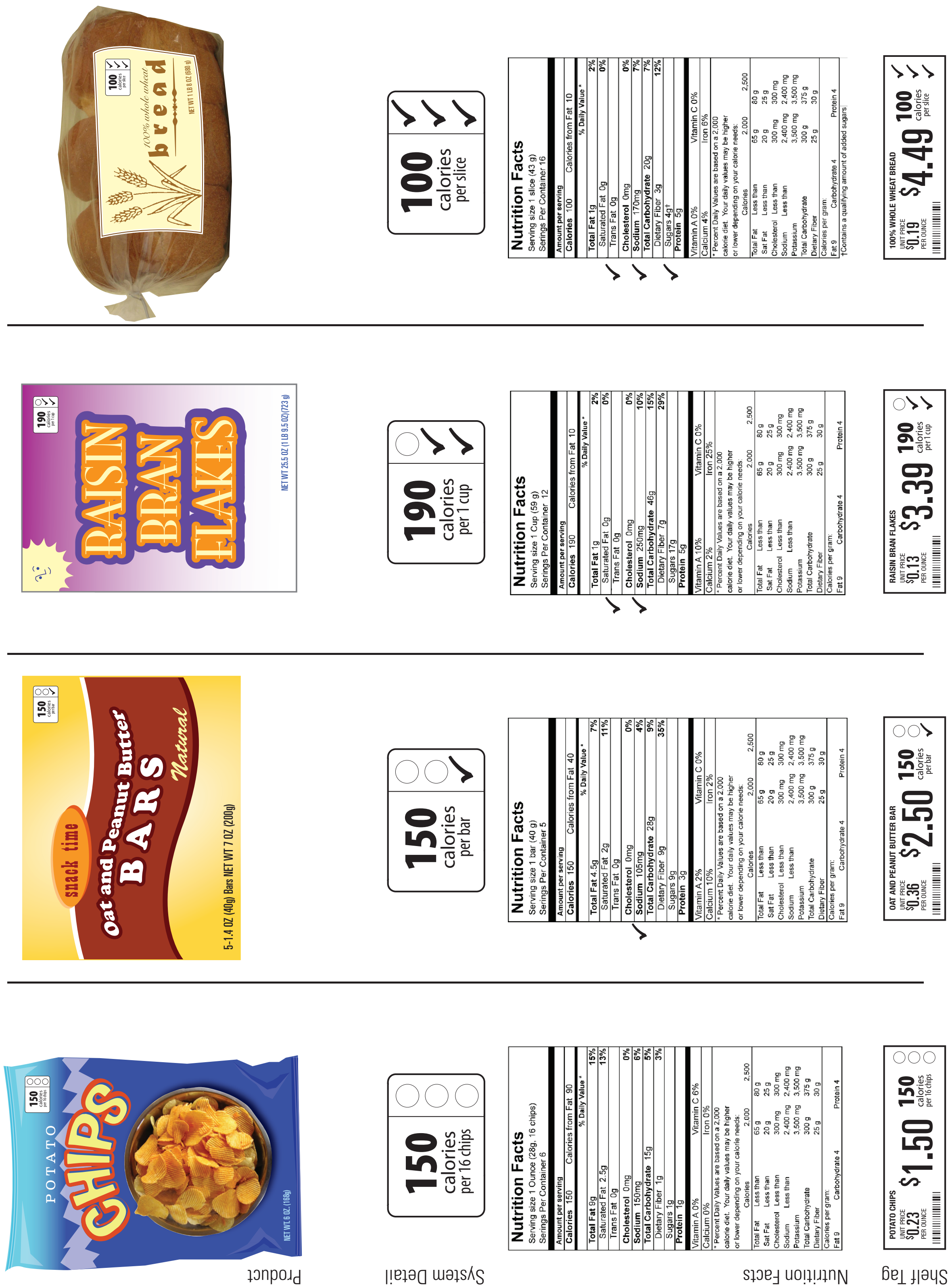


**FIGURE 7-3** Front-of-package symbol system example 3.

**BOX 7-1**
**Definition of Terms Used in Setting Nutritional Criteria**

*Front-of-Package (FOP) point*: A point that indicates that a critical nutrient component met its defined eligibility and qualifying criteria for inclusion in the FOP symbol system.

*Nutrient content claims*: Claims on food package labels that characterize and describe the level of a nutrient or dietary substance in the product.

*Disclosure level*: The threshold amount at which certain nutrients, including saturated fat and sodium, in products must be disclosed when making nutrient content claims.

*Disqualifying level*: The threshold amount at which certain nutrients, including saturated fat and sodium, in products disqualify a product from making health claims.

*Daily Value (DV)*: Reference values established by the Food and Drug Administration (FDA) and used in nutrition labeling. DV are based on recommended daily intake levels of nutrients needed for health.

*Percent DV*: Percentages found on the Nutrition Facts panel on food labels that put the amount of nutrients in the product in the context of a total diet.

*Reference Amounts Customarily Consumed (RACC)*: The amount of a food customarily consumed per eating occasion by persons in a population group as determined by FDA. RACC is used as the regulatory basis for determining labeled serving sizes on the Nutrition Facts panel.

5 and 7. A model FOP system requires a clear, systematic procedure for determining whether a given product earns zero, one, two, or three points, and the criteria used to assess products for points should balance restrictiveness with practicability. An FOP system will function among a variety of constraints and resources, which offer both guidance and complexity. Box 7-1 describes and defines the terms used in setting nutritional criteria. When developing the approach to evaluating food products the committee considered the following factors:

- Evaluation of a convenience sample of food and beverage products against relevant criteria for nutrition labeling, nutrient content and health claims, and ingredient labeling related to saturated fat, *trans* fat, sodium, and added sugars;
- Consideration of recommendations in the *Dietary Guidelines for Americans* (USDA, 2010) and products that have been determined based on their nutritional value to be eligible for use in federal food programs such as the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC);[5] and
- Identification of potential options for addressing discrepancies between product ratings based on current regulations and dietary recommendations and WIC eligibility.

Appendix E lists 95 products[6] and their relevant nutrition information that were evaluated by the committee. Nutrition and ingredient information was obtained from the NFP on product labels, manufacturers' websites, an online database of NFPs and ingredient statements,[7] and the *USDA Food and Nutrient Database for Dietary Studies, 3.0* (ARS, 2008). Each is only one of many examples of products within a product category and may not be representative of all products in its category. Each product is considered an individual food under FDA regulations, as compared to main dishes and meal products. Current regulations for nutrient content claims are consistent across all product categories of individual foods and differ from regulations for main dishes and meal products to

[5] Available online: http://www.fns.usda.gov/wic/benefitsandservices/foodpkgregs.htm (accessed March 15, 2011).
[6] It is Institute of Medicine (IOM) policy to not use brand names of products.
[7] Available online: http://www.peapod.com/ (accessed on various dates throughout 2010 and 2011).

recognize that each type of product makes a different relative contribution to the total diet. The committee did not evaluate mixed dishes (a category of individual foods), main dishes, and meal products because of the complexity of the task and resource constraints.

### Approach to Evaluating Nutrients to Limit in an FOP Symbol System

The committee notes that no one FOP symbol system, including its underlying nutrition criteria, is flawless. The proposed approach for evaluating nutrients to limit in an FOP symbol system addresses the purposes and has the strengths and limitations listed in Box 7-2 and discussed in the evaluation of nutritional criteria. A much more extensive evaluation of foods and beverages against potential criteria is needed to fully identify the strengths and limitations of the proposed approach and current regulations.

The committee considered the diversity of the food supply as well as the nutrient content of individual foods. Because of this diversity there will always be particular foods or food categories that do not appear to appropriately qualify, or not qualify, for earned "points." Although criteria based on existing labeling regulations are transparent and nonproprietary, the described approach would require modifications or exemptions to existing regulations and the development of new regulations to implement the model FOP symbol system.

## NUTRITIONAL CRITERIA

The committee determined that an FOP symbol system should not inadvertently promote products that contain amounts of saturated and *trans* fat, sodium, or added sugars that are inconsistent with *Dietary Guidelines* recommendations. Therefore, the committee developed a two-step process for evaluating products that, first, assesses products for *eligibility* for FOP points (see Figure 7-4), and, second, evaluates products for points.

> **Step 1: Eligible or not?** Eligibility criteria determine whether a product may earn FOP points for saturated and *trans* fats, sodium, or added sugars. If the product contains an amount of one or more of the stated nutrient components that is not consistent with *Dietary Guidelines* recommendations, then it is ineligible for FOP points.
>
> **Step 2: If eligible, for how many points?** If a product is eligible for FOP points, then *qualifying criteria* determine whether the product earns zero, one, two, or three FOP points. The qualifying criteria in general are more restrictive than the eligibility criteria.

In Step 1, a food or beverage can be excluded from earning FOP points for saturated and *trans* fats, sodium, and added sugars because the amount of any one of those components is considered "too high," that is, it contains an amount of saturated fat, *trans* fat, sodium, and/or added sugars and that is inconsistent with *Dietary Guidelines* recommendations. For example, a product "high" in sodium but containing no or low levels of saturated and *trans* fat and added sugars would not be eligible for FOP points. Such a product should be excluded from earning FOP points for saturated and *trans* fats and added sugars even if the amounts of these nutrient components otherwise meet qualifying criteria. In the second step, a food or beverage that meets the eligibility criteria can then be evaluated for FOP points for saturated and *trans* fats, sodium, and added sugars. These steps are illustrated in Figure 7-4.

### Eligibility Criteria

The committee outlined a potential approach to setting eligibility criteria that would use nutrient levels set by FDA that define the point at which a food product can make a health claim or nutrient content claim. FDA defines these "disclosure/disqualifying" criteria as no more than 20 percent of the Daily Value (DV) for certain nutrients (see Glossary for definition) whose consumption in excess "can lead to a diet inconsistent with dietary guidance for maintaining good health."[8] Accordingly, FDA has set >20 percent DV as the threshold amount at which certain

[8] 58 FR 2478 at 2494; January 6, 1993.

**BOX 7-2**
**Purposes, Strengths, and Limitations of the Described Approach for Evaluating Nutrients to Limit in the Model Front-of-Package (FOP) Symbol System**

*Purposes*
The model FOP symbol system:

- Provides consumers with prominent calorie content information
- Provides prominent serving size information
- Provides targeted information related to saturated and *trans* fats, sodium, and added sugars
- Facilitates consumers' comparisons of nutritional value *within* food categories
- Facilitates consumers' comparisons of nutritional value *across* most food categories

Encourages manufacturers to reformulate products

*Strengths*
The model FOP symbol system:

- Targets nutrients of public health concern
- Provides a measure of the relative amount of saturated and *trans* fats, sodium, and added sugars by assigning points when a product contains qualifying amounts of these nutrients
- Evaluates nutrient amounts consistent with science-based regulations
- Applies one set of nutritional criteria across all or most product categories similar to current regulations, with certain exceptions where technically needed
- Facilitates compliance with recommendations from the *Dietary Guidelines for Americans*
- Allows compliance to be monitored, either by chemical analysis of nutrient levels or by review of the ingredient list

*Limitations*
In the approach to evaluating products:

- Many foods that are consistent with the recommendations of the *Dietary Guidelines for Americans* or that are eligible for the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) exceed the disclosure level for saturated fat.
- Most foods, including those that are consistent with the recommendations of the *Dietary Guidelines for Americans* or that are WIC-eligible, do not meet criteria for "low saturated fat."
- No disclosure level or regulatory criteria defines "low" for *trans* fat.
- Most foods, including those that are consistent with the recommendations of the *Dietary Guidelines for Americans* or that are WIC-eligible, do not meet criteria for "low sodium."
- No disclosure level or regulatory criteria exists for "low" added sugars.

Many of these attributes were among those identified and used by the Phase I committee to evaluate existing types of FOP symbol systems (IOM, 2010a).

nutrients, including saturated fat and sodium, in individual foods must be disclosed when making nutrient content claims (disclosure levels)[9] or which disqualify a product from making health claims (disqualifying levels).[10] The committee believes that >20 percent DV is an appropriate eligibility criterion for saturated fat and sodium for an

[9] 21 CFR 101.13(h).
[10] 21 CFR 101.14(a)(4).

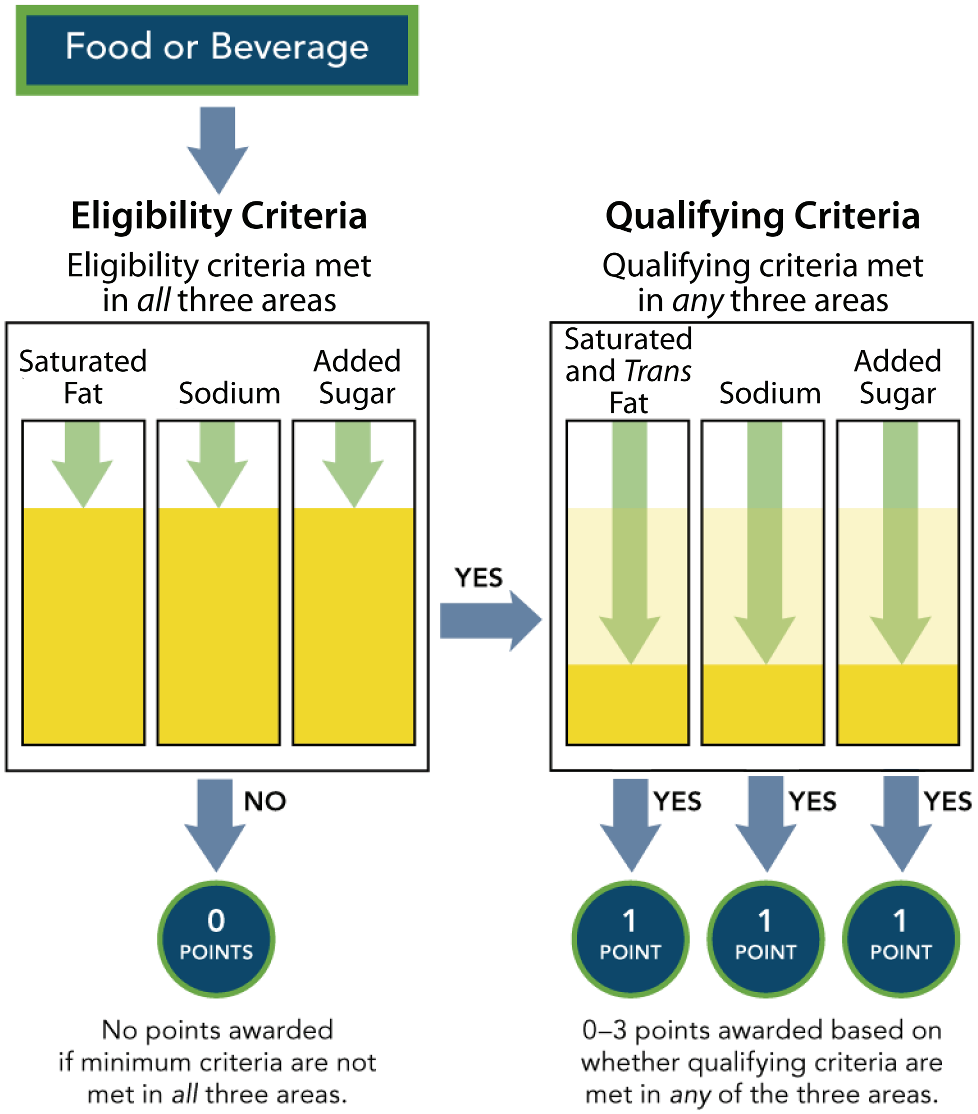


**FIGURE 7-4** Evaluation criteria for a front-of-package symbol system.

FOP system. Disclosure/disqualifying levels for main dishes (>30 percent DV) and meal products (>40 percent DV) could also be used as eligibility criteria for these types of products.

FDA has not defined disclosure/disqualifying levels for *trans* fat and added sugars in part because of the absence of the type of quantitative information from authoritative scientific groups on which the agency could support the establishment of a Daily Reference Value.[11] However, in accordance with dietary guidance that recommends that *trans* fat intake be kept as low as possible, especially by limiting foods that contain synthetic sources of *trans* fat (IOM, 2005; USDA, 2010, p. 21), a product's *trans* fat content can be evaluated when determining whether it qualifies for an FOP point for saturated and *trans* fats (see Qualifying Criteria for FOP Points). A product's added sugars content can be evaluated for eligibility based on the approach described below.

[11] 68 FR 41434; July 11, 2003.

**TABLE 7-1** Saturated Fat Content of Example Foods That Exceed the Food and Drug Administration (FDA) Disclosure/Disqualifying Level for Saturated Fat[a]

| | | Saturated Fat Content | | Percent of |
|---|---|---|---|---|
| Product[b] | Labeled Serving | g/LS | g/50 g | Calories |
| Parmesan cheese | 2 tsp (5 g) | 1 | 10 | 45 |
| Mozzarella cheese, part skim | 1 oz (28 g) | 3 | 5.1 | 36 |
| Cheddar cheese, reduced fat | 1 oz (28 g) | 3.5 | 5.8 | 37 |
| Cheddar cheese, 2% fat milk | 1 oz (30 g) | 4 | 6.7 | 40 |
| Cheddar cheese, regular | 1 oz (28 g) | 5 | 8.9 | 41 |
| Vanilla ice cream, regular fat | 0.5 cup (66 g) | 4.5 | NA | 29 |
| Olive oil | 1 tbsp (15 mL) | 2 | 6.7 | 15 |
| Peanut oil | 1 tbsp (14 g) | 2.5 | 8.9 | 19 |
| Soybean oil | 1 tbsp (14 g) | 2 | 7.1 | 15 |
| Mayonnaise | 1 tbsp (13 g) | 1.5 | 5.8 | 15 |
| Salad dressing, regular 1 | 2 tbsp (30 g) | 2.5 | 4.2 | 16 |
| Margarine, soft 1 | 1 tbsp (14 g) | 2 | 7.1 | 26 |
| Margarine, soft 2 | 1 tbsp (14 g) | 2.5 | 8.9 | 28 |
| Margarine, soft 3 | 1 tbsp (14 g) | 1.5 | 5.4 | 17 |
| Margarine, stick | 1 tbsp (14 g) | 2.5 | 8.9 | 22 |
| Butter, unsalted | 1 tbsp (14 g) | 7 | 25 | 63 |
| Peanut butter | 2 tbsp (32 g) | 3 | 4.7 | 14 |
| Potato chips | 16 pieces (30 g) | 2.5 | 4.2 | 15 |
| Chicken thighs, raw boneless skinless[c] | 4 oz (114 g) | 5 | NA | 19 |

NOTES: LS = labeled serving, NA = the small RACC rule does not apply, RACC = reference amounts customarily consumed.
[a] Contains >4 g per RACC and LS, or per 50 g if RACC is small. 21 CFR 101.13(h)(1).
[b] Products followed by numbers represent different brands.
[c] Poultry is regulated by the U.S. Department of Agriculture (USDA) and not subject to FDA disclosure regulations. Chicken thighs were included for illustrative purposes only.

**Eligibility Criteria for Saturated Fat** Table 7-1 lists the saturated fat content of example products evaluated by the committee that exceed FDA disclosure/disqualifying level. These example products would not be eligible to earn FOP points, even if the levels of other nutrients met the FOP qualifying criteria.

One limitation of using >20 percent DV for setting eligibility criteria is that some products that are consistent with *Dietary Guidelines* recommendations would be excluded, such as olive, peanut, and soybean oils; mayonnaise and some regular salad dressings; and soft margarines with liquid vegetable oil as the first ingredient (USDA, 2010, p. 40). Other products that would be excluded are WIC-eligible products,[12] such as reduced-fat cheddar cheese, part skim mozzarella cheese, and peanut butter. Except for regular ice cream and chicken thighs, the example products in Table 7-1 are not eligible based on the small Reference Amounts Customarily Consumed (RACC) rule, i.e., their RACC is 30 g or less or 2 tablespoons or less, and they contain more than 4 g of saturated fat per 50 g. Three potential solutions are suggested.

First, FDA could develop exemptions to avoid excluding oils, nuts, and foods containing oils and nuts recommended in the *Dietary Guidelines*, perhaps based on a product's saturated fat content being no more than 15 percent of total calories, a criterion used in the FDA regulation for "low saturated fat." However, even with such an exemption, peanut oil, some salad dressings, and soft margarines would still be ineligible, which suggests a need for some other basis for exempting fats and oils encouraged by the *Dietary Guidelines*.

Second, when reduced-fat versions of cheese that are WIC-eligible are evaluated against the disclosure/disqualifying level for saturated fat, FOP points also would not be allowed[13] even though suggested as alternatives to full fat cheeses in the 2010 *Dietary Guidelines for Americans* (p. 65). However, this may be appropriate inasmuch

[12] Available online: http://www.fns.usda.gov/wic/benefitsandservices/foodpkgregs.htm (accessed March 15, 2011).
[13] See footnote 1.

**TABLE 7-2** Sodium Content of Example Products That Exceed the Food and Drug Administration (FDA) Disclosure/Disqualifying Level for Sodium[a]

| | | Sodium | |
|---|---|---|---|
| Product[b] | Labeled Serving | mg/LS | mg/50 g |
| Parmesan cheese | 2 tsp (5 g) | 85 | 850 |
| Salad dressing, regular 2 | 2 tbsp (30 g) | 370 | 617 |
| Mustard | 1 tsp (5 g) | 120 | 1200 |
| Pretzels | 9 pieces (28 g) | 560 | 1000 |
| Soup crackers | 35 pieces (15 g) | 170 | 567 |
| Soups, regular varieties | 0.5 cup (120 mL) | 650+ | NA |
| Tomato juice | 0.5 cup (120 mL) | 680 | NA |

NOTES: LS = labeled serving, NA = the small RACC rule does not apply, RACC = reference amounts customarily consumed.
[a] Contains >480 mg per RACC and LS, or per 50 g if RACC is small. 21 CFR 101.13(h)(1).
[b] Products followed by numbers represent different brands.

as the *Dietary Guidelines* recommends an increase in the intake of fat-free or low-fat milk and milk products rather than cheese in order to decrease not only saturated fat but also sodium intake (USDA, 2010, p. 38).

Third, poultry products are subject to USDA regulations (see Chapter 3), which do not include disclosure or disqualifying levels. However, chicken thighs were evaluated in order to assess the impact of applying FDA's disclosure/disqualifying level to such a product.

**Eligibility Criteria for Sodium** Several example products exceeded the FDA disclosure/disqualifying level for sodium (Table 7-2) including parmesan cheese,[14] mustard, pretzels, one of four salad dressings, soup crackers, three of four regular canned soups, and a tomato juice. These example products would not be eligible to earn FOP points, even if the levels of the other nutrients met the FOP qualifying criteria. For saturated and *trans* fats and added sugars, however, similar products formulated to contain sodium that do not exceed the disclosure level, e.g., a low-sodium tomato juice, would be eligible.

**Eligibility Criteria for Added Sugars** A relatively small number of food and beverage categories contribute more than half the added sugars in the American diet: regular soda, energy drinks, and sports drinks (35.7 percent), fruit drinks (10.5 percent), candy (6.1 percent), and sugars and honey (3.5 percent) (USDA, 2010, p. 29). Collectively categorized as Sugars, Sweets, and Beverages in the *USDA Food and Nutrient Database for Dietary Studies* (USDA, 2008, pp. 93-100), these products contribute to energy intake; generally contain no or low amounts of saturated fat, *trans* fat, and sodium; and provide little or no essential nutrients unless fortified, which would be inconsistent with FDA fortification policy.[15] The 2010 *Dietary Guidelines for Americans* 2010 recommends limiting their consumption (p. 67). Accordingly, any product that is categorized as Sugars, Sweets, and Beverages and contains added sugars would not earn FOP points for saturated and *trans* fats and sodium even though the levels of those nutrients met the FOP qualifying criteria.

Other major contributors to added sugars intake include grain-based desserts (12.9 percent), dairy-based desserts (6.5 percent), and ready-to-eat cereals (3.8 percent) (USDA, 2010, p. 29). Some products in these categories can make meaningful contributions to dietary fiber and/or essential nutrient intakes and therefore should be evaluated for potentially earning FOP points. Some grain-based and dairy-based desserts may be excluded because they exceed eligibility criteria for saturated fat and/or sodium content. Eligible grain-based and dairy-based desserts and ready-to-eat cereals can be evaluated against the qualifying criteria for FOP points for saturated and *trans* fats, sodium, and added sugars.

[14] Parmesan cheese also would not be eligible based on saturated fat content. See Table 7-1.
[15] 21 CFR 104.20.

**TABLE 7-3** Examples of Products Categorized as Sugars, Sweets, or Beverages[a]

| Product | Reason |
|---|---|
| Cola soft drink | Sweetened beverage |
| Lemon-lime soft drink | Sweetened beverage |
| Sweetened tea | Sweetened beverage |
| Lemon-lime sport drink | Sweetened beverage |
| Chocolate-peanut candy | Sweets |
| Apricot preserves | Sweets |

[a] *USDA Food and Nutrient Database for Dietary Studies* (USDA, 2008, pp. 93-100).

Table 7-3 lists example products that would not be eligible for earning points for saturated and *trans* fats and sodium because of added sugars content.

## Qualifying Criteria for Nutrient Component FOP Points

If a food or beverage product meets the more general criteria for eligibility for FOP points, then it can be evaluated according to qualifying criteria to determine whether it qualifies for one or more FOP points for saturated and *trans* fats, sodium, or added sugars.

### *Qualifying Criteria for Saturated and* Trans *Fat FOP Point*

A practical approach for an FOP symbol system would be to evaluate the amount of saturated fat and *trans* fat separately. The NFP provides information on the content of both components, which together are referred to as "solid fats" in the *Dietary Guidelines* (USDA, 2010, p. 27). If the qualifying criteria for *both* saturated fat and *trans* fat are met, then a product would earn at least one FOP point.

Regarding saturated fat, FDA has defined criteria for several claims that characterize the amount of saturated fat in products, which could be used to qualify products for one FOP saturated fat point (Table 7-4). The saturated

**TABLE 7-4** Criteria for Nutrient Content Claims That Characterize the Amount of Saturated Fat[a]

| Product Type | Low | Healthy | Extra Lean | Lean |
|---|---|---|---|---|
| Individual foods | ≤1 g per RACC and ≤15% of calories | ≤1 g per RACC and ≤15% of calories | NA | NA |
| Seafood and game meat | ≤1 g per RACC and ≤15% of calories | <2 g per RACC and 100 g | <2 g per RACC and 100 g | ≤4.5 g per RACC and 100 g |
| Main dishes[b] and meal products[c] | ≤1 g per 100 g and ≤10% of calories | ≤1 g per 100 g and ≤10% of calories | <2 g per 100 g and LS | ≤4.5 g per 100 g and LS |
| Mixed dishes not measurable with a cup[d] | NA | NA | NA | ≤3.5 g per RACC |

NOTES: LS = labeled serving size, NA = these claims do not apply to the identified product type RACC (reference amounts customarily consumed).
[a] SOURCE: 21 CFR 101. Food labeling Guide: Guidance for Industry. September 1994; revised April 2008. Food and Drug Administration. See Appendices A and B. Available online: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/default.htm (accessed May 18, 2011).
[b] Defined in 21 CFR 101.13(m).
[c] Defined in 21 CFR 101.13(l).
[d] Defined in 21 CFR 101.12(b) in Table 7-2.

fat criteria for "healthy"[16] individual foods and main dishes and meal products are the same as for "low" saturated fat.[17] Similarly the criteria for "healthy"[18] saturated fat in seafood and game meat are the same as for "extra lean."[19] Claims for "healthy," "lean," and "extra lean" include criteria for other nutrients, such as total fat and cholesterol; these additional criteria need not apply if the saturated fat criteria were used for qualifying a product for an FOP saturated fat point.

Regarding *trans* fat, FDA has not defined criteria for "low" levels because of the lack of a basis for determining a DV. Given the absence of defined criteria for characterizing the amount of *trans* fat in foods and beverages, an approach for qualifying a product for an FOP saturated and *trans* fat point is to use FDA regulations for declaring the amount of *trans* fat in the NFP. For example, a product could qualify if its NFP declares 0 g *trans* fat per serving (i.e., less than 0.5 g per labeled serving).[20] A product could also qualify if the NFP declares 0.5 g or more *trans* fat per serving *and* the ingredients statement *does not list* a partially hydrogenated vegetable oil. Any *trans* fat in such products would be from naturally occurring sources. Limits on the qualifying amount of saturated fat would limit the amount of naturally occurring *trans* fat (USDA, 2010, p. 26).

To assess this approach, the committee evaluated several example foods, including poultry products, against criteria for "low saturated fat" and for labeled *trans* fat content. Table 7-5 lists example products that were not "low" in saturated fat and/or that declared 0.5 g or more *trans* fat in the NFP and a partially hydrogenated vegetable oil in the ingredients statement—products that would not, under this system, receive an FOP point for saturated and *trans* fats. This analysis included olive, peanut, and soybean oils; all three examples of soft margarines with liquid vegetable oil as their first ingredient; a mayonnaise; one of two examples of regular salad dressings; and peanut butter even though they exceeded the disclosure/disqualifying level for saturated fat and would not be eligible for FOP points unless exempted by FDA. As mentioned above, chicken thighs (regulated by USDA) would not be eligible if evaluated against FDA's disclosure/disqualifying level, but were included for illustrative purposes.

The sugar cookie example illustrates a case in which a product can be low in saturated fat, but not qualify because it contains 1.5 g *trans* fat per labeled serving and lists a partially hydrogenated oil in the ingredients statement. In contrast, the chocolate chip cookie and snack cracker examples would not qualify because of both saturated fat and *trans* fat content. And, the breakfast bar and toaster pastry examples would not qualify because of saturated fat content even though they contained no *trans* fat.

However, qualifying a product for an FOP saturated fat point based on criteria for "low saturated fat" may be too restrictive. Several of the example products are consistent with *Dietary Guidelines* recommendations or are WIC-eligible but would not qualify for a point if evaluated against "low saturated fat" criteria. The 1 percent fat milk, olive and soybean oils, mayonnaise, a salad dressing, the four salmon examples, and walnuts contain ≤15 percent of total calories from saturated fat but 1.1 to 2.6 g per RACC (ranging from 5.5 to 13 percent DV). The peanut oil, three soft margarines, chicken thighs, and WIC-eligible eggs and peanut butters also would not qualify.

As a means of expanding the range of products that qualify for a saturated fat point, FDA should evaluate the appropriateness of a qualifying saturated fat criterion based on no more than 10 percent DV per RACC (i.e., no more than 2 g per RACC), an amount that may be viewed as "moderate," without a percentage of calories criterion. Such a criterion would qualify the breakfast bar, toaster pastry, 1 percent fat milk, egg, olive and soybean oils, soft margarines 1 and 3, mayonnaise, two of three salmon products, and walnuts. To be consistent with WIC, the qualifying criteria for eligible peanut butter could be increased to 3 g per RACC.[21] Another approach for qualifying seafood (and meats and poultry) would be to use the criteria for "extra lean" or "lean." All salmon examples would qualify if evaluated against criteria for "lean" but not "extra lean," and the chicken thighs example would not qualify against criteria for either "extra lean" or "lean" (see Appendix Table E-2). The criteria for "low saturated fat" and "extra lean" are also likely to be too restrictive for qualifying main dishes and meal products, although this was not evaluated by the committee.

[16] 21 CFR 101.65(d)(2).
[17] 21 CFR 101.62(c).
[18] 21 CFR 101.65(d)(2).
[19] 21 CFR 101.62(e)(4).
[20] 21 CFR 101.9(c)(2)(ii).
[21] This presumes peanut butters are exempted from the eligibility criteria.

**TABLE 7-5** Saturated Fat Content of Selected Example Products Compared to Criteria for "Low in Saturated Fat" and Content of *Trans* Fat and Partially Hydrogenated Vegetable Oil

| Product[a] | Labeled Serving | Saturated Fat g/LS | Saturated Fat g/RACC | Percent of calories | Not Low SFA[b] | Contains TFA and PHVO[c] |
|---|---|---|---|---|---|---|
| Sugar cookies | 4 (40 g) | 1 | <1 | 7 | | x |
| Chocolate chip cookies | 1 pkg (42 g) | 3 | 2.1 | 13 | x | x |
| Snack crackers | 9 (32 g) | 2 | 1.9 | 12 | x | x |
| Breakfast bar | 1 bar (40 g) | 2 | 2 | 12 | x | |
| Toaster pastry | 1 pastry (52 g) | 2 | 1.5 | 9 | x | |
| Milk, 1% fat | 1 cup (240 mL) | 1.5 | 1.5 | 12 | x | |
| Ricotta cheese, part skim | 0.25 cup (62 g) | 4 | 3.5 | 36 | x | |
| Egg | 1 large (50 g) | 1.5 | 1.5 | 19 | x | |
| Olive oil | 1 tbsp (15 mL) | 2 | 2 | 15 | x | |
| Peanut oil | 1 tbsp (14 g) | 2.5 | 2.5 | 19 | x | |
| Soybean oil | 1 tbsp (14 g) | 2 | 2 | 15 | x | |
| Margarine, soft 1 | 1 tbsp (14 g) | 2 | 2 | 26 | x | |
| Margarine, soft 2 | 1 tbsp (14 g) | 2.5 | 2.5 | 28 | x | |
| Margarine, soft 3 | 1 tbsp (14 g) | 1.5 | 1.5 | 17 | x | |
| Mayonnaise | 1 tbsp (13 g) | 1.5 | 1.7 | 15 | x | |
| Salad dressing, regular 1 | 2 tbsp (30 g) | 2.5 | 2.5 | 16 | x | |
| Salmon fillets, frozen raw | 4 oz (114 g) | 1.5 | 1.4 | 7 | x | |
| Salmon fillets, raw | 3 oz (85 g) | 2.6 | 3.4 | 13 | x | |
| Salmon steaks, raw | 3.5 oz (99 g) | 1 | 1.1 | 6 | x | |
| Salmon, canned | 0.25 cup (60 g) | 1.5 | 1.4 | 12 | x | |
| Chicken thighs, raw boneless skinless[d] | 4 oz (114 g) | 5 | 5 | 19 | x | |
| Walnuts, shelled | 0.25 cup (30 g) | 2 | 2 | 9 | x | |
| Peanut butter | 2 tbsp (32 g) | 3 | 3 | 14 | x | |

NOTES: LS = labeled serving size, PHVO = partially hydrogenated vegetable oil, pkg = package, RACC = reference amounts customarily consumed, SFA = saturated fat, TFA = *trans* fat.
[a] Products followed by numbers represent different brands.
[b] Contains >1 g saturated fat per RACC and/or >15% of calories from saturated fat.
[c] Contains ≥0.5 g *trans* fat per LS and PHVO in ingredients statement.
[d] Poultry is regulated by the U.S. Department of Agriculture; chicken thighs were included for illustrative purposes only.

Extensive computer modeling is needed to compare the saturated fat content of a wide variety of products against various criteria to determine which approach results in products appropriately earning an FOP saturated fat point.

### *Qualifying Criteria for Sodium FOP Points*

FDA has defined criteria for "low sodium" and "healthy" claims that characterize the amount of sodium in a product, which could potentially be used to qualify a product for an FOP sodium point (Table 7-6). Table 7-7 lists several example products that were evaluated against the sodium criteria for "low" claims (≤140 mg per RACC) and "healthy" claims (≤480 mg per RACC). Mayonnaise, a soft margarine, and peanut butter were included in this analysis even though they exceeded the disclosure/disqualifying level for saturated fat and therefore would not be eligible for evaluation for an FOP sodium point unless exempted by FDA.

Of the example products listed,[22] only seven met the criteria for "low sodium" but all met the sodium criteria for "healthy." Thus, qualifying criteria for an FOP sodium point based on the criteria for a "healthy" claim may be more realistic than one based on "low sodium." Qualifying criteria based on "healthy" sodium would allow

[22] The peanut butter example contains added salt and added sugars, but some peanut butters do not contain added salt and added sugars.

**TABLE 7-6** Criteria for Nutrient Content Claims That Characterize the Amount of Sodium

| Product | Low[a] | Healthy[b] |
|---|---|---|
| Individual foods[c] | ≤140 mg per RACC (or per 50 g if RACC is small) | ≤480 mg per RACC and LS (or per 50 g if RACC is small) |
| Main dishes and meal products | ≤140 mg per 100 g | ≤600 mg per LS |

NOTES: LS = labeled serving size, RACC = reference amounts customarily consumed. A small RACC is ≤30 g or ≤2 tablespoons.
[a] 21 CFR 101.61(b)(4) and 101.61(b)(5).
[b] 21 CFR 101.65(d)(2)(ii).
[c] Includes seafood and game meat.

**TABLE 7-7** Sodium Content of Selected Example Foods That Meet the Sodium Criteria for "Low" and/or "Healthy"

| | | Sodium mg per | | | | |
|---|---|---|---|---|---|---|
| Product[a] | Labeled Serving | LS | RACC | 50 g | Low[b] | Healthy[c] |
| 100% whole wheat bread | 1 slice (43 g) | 170 | 198 | NA | no | yes |
| Graham crackers | 8 pieces (31 g) | 180 | 174 | 290 | no | yes |
| Animal crackers | 13 pieces (30 g) | 75 | 75 | 125 | yes | yes |
| Breakfast bar | 1 bar (40 g) | 105 | 105 | NA | yes | yes |
| Shredded wheat cereal | 1 cup (49 g) | 0 | 0 | NA | yes | yes |
| Toasted oat cereal | 1 cup (28 g) | 160 | NA | 286 | no | yes |
| Crisped rice cereal | 1.25 cup (33 g) | 190 | NA | 288 | no | yes |
| Oatmeal, old-fashioned | 0.5 cup (40 g) | 0 | 0 | NA | yes | yes |
| Oatmeal, instant plain | 1 package (25 g) | 75 | 120 | NA | yes | yes |
| Oatmeal, instant with fruit and nuts | 1 package (37 g) | 190 | 282 | NA | no | yes |
| Chocolate milk, 1% fat | 1 cup (240 mL) | 150 | 150 | NA | no | yes |
| Yogurt, plain nonfat | 1 cup (227 g) | 190 | 188 | NA | no | yes |
| Margarine, soft 1 | 1 tbsp (14 g) | 100 | 100 | 357 | no | yes |
| Margarine, soft 2 | 1 tbsp (14 g) | 90 | 90 | 321 | no | yes |
| Margarine, soft 3 | 1 tbsp (14 g) | 85 | 85 | 304 | no | yes |
| Mayonnaise | 1 tbsp (13 g) | 70 | 81 | 269 | no | yes |
| Salad dressing, regular 1 | 2 tbsp (30 g) | 260 | 260 | 433 | no | yes |
| Salad dressing, light 1 | 2 tbsp (31 g) | 290 | 280 | 468 | no | yes |
| Salad dressing, light 2 | 2 tbsp (32 g) | 290 | 272 | 453 | no | yes |
| Tuna fish, solid white in water | ~0.25 cup (55 g) | 190 | 190 | NA | no | yes |
| Kidney beans, canned | 0.5 cup (130 g) | 360 | 360 | NA | no | yes |
| Peanut butter | 2 tbsp (32 g) | 130 | 130 | 203 | no | yes |
| Soups, "healthy" | 0.5 cup (120 mL) | 410 | 410 | NA | no | yes |
| Mixed vegetable juice, regular | 1 can (5.5 oz) | 330 | 480 | NA | no | yes |
| Mixed vegetable juice, low sodium | 1 can (5.5 oz) | 80 | 116 | NA | yes | yes |
| Tomato juice, low sodium | 8 fl oz (240 mL) | 140 | 140 | NA | yes | yes |
| Tomatoes, canned | 0.5 cup (121 g) | 220 | 236 | NA | no | yes |

NOTES: LS = labeled serving size, NA = the small RACC rule does not apply, RACC = reference amounts customarily consumed.
[a] Products followed by numbers represent different brands.
[b] Contains ≤140 mg per RACC, or per 50 g if RACC is small. 21 CFR 101.16(b)(4).
[c] Contains ≤480 mg per RACC and LS, or per 50 g if RACC is small. 21 CFR 101.65(d)(2)(ii).

**TABLE 7-8** Potential Qualifying Criteria for a Front-of-Package Added Sugars Point for Individual Foods

| Total Sugars Content | Condition and/or Rationale |
|---|---|
| 0 g on NFP | Meets criteria for "sugar free"[a] |
| ≥0.5 g per RACC | Products with no ingredient recognized as added sugars listed in the ingredients statement[b] |
| ≤6 g per ounce | Breakfast cereals that meet the WIC requirement for sugars[c] |
| ≤5 g per RACC | Products with an ingredient recognized as added sugars *except* for canned products containing tomatoes and/or other vegetables and yogurt products and substitutes[d] |
| ≤10 g per RACC | Canned products with tomatoes and other vegetables that contain naturally occurring sugars as well as an ingredient recognized as added sugars[e] |
| ≤20 g per RACC | Yogurt products and substitutes that contain a low calorie sweetener and an ingredient recognized as added sugars[f] |

NOTES: LS = labeled serving size, NFP = Nutrition Facts panel, RACC = reference amounts customarily consumed, WIC = Special Supplemental Nutrition Program for Women, Infants and Children.

[a] Contains <0.5 g sugars per RACC and LS. 21 CFR 101.60(c)(1).

[b] Applies to products containing only naturally occurring sugars such as fruits, fruit juices, and milk.

[c] Contains no more than 21.2 g sucrose and other sugars per 100 g of dry cereal. Available online: http://www.fns.usda.gov/wic/benefitsandservices/foodpkgregs.htm (accessed March 15, 2011).

[d] This would qualify WIC-eligible peanut butters and canned mature legumes. The latter contains small amounts of added sugars to prevent stress resulting from the canning process; however, WIC does not specify what constitutes a small amount of sugar. The 5 g represents 20 calories or 1 percent of 2,000 calories. Available online: http://www.fns.usda.gov/wic/benefitsandservices/foodpkgregs.htm (accessed March 15, 2011).

[e] WIC requirements allow small amounts of sugars to be added to vegetables that are naturally sugar-containing during the canning process to prevent stress resulting in membrane rupture; however, WIC does not specify what constitutes a small amount of sugar. The 10 g represents 40 calories or 2 percent of 2,000 calories. Available online: http://www.fns.usda.gov/wic/benefitsandservices/foodpkgregs.htm (accessed March 15, 2011).

[f] Half the sugar should come from milk as estimated from the protein and lactose contents of plain yogurt and products expected to be covered by this criterion.

more foods that are consistent with the *Dietary Guidelines* recommendations and/or are WIC-eligible to earn an FOP sodium point, as well as foods that have been specially formulated to meet regulations for a "healthy" claim such as some soups and vegetable juices. The qualifying criteria also provide a more realistic target for product reformulation and new product development.

A limitation is that products that pass the eligibility criteria for sodium would automatically qualify for a sodium point based on "healthy," because the cut-off for qualifying for an FOP sodium point based on "healthy" is the same as the cut-off for eligibility based on the disclosure amount. This limitation could be addressed by reducing the qualifying cut-off for sodium over time as part of an overall strategy to reduce sodium in the food supply.

### *Qualifying Criteria for Added Sugars*

Although added sugars are not declared in the NFP, the committee identified an approach for determining whether a product qualifies for an FOP point for added sugars. The approach uses FDA's claim criteria for "sugar free" and "no added sugars," as well as the amount of total sugars declared on the NFP in conjunction with specific conditions. Potential criteria and associated rationale or conditions for individual foods are listed in Table 7-8. Criteria for meal products and main dishes could be developed and evaluated based on a similar approach.

FDA regulations provide for claims of "no added sugars" and "without added sugars" if no sugar or sugar-containing ingredient is added during processing. 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, and including ingredients that may functionally increase the sugars content of a food, such as enzymes.[23]

The *Dietary Guidelines* list the following as examples of added sugars: anhydrous dextrose, brown sugar, con-

[23] 21 CFR 101.60(c)(2).

**TABLE 7-9** Sugars Content of Selected Example Foods That Do and Do Not Meet Potential Front-of-Package Criteria for Added Sugars

| Product[a] | Labeled Serving | Total Sugars g/LS | Total Sugars g/RACC | Added Sugars | Meets Criteria[b] |
|---|---|---|---|---|---|
| 100% whole wheat bread | 1 slice (43 g) | 4 | 4.6 | yes | yes |
| Graham crackers | 8 pieces (31 g) | 8 | 7.7 | yes | no |
| Animal crackers | 13 pieces (30 g) | 8 | 8 | yes | no |
| Breakfast bar | 1 bar (40 g) | 9 | 9 | yes | no |
| Toasted oat cereal | 1 cup (28 g) | 1 | 1.1 | yes | yes |
| Sweetened toasted oat cereal | 1 cup (28 g) | 9 | 9.6 | yes | no |
| Oatmeal, instant plain | 1 package (25 g) | 0 | 0 | yes | yes |
| Oatmeal, instant with fruit, nuts | 1package (37 g) | 11 | 16 | yes | no |
| Milk, 1% fat | 1 cup (240 mL) | 12 | 12 | no | yes |
| Chocolate milk, 1% fat | 1 cup (240 mL) | 25 | 25 | yes | no |
| Yogurt, plain nonfat | 1 cup (227 g) | 18 | 18 | no | yes |
| Yogurt, sweetened 1, fat free, LCS | 1 container (170 g) | 14 | 18.5 | yes | yes |
| Yogurt, sweetened 2, fat free | 1 cup (225 g) | 33 | 33 | yes | no |
| Yogurt, sweetened 3, low fat | 2.25 oz (64 g) | 10 | 35 | yes | no |
| Yogurt, sweetened 4, low fat | 4 oz (113 g) | 16 | 32 | yes | no |
| Yogurt, sweetened 5, low fat | 1 container (113 g) | 13 | 26 | yes | no |
| Salad dressing, light 1 | 2 tbsp (31 g) | 2 | 2 | yes | yes |
| Orange juice, 100% | 8 fl oz (240 mL) | 22 | 22 | no | yes |
| Grape juice, 100% | 1 bottle (10 oz) | 49 | 39 | no | yes |
| Kidney beans, canned | 0.5 cup (130 g) | 2 | 2 | yes | yes |
| Peanut butter | 2 tbsp (32 g) | 3 | 3 | yes | yes |
| Tomato soup, "healthy" | 0.5 cup (120 mL) | 10 | 10 | yes | yes |
| Tomatoes, canned | 0.5 cup (121 g) | 3 | 3 | no | yes |
| Stewed tomatoes, canned | 0.5 cup (126 g) | 7 | 7 | yes | yes |

NOTE: LCS = low calorie sweetener, LS = labeled serving size, RACC = reference amounts customarily consumed.
[a] Products followed by numbers represent different brands.
[b] See Table 7-8 for criteria.

fectioner's powdered sugar, corn syrup, corn syrup solids, dextrin, fructose, high-fructose corn syrup, honey, invert sugar, lactose, malt syrup, maltose, maple syrup, molasses, nectars (e.g., peach nectar, pear nectar), pancake syrup, raw sugar, sucrose, sugar, white granulated sugar, cane juice, evaporated corn sweetener, fruit juice concentrate, crystal dextrose, glucose, liquid fructose, sugar cane juice, and fruit nectar (USDA, 2010, p. 75).

A selection of example products evaluated against potential qualifying criteria for added sugars is listed in Table 7-9. Peanut butter was included in the analysis even though it exceeded the disclosure/disqualifying level for saturated fat and would be excluded from earning FOP points unless exempted by FDA. Not earning an added sugars point are the following products: Graham and animal crackers; a breakfast bar; sweetened toasted oat cereal; instant oatmeal with added sugars, fruit, and nuts; chocolate-flavored milk; and four sweetened yogurts. Products with added sugars that would earn an FOP point include 100 percent whole wheat bread, a toasted oat cereal, a yogurt sweetened with an added sugar and low calorie sweetener, a light salad dressing, canned kidney beans, peanut butter, a tomato soup that meets the criteria for "healthy," and canned stewed tomatoes. Because the amount of total sugars would vary among products that qualify for an added sugars point, total sugars in the NFP could be footnoted with a statement such as "Contains no added sugars" or "Contains a qualifying amount of added sugars." The latter is depicted for 100 percent whole wheat bread in Figures 7-1 through 7-3.

## OVERALL PRODUCT EVALUATION

After evaluating a limited number of foods and beverages against current regulations for nutrient content claims, the committee identified *potential* eligibility and qualifying criteria for individual foods (Table 7-10) and

**TABLE 7-10** Potential Criteria for a Front-of-Package Symbol System for Individual Foods

| Nutritional Component | Eligibility Criteria[a] | Qualifying Criteria[b] |
|---|---|---|
| Saturated fat | ≤4 g per RACC and LS;<br>or per 50 g if RACC is small[c] | ≤2 g per RACC[d]<br>≤4.5 g per RACC and per 100 g for seafood and game meats[e]<br>≤3.5 g per RACC for mixed dishes not measurable with a cup[f] |
| *Trans* fat | | <0.5 g per LS, *or*<br>≥0.5 g per LS and product *does not* contain PHVO |
| Sodium | ≤480 mg per RACC and LS;<br>or per 50 g if RACC is small | ≤480 mg per RACC and LS; or per 50 g if RACC is small |
| Added sugars | Products not categorized as sugars, sweets, and beverages[g] | "Sugar-free," "No added sugars," or total sugars content with specified conditions[h] |

NOTES: LS, labeled serving, PHVO, partially hydrogenated vegetable oil, RACC, reference amounts customarily consumed. A small RACC is ≤30 g or ≤2 tablespoons.
[a] Products that meet all eligibility criteria may be evaluated for a front-of-package point for saturated and *trans* fats, sodium, and added sugars.
[b] Products that meet the qualifying criteria for a given nutritional component earn an FOP point for that component. To earn an FOP saturated and *trans* fats point, products must meet the qualifying criteria for both fats.
[c] Some oils, foods containing oils, nuts, foods containing nuts, and seafood and game meats that exceed the saturated fat disclosure/disqualifying level could be exempted based on Food and Drug Administration (FDA)-defined criteria.
[d] Criteria based on 10 percent Daily Value (DV) to be determined by FDA.
[e] Saturated fat criteria for "lean" seafood and game meats.
[f] Saturated fat criteria for "lean" mixed dishes not measurable with a cup.
[g] *USDA Food and Nutrient Database for Dietary Studies* (USDA, 2008, pp. 93-100). Examples include regular soda, energy drinks, sports drinks, fruit drinks, candy, sugars, and honey.
[h] Qualifying sugars criteria include the following:

- Product meets "sugar free" claim criteria, or
- Product contains ≥5 g sugars per LS with no ingredient recognized as added sugars listed in the ingredients statement, or
- Product meets WIC sugars requirement for breakfast cereals, or
- Product contains ≤5 g total sugars per RACC and an ingredient recognized as added sugars *except* for canned products containing tomatoes and/or other vegetables and yogurt products and substitutes, or
- Canned products that contain ≤10 g total sugars per RACC and tomatoes and/or other vegetables that contain naturally occurring sugars as well as an ingredient recognized as added sugars, or
- Yogurt products and substitutes that contain ≤20 g total sugars per RACC, a low calorie sweetener, and an ingredient recognized as added sugars. Half the total sugars should come from milk as estimated from the protein and lactose contents of plain yogurt and products expected to be covered by this criterion.

for main dishes and meat products (Table 7-11). The qualifying criteria in general are more restrictive than the eligibility criteria. For example, the eligibility criterion for saturated fat is no more than 4 g per RACC (or per 50 g if the RACC is small), and the qualifying criterion is no more that 2 g per RACC. Thus, products that contain more than 4 g per RACC would not be eligible to receive FOP points, those that contain 4 g or less but more than 2 g per RACC would not qualify for a saturated fat point (but could possibly qualify for sodium and/or added sugars FOP points), and those that contain less than or equal to 2 g per RACC would qualify for a saturated fat point if they also met the criterion for *trans* fat.

The criteria are *not* committee recommendations. Rather, the committee views the criteria as starting points for the extensive computer modeling that is needed to determine if the potential criteria are consistent with appropriate ratings for saturated and *trans* fats, sodium, and added sugars across a wide variety of foods and beverages, main dishes, and meal products. The criteria should balance restrictiveness with practicability. Criteria that are too restrictive may prevent foods and beverages that are consistent with the *Dietary Guidelines* recommendations and/or that are WIC-eligible from displaying FOP points, as well as be a disincentive to product reformulation and new product development. For example, it is challenging for many products to meet "low sodium" criteria for a variety of reasons, including consumer acceptance, shelf life, and microbiological safety (IOM, 2010b). Manufacturers may be more motivated to reformulate "high sodium" products to attain the current sodium criteria for "healthy"

**TABLE 7-11** Potential Nutritional Criteria for a Front-of-Package Symbol System for Main Dishes and Meal Products

| Nutritional Component | Eligibility Criteria[a] | Qualifying Criteria[b] |
|---|---|---|
| Saturated fat | ≤6 g per LS for main dishes[c]<br>≤8 g per LS for meal products[c] | ≤4.5 g per 100 g and per LS[d] |
| *Trans* fat | | 0 g per LS, *or*<br>≥0.5 g per LS and *does not* contain PHVO |
| Sodium | ≤720 mg per LS for main dishes[e]<br>≤960 mg per LS for meal products[e] | ≤600 mg per LS[e] |
| Added sugars | Products not categorized as Sugars, Sweets, and Beverages[f] | "No added sugars" plus total sugars content with specified conditions to be determined by FDA |

NOTES: FDA = Food and Drug Administration, LS = labeled serving size, PHVO = partially hydrogenated vegetable oil.
[a] Products that meet all eligibility criteria may be evaluated for a front-of-package point for saturated and *trans* fats, sodium, and added sugars.
[b] Products that meet the qualifying criteria for a given nutritional component earn an FOP point for that component. To earn an FOP saturated and *trans* fats point, products must meet the qualifying criteria for both saturated fat and *trans* fat.
[c] Disclosure/disqualifying level.
[d] Saturated fat criteria for lean main dishes and meals.
[e] Sodium criterion for "healthy" claim.
[f] *USDA Food and Nutrient Database for Dietary Studies* (USDA, 2008, pp. 93-100). Examples include regular soda, energy drinks, sports drinks, fruit drinks, candy, sugars, and honey.

than to lower levels that may be unacceptable to consumers. The qualifying amount for sodium could be reduced over time as part of an overall strategy to reduce sodium in the food supply.

Under the two-step approach for evaluating products, manufacturers have two incentives for improving product formulations. One incentive is to lower saturated fat and/or sodium below current FDA disclosure levels to enable the product's eligibility to earn FOP points. Manufacturers of products potentially eligible for FOP points, i.e., products that do not exceed the FDA disclosure/disqualifying levels for saturated fat and sodium and are not a Sugars, Sweet, or Beverage with added sugars, will have an incentive to formulate products to meet qualifying criteria for saturated and *trans* fats and/or added sugars and therefore earn FOP points.

Table E-2 (Appendix E) lists the potential FOP points earned for all the example foods and beverages evaluated by the committee; points for the bakery product examples are provided in Table 7-12 for illustrative purposes. The product examples in Appendix E were evaluated against all criteria in Table 7-10 *except* for the potential qualifying criteria for saturated fat, in which case the criteria for "low saturated fat" were used. The 100 percent whole wheat bread example earned three FOP points. The animal and graham cracker examples earned two FOP points, for saturated and *trans* fats and for sodium. The snack cracker example also earned two FOP points, one each for sodium and added sugars. The soup cracker example earned no FOP points because its sodium content exceeded the FDA disclosure/disqualifying level for sodium, disqualifying it entirely. If the soup cracker were reformulated to reduce the sodium content to below the disclosure/disqualifying level for sodium, then it would earn three FOP points. The other bakery product examples earned one FOP point, for sodium.

Many of the products listed in Table E-2 that are consistent with dietary recommendations and/or are WIC-eligible would *not* be eligible to earn FOP points because they exceed the disclosure/disqualifying level for saturated fat and/or do not meet the criteria for "low" saturated fat. This especially was the case for some oils, nuts, foods containing nuts or oils, and salmon, which are relatively lower in saturated fat and higher in mono- and polyunsaturated fats. As suggested in Table 7-10, FDA should consider exemptions and/or alternative eligibility criteria to the saturated fat disclosure/disqualifying level for such products and qualifying criteria for saturated fat based on 10 percent of the DV per RACC. Seafood, including salmon, and game meats could be evaluated for both eligibility and qualification based on criteria for "lean."

The three 100 percent fruit juices evaluated by the committee would earn three FOP points. These products contain no saturated or *trans* fats, no or very little sodium, 22 to 39 g of total sugars (all naturally occurring), and

**TABLE 7-12** Front-of-Package Points for Examples of Bakery Products Evaluated Against Potential Eligibility and Qualifying Criteria

| Product | SFA/TFA[a] | Sodium | Added sugars | FOP Points |
|---|---|---|---|---|
| Bread, 100 percent whole wheat | ✓ | ✓ | ✓ | 3 |
| Animal crackers | ✓ | ✓ | | 2 |
| Graham crackers | ✓ | ✓ | | 2 |
| Snack crackers | | ✓ | ✓ | 2 |
| Oat and peanut butter bar | | ✓ | | 1 |
| Sugar cookies | | ✓ | | 1 |
| Chocolate chip cookies | | ✓ | | 1 |
| Toaster pastry | | ✓ | | 1 |
| Soup crackers | (✓) | (✓) | (✓) | 0[b] |

NOTES: SFA = saturated fat, TFA = *trans* fat.
(✓) = Product would have earned points for SFA/TFA, sodium, and added sugars if it had not been excluded because of sodium content.
[a] Products were evaluated against the criteria listed in Table 7-10 except that "low saturated fat" was used instead of ≤2 g per reference amounts customarily consumed.
[b] Product exceeds the disclosure/disqualifying amount for sodium.

110 to 160 calories per 8 fluid ounces (Table E-1). Concern has been raised about the over-consumption of 100 percent fruit juices, especially among children, because of their high energy content (AAP, 2001, 2006, p. 551). The *Dietary Guidelines* recommend an increase in fruit intake (p. 34) and recognize that 100 percent fruit juices can be part of a healthy diet; however, because 100 percent fruit juices lack dietary fiber and can contribute extra calories when consumed in excess, the *Dietary Guidelines* recommend that the majority of the fruit come from whole fruit (USDA, 2010, p. 36). The declaration of calorie content on the FOP will help consumers recognize the high energy content of 100 percent fruit juices.

Concern also has been raised about the added sugars content of breakfast cereals marketed to children (Batada et al., 2008; Bell et al., 2009), and the committee recognized that some FOP systems have been criticized in relation to their rating of sugar-sweetened cereals. With the FOP system proposed by the committee, consumers will be able to *quickly* distinguish among cereals. Cereal manufacturers have gradually reduced the amount of added sugars in cereals advertised to children. Specifically, the sugar content in many cereals has been reduced from 12 to 15 grams to 10 or 11 grams per serving, and some manufacturers have indicated their intent to reduce added sugars to below 10 grams.[24] The reduced levels still exceed the sugars requirement for WIC eligibility (no more than 6 grams of sucrose and other sugars per 1 ounce dry cereal), which has been proposed as a possible qualifying criterion for FDA to consider. The three sweetened breakfast cereals evaluated by the committee were not WIC-eligible, as two contained 12 g added sugars per ounce and one contained 9 g per ounce (Table E-3). Although not earning an added sugars point, the three cereals would earn two FOP points, one for saturated and *trans* fats and one for sodium.

## ALIGNMENT WITH THE REGULATORY ENVIRONMENT

Points for saturated and *trans* fats, sodium, and added sugars that are displayed in a FOP symbol system would be implied nutrient content claims.[25] However, the eligibility and qualifying criteria for the FOP system described in this chapter are not entirely consistent with current regulations for nutrient content claims. Some, but not all, of these inconsistencies are discussed below. As it develops and tests an FOP symbol system, FDA will need to address inconsistencies between potential criteria and current regulations in addition to performing

[24] The Children's Food & Beverage Advertising Initiative in Action: A Report on Compliance and Implementation During 2009, p. 9. Available online: http://www.bbb.org/us/storage/0/Shared%20Documents/BBBwithlinks.pdf (accessed July 7, 2011).
[25] 21 CFR 101.13(b)(2).

extensive computer modeling to assess a variety of foods and beverages, main dishes, and meal products against potential eligibility and qualifying criteria.

As an example of inconsistency between the proposed criteria and current regulations, saturated fat and sodium disclosure/disqualifying levels are eligibility criteria only when used as disqualifying amounts for health claims. When pertaining to nutrient content claims, foods that exceed disclosure/disqualifying levels are only required to bear a statement disclosing that the nutrient exceeding the specified level is present in the food, e.g., "See nutrition information for [saturated fat and/or sodium] content."

Other inconsistencies include that current FDA regulations for nutrient content claims for individual foods are consistent across all product categories, e.g., the criteria for "low saturated fat" are the same for breakfast cereals, grain-based desserts, dairy products, vegetable oils, salad dressings, nuts, and seafood. As such, nutrient content claims for saturated fat do not provide exemptions for oils, nuts, foods containing oils and nuts, or certain types of seafood (e.g., salmon)—foods whose consumption is recommended by the *Dietary Guidelines*. Current regulations for saturated fat claims also do not require a product to contain less than 0.5 g *trans* fat per labeled serving; however, they do require declaration of the amount of monounsaturated and polyunsaturated fats in the NFP and thus provide a source of such information for consumers.

Current FDA regulations for "no added sugars" do not make exemptions for otherwise healthful foods that contain a small amount of added sugars, such as WIC-eligible breakfast cereals, whole wheat bread, peanut butter, and canned vegetables, or for yogurts that contain both added sugars and a low calorie sweetener. "No added sugars" and the amount of total sugars per labeled serving are not qualifying criteria for saturated fat or sodium content claims; nor are entire categories of foods and beverages excluded from making saturated fat or sodium content claims because of added sugars content.

In order for the FOP symbol to appear on as many products as possible, a similar approach for evaluating foods containing saturated fats or sodium, e.g., meat and poultry products should be assessed. In doing so, USDA would need to address some regulatory issues that currently deviate from FDA's regulations. For example, USDA does not currently require *trans* fat to be listed on nutrition labels, but information on the amount of *trans* fat in a serving is needed to determine whether a product exceeds the qualifying criteria. In addition, because USDA regulations do not include disclosure/disqualifying levels, regulations to implement an FOP symbol system would need to include those or other such levels determined by the agency to be appropriate for setting eligibility and qualifying criteria.

Finally, as with all regulatory actions, public input must be solicited on an FOP symbol system and its nutritional criteria.

## SUMMARY AND CONCLUSIONS

This chapter described the characteristics of a model FOP symbol system and presented an approach for developing criteria for and evaluating the amount of saturated and *trans* fats, sodium, and added sugars in foods and beverages consistent with these characteristics. Successful FOP symbol systems do not provide specific nutrient information but rather offer consumers guidance based on that information and give some idea of the healthfulness of the choice on an ordinal scale. Because of public concern about overweight and obesity, an FOP symbol system should display calories per serving expressed in a common household measure consistent with the NFP. Criteria for evaluating products for saturated and *trans* fats, sodium, and added sugars content should proceed in a two-step process:

1. Determine whether a product may earn FOP points, based on *eligibility criteria* that determine whether the product contains an amount of one or more of the stated nutrient components that is not consistent with the *Dietary Guidelines* recommendations. If a product's level of even one nutrient component exceeds the criteria threshold, then the product is ineligible for FOP points and would carry only calories per serving size.
2. Determine whether a product that meets the eligibility criteria earns FOP points for one or more of the following: saturated and *trans* fats, sodium, and/or added sugars based on *qualifying criteria* that assess acceptably low amounts.

**BOX 7-3**
**Limitations Associated with Criteria for Limits on Nutrient Components in a Front-of-Package (FOP) Symbol System Based on Current Regulations and Potential Solutions**

Saturated Fat

- Disclosure/disqualifying level as the basis for exclusion from earning FOP points is too restrictive for many products that are consistent with the *Dietary Guidelines* recommendations and/or are eligible for the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). A solution would be to exempt certain products from Food and Drug Administration (FDA)-based eligibility criteria.
- "Low" criteria as the basis for qualifying for an FOP point are too restrictive for most product categories, especially products that are consistent with the *Dietary Guidelines* recommendations and/or are WIC-eligible. A solution would be to develop qualifying criteria based on 10 percent Daily Value (DV) per Reference Amounts Customarily Consumed (RACC) for individual foods and on "lean" for seafood and game meats.
- Examples of products that are adversely affected by the disclosure/disqualifying level and/or criteria for "low" include some oils, nuts, foods containing oils and nuts (such as salad dressings, mayonnaise, soft margarines, and peanut butter), 1 percent milk, eggs, and salmon.

*Trans* Fat

- No regulatory criteria exist for "low" or "high" amounts. A solution would be to qualify products based on the *trans* fat declared in the Nutrition Facts panel and the absence or presence of a partially hydrogenated vegetable oil in the ingredients list.

Sodium

- "Low sodium" criteria are overly restrictive as qualifying criteria for most products on the market. A solution would be to qualify products based on "healthy" criteria.
- For individual foods, there is no gap between the FDA disclosure/disqualifying level[a] and the "healthy" criteria.[b] As a result, "healthy" may appear too lenient as a qualifying criterion, at least for some products. This is not the case for main dishes and meal products, which have a significant gap between disclosure and "healthy" levels. A solution for individual foods would be to lower the criteria for "healthy" as a national sodium reduction initiative proceeds.

Added sugars

- No regulatory criteria exist for "low" or "high" amounts, and no analytical methods are available for monitoring compliance. Evaluation must rely on claim criteria for "sugar free" and "no added sugars" as well as the amount of total sugars declared in the Nutrition Facts panel in conjunction with food specifications.
- 100 percent fruit juices do not contain added sugars but do contain a relatively high amount of naturally occurring sugars, and juices can contribute to extra calories when consumed in excess. FOP declaration of calories will help to make consumers aware of the high energy content, even as the FOP points indicate the juices to be a relatively healthy beverage.
- Presweetened cereals that do not meet the WIC sugar requirement could earn up to two FOP points, one for saturated and *trans* fats and one for sodium. Consumers will be able to identify cereals that do and do not earn an FOP point for added sugars.

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[a] Sodium disclosure/disqualifying level is >480 mg per RACC and labeled serving (LS), or per 50 g if RACC is small.
[b] Sodium "healthy" criteria is ≤480 mg per RACC and LS, or per 50 g if RACC is small.

The criteria for evaluating nutrients to limit through an FOP symbol system should be based on FDA labeling requirements and therefore transparent and nonproprietary and the FOP symbol system should be integrated with the NFP so the two can be mutually reinforcing. Current FDA regulations will require modifications and/or exemptions, and new regulations will need to be developed along with food group specifications to find an appropriate balance between restrictiveness and practicality. The approach described in this chapter has strengths and limitations (listed in Box 7-2 and Box 7-3). No one FOP symbol system, including its underlying nutrition criteria, is flawless. Nonetheless, the committee believed that development of an FOP symbol system based on the model and approach described here can be achieved, with extensive computer modeling and solicitation of public input.

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# 8

# Promotion, Evaluation, and Monitoring for Front-of-Package Symbol Systems

## INTRODUCTION

The burden of nutrition-related diseases including type 2 diabetes, cancer, and cardiovascular disease on the health of the American population is high, and the prevalence of certain diseases such as diabetes have dramatically increased over the past few decades because of obesity (Lopez et al., 2006). In an effort to improve public health nutrition, national and international efforts have focused on developing health promotion initiatives and policies to raise public awareness about the relationships between nutrition, health, and food choices (WHO, 2002). For the past two decades in the United States, federally mandated nutrition labeling, i.e., the Nutrition Facts panel (NFP), has been a source of standardized information about the nutritional content of food products at the point of purchase. Front-of-package (FOP) nutrition rating symbol systems are another tool that provide consumers with information and guidance on food choices, and a variety of such systems have been developed by food manufacturers and retailers, as well as by nonprofit organizations such as the American Heart Association (Nestle and Jacobson, 2000). As described in Chapter 4, a proliferation of FOP nutrition labeling and claims followed inauguration of the NFP on the back of food product packages in the early 1990s. Although a variety of FOP systems have been developed since that time, the public health impact of various formats for an effective system has been robustly debated, but little evaluation has been done (Lobstein et al., 2007).

Despite the limitations and uncertainty in relevant fields of research, the committee's review of available evidence (discussed in Chapters 4 through 6) revealed that, in addition to time constraints when shopping, concerns about price, and taste preferences, many consumers have difficulty understanding and using the nutrition information provided on FOP nutrition labeling, as well as on the NFP. As a result, the committee concluded that a simplified FOP symbol system that provides readily accessible and understandable nutrition information and is linked to the NFP would be a preferable option to the current package environment. The specific goals of an effective FOP symbol system include simplifying consumers' purchase decisions, encouraging food and beverage manufacturers to develop healthier products, and encouraging food retailers to promote purchase of healthier options among food products.

This chapter examines ways in which social marketing techniques and principles can be applied to inform promotion, monitoring, and evaluation of FOP symbol systems to enhance their effectiveness in guiding food choice and purchase behaviors. Specifically, the committee introduces the tenets and processes of social marketing, briefly highlights evidence supporting the effectiveness of social marketing in changing health behaviors, and describes the application of social marketing techniques to FOP symbol systems. The committee's recommendations for a simplified FOP symbol system include extensive testing and consumer evaluation prior to implementation. The committee did not examine questions specific to implementation of an FOP symbol system, including responsibilities for its cost, management, and enforcement.

## SOCIAL MARKETING APPROACH TO CHANGING HEALTH BEHAVIOR

### Principles of Social Marketing

Social marketing, the application of commercial marketing techniques to the development, implementation, evaluation, and dissemination of programs designed to influence health-relevant behaviors in target audiences, offers a systematic approach to guide the promotion of health behavior in defined populations (Andreasen, 1995). In addition, an effective marketing mix yields an opportune interchange that minimizes barriers and maximizes benefits to promote a given behavior among a target audience. The process of social marketing involves identification of an optimal "marketing mix" of the four Ps of marketing: *product, price, place*, and *promotion* (NCI, 2004). Details of the marketing mix are shown in Table 8-1. The four Ps of social marketing are substantively grounded in behavior change theory, which guides assessment of the behavior of target audience members and offers insight into factors that might influence behavior change (NCI, 2004). Thus, this approach is ideally suited to the goal of a single, simplified FOP symbol system, i.e., maximizing the opportunity to encourage consumers to make healthier food choice and purchase decisions while minimizing barriers.

### Rationale for a Social Marketing Approach

Considerable evidence supports the effectiveness of social marketing in modifying health behavior at the population level (Hogan et al., 2002; Snyder, 2007). A recent review of evidence of the effectiveness of health communication campaigns, drawing upon meta-analyses and other literature, revealed that health communication campaigns, on average, influence relevant community behavior by approximately 5 percentage points with somewhat greater impact shown for nutrition campaigns (Snyder, 2007). One such social marketing campaign that resulted in behavior change is VERB: *It's What You Do*. This campaign, administered by the Centers for Disease Control and Prevention (CDC) from 2002 to 2006, promoted physical activity among youth ages 9-13 years (Caville and Maibach, 2008). The campaign used a combination of paid advertising, marketing strategies, and partnership efforts and employed branding and message strategy grounded in behavioral theory that was developed and integrated into campaign planning and implementation (Bandura, 1986; Ajzen, 1991; Huhman et al., 2004). Through development of messages derived from consumer research, and dissemination through multiple media and marketing efforts, the VERB campaign achieved significant population impact (Banspach, 2008; Huhman et al., 2010).

**TABLE 8-1** The Marketing Mix of the Four Ps

| Marketing Mix Component | Definition | Examples |
|---|---|---|
| Product | The promoted behavior and attendant benefits | Choose a healthier food product while grocery shopping |
| Price | The barriers or costs associated with adoption of the promoted behavior | Time<br>Money<br>Taste |
| Place | A convenient location to deliver the product and its benefits | Point of purchase |
| Promotion | The process of delivering the product and its benefits to the target market | Communication campaigns<br>Branding strategies |

*Branding and Communication*

Social marketing through public health branding utilizes commercial branding practices, including modeling of desired behaviors and imagery (e.g., attractive, energetic people eating fruits and vegetables), to promote healthy behaviors (Evans et al., 2008). Social marketing through mass communication and branding around nutrition has increased dramatically during the past decade and shows considerable promise as a tool for behavior change (Grilli et al., 2000; Bauman et al., 2006; Snyder, 2007; Evans et al., 2008; Hornick et al., 2008).

The committee's review of evidence acknowledges the increasingly cluttered food package environment (see Chapter 6) and highlights the need for FOP symbol systems to be distinctive, readily assessable, and consistent across all food packages in order to be recognized and used by consumers. The committee identified four attributes that are common to successful FOP symbol systems:

- *simple*, understanding does not require specific or sophisticated nutritional knowledge;
- *interpretive*, nutrition information is provided as guidance rather than as specific facts;
- *ordinal*, nutritional guidance is offered through a scaled or ranked approach; and
- *supported by communication* with readily remembered names or identifiable symbols.

## Application of Social Marketing Campaigns to FOP Systems

As discussed above, social marketing provides a useful framework to guide the promotion and evaluation of FOP nutrition rating systems and symbols. The committee identified potential stages in successful social marketing campaigns that could be applied to the promotion of an FOP system. Figure 8-1 summarizes the stages that are common to successful campaigns; their application to FOP labeling systems is discussed below.

Phase I of the study, *Examination of Front-of-Package Nutrition Rating Systems and Symbols* (IOM, 2010), involved preliminary activities designated in Stage 1 of the social marketing process, *Campaign Planning and Strategy Development*. These activities included conducting a review of 20 representative FOP labeling systems; characterizing the strengths and limitations of existing systems; designing key objectives to encourage consumers to choose foods and beverages that are lower in calories, sodium, and saturated and *trans* fats; and identifying the market audience as the general U.S. population. The aim of Phase II is to expand upon these planning and strategy development activities to develop a set of recommendations and a research agenda that will optimize the impact and support promotion of an FOP symbol system on consumer food choice and purchase behavior. While Stages 2 through 4 outlined in Figure 8-1 are essential components for comprehensive implementation strategy, specific recommendations for those areas are beyond the scope of the committee's task.

Special consideration should be given to audience segmentation (e.g., parents with young children, adolescents, families living on tight budgets) and to integrating promotion and education efforts around FOP package labeling in food and nutrition assistance programs such as Supplemental Nutrition Assistance Program (SNAP) and SNAP Nutrition Education (SNAP-ED), Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), the U.S. Department of Agriculture (USDA) commodities program, and the National School Lunch and School Breakfast programs (NSLP/SBP). Effective FOP symbol systems could serve to inform and unify federal and local nutrition assistance programs and education efforts around shared public health nutrition goals and standards. Finally, promotion of FOP symbol systems is encouraged with branding and media campaigns to increase awareness, use of compelling images and sources, development of a related slogan, and distribution through multiple channels.

A promotion and implementation campaign will need to include information and messages that complement, and in some cases, further describe an FOP symbol system. For example, messaging around calorie content in terms of overall calorie needs and anchoring statements—such as those used or proposed in menu labeling efforts across the country—will be important to help consumers put calorie content information into perspective. In addition, messaging around saturated and *trans* fats, added sugar, and sodium will be essential to help consumers better understand the simplified icon with the zero, one, two, or three symbols depicting nutrients of concern.

**Four Ps of Social Marketing**
- *Product*: the FOP symbol system
- *Price*: financial, time, effort, and cost of selecting healthier food, and time and effort of interpreting FOP labels
- *Place*: FOP systems are recommended to appear on all food and beverage products, at point of purchase, and integrated with food and nutrition assistance programs, such as WIC and SNAP
- *Promotion*: branding and media campaigns around the FOP system; use of compelling images and sources, develop related slogan; and distribute through multiple channels

**Stage 1: Campaign Planning and Strategy Development**
- Review representative FOP symbol systems
- Characterize strengths and limitations of existing FOP systems
- Designate key communication objectives of FOP campaign
- Identification of the market audience
- Develop a research agenda to evaluate FOP symbol systems
- Suggest social marketing strategies to promote FOP labeling systems

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**Step 2: Formative Research to Develop and Pretest Concepts, Messages, and Material**
- Develop consistent, clear, relevant, and appealing messages;
- Select and define target populations;
- Conduct formative research on diet-related awareness, knowledge, attitudes, and behaviors of target population;
- Test impact of messages on intended behavior change;
- Create awareness of FOP labels and develop favorable associations with consumer behavior through branding and social modeling; and
- Employ multiple communication channels to maximize population reach and effectiveness of FOP labels.

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**Step 3: Implementation**
- Program launch with a kick-off event or media event to create awareness of FOP campaign; and
- Engage in process evaluation to assess dissemination efforts and evaluate campaign reach.

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**Step 4: Evaluate Effectiveness and Make Refinements**
- Implement measures to assess consumer awareness, knowledge, attitudes, and behavior relevant to FOP symbol systems;
- Establish and implement techniques for monitoring and evaluation of campaign relevant outcomes; and
- Modify campaign to reflect findings from results and outcomes of monitoring and evaluation.

**FIGURE 8-1** Application of social marketing to a front-of-package symbol system.

## PROMOTION, MONITORING, EVALUATION, AND RESEARCH

### Promotion

The committee identified a number of ways in which social marketing strategies can be applied to FOP symbol systems to guide food choice and purchase behaviors. Based on its review of existing public health campaigns, the committee concluded that in order to be effective, promotion of FOP symbol systems must be a well-funded, sustained effort and must be dynamic, refreshed on a regular basis, and carried out by multiple stakeholders representing both public and private interests. Further, campaigns that focus on behavioral goals that are effective and actionable have a greater chance for success. Comprehensive, multi-level approaches that speak to environmental and policy constraints, socio-cultural influences, and individual-level factors that affect dietary behavior change are encouraged.

### Monitoring, Evaluation, and Research

Monitoring, evaluation, and research are essential components of an FOP symbol system. Addressing these components includes:

- Identifying the steps toward reaching the goal of making healthier choices;
- Conducting research designed to assess success in reaching each step; and
- Enhancing system components and taking corrective action where necessary.

Research should be conducted by governmental and nongovernmental organizations as well as by academic and industry stakeholders to assess the needs and preferences of target audiences to better understand the factors that influence consumer food choice and purchase behavior. For example, research could examine whether differentiating between fat, sodium, and added sugar points on the FOP has any impact on food choices and purchasing decisions. In addition, research should determine if consumers see nutrition information on the FOP as marketing materials or as credible health or government statements. In addition formative research is necessary to test and refine messages and to determine the best approaches and channels to promote an FOP system. Monitoring through both process and outcome evaluation is needed to assess effectiveness and impact and to refine and strengthen program components. Assessment of the impact of an FOP symbol system on product reformulation is also necessary. Placing special emphasis to nutritionally at-risk subpopulations such as those with low incomes, low literacy/numeracy skills, or low levels of education, is an important component of these processes. Ongoing research will also help to guide and strengthen implementation efforts and help inform any corrective action where necessary. Table 8-2 illustrates the process necessary to monitor, evaluate, and improve an FOP symbol system.

## FINDINGS AND CONCLUSIONS

### Findings

Social marketing campaigns have been effectively implemented to modify a diversity of health behaviors, including behaviors relevant to diet and nutrition (Grilli et al., 2000; Hogan et al., 2002; Snyder and Hamilton, 2002; Bauman et al., 2006; Evans et al., 2008). With careful development and implementation, a social marketing campaign to promote FOP symbol systems has considerable potential to change nutrition-related behaviors in the population. Review of existing public health campaigns suggests that to be effective, FOP symbol system implementation must be well-funded, sustained, refreshed, and carried out by multi-sector collaborations including stakeholders from public health, medical, education, science, industry, and government. The committee's review of relevant campaigns organized by the social marketing framework suggests that FOP symbol systems should focus on actionable behaviors. In addition, comprehensive, multi-level approaches that address a combination of factors

**TABLE 8-2** Ongoing Monitoring, Evaluation, and Improvement of the New Front-of-Package System

| Process Toward Healthier Choices | Evaluation/Research | Revision of FOP System |
|---|---|---|
| Consumers encounter the FOP symbol system in national, local, social, and/or in-store media | Recognition of the FOP symbol system across demographic groups | Examine message delivery by each medium across demographic groups and bolster shortcomings |
| Consumers understand that products receiving FOP symbols with more nutritional points are healthier choices | Perceptions of the healthfulness of products receiving more or less nutritional points versus perceptions of the same products without the FOP symbol system | Revise symbol design or sharpen communication of the symbol's meaning |
| Consumers perceive purchases of products with the FOP symbol system displaying more nutritional points more positively, compared to purchases of products with FOP symbols displaying fewer nutritional points | Perceptions of the purchasers of products with the FOP symbol system displaying more nutritional points compared to perceptions of the purchasers of products with an FOP symbol system displaying fewer nutritional points | Improve communications' ability to stimulate the desired inference |
| Consumers make healthier choices at the point of purchase | • Retail activity behind healthier options before and after the introduction of the FOP symbol system<br>• Interviews with retail managers<br>• Share of shelf space accounted for by healthier options before and after the introduction of the FOP symbol system<br>• Interviews with manufacturers<br>• Sales of healthier options before and after the introduction of the FOP symbol system<br>• Econometric modeling of the impact of price, promotion, retail presence, and FOP symbol system to understand what may account for the sales pattern | • Solicit possible adaptations of the program in keeping with consumer and retailer needs<br>• Solicit possible adaptations of the program in keeping with consumer and manufacturer needs |

such as environmental and policy constraints as well as individual-level factors are important areas to encourage (Grilli et al., 2000; Hogan et al., 2002; Snyder and Hamilton, 2002; Bauman et al., 2006; Evans et al., 2008).

A robust monitoring and evaluation approach is essential to ascertain the mechanisms underlying consumer purchasing behaviors relevant to FOP symbol systems. Such an approach will help inform campaign implementation and refinement. Integration of promotion of FOP symbol systems informed by basic communication and social marketing science into existing and relevant social marketing campaigns, such as *Fruits and Veggies—More Matters* and food and nutrition assistance programs and education efforts, can lead to widespread adoption and promotion of FOP symbol systems. Such coordinated and complementary efforts will also help to maximize use of limited public health resources, provide consistent messages in different venues, and capitalize upon the shared public health goal of promoting healthy behaviors and ultimately reducing obesity and diet-related chronic diseases.

### Conclusions

Implementation of an FOP symbol system must include a multi-stakeholder, multi-faceted, ongoing awareness and promotion campaign. The characteristics of a successful campaign are as follows:

- Include a combination of the four key tenets of marketing: product, price, place, and promotion;
- Involve the four stages of the social marketing process including
  - Planning and strategy development;
  - Development of pretesting concepts, messages, and materials;
  - Implementation; and
  - Evaluation of in-market effectiveness and refinement; and
- Be integrated into existing and relevant social marketing campaigns, as well as food and nutrition assistance programs and education efforts such as SNAP and SNAP-ED, WIC, and the USDA NSLP/SBP.

Additionally, in order to be successful, federal agencies and interested stakeholders, including private and nongovernmental organizations, should support the FOP symbol system, emphasizing its impact on consumer purchases and consumption behaviors.

Monitoring and evaluation are essential components of the process to ensure that the needs, values, and preferences of the targeted audiences are assessed and integrated into campaign components. A variety of monitoring and evaluation efforts should be used to capture key campaign components and to continually refine, strengthen, and refresh efforts. Formative evaluation, qualitative and quantitative research, and process and outcome evaluation are all important to consider and employ to best assess program effectiveness and continued refinement of an FOP symbol system.

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# 9

# Recommendations

## INTRODUCTION

In Phase I of the study to examine front-of-package (FOP) nutrition rating systems, the committee concluded that such systems are only one among many approaches that provide information to improve the ability of consumers to make healthy food choices. In Phase II of the study the committee found that the variety of FOP systems in the marketplace predominantly focused on provision of nutrition information at the point of purchase. The evidence reviewed on consumer use of nutrition information and product choices, understanding FOP labeling systems, and effects of food package information on consumer choices suggested that an approach that provides nutrition information only has had limited success in encouraging healthier consumer food choice and purchase decisions. Importantly, this evidence led the committee to conclude that a shift is needed from an approach that provides information only to one that encourages consumers to make healthier food choices and purchase decisions. To develop its recommendations for this type of FOP symbol system, the committee identified the characteristics of successful FOP systems and then incorporated them into a model FOP symbol system for food packages and shelf tags.

## RECOMMENDATIONS FOR FOP SYSTEMS AND SYMBOLS

As noted in the Phase I report, "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." Using the Phase I conclusions as a starting point, the Phase II committee determined that the most critical nutrition components to include in FOP symbol systems are calories, saturated and *trans* fats, sodium, and added sugars. The Phase I committee concluded that there is insufficient evidence to support inclusion of total fat, cholesterol, total carbohydrate or added sugars, protein, fiber, vitamins, and minerals other than sodium on a FOP label. Furthermore, the committee determined that added sugars should not be a component of an FOP nutrition rating system because of insufficient evidence about the contribution of added sugars beyond calories to the most pressing diet-related health concerns among Americans; the inability to distinguish analytically between added and naturally occurring sugars in foods without obtaining proprietary product information and including that information on the Nutrition Facts panel (NFP); and the relatively small number of food categories with high amounts of added sugars. This committee reconsidered this Phase I conclusion in light of events occurring after the release of the Phase I report, specifically the release of the 2010 *Dietary Guidelines for Americans* and the development of an approach to evaluating added sugars content. The 2010 *Dietary Guidelines* *for Americans*, which is the federal government's nutrition policy document, strongly recommends reducing intakes of calories from added sugars and consumption of foods containing added sugars. These products contribute to energy intake; generally contain no or low amounts of saturated and *trans* fats and sodium; and provide little or no essential nutrients unless fortified, which is not consistent with Food and Drug Administration (FDA) fortification policy.[1] A relatively small number of food and beverage categories contribute more than half the added sugars in the American diet.

The committee developed an approach to evaluating added sugars based on products categorized as Sugars, Sweets, and Beverages in the U.S. Department of Agriculture (USDA) *Food and Nutrient Database for Dietary Studies* that addresses previous concerns about analyzing foods for added sugars content. Simply stated, any product that is categorized as Sugars, Sweets, and Beverages in the USDA *Food and Nutrient Database for Dietary Studies* and contains added sugars would not be eligible to earn FOP points. As a consequence, major contributors of added sugars to diets, such as beverages, sugars, and sweets, would erroneously appear as being healthy because they are low in saturated and *trans* fats and sodium.

The strong recommendation from the 2010 *Dietary Guidelines for Americans*, along with the development of this approach to evaluating added sugars, led the committee to conclude that added sugars are an important component that should be included in a FOP nutrition rating system. This conclusion is consistent with the principle that an FOP symbol system should not inadvertently promote products that are inconsistent with current federal dietary guidance.

Among consumers with low literacy skills, the evidence reviewed indicates that a simple rating system diminishes the differences in choosing the healthier product between high- and low-literacy adults. FOP labeling, especially using a simple symbol, might serve as a cue or signal for consumers, helping them distinguish between products of greater and lesser nutritional quality. These findings indicate that using simple symbols to summarize complex information about product quality may be especially valuable to low-literacy populations. From its review of existing FOP systems, the committee identified four attributes that are common to most successful FOP systems:

1. simple, understanding does not require specific or sophisticated nutritional knowledge;
2. interpretive, nutrition information is provided as guidance rather than as specific facts;
3. ordinal, nutritional guidance is offered through a scaled or ranked approach; and
4. supported by communication with readily remembered names or identifiable symbols.

In considering its task to evaluate the potential benefits of a single, standardized front-label food guidance system regulated by FDA, the committee recognized that it was not constituted to evaluate regulatory or related considerations involving universal implementation of a single, standardized system. Furthermore, the committee recognized that it did not have the expertise to consider possible First Amendment issues that could arise as such a system was developed and implemented as described below. However, because the evidence showed that there are no flawless FOP symbol systems in the marketplace, the committee concluded that a single, standardized system that is easily understood by most age groups and appears on all products would be the best option for encouraging consumers to make healthier food choice and purchase decisions.

The committee determined that a single, standardized system for all foods would provide the following specific benefits:

- Prominently provide in one symbol system information about calorie content and serving size and targeted information related to nutrients and most foods with added sugars that are strongly associated with public health concerns for Americans;
- Facilitate comparisons of nutritional value *within* as well as *across* food categories; and
- Encourage product reformulation.

[1] 21 CFR 104.20.

The committee therefore makes the following recommendation:

*Recommendation 1*

**FDA and USDA should develop, test, and implement a single, standardized FOP system to appear on all food and beverage products. The system should have the following eight characteristics:**

- **One simple, standard symbol translating information from the NFP on each product into a quickly and easily grasped health meaning, making healthier options unmistakable;**
- **Displaying:**
  - **Calories in common household measure serving sizes** (shelf tags to be used on bulk items such as fruits and vegetables as well as packaged goods), and
  - **Zero to three nutritional "points"** (for saturated and *trans* fats, sodium, and added sugars);
- **Appearing on all grocery products, allowing consumers to compare food choices across and within categories** (universal implementation must be preceded by consumer testing and conducted in conjunction with an education and promotion program);
- **Appearing in a consistent location across products;**
- **Practical to implement by being consistent with nutrition labeling regulations;**
- **Integrated with the NFP so that the FOP symbol system and the NFP are mutually reinforcing;**
- **Providing a nonproprietary, transparent translation of nutrition information into health meaning; and**
- **Made prominent and useful to consumers through an ongoing and frequently refreshed program of promotion integrating the efforts of all concerned parties.**

Implementation of this system will require modifications of and/or exemptions to current FDA regulations and development of both new regulations and food group specifications for establishing evaluative criteria. Because the NFP does not declare added sugars, the total sugars declaration could be footnoted with a statement such as "Contains no added sugars" or "Contains a qualifying amount of added sugars." A single, standardized FOP symbol system should be the only FOP system appearing on products. For products not meeting the evaluative criteria for an ordinal indicator symbol, the FOP label should still display calorie and serving size information. Examples of symbol systems that are consistent with these recommendations are presented in Chapter 7.

## RECOMMENDATIONS FOR MONITORING, EVALUATION, AND FUTURE RESEARCH

Based on its review of existing public health campaigns, the committee concluded that implementation of an effective FOP system must be a well-funded, sustained effort that is dynamic, refreshed on a regular basis, and carried out by a public-private partnership. The committee further concluded that, in order to be successful, federal agencies and interested stakeholders, including private and nongovernmental organizations, should support the FOP symbol system, emphasizing its impact on consumer purchase and consumption behavior.

Research should be conducted to assess the needs and preferences of target audiences to better understand factors that influence consumer food choice and purchase behavior. In addition, formative research is necessary to test and refine messages and to determine the best approaches and channels to promote an FOP system. Monitoring through both process and outcome evaluation is needed to assess the effectiveness and impact and to refine and strengthen program components. Placing special emphasis to nutritionally at-risk subpopulations such as those with low incomes, low literacy/numeracy skills, or low levels of education, is an important component of the evaluation process. However, the committee recognizes that any FOP system is likely to have a narrow influence on food purchase decisions of consumers whose access or resources to purchase healthier foods is impacted by economic and/or geographic limitations. An evaluation of the impact of the FOP symbol system on product reformulation is also necessary. Ongoing research will help to guide and strengthen implementation efforts and help inform corrective actions where necessary. Lastly, research should measure success at each stage of the process toward encouraging consumers to make healthier food choices and to guide remedial action where necessary. For example, research could examine whether differentiating between fat, sodium, and added sugars points on the FOP label has any impact on food choices and purchasing decisions. Based on these conclusions the committee makes the following recommendation:

*Recommendation 2*

**Implementation of a new FOP symbol system should include a multi-stakeholder, multi-faceted awareness and promotion campaign that includes ongoing monitoring, research, and evaluation.**

## SUMMARY

The committee's recommendations for a single, simple, FOP symbol system are derived from its review and analysis of evidence from the published literature and unpublished reports, as well as from information provided by food manufacturers, consumer organizations, government agencies, nongovernmental organizations, and other stakeholders. The aim of the FOP symbol system is to help consumers identify and choose products that are more consistent than others with the 2010 *Dietary Guidelines for Americans* for saturated and *trans* fats, sodium, and added sugars, based on a set of criteria to make that distinction. Based on an evaluation of a limited number of products, the committee found certain criteria for "low saturated fat" and "low sodium" to be overly stringent for products that are consistent with a healthful diet, which suggests that FDA consider alternative criteria developed through the regulatory process to allow certain foods and foods encouraged by the *Dietary Guidelines for Americans* to receive points as appropriate. The committee acknowledged the potential shortcomings of any FOP system that were identified during Phase I, and explored whether and how consumers might use the information provided by a FOP symbol system. Although the committee's task included developing recommendations for an FOP system that would best promote health and maximize its use, it did not include developing recommendations about consumption practices after purchase.

The committee's recommendations are presented as guidance to the study sponsors for developing a single, standardized FOP symbol system that is easily understood and consistent across food product categories and that encourages consumers to make healthier food choices and purchasing decisions.

# Appendix A

# Acronyms and Glossary

## ACRONYMS

| | |
|---|---|
| **%DI** | Percent Daily Intake |
| **%DV** | Percent Daily Value |
| | |
| **AHA** | American Heart Association |
| **AI** | Adequate Intake |
| **AMS** | Agricultural Marketing Service |
| | |
| **BMI** | Body Mass Index |
| **BMRB** | British Market Research Bureau |
| | |
| **CDC** | Centers for Disease Control and Prevention |
| **CFSAN** | Center for Food Safety and Applied Nutrition |
| **CHD** | Coronary heart disease |
| **CIAA** | Confédération des Industries Agro-Alimentaires de l'UE (Confederation of the Food and Drink Industries of the EU) |
| **CNPP** | Center for Nutrition Policy and Promotion |
| | |
| **DGA** | *Dietary Guidelines for Americans* |
| **DoE** | Department of Energy |
| **DRI** | Dietary Reference Intakes |
| **DRV** | Daily Reference Value |
| **DV** | Daily Value |
| | |
| **EAR** | Estimated Average Requirement |
| **EER** | Estimated Energy Requirement |
| **EPA** | Environmental Protection Agency |
| **EPIA** | Egg Products Inspection Act |
| **EU** | European Union |

| | |
|---|---|
| **FD&C Act** | Federal Food, Drug, and Cosmetic Act |
| **FDA** | U.S. Food and Drug Administration |
| **FLAPS** | Food Label and Package Survey |
| **FMIA** | Federal Meat Inspection Act |
| **fMRI** | Functional Magnetic Resonance Imaging |
| **FOP** | Front-of-package |
| **FSA** | Food Standards Agency |
| **FSIS** | Food Safety and Inspection Service |
| **FTC** | Federal Trade Commission |
| | |
| **GDA** | Guideline Daily Amounts |
| **GMA** | Grocery Manufacturer's Association |
| **GMA/IFIC** | Grocery Manufacturer's Association/International Food and Information Council |
| | |
| **HHS** | U.S. Department of Health and Human Services |
| | |
| **IOM** | Institute of Medicine |
| | |
| **LCS** | Low-calorie sweetener |
| **LS** | Labeled serving size |
| **LSRO** | Life Sciences Research Organization |
| | |
| **M-% DI** | Monochrome Percent Daily Intake |
| **MTL** | Multiple Traffic Light |
| | |
| **NAS** | National Academy of Sciences |
| **NCHS** | National Center for Health Statistics |
| **NFP** | Nutrition Facts panel |
| **NIH** | National Institutes of Health |
| **NIP** | Nutrition Information panel |
| **NLEA** | Nutrition Labeling and Education Act |
| **NRC** | National Research Council |
| **NSLP/SBP** | National School Lunch and Breakfast Programs |
| | |
| **PHVO** | Partially hydrogenated vegetable oil |
| **PPIA** | Poultry Products Inspection Act |
| | |
| **RACC** | Reference Amounts Customarily Consumed |
| **RDA** | Recommended Dietary Allowance |
| **RDI** | Reference Daily Intake |
| | |
| **SNAP** | Supplemental Nutrition Assistance Program |
| **SNAP–Ed** | Supplemental Nutrition Assistance Program Education |
| **STL** | Single Traffic Light |
| | |
| **TL** | Traffic Light |
| | |
| **UL** | Tolerable Upper Level |
| **US RDA** | Recommended Daily Allowances |
| **USDA** | U.S. Department of Agriculture |

| | |
|---|---|
| **WHO** | World Health Organization |
| **WIC** | Special Supplemental Nutrition Program for Women, Infants, and Children |
| **WTP** | Willingness-to-pay |

## GLOSSARY

**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. The Food and Drug Administration (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 (For regulatory language see 21 CFR 101.60[c][2]).

**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.

**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.

**Daily Reference Value (DRV)**

A set of dietary references that applies to fat, saturated fat, cholesterol, carbohydrate, protein, fiber, sodium, and potassium. They are part of the FDA Daily Value label reference.

**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 Reference Daily Intakes (RDIs) and DRVs.

***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 (HHS) and U.S. Department of Agriculture (USDA) 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 Academies 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 levels 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 with 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).

**Disqualifying level**

The levels of total fat, saturated fat, cholesterol, or sodium in a food above which the food will be disqualified from making a health claim. Levels are specified in 21 CFR 101.14(a)(4).

**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.

**Front-of-package (FOP) nutrition rating systems and symbols**
Systems that use nutrient rating 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 shelf tags.

**Guideline Daily Amounts (GDAs)**
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, European Union (EU), and government guidelines. GDAs were first seen in the United Kingdom and are increasingly being used in the 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 substance, 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 resoureces, 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 (EERs) 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.

**Healthier choices**
A term used in this report that refers to meeting guidelines of qualifying criteria for saturated and *trans* fats, sodium, and added sugars.

**Interpretative**
Offering interpretations, explanations, or guidance.

**Labeled serving size**
Serving size as determined by the product manufacturer; based on the Reference Amounts Customarily Consumed (RACC) and regulations for determing serving size.

**Main dishes**
Weigh at least 6 ounces (oz) per labeled serving; contain not less than 40 g of food, or combinations of foods, from at least *two* of the following four food groups: bread, cereal, rice, and pasta group; fruits and vegetables group; milk, yogurt, and cheese group; and meat, poultry, fish, dry beans, eggs, and nuts group; and are represented as, or is in a form commonly understood to be, a main dish (e.g., not a beverage or a dessert). See full requirements in 21 CFR 101.13(m).

**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.

**Meal products**

Weigh at least 10 oz per labeled serving; contain not less than *three* 40 g portions of food, or combinations of foods, from two or more of the following four food groups: bread, cereal, rice, and pasta group; fruits and vegetables group; milk, yogurt, and cheese group; and meat, poultry, fish, dry beans, eggs, and nuts group; and are represented as, or is in a form commonly understood to be, breakfast, lunch, dinner, or meal. See full requirements in 21 CFR 101.13(l).

**Mixed dishes not measurable with a cup**

Examples include burritos, egg rolls, pizza, pizza rolls, quiches, all types of sandwiches. Defined in 21 CFR 101.12(b) in Table 2.

**MyPlate**

An illustration of the five food groups using a place setting. It is part of a larger communications initiative based on 2010 *Dietary Guidelines for Americans* to help consumers make better food choices and to remind Americans to eat healthfully.

**MyPyramid**

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

**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 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 (CDC) BMI charts.

**Ordinal**

Of or pertaining to order, rank, scale, or position in a series.

**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 the National Research Council (NRC) in 1968 and 1989.

**Points**

A term used throughout this report to indicate that a critical component nutrient met its defined eligibility and qualifying criteria for the purpose of inclusion in the FOP symbol system.

**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 Amounts 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. Levels are specified in 21 CFR 101.12.

**Reference Daily Intake (RDI)**
Nutrient reference values for vitamins and minerals established by FDA. In conjuction with DRVs are known as Daily Values on Nutrition Facts panel and are specified in 21 CFR 101.9(7)(iii) and (8)(iv).

**Salient/Salience**
Prominent or conspicuous; a striking point or feature.

**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.

**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 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.

**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.

# Appendix B

# History of Nutrition Labeling[1]

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.[2,3,4] 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.[5] This

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[1] This Appendix contains material excerpted from: IOM. 2010. *Front-of-Package Nutrition Rating Systems and Symbols: Phase I Report.* Washington, DC: The National Academies Press.

[2] Federal Food, Drug, and Cosmetic Act, Sec. 411(c)(3) (21 U.S.C. Part 350).

[3] 6 FR 5921.

[4] 31 FR 8521.

[5] 37 FR 6493.

action was based on Section 201(n) of the Federal Food, Drug, and Cosmetic Act of 1938 (FD&C Act)[6] 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) of protein, vitamins A and C, thiamin, riboflavin, niacin, calcium, and iron.[7] 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.[8]

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.[9] 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.[10]

### 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.[11] 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."[12] 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 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

[6] Federal Food, Drug, and Cosmetic Act, Sec. 201(n).
[7] 38 FR 6493.
[8] 56 FR 60302 at 60303.
[9] 43 FR 25296.
[10] 44 FR 75990.
[11] Federal Food, Drug, and Cosmetic Act, Sec. 403.
[12] 38 FR 6950 at 6961, paragraph (i) and (i)(1).

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.[13] 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.[14] During the late 1970s and throughout the 1980s 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,[15] to establish policies concerning the fortification of foods,[16] to include sodium content in nutrition labeling and provide for claims about sodium[17] and cholesterol content,[18] and to allow for food labeling experiments, such as experiments on supermarket shelf labeling.[19]

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.[20] *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.

## 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).[21] 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[22] and a notice of public hearings to

[13] 52 FR 28843.
[14] 55 FR 5176.
[15] 43 FR 43248 and 43261.
[16] 45 FR 6314.
[17] 47 FR 26580 and 49 FR 15510.
[18] 51 FR 42584.
[19] 69 FR 15236.
[20] 54 FR 32610.
[21] 55 FR29487.
[22] 54 FR 32610.

be held across the country to address the content and format of the nutrition label, ingredient labeling, and both nutrient content and health claims.[23] 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.[24] 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[25] and to establish regulations for determining serving sizes to be used in nutrition labeling.[26] 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 pp. 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 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.[27]

[23] 54 FR 38806.
[24] 55 FR 29487.
[25] 55 FR 29478.
[26] 55 FR 29517.
[27] 55 FR 29487.

### 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,[28] the most significant food labeling legislation in 50 years. The NLEA amended the Federal Food, Drug, and Cosmetic Act[29] to give FDA explicit authority to require nutrition 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[30] and a proposal on serving sizes.[31] General principles for nutrient content claims and the definition of terms for claims to be allowed were also proposed,[32] as were general principles for health claims,[33] 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.[34] 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

[28] Nutrition Labeling and Education Act of 1990. Public Law 101-535, 104 Stat 2353.
[29] Federal Food, Drug, and Cosmetic Act, sec. 403(q) and (r).
[30] 56 FR 60366.
[31] 56 FR 60394.
[32] 56 FR 60421 and 60478.
[33] 56 FR 60537.
[34] 57 FR 32058.

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.[35] 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.[36] 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 months of enactment of the act.[37] 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.[38] 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 for these nutrients became required, however, if they were added to the product or if claims related to their 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 oligosaccharides 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). Oppos-

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[35] 56 FR 13564.
[36] 56 FR 60302.
[37] *Nutrition Labeling and Education Act* of 1990. Public Law 101-535, 104 Stat 2353, Sec. 2(b).
[38] 58 FR 2079 (FDA) and 58 FR 632 (USDA).

ing 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 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.[39] 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.[40] 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.[41]

### *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.[42] 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 1 year any regulations that required the use of, or were based upon, RDAs other than those in effect at that time.[43] 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.[44] 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.[45] 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 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.[46]

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[39] 64 FR 62746.
[40] 68 FR 41434.
[41] 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).
[42] 55 FR 29476 and 56 FR 60366.
[43] *Dietary Supplement Act* of 1992, Public Law 102-571.
[44] 58 FR 2206.
[45] 60 FR 67164.
[46] 72 FR 62149.

*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."[47] 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.[48] 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 1,000 calories (LSRO, 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[49] and the public hearings[50] on nutrition labeling. Many speakers at the 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.[51] FDA also initiated a cooperative pilot program with industry to test alternative formats which led to several industry sponsored studies,[52] and it held a public meeting on the subject.[53] 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.[54] At the end of the comment period, when a format had been

[47] *Nutrition Labeling and Education Act* of 1990. Public Law 101-535, 104 Stat 2353, Sec. 2(b)(1)(A).
[48] 58 FR 2206.
[49] 54 FR 32610.
[50] 54 FR 38806.
[51] 56 FR 23072.
[52] 56 FR 29963.
[53] 57 FR 11277.
[54] 57 FR 32058.

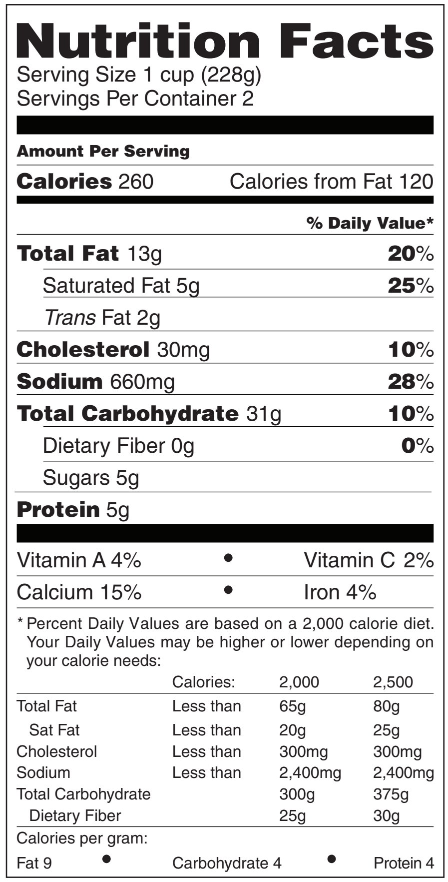


**FIGURE B-1** Nutrition Facts panel.

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").[55] 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 B-1). Noticeably, a few nutrients are lacking a value in the %DV column. For *trans* fat and

[55] 58 FR 2079.

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.

## 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[56] 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.[57] 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) for each category.[58] Procedures for converting the RACC values to serving sizes expressed in common household measures were specified in the regulations.[59]

### *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. Additionally, for products that have a RACC of 100 g or more and are individual units within a multi-serving package, if the unit contains more than 150 percent but less than 200 percent of the RACC, the manufacturer may declare the individual unit as one or two servings. 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.[60] 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.

[56] *Nutrition Labeling and Education Act* of 1990. Public Law 101-535, 104 Stat 2353, Sec. 2(a)(q)(1)(A)(i).
[57] 58 FR 2229.
[58] 58 FR 2229.
[59] 58 FR 2229.
[60] 70 FR 17010.

*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 and 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.[61] 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.[62] 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 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.[63] 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"[64] 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."[65] The current definitions for all these claims on FDA-regulated food items can be found here in 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.[66]

Briefly, in developing the criteria for claims, FDA took into account the dietary recommendations for each nutrient and generally considered the amounts of the nutrient present per RACC, per serving size, and per 100 g (or per 50 g if the serving size is small); 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.

[61] 70 FR 17008.
[62] *Nutrition Labeling and Education Act* of 1990. Public Law 101-535, 104 Stat 2353, Sec. 3(a)(r)(1).
[63] *Nutrition Labeling and Education Act* of 1990. Public Law 101-535, 104 Stat 2353, Sec. 3(b)(1)(A)(iii).
[64] 58 FR 2302 (FDA) and 58 FR 632 (USDA).
[65] 59 FR 24232 (FDA) and 59 FR 24220 (USDA).
[66] 58 FR 2302.

*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.[67] 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").[68]

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."[69] 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 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.[70] Again, in the case of foods inherently free of a nutrient, claims for "low" levels of a nutrient must refer to all foods of that type rather than to a particular brand to which the labeling is attached.

*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."[71] 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.[72] "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.[73]

*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

[67] 58 FR 2302.
[68] 58 FR 2302.
[69] 58 FR 2302.
[70] 58 FR 2302.
[71] 58 FR 2302.
[72] 56 FR 60421.
[73] 56 FR 60421.

or present in a certain amount (e.g., "high in wheat bran" implies that the food is high in fiber).[74] 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[75] and final rules[76] 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 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."[77] 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. 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.[78] 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.[79]

## 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,[80] amendments to serving size regulations,[81] and the establishment of new reference values.[82] 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.

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[74] 56 FR 60421.
[75] 58 FR 2944 (FDA) and 58 FR 688 (USDA).
[76] 59 FR 24232 (FDA) and 59 FR 24220 (USDA).
[77] 59 FR 24232.
[78] 62 FR 15390 (FDA) and 63 FR 7279 (USDA).
[79] 70 FR 56828 (FDA) and 71 FR 1683 (USDA).
[80] 70 FR 17008.
[81] 70 FR 17101.
[82] 72 FR 62149.

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# ANNEX
## MILESTONES IN NUTRITION LABELING

**TABLE B-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 | |
| 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 |

*continued*

**TABLE B-1** Continued

| Date | Activity | References | Nutrition Labeling | Claims |
|---|---|---|---|---|
| 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 |
| 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 Part 101.108 | 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 |
| 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 |

**TABLE B-1** Continued

| Date | Activity | References | Nutrition Labeling | Claims |
|---|---|---|---|---|
| 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 | |
| 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 Part 101.9 | 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, and 105.66 | | X |

*continued*

**TABLE B-1** Continued

| Date | Activity | References | Nutrition Labeling | Claims |
|---|---|---|---|---|
| 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 permit nutrient content claims to be made for butter | 56 FR 60512; 21 CFR Part 101.67 | | |
| 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 |
| 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 1-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, and 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, 101.56, 101.60, 101.61, 101.62, 101.65, 101.69, and 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 |
| 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 |

**TABLE B-1** Continued

| Date | Activity | References | Nutrition Labeling | Claims |
|---|---|---|---|---|
| 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 | |
| 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; 21 CFR Part 101 | X | |

*continued*

**TABLE B-1** Continued

| Date | Activity | References | Nutrition Labeling | Claims |
|---|---|---|---|---|
| 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; 21 CFR Part 101 | X | |
| 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 |
| 2010 | Final rule to require nutrition labeling of major cuts of meat and poultry and on all ground or chopped meat and poultry products on labels or at point-of-purchase (USDA) | 75 FR 82148-82167; CFR Parts 317 and 318 | 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.

# Appendix C

# FDA Regulatory Requirements for Nutrient Content Claims

## 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).<br>• Contains no ingredient that is fat or understood to contain fat, except as noted below.*<br>• "__% Fat Free" may be used if food meets the requirements for "low fat" and the % declared is in same type size as "fat free."<br>• 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).<br>• Contains no ingredient that is understood to contain saturated fat except as noted below.*<br>• 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).<br>• Contains no ingredient that contains cholesterol except as noted below.*<br>• 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.<br>• 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. |

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

| | |
|---|---|
| Sodium | • Less than 5 mg per RACC and per labeled serving (or, for meals and main dishes, less than 5 mg per labeled serving).<br>• Contains no ingredient that is sodium chloride or generally understood to contain sodium except as noted below.*<br>• "Salt Free" must meet criterion for "sodium free."<br>• "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." |
| 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).<br>• Contains no ingredient that is a sugar or generally understood to contain sugars except as noted below.*<br>• Disclose calorie profile (e.g., "low calorie" or "not a low calorie food").<br>• "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).<br>• 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).<br>• 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.<br>• Meals and main dishes: 1 g or less per 100 g and less than 10% of calories from saturated fat.<br>• 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).<br>• Meals and main dishes: 20 mg or less per 100 g.<br>• 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.<br>• 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).<br>• Meals and main dishes: 140 mg or less per 100 g.<br>• "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 of 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).<br>• Reference food may not be "low calorie."<br>• 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).<br>• 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).<br>• Reference food may not be "low saturated fat."<br>• 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).<br>• Reference food may not be "low cholesterol."<br>• Cholesterol claims only allowed when food contains 2 g or less saturated fat per RACC, or, for meals and main dishes, per 100 g.<br>• 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).<br>• 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 (e.g., 3 g or less fat per RACC).<br>• Low saturated fat (e.g., 1 g or less per RACC and 15% or less of calories from saturated fat).<br>• 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.<br>• 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.<br>• 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.<br>• 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.<br>• Saturated fat: Less than 2 g per RACC and per 100 g.<br>• Sodium: Same as for individual food.<br>• Cholesterol: Less than 95 mg per RACC and per 100 g.<br>• Beneficial nutrients: At least 10% of Daily Value for vitamin A, vitamin C, calcium, iron, protein, or fiber per RACC.<br>• Fortification in accordance with Fortification Policy in 21 CFR 104.20. |
| Meal or main dish | • Low fat (e.g., 3 g or less per 100 g and not more than 30% of calories from fat).<br>• Low saturated fat (e.g., 1 g or less per 100 g and less than 10% of calories from saturated fat).<br>• Sodium: 600 mg or less per labeled serving.<br>• Cholesterol: 90 mg or less per labeled serving.<br>• 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.<br>• 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."<br>• 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.<br>• Meals or main dishes must meet the definition for "low calorie" or "low fat" meal and be labeled to indicate which definition is met.<br>• "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."<br>• "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."<br>• 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.<br>• May be used on main dishes to indicate that the product contains a food that meets the definition and the food that is the subject of the claim is clearly identified (e.g., the serving of broccoli in this product is high in vitamin C). |
| Good source | • Contains 10-19% of the DV per RACC.<br>• May be used on main dishes to indicate that the product contains a food that meets the definition and the food that is the subject of the claim is clearly identified. |
| More | • Contains at least 10% more of the DV per RACC than appropriate reference food.<br>• 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).<br>• 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, multi-mineral 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.<br>• The name of the nutrients that are the subject of the claim are included as part of the claim.<br>• Each nutrient must have existing scientific evidence of antioxidant activity.<br>• The level of each nutrient must be sufficient to meet the definition for “high,” “good source,” or “more.”<br>• 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”).
[§] Must name the antioxidant as a criteria for an antioxidant claim.

DV = Daily Value
RACC = Reference Amounts Customarily Consumed
RDI = Reference Daily Intake
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. Available online: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/default.htm (accessed September 11, 2010).

# Appendix D

# Approach to Literature Review

## APPROACH TO GATHERING EVIDENCE

The committee developed an approach to review and evaluate a broad range of evidence generated through general and focused literature searches. This approach included: (1) establishing research objectives, (2) developing a literature search strategy, and (3) setting eligibility criteria to evaluate and rate the evidence.

### Research Objectives

The committee refined the Statement of Task's broad study objectives into more specific research goals to guide the literature search. The Statement of Task identified the following broad study objectives:

- consider the potential benefits of a single, standardized, front-label food guidance system administrated by the Food and Drug Administration (FDA),
- assess which icons are most effective with consumer audiences, and
- develop conclusions and recommendations about the system/icons that best promote health and how to maximize their use.

From these objectives, the committee developed research goals, specifically to examine literature relevant to:

- Food package regulation and the regulatory environment, including federal agency jurisdiction over animal-based food products;
- The context for consumers' use of nutrition information and product choices;
- Consumer understanding and use of front-of-package (FOP) labeling systems, point-of-purchase labeling, and shelf tags;
- Impact of the FOP labeling environment, including package design, package clutter, and product claims on consumer food choice and behavior;
- Design models of FOP symbol systems and influences of symbol systems on consumer food choice and behavior;
- Nutrients to limit and nutrient thresholds consistent with current dietary guidance; and
- FOP educational and promotional health campaigns.

## LITERATURE SEARCH STRATEGY

In order to review the most relevant scientific literature available, study staff initially searched a range of online bibliographic databases, including ABI/INFORM, Academic Search Premier, AGRICOLA, ASAPII, EMBASE, New York Academy of Medicine's Grey Literature Collection, NTIS government documents, PsychINFO, PubMed/MEDLINE, Science Direct, Web of Science, and WorldCat/First Search. To identify primary literature, staff first conducted general searches on topics relevant to assessment of consumer information processing, use, and understanding of FOP systems and symbols, as well as advertising, marketing, and merchandising of food products. Using the results of the primary search, staff developed key search terms and then conducted secondary searches. They chose search terms based on relevance to the study objectives and topic areas identified by the committee. Searches were limited to English language publications. After the initial search, staff designed a comprehensive search strategy in consultation with librarians at the George E. Brown Jr. Library of the National Academies. Search terms incorporated relevant MeSH (Medical Subject Headings) terms as well as terms from the EMBASE thesaurus. Table D-1 provides an example of how searches were conducted; only a subset of terms from the overall search are shown because inclusion of the entire search in the report was not practical.

**TABLE D-1** Example of Searches Using Key Words to Identify Relevant Literature

| Search No. | Search Terms | Number of Hits |
|---|---|---|
| 1 | Labeling / or food labeling / or percentage ingredient labeling | 2,190 |
| 2 | Consumer information / or health claims | 1,348 |
| 3 | "Product packaging" or "product labeling" | 69 |
| 4 | Packaging material / or packaging | 2,708 |
| 5 | "Package design" or "product claim" or ecolabel* or "ecolabel" or "fair trade" | 277 |
| 6 | "front label" or "front of package" or "net content?" or "ingredient statement" or "statement of identity" or "label component" | 23 |
| 7 | "nutrition fact? panel?" or "nutrition fact? information" or "NF Panel" or "NF information" or "nutrition label" | 1,405 |
| 8 | Or / 1-7 | 7,413 |
| 9 | Limit 8 to English and years 2000-2011 | 3,449 |
| 10 | 9 and consumer | 996 |
| 11 | Consumers | 1,590 |
| 12 | "Family and consumer science" / or exp consumer science | 15,205 |
| 13 | Exp consumer behavior / or consumer acceptance / or consumer attitudes / or consumer preferences / or consumer satisfaction | 7,440 |
| 14 | Consumer economics / or consumer purchasing | 537 |
| 15 | "Consumer perception?" or "consumer decision" or "consumer choice?" | 619 |
| 16 | Consumer surveys | 1,535 |
| 17 | Or / 10-16 | 16,380 |
| 18 | 9 and 17 | 1,016 |
| 19 | "clutter" or "information overload" or "eye tracking" or "package design" | 120 |
| 20 | 9 and 19 | 6 |
| 21 | 10 and 19 | 2 |
| 22 | 9 and reformulation | 3 |
| 23 | Food choices / or food intakes | 15,707 |
| 24 | 9 and 23 | 220 |
| 25 | Nutrient intake | 11,371 |
| 26 | Diet | 21,358 |
| 27 | 25 or 26 | 29,564 |
| 28 | 9 and 27 | 106 |
| 29 | "agribusiness and business economics" / or marketing | 6,227 |
| 30 | Advertising / or food marketing / or market analysis / or market development / or market channels / or marketing strategies / or exp social marketing | 4,799 |
| 31 | 29 or 30 | 10,659 |
| 32 | 9 and 31 | 190 |

**TABLE D-1** Continued

| Search No. | Search Terms | Number of Hits |
|---|---|---|
| 33 | Grocery stores / or food purchasing / or supermarkets | 2,182 |
| 34 | 9 and 33 | 114 |
| 35 | Exp literacy / or readability / or numeracy / or “numer* litera*” | 412 |
| 36 | 9 and 35 | 6 |
| 37 | Low income households / or poverty | 2,958 |
| 38 | 9 and 37 | 9 |
| 39 | Exp socioeconomic status | 3211 |
| 40 | 8 and 39 | 35 |
| 41 | Health beliefs / or food beliefs | 1,401 |
| 42 | 9 and 41 | 62 |
| 43 | Exp “human health and safety” | 19,752 |
| 44 | 9 and 43 | 211 |
| 45 | Health promotion / or public health | 6777 |
| 46 | 9 and 45 | 225 |
| 47 | Education / or health education / or nutrition education | 7,952 |
| 48 | 9 and 47 | 100 |
| 49 | “National labeling and education act” | 3 |
| 50 | “Laws and regulations” / or “bans and sanctions” / or consumer protection / or deregulation / or labeling / or law enforcement / or market regulations / or ownership / or patents / or product certification / or “standards and grades” / or trade regulations / or compliance / or “food law?” | 22,579 |
| 51 | 9 and 50 | 585 |
| 52 | “Purchase behavior” or “purchase intention” | 83 |
| 53 | 9 and 52 | 12 |

Staff limited the searches to English language and to publication dates of 2000 and later. The initial search retrieved more than 4,900 citations, including more than 1,000 business citations, which were then sorted into predefined topics identified by the committee. The topical search terms included

- Advertising/marketing
- Brand names
- Brand preferences
- Choice behavior
- Clutter
- Consumer behavior
- Diet/nutrient intake
- Education
- Food choice
- Food law and legislation
- Health promotion
- Health/food beliefs
- Health/safety
- Literacy/numeracy
- Low income/poverty
- Nutrition labeling information
- Purchase intention
- Reformulation
- Retail/purchasing
- Socioeconomics

**BOX D-1**
**Research Taxonomy**

**Intervention studies**

Includes randomized trials, field experiments, quasi-experimental studies

- Consumer behavior
- Consumer choice
- Diet and nutrient intake
- Education and food choice
- Food choice and behavior
- Health and food beliefs and attitudes
- Health literacy
- Nutrition Facts panel and nutrition information
- Purchase intent

**Observational studies**

Includes surveys, descriptive studies

- Brand preference
- Food law and legislation
    - o United States
    - o International
- Health and safety labeling
    - o Health claims
    - o Nutrient profiling
- Package clutter
    - o Eye-tracking
    - o Purchase intent
- Product reformulation
- Socioeconomic factors in food availability and choice

**Reviews**

Includes narrative reviews, evidence-based reviews, meta-analyses on any search topic

Relevant references obtained from the initial search were then screened and categorized according to the research taxonomy shown in Box D-1, and then annotated by staff. The committee was provided reference lists of key citations in tabulated format for evaluation and rating.

## EVIDENCE RATING

Studies were segregated by design into the first level of the literature review and evaluation process as follows:

- Experimental studies, including randomized controlled trials, field experiments, online or lab experiments
- Descriptive/observational studies, including cohort, cross-sectional, and ecological designs
- Reviews

The committee rated experimental studies, including field, laboratory, and online experiments as the strongest type of evidence, but also considered observational and descriptive research. To evaluate this type of evidence, the committee considered the quality of the research design as well as whether the evidence was supportive of any experimental research. Reviews were included but not rated. To evaluate the literature for further consideration and inclusion in the report, the committee assessed the evidence according to the following factors:

- Inclusion criteria, based on methodological approach, including adequate control group, blinding or no blinding, appropriate statistics
  - I—Inclusion criteria are reasonable and appropriate
  - II—Some criteria missing or not adequate
  - III—Inclusion criteria absent or not satisfactory
- Generalizability of the study/Population demographics
  - I—Sample is representative of the target population. Sufficiently large to cover both sexes, wide age range, and other important feature of the target populations (e.g., diet)
  - II—Sample is representative of a relevant subgroup of the target population, but not the entire population
  - III—Sample is representative of a narrow subgroup of subjects only, and is of limited applicability to other subgroups
- Food product category
  - I—3 or more products
  - II—2 or fewer products
  - III—No products in the study

Staff maintained and posted on the committee's portal a reference database of the evaluated evidence. The database was searchable by keywords, annotations, or other criteria. Bibliographies were updated throughout the study and as committee members requested journal articles and other resources.

# Appendix E

# Evaluation of Nutrient Content of Selected Example Foods

Chapter 7 described a model front-of-package (FOP) symbol system and an approach for evaluating the amount of saturated and *trans* fats, sodium, and added sugars in foods and beverages. This appendix provides relevant nutrition information for a convenience sample of 95 products[1] used by the committee to assess strengths and limitations of and regulatory issues associated with nutritional criteria for an FOP symbol system based on current regulations for nutrition and ingredient labeling and nutrient content and health claims.

Table E-1 provides nutrition and ingredient information obtained from the Nutrition Facts panel (NFP) on product labels, manufacturers' websites, an online database of NFPs, and ingredient statements,[2] and the *USDA Food and Nutrient Database for Dietary Studies, 3.0*. Each product is only one of many examples of products within a category and may not be representative of all products in its category. The items are organized by Food and Drug Administration (FDA) product categories for individual foods, then by lowest to highest reference amounts customarily consumed (RACC) within a category.[3]

Table E-2 displays the FOP points earned by the product examples based on the following two-step approach for evaluation:

> **Step 1:** Determine whether a product should not earn any FOP points for saturated and *trans* fats, sodium, or added sugars based on *eligibility criteria* because the product contains an amount of one or more of the stated nutrient components that is not consistent with the *Dietary Guidelines*.
> **Step 2:** Determine whether a product that meets the eligibility criteria earns FOP points for saturated and *trans* fats, sodium, and/or added sugars based on *qualifying criteria* that assess acceptable amounts.

The first step excludes a food or beverage from earning FOP points for saturated and *trans* fats, sodium, and added sugars because the amount of any one of these components is considered "too high." For example, a product "high" in sodium but containing no or low levels of saturated fat, *trans* fat, and added sugars would not be viewed as consistent with the *Dietary Guidelines*. Such a product should be excluded from earning FOP points for saturated and *trans* fats and added sugars even if the amounts of these nutrient components otherwise meet qualifying criteria. In the second step, a food or beverage that meets the eligibility criteria can then be evaluated

[1] It is Institute of Medicine (IOM) policy to not use brand names of products.
[2] Available online: http://www.peapod.com/ (accessed on various dates throughout 2010 and 2011).
[3] Food product categories as identified in 21 CFR 170.3.

for FOP points for saturated and *trans* fats, sodium, and added sugars. The following criteria were used for each nutrient component:

*Eligibility Criteria:* A product was eligible for FOP points if it:

- did not exceed the disclosure level for saturated fat (i.e., it contained ≤4 g per RACC and labeled serving [LS], or per 50 g if RACC is small),[4]
- did not exceed the disclosure level for sodium (i.e., it contained ≤480 mg per RACC and LS, or per 50 g if RACC is small),[5] and
- was not categorized as a Sugars, Sweets, or Beverage.[6]

*Qualifying Criteria:* A product qualified for a:

- saturated and *trans* fats FOP point if it was "low" in saturated fat (i.e., it contained ≤1 g per RACC and ≤15% of calories)[7] *and* contained < 0.5 g per LS or ≥0.5 g per LS product but no partially hydrogenated vegetable oil (PHVO),
- sodium FOP point if it met the sodium criteria for "healthy" (i.e., it contained ≤480 mg per RACC and LS, or per 50 g if RACC is small),[8] and
- added sugars FOP point if it met the criteria listed in Chapter 7, Table 7-8.

A check mark means that the product earned an FOP point for the indicated nutrient component. A check mark in parentheses means that the product would have earned a point for the indicated nutrient component if the product had not exceeded the disclosure level for saturated fat or sodium or had not been categorized as a Sugar, Sweet, or Beverage. The products are organized by FDA product categories for individual foods, then by highest to lowest FOP points within each category.

Table E-3 displays the number of FOP points for examples of fish and poultry products that were evaluated against various criteria for saturated fat content, including "low," "healthy/extra lean," and "lean." The products were *not* evaluated for eligibility against the disclosure level for saturated fat because it is more stringent than the criteria for "lean." The fish and poultry products are organized by highest to lowest FOP points earned when evaluated against "lean" criteria.

[4] 21 CFR 101.13(h)(1).
[5] 21 CFR 101.13(h)(1).
[6] *USDA Food and Nutrient Database for Dietary Studies, 3.0.* 2008. Beltsville, MD: U.S. Department of Agriculture, Agricultural Research Service, Food Surveys Research Group. Pp. 93-100.
[7] 21 CFR 101.62(c)(2).
[8] 21 CFR 101.65(d)(2)(ii).

**TABLE E-1** Reference Amounts Customarily Consumed and Nutrient Content of Select Individual Example Foods in Amount per Labeled Serving

| Product Category | RACC | Labeled Serving | | Energy kcal | SFA g | TFA g | Sodium mg | Total Sugars g | Added Sugar yes/no |
|---|---|---|---|---|---|---|---|---|---|
| *Bakery Products* | | | | | | | | | |
| Soup crackers | 15 g | 35 crackers | 15 g | 70 | 1 | 0 | 170 | 0 | no |
| Graham crackers | 30 g | 8 pieces | 31 g | 170 | 1 | 0 | 180 | 8 | yes |
| Animal crackers | 30 g | 13 pieces | 30 g | 120 | 0 | 0 | 75 | 8 | yes |
| Sugar cookies | 30 g | 4 cookies | 40 g | 130 | 1 | 1.5 | 115 | 12 | yes |
| Chocolate chip cookies | 30 g | 1 package | 42 g | 210 | 3 | 3 | 140 | 13 | yes |
| Snack crackers | 30 g | 9 crackers | 32 g | 150 | 2 | 3 | 230 | 2 | no |
| Oat and peanut butter bar | 40 g | 1 bar | 40 g | 150 | 2 | 0 | 105 | 9 | yes |
| Toaster pastry | 40 g | 1 pastry | 52 g | 210 | 2 | 0 | 240 | 17 | yes |
| Bread, 100% whole-wheat | 50 g | 1 slice | 43 g | 100 | 0 | 0 | 170 | 4 | yes |
| *Beverages (non-dairy and non-100% juice)* | | | | | | | | | |
| Cola soft drink, diet | 240 mL | 12 fl oz | 355 mL | 0 | 0 | 0 | 35 | 0 | no |
| Cola soft drink | 240 mL | 12 fl oz | 355 mL | 140 | 0 | 0 | 50 | 39 | yes |
| Lemon-lime soft drink | 240 mL | 12 fl oz | 355 mL | 140 | 0 | 0 | 65 | 38 | yes |
| Sweetened tea | 240 mL | 8 fl oz | 240 mL | 50 | 0 | 0 | 110 | 14 | yes |
| Lemon-lime sport drink | 240 mL | 8 fl oz | 240 mL | 90 | 0 | 0 | 20 | 24 | yes |
| *Breakfast Cereals* | | | | | | | | | yes |
| Toasted oats | 30 g | 1 cup | 28 g | 100 | 0 | 0 | 160 | 1 | yes |
| Crisped corn | 30 g | 1 cup | 31 g | 120 | 0 | 0 | 240 | 3 | yes |
| Crisped rice | 30 g | 1.25 cup | 33 g | 130 | 0 | 0 | 190 | 4 | yes |
| Sweetened toasted oats | 30 g | 1 cup | 28 g | 110 | 0 | 0 | 160 | 9 | yes |
| Sweetened cereal 1 | 30 g | 1 cup | 29 g | 110 | 0.5 | 0 | 135 | 12 | yes |
| Sweetened cereal 2 | 30 g | 0.75 cup | 28 g | 110 | 0 | 0 | 160 | 12 | yes |
| Oatmeal, old fashioned | 40 g | 0.5 cup | 40 g | 150 | 0 | 0 | 0 | 1 | no |
| Oatmeal, instant plain | 40 g | 1 package | 25 g | 100 | 0 | 0 | 75 | 0 | no |
| Oatmeal, instant with fruit, nuts | 55 g | 1 package | 37 g | 140 | 0 | 0 | 190 | 11 | yes |
| Shredded wheat | 55 g | 1 cup | 49 g | 170 | 0 | 0 | 0 | 0 | no |
| Bran flakes with raisins | 55 g | 1 cup | 59 g | 190 | 0 | 0 | 250 | 17 | yes |
| *Dairy Products* | | | | | | | | | |
| Milk, 1% fat | 240 mL | 1 cup | 240 mL | 110 | 1.5 | 0 | 130 | 12 | no |
| Chocolate milk, 1% fat | 240 mL | 1 cup | 240 mL | 158 | 1.5 | 0 | 152 | 25 | yes |
| Yogurt, plain nonfat | 225 g | 1 cup | 227 g | 130 | 0 | 0 | 190 | 18 | no |
| Yogurt, sweetened 1, fat free, LCS | 225 g | 1 container | 170 g | 100 | 0 | 0 | 85 | 14 | yes |
| Yogurt, sweetened 2, fat free | 225 g | 1 cup | 225 g | 180 | 0 | 0 | 150 | 33 | yes |
| Yogurt, sweetened 3, low fat | 225 g | 2.25 oz | 64 g | 70 | 0 | 0 | 30 | 10 | yes |
| Yogurt, sweetened 4, low fat | 225 g | 4 oz | 113 g | 100 | 1 | 0 | 70 | 16 | yes |
| Yogurt, sweetened 5, low fat | 225 g | 1 container | 113 g | 100 | 1.5 | 0 | 75 | 13 | yes |

*continued*

**TABLE E-1** Continued

| Product Category | RACC | Labeled Serving | | Energy kcal | SFA g | TFA g | Sodium mg | Total Sugars g | Added Sugar yes/no |
|---|---|---|---|---|---|---|---|---|---|
| Parmesan cheese | 5 g | 2 tsp | 5 g | 20 | 1 | 0 | 85 | 0 | no |
| Mozzarella, part skim | 30 g | 1 oz | 28 g | 72 | 3 | 0 | 175 | 0 | no |
| Cheddar, reduced fat | 30 g | 1 oz | 28 g | 80 | 3.5 | 0 | 206 | 0 | no |
| Cheddar cheese, 2% fat milk | 30 g | 1 oz | 30 g | 90 | 4 | 0 | 260 | 0 | no |
| Cheddar cheese | 30 g | 1 oz | 28 g | 110 | 5 | 0 | 180 | 0 | no |
| Ricotta, part skim | 55 g | 0.25 cup | 62 g | 100 | 4 | 0 | 60 | 3 | no |
| *Desserts* | | | | | | | | | |
| Ice cream, vanilla regular | 0.5 cup | 0.5 cup | 66 g | 140 | 4.5 | 0 | 45 | 12 | yes |
| Ice cream, vanilla light | 0.5 cup | 0.5 cup | 66 g | 100 | 2 | 0 | 45 | 11 | yes |
| Ice cream, vanilla fat free | 0.5 cup | 0.5 cup | 66 g | 90 | 1 | 0 | 55 | 14 | yes |
| Ice cream, vanilla no sugar added | 0.5 cup | 0.5 cup | 66 g | 90 | 2.5 | 0 | 45 | 4 | no |
| *Eggs* | | | | | | | | | |
| Egg, large | 50 g | 1 egg | 50 g | 70 | 1.5 | 0 | 65 | 0 | no |
| *Fats and Oils* | | | | | | | | | |
| Canola oil | 1 tbsp | 1 tbsp | 14 g | 120 | 1 | 0 | 0 | 0 | no |
| Corn oil | 1 tbsp | 1 tbsp | 14 g | 120 | 2 | 0 | 0 | 0 | no |
| Peanut oil | 1 tbsp | 1 tbsp | 14 g | 120 | 2.5 | 0 | 0 | 0 | no |
| Soybean oil | 1 tbsp | 1 tbsp | 14 g | 120 | 2 | 0 | 0 | 0 | no |
| Olive oil | 1 tbsp | 1 tbsp | 15 mL | 120 | 2 | 0 | 0 | 0 | no |
| Margarine, soft 1 | 1 tbsp | 1 tbsp | 14 g | 70 | 2 | 0 | 100 | 0 | no |
| Margarine, soft 2 | 1 tbsp | 1 tbsp | 14 g | 80 | 2.5 | 0 | 90 | 0 | no |
| Margarine, soft 3 | 1 tbsp | 1 tbsp | 14 g | 80 | 1.5 | 0 | 85 | 0 | no |
| Margarine, stick | 1 tbsp | 1 tbsp | 14 g | 100 | 2.5 | 2.5 | 105 | 0 | no |
| Butter, sweet unsalted | 1 tbsp | 1 tbsp | 14 g | 100 | 7 | 0 | 0 | 0 | no |
| Mayonnaise | 15 g | 1 tbsp | 13 g | 90 | 1.5 | 0 | 70 | 0 | no |
| Salad dressing, regular 1 | 30 g | 2 tbsp | 30 g | 140 | 2.5 | 0 | 260 | 1 | yes |
| Salad dressing, regular 2 | 30 g | 2 tbsp | 30 g | 130 | 2 | 0 | 370 | 2 | yes |
| Salad dressing, light 1 | 30 g | 2 tbsp | 31 g | 80 | 1 | 0 | 290 | 2 | yes |
| Salad dressing, light 2 | 30 g | 2 tbsp | 32 g | 80 | 1 | 0 | 290 | 2 | yes |
| *Fish, Shellfish, Game Meats (Poultry)* | | | | | | | | | |
| Tuna fish, canned solid in water | 55 g | ~0.25 cup | 55 g | 70 | 0.5 | 0 | 190 | 0 | no |
| Salmon, canned | 55 g | 0.25 cup | 60 g | 110 | 1.5 | 0 | 270 | 0 | no |
| Salmon steaks, raw | 110 g | 3.5 oz | 99 g | 142 | 1 | 0 | 45 | 0 | no |
| Salmon fillets, raw | 110 g | 3 oz | 85 g | 180 | 2.5 | 0 | 50 | 0 | no |
| Salmon fillets, frozen raw | 110 g | 4 oz | 114 g | 190 | 1.5 | 0 | 55 | 0 | no |
| Chicken breasts, boneless skinless | 114 g | 4 oz | 114 g | 120 | 0 | 0 | 80 | 0 | no |
| Chicken thighs, boneless skinless | 114 g | 4 oz | 114 g | 240 | 5 | 0 | 90 | 0 | no |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| *Fruits and 100% Fruit Juices* | | | | | | | | | |
| Orange juice | 240 mL | 8 fl oz | 240 mL | 110 | 0 | 0 | 0 | 22 | no |
| Apple juice | 240 mL | 8 fl oz | 240 mL | 110 | 0 | 0 | 20 | 26 | no |
| Grape juice | 240 mL | 1 bottle | 10 oz | 200 | 0 | 0 | 20 | 49 | no |
| *Legumes* | | | | | | | | | |
| Tofu, firm | 85 g | 3 oz | 85 g | 50 | 0 | 0 | 30 | 0 | no |
| Kidney beans | 130 g | 0.5 cup | 130 g | 110 | 0 | 0 | 360 | 2 | yes |
| *Nuts and Seeds* | | | | | | | | | |
| Walnuts, shelled | 30 g | 0.25 cup | 30 g | 200 | 2 | 0 | 0 | 1 | no |
| Peanut butter | 2 tbsp | 2 tbsp | 32 g | 190 | 3 | 0 | 130 | 3 | yes |
| *Sauces, Condiments* | | | | | | | | | |
| Mustard | 1 tsp | 1 tsp | 5 g | 5 | 0 | 0 | 120 | 1 | yes |
| Vinegar, white wine | 1 tbsp | 1 tbsp | 15 mL | 0 | 0 | 0 | 0 | 0 | no |
| *Snacks* | | | | | | | | | |
| Potato snack | 30 g | 16 pc | 30 g | 150 | 2.5 | 0 | 150 | 1 | yes |
| Pretzels | 30 g | ~9 pieces | 28 g | 110 | 0 | 0 | 560 | <1 | yes |
| Fruit snack, sweetened 1 | 30 g | 1 | 15 g | 50 | 0 | 0 | 55 | 7 | yes |
| Fruit snack, sweetened 2 | 30 g | 1 pouch | 25 g | 90 | 0 | 0 | 45 | 12 | yes |
| *Soups* | | | | | | | | | |
| Cream of mushroom | 245 g* | 0.5 cup | 120 mL | 100 | 1 | 0 | 870 | 1 | no |
| Chicken with noodles | 245 g* | 0.5 cup | 120 mL | 70 | 0 | 0 | 650 | 7 | no |
| Vegetable | 245 g* | 0.5 cup | 120 mL | 100 | 0.5 | 0 | 650 | 7 | no |
| Tomato | 245 g* | 0.5 cup | 120 mL | 90 | 0 | 0 | 480 | 12 | yes |
| Cream of mushroom, “healthy” | 245 g* | 0.5 cup | 120 mL | 60 | 0.5 | 0 | 410 | 1 | no |
| Chicken with noodles, “healthy” | 245 g* | 0.5 cup | 120 mL | 70 | 0.5 | 0 | 410 | 2 | no |
| Vegetable, “healthy” | 245 g* | 0.5 cup | 120 mL | 100 | 0 | 0 | 410 | 5 | no |
| Tomato, “healthy” | 245 g* | 0.5 cup | 120 mL | 90 | 0 | 0 | 410 | 10 | yes |
| *Sugars and Sweets* | | | | | | | | | |
| Apricot preserves | 1 tbsp | 1 tbsp | 20 g | 50 | 0 | 0 | 10 | 10 | yes |
| Chocolate-peanut candy | 40 g | 1 piece | 21 g | 110 | 2.5 | 0 | 75 | 11 | yes |
| *Vegetables including Juices* | | | | | | | | | |
| Tomatoes, canned | 130 g | 0.5 cup | 121 g | 25 | 0 | 0 | 220 | 3 | no |
| Stewed tomatoes, canned | 130 g | 0.5 cup | 126 g | 35 | 0 | 0 | 460 | 7 | yes |
| Mixed vegetable juice | 240 mL | 1 can | 5.5 oz | 30 | 0 | 0 | 330 | 6 | no |
| Mixed vegetable juice, low sodium | 240 mL | 1 can | 5.5 oz | 30 | 0 | 0 | 80 | 6 | yes |
| Tomato juice | 240 mL | 8 fl oz | 240 mL | 50 | 0 | 0 | 680 | 7 | no |
| Tomato juice, low sodium | 240 mL | 8 fl oz | 240 mL | 50 | 0 | 0 | 140 | 7 | no |

ABBREVIATIONS: LCS = low calorie sweetener, RACC = reference amounts customarily consumed, SFA = saturated fat, TFA = *trans* fat.

NOTES:

- Each product listed in the table is only one example of its type and may not be representative of others in the category.
- Products followed by numbers represent different brands.
- Nutrition and ingredient information was obtained from the Nutrition Facts panel on product labels, manufacturers’ websites, an online database of Nutrition Facts panels and ingredient statements (Available online: http://www.peapod.com/ [accessed on various dates throughout 2010 and 2011]) and the *USDA Food and Nutrient Database for Dietary Studies, 3.0* (Available online: http://www.nal.usda.gov/fnic/foodcomp/search/ [accessed on various dates throughout 2010 and 2011]).
- Chicken is regulated by the U.S. Department of Agriculture but is included as an example product.
- “Healthy” = meets regulatory requirements for a health claim.

*Reconstituted.

**TABLE E-2** Front-of-Package Points for Examples of Individual Foods Evaluated Against Potential Eligibility and Qualifying Criteria

| Product | SFA/ TFA | Sodium | Added sugars | FOP Points | Comments |
|---|---|---|---|---|---|
| *Bakery products* | | | | | |
| Bread, 100% whole-wheat | ✓ | ✓ | ✓ | 3 | |
| Animal crackers | ✓ | ✓ | | 2 | |
| Graham crackers | ✓ | ✓ | | 2 | |
| Snack crackers | | ✓ | ✓ | 2 | |
| Oat and peanut butter bar | | ✓ | | 1 | |
| Sugar cookies | | ✓ | | 1 | |
| Chocolate chip cookies | | ✓ | | 1 | |
| Toaster pastry | | ✓ | | 1 | |
| Soup crackers | (✓) | (✓) | (✓) | 0 | Exceeds sodium disclosure |
| *Beverages (non-dairy and non-100% juice)* | | | | | |
| Cola soft drink. diet | ✓ | ✓ | ✓ | 3 | |
| Cola soft drink | (✓) | (✓) | | 0 | Sugars, sweets, beverages |
| Lemon-lime soft drink | (✓) | (✓) | | 0 | Sugars, sweets, beverages |
| Sweetened tea | (✓) | (✓) | | 0 | Sugars, sweets, beverages |
| Lemon-lime sport drink | (✓) | (✓) | | 0 | Sugars, sweets, beverages |
| *Breakfast cereals* | | | | | |
| Shredded wheat | ✓ | ✓ | ✓ | 3 | |
| Oatmeal, instant plain | ✓ | ✓ | ✓ | 3 | |
| Toasted oats | ✓ | ✓ | ✓ | 3 | |
| Oatmeal, old fashioned | ✓ | ✓ | ✓ | 3 | |
| Crisped corn | ✓ | ✓ | ✓ | 3 | |
| Crisped rice | ✓ | ✓ | ✓ | 3 | |
| Sweetened toasted oats | ✓ | ✓ | | 2 | |
| Sweetened cereal 1 | ✓ | ✓ | | 2 | |
| Sweetened cereal 2 | ✓ | ✓ | | 2 | |
| Oatmeal, instant with fruit, nuts | ✓ | ✓ | | 2 | |
| Bran flakes with raisins | ✓ | ✓ | | 2 | |
| *Dairy products* | | | | | |
| Milk, 1% fat | | ✓ | ✓ | 2 | |
| Chocolate milk, 1% fat | | ✓ | | 1 | |
| Ricotta, part skim | | ✓ | ✓ | 2 | |
| Parmesan cheese | | (✓) | (✓) | 0 | Exceeds SFA, sodium disclosure |
| Cheddar cheese | | (✓) | (✓) | 0 | Exceeds SFA disclosure |
| Cheddar cheese, 2% fat milk | | (✓) | (✓) | 0 | Exceeds SFA disclosure |
| Cheddar cheese, reduced fat | | (✓) | (✓) | 0 | Exceeds SFA disclosure |
| Mozzarella, part skim | | (✓) | (✓) | 0 | Exceeds SFA disclosure |
| Yogurt, plain nonfat | ✓ | ✓ | ✓ | 3 | |
| Yogurt, sweetened 1, fat free, LCS | ✓ | ✓ | ✓ | 3 | |
| Yogurt, sweetened 2, fat free | ✓ | ✓ | | 2 | |
| Yogurt, sweetened 3, low fat | ✓ | ✓ | | 2 | |

| | | | | | |
|---|---|---|---|---|---|
| Yogurt, sweetened 4, low fat | ✓ | ✓ | | 2 | |
| Yogurt, sweetened 5, low fat | | ✓ | | 1 | |
| *Desserts* | | | | | |
| Ice cream, vanilla regular | | (✓) | | 0 | Exceeds SFA disclosure |
| Ice cream, vanilla light | | ✓ | | 1 | |
| Ice cream, vanilla fat free | ✓ | ✓ | | 2 | |
| Ice cream, vanilla no sugar added | | ✓ | ✓ | 2 | |
| *Eggs* | | | | | |
| Egg, large | | ✓ | ✓ | 2 | |
| *Fats and oils* | | | | | |
| Canola oil | ✓ | ✓ | ✓ | 3 | |
| Corn oil | ✓ | ✓ | ✓ | 3 | |
| Olive oil | | (✓) | (✓) | 0 | Exceeds SFA disclosure |
| Peanut oil | | (✓) | (✓) | 0 | Exceeds SFA disclosure |
| Soybean oil | | (✓) | (✓) | 0 | Exceeds SFA disclosure |
| Margarine, soft 1 | | (✓) | (✓) | 0 | Exceeds SFA disclosure |
| Margarine, soft 2 | | (✓) | (✓) | 0 | Exceeds SFA disclosure |
| Margarine, soft 3 | | (✓) | (✓) | 0 | Exceeds SFA disclosure |
| Margarine, stick | | (✓) | (✓) | 0 | Exceeds SFA disclosure |
| Butter, sweet unsalted | | (✓) | (✓) | 0 | Exceeds SFA disclosure |
| Mayonnaise | | (✓) | (✓) | 0 | Exceeds SFA disclosure |
| Salad dressing, regular 1 | | (✓) | (✓) | 0 | Exceeds SFA disclosure |
| Salad dressing, regular 2 | | (✓) | (✓) | 0 | Exceeds sodium disclosure |
| Salad dressing, light 1 | ✓ | ✓ | ✓ | 3 | |
| Salad dressing, light 2 | ✓ | ✓ | ✓ | 3 | |
| *Fish, Shellfish, Game meats (Poultry)* | | | | | |
| Chicken breasts, boneless skinless | ✓ | ✓ | ✓ | 3 | |
| Tuna fish, solid white in water | ✓ | ✓ | ✓ | 3 | |
| Salmon fillets, frozen raw | | ✓ | ✓ | 2 | |
| Salmon fillets, raw | | ✓ | ✓ | 2 | |
| Salmon steaks, raw | | ✓ | ✓ | 2 | |
| Salmon, canned | | ✓ | ✓ | 2 | |
| Chicken thighs, boneless skinless | | (✓) | (✓) | 0 | Exceeds SFA disclosure |
| *Fruits and Fruit Juices (100%)* | | | | | |
| Orange juice | ✓ | ✓ | ✓ | 3 | |
| Apple juice | ✓ | ✓ | ✓ | 3 | |
| Grape juice | ✓ | ✓ | ✓ | 3 | |
| *Legumes* | | | | | |
| Kidney beans, canned | ✓ | ✓ | ✓ | 3 | |
| Tofu, firm | ✓ | ✓ | ✓ | 3 | |
| *Nuts and Seeds* | | | | | |
| Walnuts, shelled | | ✓ | ✓ | 2 | |
| Peanut butter | | (✓) | (✓) | 0 | Exceeds SFA disclosure |

*continued*

**TABLE E-2** Continued

| Product | SFA/ TFA | Sodium | Added sugars | FOP Points | Comments |
|---|---|---|---|---|---|
| *Sauces, Condiments* | | | | | |
| Mustard | (✓) | (✓) | (✓) | 0 | Exceeds sodium disclosure |
| Vinegar, white wine | ✓ | ✓ | ✓ | 3 | |
| *Snacks* | | | | | |
| Potato snack | | | | 0 | Exceeds SFA disclosure |
| Pretzels | (✓) | (✓) | (✓) | 0 | Exceeds sodium disclosure |
| Fruit snack, sweetened 1 | | | | 0 | Sugars, sweets, beverages |
| Fruit snack, sweetened 2 | | | | 0 | Sugars, sweets, beverages |
| *Soups* | | | | | |
| Cream of mushroom | (✓) | (✓) | (✓) | 0 | Exceeds sodium disclosure |
| Chicken with noodles | (✓) | (✓) | (✓) | 0 | Exceeds sodium disclosure |
| Vegetable | (✓) | (✓) | (✓) | 0 | Exceeds sodium disclosure |
| Tomato | ✓ | ✓ | | 2 | |
| Cream of mushroom, "healthy" | ✓ | ✓ | ✓ | 3 | |
| Chicken with noodles, "healthy" | ✓ | ✓ | ✓ | 3 | |
| Vegetable, "healthy" | ✓ | ✓ | ✓ | 3 | |
| Tomato, "healthy" | ✓ | ✓ | ✓ | 3 | |
| *Sugars and sweets* | | | | | |
| Chocolate-peanut candy | | (✓) | | 0 | Sugars, sweets, beverages |
| Apricot preserves | (✓) | (✓) | | 0 | Sugars, sweets, beverages |
| *Vegetables including juices* | | | | | |
| Mixed vegetable juice | ✓ | ✓ | ✓ | 3 | |
| Mixed vegetable juice, low sodium | ✓ | ✓ | ✓ | 3 | |
| Tomato juice | (✓) | (✓) | (✓) | 0 | Exceeds sodium disclosure |
| Tomato juice, low sodium | ✓ | ✓ | ✓ | 3 | |
| Tomatoes, canned | ✓ | ✓ | ✓ | 3 | |
| Stewed tomatoes, canned | ✓ | ✓ | ✓ | 3 | |

ABBREVIATIONS: LCS = low calorie sweetener, LS = labeled serving, SFA = saturated fat, TFA = *trans* fat.

NOTES:

- Each product listed in the table is only one example of its type and may not be representative of others in the category.
- Products followed by numbers represent different brands.
- Nutrient and ingredient information for the products listed in the table are provided in Table E-3.
- Chicken is regulated by USDA but is included as an example product.
- ✓ means that the product earned an FOP point for the indicated nutrient component.
- (✓) means that the product would have a earned an FOP point for the indicated nutrient component if the product had not exceeded the disclosure level for SFA or sodium or had not been categorized as a Sugar, Sweets, or Beverage.

CRITERIA:

A product was eligible for FOP points if it:

- did not exceed the disclosure level for saturated fat (i.e., it contained ≤4 g per RACC and labeled serving [LS], or per 50 g if RACC is small) (21 CFR 101.13(h)(1),
- did not exceed the disclosure level for sodium (i.e., it contained ≤480 mg per RACC and LS, or per 50 g if RACC is small), (21 CFR 101.13(h)(1)), and
- was not categorized as a Sugars, Sweets, or Beverage (*USDA Food and Nutrient Database for Dietary Studies, 3.0.* 2008. Beltsville, MD: U.S. Department of Agriculture, Agricultural Research Service, Food Surveys Research Group. Pp. 93-100).

A product qualified for a:

- saturated and *trans* fats FOP point if it was “low” in saturated fat (i.e., it contained ≤1 g per RACC and ≤15% of calories) (21 CFR 101.62(c)(2)) *and* contained <0.5 g per LS or ≥0.5 g per LS product but no partially hydrogenated vegetable oil,
- sodium FOP point if it met the sodium criteria for “healthy” (i.e., it contained ≤480 mg per RACC and LS, or per 50 g if RACC is small) (21 CFR 101.65(d)(2)(ii)), and
- added sugars point if it met the criteria listed in Chapter 7, Table 7-8.

**TABLE E-3** Front-of-Package Points for Example Fish and Poultry Products Evaluated Against Various Criteria for Saturated Fat Content

| Product | Low | Healthy/Extra Lean | Lean |
|---|---|---|---|
| Salmon fillets, raw | 2 | 2 | 3 |
| Salmon, canned | 2 | 2 | 3 |
| Salmon fillets, frozen raw | 2 | 3 | 3 |
| Salmon steaks, raw | 2 | 3 | 3 |
| Chicken breasts, boneless skinless | 3 | 3 | 3 |
| Tuna fish, canned solid in water | 3 | 3 | 3 |
| Chicken thighs, boneless skinless | 2 | 2 | 2 |

NOTES:
- Nutrient and ingredient information for the products listed in the table are provided in Table E-2.
- Chicken is regulated by USDA but is included as an example product.
- Products were *not* evaluated for eligibility against the disclosure level for saturated fat (>4 g per RACC and LS).
- "Low" saturated fat: ≤1 g per RACC and ≤15% of calories.
- Healthy/extra lean: ≤2 g per RACC and per 100 g.
- Lean: ≤4.5 g per RACC and per 100 g.
- Products meet sodium "healthy" criteria (≤480 mg per RACC and LS) and contain no sugars.

# Appendix F

# Workshop Agenda

**Consumer Behavior Research and Front-of-Package Nutrition Rating Systems and Symbols: What Do Consumers Know, Understand, and Use?**

The Washington Club, 15 DuPont Circle, NW, Washington, DC 20036

| | |
|---|---|
| 8:00 am | Welcome<br>*Ellen Wartella*, Committee Chair and Workshop Moderator |

**RECENT CONSUMER RESEARCH ON FRONT-OF-PACKAGE SYSTEMS AND SYMBOLS**
**8:05-10:30 AM**

| | |
|---|---|
| 8:05 | Food and Drug Administration's Consumer Research<br>*Chung-Tung Jordan Lin and Alan Levy, Food and Drug Administration* |
| 8:35 | Recent Work at the Rudd Center Food Policy and Obesity, Yale University<br>*Kelly Brownell, Rudd Center* |
| 9:05 | Grocery Manufacturers Association Initiative and the International Food Information Council Foundation Consumer Research<br>*Regina Hildwine, Grocery Manufacturers Association*<br>*Marianne Smith-Edge, International Food Information Council* |
| 9:35 | Discussion with Committee |
| 10:30 | Break |

**ADDITIONAL CONSUMER RESEARCH ISSUES**
**10:45 AM-12:00 PM**

| | |
|---|---|
| 10:45 | Health Literacy and Population Subgroups<br>*Christina Zarcadoolas, Mt. Sinai School of Medicine* |
| 11:00 | Consumer Use of Back of Panel<br>*John Kozup, Villanova University* |

11:15 Relationship of Labeling to Product Reformulation
*Christine Johnson, New York City Department of Health*

11:30 Discussion with Committee
*Christine Johnson, New York City Department of Health*

**OPEN FORUM—PUBLIC COMMENT**
**12:00-1:00 PM**

12:00 pm Comments from the Floor

1:00 pm Adjourn

# Appendix G

# Committee Member and Consultant Biographical Sketches

## COMMITTEE MEMBERS

**Ellen A. Wartella, Ph.D.** (*Chair*), is Sheikh Hamad bin Khalifa Al-Thani Professor of Communication, professor of psychology, professor of human development and social policy, and director of the Center on Media and Human Development in the School of Communication at Northwestern University. She is a 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 (IOM) 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 and 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.** (*Vice Chair*), 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 and the American Heart Association's Arteriosclerosis, Thrombosis and Vascular Biology Council and Nutrition, Physical Activity and Metabolism Council. 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 IOM Dietary Reference Intake macronutrient panel, and the IOM Food Forum. She currently serves as co-chair of the National Institutes of Health's (NIH's) Adult Treatment Panel IV (ATP IV) for cholesterol guidelines. Dr. Lichtenstein completed her undergraduate work at Cornell University, holds a master's degree from the Pennsylvania State University, and master's 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 10 IOM committees, 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, and 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.

**James Crimmins, Ph.D.,** is adjunct professor at Northwestern University and a marketing consultant. He worked in advertising for 27 years and served for the past several years as Worldwide Brand Planning Director and Chief Strategic Officer of DDB Chicago. In that capacity, he has led strategic planning for a wide array of advertisers including Budweiser, Betty Crocker, Dell Computers, Home Depot, OfficeMax, and JCPenny. He also developed strategic tools for DDB that were taught to DDB personnel around the world. Dr. Crimmins led the DDB team that won 44 EFFIEs—the American Marketing Association's award for proven advertising effectiveness. He received a B.A. in sociology from the University of Illinois and a master's in statistics and a Ph.D. in sociology from the University of Chicago.

**Brian Elbel, M.P.H., Ph.D.,** is assistant professor of medicine and health policy at the New York University (NYU) School of Medicine and the NYU Wagner Graduate School of Public Service. Dr. Elbel studies consumer and patient decision-making as it relates to health and healthcare, largely from the perspective of behavioral economics. He has a particular interest in vulnerable groups and the role and influence of public policy on health. He is engaged in research examining consumer choice of health plans and hospitals, including response to quality information. Additionally, he is examining choices that influence health more directly, including how individuals choose which foods to consume. He has studied, and is continuing to study, the impact of public policies mandating calorie labeling in restaurants. His research has been funded by the NIH, the Agency for Healthcare Research and Quality, the Robert Wood Johnson Foundation, the National Science Foundation, and the Russell Sage Foundation.

Dr. Elbel received a B.A. from The University of Texas at Austin and M.P.H. and Ph.D. degrees in health policy/health economics from Yale University.

**Tracy A. Fox, M.P.H., R.D.,** is president of Food, Nutrition and Policy Consultants, LLC, in Washington, DC, specializing in food and nutrition policy and programs at the federal, state, and local levels. She works with government, schools, foundations, and nonprofit and for-profit organizations in policy and program enhancements and advocacy to promote positive environmental change. Ms. Fox worked with the Centers for Disease Control and Prevention (CDC) to collect, analyze, document, and publicize success stories of school- and district-based nutrition and physical activity initiatives. She has worked with CDC to evaluate promising childhood obesity prevention projects across the country in Head Start and day care programs, school districts, community- and state-based food policy councils, and after-school programs. Ms. Fox was a member of the IOM Committee on Nutrition Standards for Foods in School and the IOM Committee on Local Government Actions to Prevent Childhood Obesity. She is president of the Society for Nutrition Education and is active on a number of boards and coalitions. 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. She is a retired Commander from the United States Navy Reserve Medical Service Corps. 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.

**Elizabeth Howlett (formerly Creyer), Ph.D.,** is professor of marketing and logistics in the Sam Walton College of Business at the University of Arkansas, Fayetteville. She has research expertise in the area of consumer health and welfare issues with a particular emphasis on nutrition-related issues. A large body of her research has examined how the provision of nutrition information affects consumers' evaluative and choice processes. In particular, she has explored the influence of package claims (nutrient content, structure function) and the effects of the Nutrition Facts panel information. Currently, she is developing a stream of research that focuses on the effects of sodium information provision and front-of-package sodium labeling. Most recently her research has focused on the impact of calorie labeling on restaurant menus and menu boards. Her research was instrumental in helping the New York City Department of Health and Mental Hygiene, the city of Philadelphia, King County Washington (Seattle), and the state of California formulate and pass restaurant labeling mandates and legislation. These initiatives, in turn, generated national attention, which culminated in the inclusion of a restaurant labeling mandate in the National Health Care Reform bill.

**Matthew W. Kreuter, Ph.D., M.P.H.,** is professor and founding director of the Health Communication Research Laboratory at Washington University in St. Louis, one of five National Cancer Institute–designated Centers of Excellence in Cancer Communication Research. 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 is a member of the IOM'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 and chair of the Department 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 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, Coca-Cola Company, Children's Food and Beverage Advertising Initiative, and Children's Advertising Review Unit. She received her Ph.D. in Nutrition from the University of California, Berkeley.

**Mary T. Story, Ph.D., R.D.,** is professor in the Division of Epidemiology and Community Health and senior associate dean for academic and student affairs 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 nearly 400 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 was a member of the IOM Committee on Food Marketing to Children and Youth, the IOM Committee on Nutrition Standards for Foods in Schools, and the IOM Committee on Local Government Actions to Prevent Childhood Obesity. She is a current member of the IOM Standing Committee on Childhood Obesity Prevention. She was elected to the IOM in 2010.

## CONSULTANTS

**Kelly D. Brownell, Ph.D.,** is a professor of psychology, professor of epidemiology and public health, and the director of the Rudd Center for Food Policy and Obesity at Yale University. At Yale he served as chair of the Department of Psychology and earlier he was a professor in the Department of Psychiatry at the University of Pennsylvania School of Medicine. His work is focused on environmental factors that contribute to obesity; the specific effects of the "toxic environment" that encourage overeating and physical inactivity; bias, prejudice, discrimination, and obesity; the impact of government policies on food prices and food consumption patterns; interventions in schools; and changing public policy as a means of improving eating and activity in the population. Dr. Brownell is a member of the IOM.

**Christopher Casey, B.F.A., M.P.H.,** is director of communication for the Health Communication Research Laboratory (HCRL) in the George Warren Brown School of Social Work at Washington University, Saint Louis. He directs visual communications at HCRL, managing and producing print, web, and interactive graphics for intervention materials. He has worked for more than 10 years developing and conducting research in communication-based strategies to improve population health. Mr. Casey has also worked on NIH and CDC-funded programs seeking to increase the reach and effectiveness of health information, particularly in the area of populations most affected by health disparities. He received his B.F.A. from the University of Missouri and his M.P.H. from St. Louis University.

**Lila Rutten, Ph.D., M.P.H.,** is a behavioral scientist with SAIC, Inc., National Cancer Institute (NCI) Frederick, in support of NCI's Health Communication and Informatics Research Branch. Her current responsibilities include managing/coordinating the Health Information National Trends Survey (HINTS), assisting in the dissemination efforts of the Centers for Excellence in Cancer Communication Research (CECCR), and supporting branch and program activities related to the role of health communication in shaping cancer-relevant behavior. Dr. Rutten has served as an active member of NCI's team of scientists since 2001, when she joined NCI as a cancer prevention fellow. In addition to her work with NCI, Dr. Rutten currently serves as a methodological consultant to the Center for Human Nutrition and has served as an adjunct faculty member in the Department of Psychology at Augsburg College and in the Department of Behavioral Science at the College of Mount Saint Joseph. Dr. Rutten received her Ph.D. in psychology from Miami University and her M.P.H. from Harvard University.

**Marlene B. Schwartz, Ph.D.,** is deputy director for the Rudd Center for Food Policy and Obesity at Yale University. Prior to joining the Rudd Center, she served as co-director of the Yale Center for Eating and Weight Disorders from 1996 to 2006. Dr. Schwartz's research and community service address how home environments, school landscapes, neighborhoods, and the media shape the eating attitudes and behaviors of children. She has collaborated with the Connecticut State Department of Education to evaluate nutrition and physical activity policies in schools and preschools throughout the state. She co-chaired the Connecticut Obesity Task Force in 2010 and has provided expert testimony on obesity-related state policies. She also serves on the Board of Directors of the Connecticut Food Bank. Dr. Schwartz has received research grants from the Robert Wood Johnson Foundation, the U.S. Department of Agriculture and the NIH to study school wellness policies, the preschool nutrition environment, the effect of food marketing on children, the relationship between food insecurity and nutrition, and how federal food programs can improve the accessibility and affordability of healthy foods in low-income neighborhoods. She received her Ph.D. in psychology from Yale University in 1996.

**Amy Scott, B.F.A.,** is a graphic designer for UPBrand Collaborative in St. Louis. She works on brand strategy and design for companies around the country, producing print collateral and web graphics showcasing each organization's unique story. She previously worked with the Health Communication Research Laboratory (HCRL) at Washington University in St. Louis on grant-funded research projects developing informational graphics and print collateral for public health materials. She received her B.F.A. from the Sam Fox School of Design & Visual Arts at Washington University.

**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.