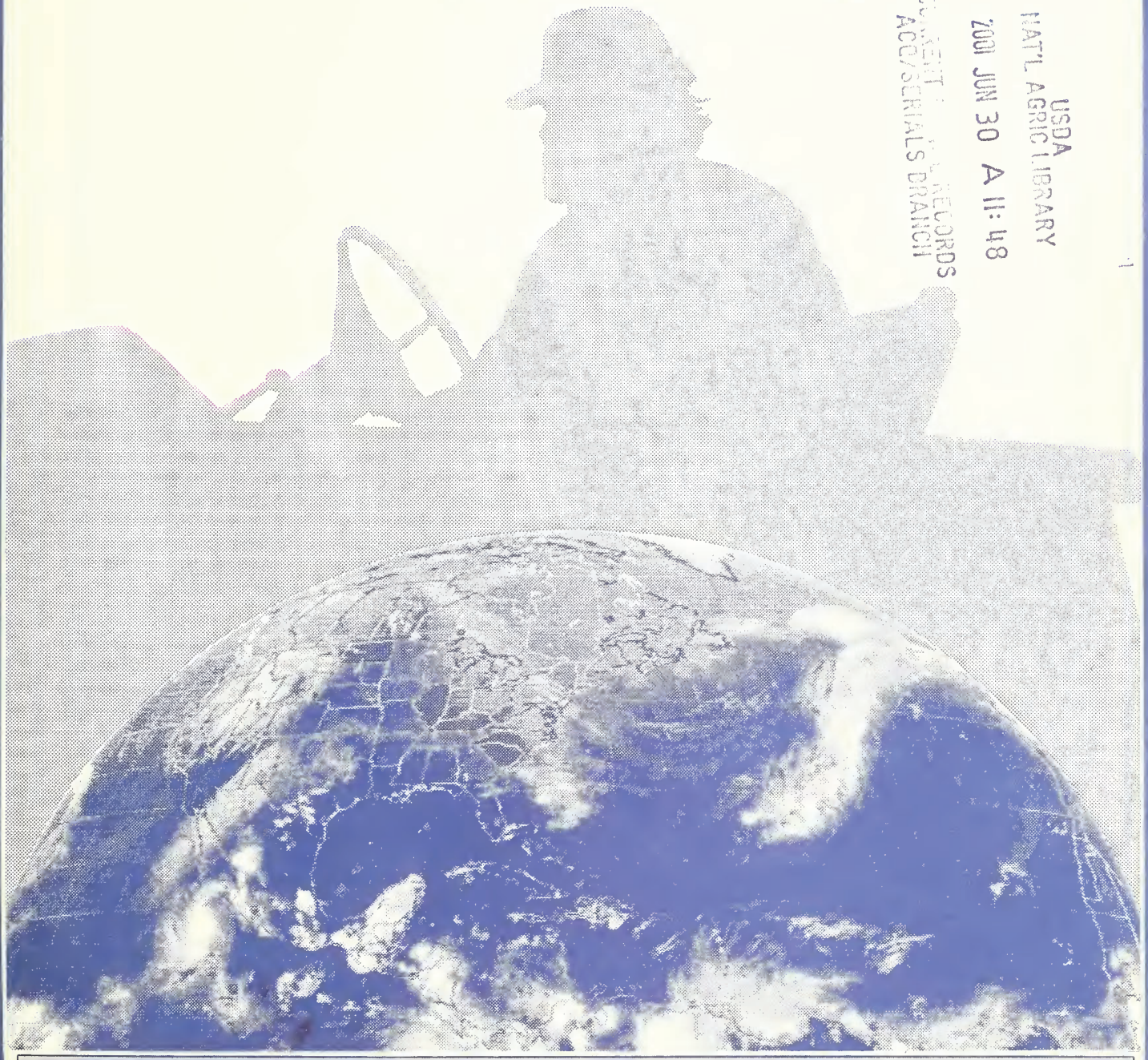
Agriculture in a World of Change



Proceedings of Outlook '91

67th Annual Outlook Conference

U.S. Department of Agriculture Washington, D.C.
November 27-29, 1990

ANNUAL AGRICULTURAL OUTLOOK CONFERENCE
United States Department of Agriculture
Washington, D.C. 20250-3900

Outlook '91, Session C14 Wednesday, November 28, 1990

Nutrition Labeling: Current Status and Comparison of Various Proposals

Donna V. Porter [Specialist in Life Sciences, Congressional Research Service, Library of Congress] and
Robert Earl [Staff Officer, Food and Nutrition Board, Institute of Medicine].

[The authors were the former co-project directors of the IOM report Nutrition Labeling: Issues and Directions for the 1990s. These remarks represent only the authors' opinions on the issues reviewed and do not represent the opinion of the Institute of Medicine, National Academy of Sciences, the Library of Congress, the Congressional Research Service, or the U.S. Congress].

What a difference a year can make! A year ago, nutrition labeling policy in the U.S. was operating under a 1938 law, 1973 regulations, and 12 years of Federal legislation which was not enacted. About a year ago, Congress had introduced, but taken no action on nutrition labeling legislation; there were rumors of new proposed FDA-regulations and the Institute of Medicine Expert Committee was about to have its second meeting. Now we have a new law, the Nutrition Labeling and Education Act of 1990 (P.L.101-535); the first phase of proposed regulations have been published by FDA; USDA is considering revised nutrition labeling; and the IOM report has been released.

In the early 1970s the Federal Government embarked on its current policy of nutrition labeling, precipitated in part by the recommendations of the 1969 White House Conference on Food, Nutrition and Health. The policy at that time resulted in the voluntary program we are all familiar with, which included a specific list of nutrients and order of appearance on food labels. That policy which was progressive and seemingly far-reaching for the 1970's is, by comparison, outmoded and outdated by today's standards.

Environment for Change

A number of developments in the last two decades have resulted in the current situation that suggests that reform in food labeling and particularly nutrition information on food labels was needed. These changes include the consensus in the field of nutrition that dietary patterns have a definite impact on long-term health of an individual and that changes in those patterns can have an

influence on health. This consensus was exemplified by the recommendations of the Surgeon General's Report on Nutrition and Health, and the NRC report Diet and Health: Implications for Reducing Risk of Chronic Disease. And further supporting this consensus is the 1990 edition of Nutrition and Your Health: Dietary Guidelines for Americans, released earlier this month, by USDA and DHHS. Coupled with this consensus on the relationship between diet and disease, and as a result of it, there has been increasing attention and desire by consumers for more nutrient information on the foods so that they can better select a healthful diet. One way to assist consumers in selecting more nutritious foods by providing them with more information on the nutrient content of the foods that they are eating, and one means of achieving this is to improve the information provided at the point of food selection.

By 1989, several events put changes in nutrition labeling in motion. In the spring of 1989 Congress introduced legislation that focused on reform of FDA's labeling program, which was subsequently enacted into law in November 1990. In August of 1989, FDA and USDA announced in the Federal Register an initiative to reform food labeling in a proposed notice of rulemaking which asked for public comment and announced hearings which were held in four major cities in the fall of 1989. By July 1990, FDA had proposed the first in a series of new food labeling regulations. In September 1990, the Institute of Medicine (IOM) of the National Academy of Sciences released a one-year study on the scientific and practical aspects of nutrition labeling reform, prepared at the request of the Departments of Health and Human Services, and Agriculture. The IOM Committee on the Nutrition Components of Food Labeling had been established to:

o assess the implications of current knowledge of nutrition and health for food labeling;
o recommend the content and appropriate format for food labels, taking into account the scientific data base as well as the means to communicate effectively with the public;
o examine current laws and regulations governing ingredient and nutrition labeling; and
o propose options for modifying current laws and regulations.

The IOM Committee identified a number of deficiencies in the current nutrition labeling system, including that nutrition labeling is not currently mandatory on all packaged food, nor required in conjunction with the sale of fresh food; nutrition panel information is not uniform across all food products; current labels carry information about some nutrients that should not be or do not need to be listed, while other nutrients are omitted; ingredient labeling is incomplete and misleading; current format is too confusing and complex; principal display panel disclosures of nutrient content are misleading and not based on established standardized definitions.

The IOM study, the July 1990 FDA proposed regulations, and the

Nutrition Labeling and Education Act of 1990 (P.L. 101-535, referred to hereinafter as the 1990 Act), address a number of the same issues on food labeling reform, such as foods covered by nutrition labeling, nutrient content information, label presentation options, and legislation and regulation. However, certain specifics of the proposals for change differ among these groups, with the IOM report (Nutrition Labeling: Issues and Directions for the 1990s) going further than either of the other efforts. This presentation will review the recommendations of the IOM study and describe the differences with the FDA and Congressional efforts on nutrition labeling.

Foods Covered by Nutrition Labeling

In the area of foods to be covered, the IOM report recommended that most packaged food be required to carry nutrition labeling. The Committee also recommended that infant foods, institutional packages, and commodity foods should carry nutrition labeling. It recommended exemptions for a few foods from this requirement (small packages, foods with no nutritional significance), only after all other possible alternatives had been exhausted. The FDA proposal and 1990 Act include these exemptions as well as others for specialized food products, food sold in restaurants or prepared in grocery stores, and institutional foods.

The IOM study recommended that fresh foods (produce, meat, poultry, and seafood) should be required to be sold with nutrition information provided at the point of purchase for the most frequently consumed products in each category. The report recommended that the agencies allow flexibility in the format and nutrient information required for the labeling of fresh foods for which they were responsible: FDA for produce and seafood; USDA for meat and poultry. The FDA proposal expressly includes nutrition labeling for produce and requests comments on seafood. The 1990 Act includes a provision for nutrition information to be provided for the 20 most commonly consumed items each in the produce and seafood categories. Meat and poultry were not included in either the FDA proposal or the new law since these products are under USDA's jurisdiction.

Because the American public is currently consuming so many meals away from home, the IOM report also recommended that restaurants be required to make nutrition information available to consumers. Limited-menu restaurants (e.g., fast food) would be required to provide information on package wrappers or in some other form at the point of purchase. Other restaurants would be required to provide a statement on their menus that nutrition information is available upon request. Additionally, the report encouraged restaurants to participate in programs that use descriptive symbols or terms on menus to allow consumers to choose more healthful menu items. The report also encouraged noncommercial food service settings to provide nutrition information. provided in . The FDA proposed rules and 1990 Act expressly omit foods sold in restaurants from providing nutrition

information. However, in October 1990, FDA and USDA met with industry representatives to discuss options for providing nutrition information in restaurants.

Nutrient Content Information

The IOM study recommended that the following nutrient information be required to be added to the current nutrition information panel per serving: total calories from fat, saturated and unsaturated fat; saturated and unsaturated fat in grams; cholesterol in milligrams; and dietary fiber in grams. The report called for retaining calcium and iron, while at the same time eliminating the required listing of the percent of U.S. Recommended Daily Allowances (U.S. RDA) for protein and for vitamins A, C, thiamin, niacin, and riboflavin -- none of which are current public health concerns. The report's recommendations allow the optional listing of all micronutrients for which Recommended Dietary Allowances (RDA) exist, monounsaturated and polyunsaturated fats, complex carbohydrates and sugars, potassium, and calories from protein and carbohydrate components. The FDA proposal requires many of the same provisions, except it would allow the optional listing of unsaturated fatty acids and the calories from saturated, unsaturated, polyunsaturated and monounsaturated fatty acids, insoluble and soluble fiber content, while requiring the listing of vitamins A, C, calcium and iron. The 1990 Act contains similar provisions to the IOM study except only the amount of saturated fat (in grams) and the calories from total fat would be required while the listing of calories from saturated and unsaturated fat would be optional. In addition, the new law requires that the amount of complex carbohydrates and sugar contained in the product be listed in grams. The new law retains the listing of currently required vitamin and minerals for as long as they are determined to be of continued usefulness to consumers.

Presentation of Label Information

Each of the current proposals or recommendations calls for serving size to be retained as the reference unit for providing nutrition information. The IOM recommended that the serving sizes be expressed in common household measures followed by weight in metric measures, with the serving size and the number of servings per container being rounded down to the nearest whole number, and that the agencies establish uniform serving sizes for a limited number of different food categories. FDA's proposed rules would require serving size to be stated in U.S. and metric units, with the option of also stating serving size in household measures. The agency has proposed standardized serving sizes for 159 food categories. The 1990 Act also requires that serving sizes be stated in household units appropriate for the food and be standardized for food categories.

With regard to dietary reference values, the IOM study recommended that the U.S. RDAs be updated using the values in the 10th edition of the RDAs. FDA has proposed that the U.S. RDAs be

replaced with RDIs (reference daily intakes) established for those nutrients for which an RDA exists. These values for specific nutrients would be adjusted for population-weighted means of dietary requirements. In addition, FDA has proposed that DRVs (daily reference values) be established for macronutrients based on current dietary recommendations so that a manufacturer could provide a nutrition profile for all the food components contained in the product. The new law does not specifically address the RDA issue.

The IOM study recommended that rigorous consumer testing should take place before any change is made in label format. Figure 1 provides an example of the current label. The IOM report, while not recommending a particular label format, provided several examples of the manner by which it's recommendations might appear. Figure 2 features the Committee's mandatory content recommendations. Figure 3 provides an example of the Committee's mandatory and optional content recommendations. This example begins to show how cluttered the label can become. Manufacturers would be unlikely to provide all this information, but might chose to declare those nutrients that highlight the attributes of a food product. Figure 4 provides a suggested layout for the Committee's mandatory and optional recommendations with information on the nutrient content "as prepared."

The IOM report also recommended that public and private consumer education initiatives would be needed to assist Americans to use the new labels. FDA has initiated labeling format studies using consumer focus groups and mall-intercept surveys to determine the most appropriate label format to be required on packages in the future. The 1990 Act requires that, within a year, the Secretary of DHHS propose revisions to the label format such that consumers can better understand the information that is to be conveyed.

The IOM study did not address the issue of health claims. However, it did address the use of nutrient content descriptors. For descriptors, the IOM Committee suggested a framework by which minimum benchmark values would be set for nutrients for which intake should be increased and maximum benchmark values would be set for those for which intake should be decreased. The framework is designed to allow statements concerning nutrient content to be standardized and rational in light of the recent proliferation of such terms and also to be supported by the information provided on the nutrition panel. FDA proposed regulations for health messages in a separate notice in February 1990, proposed tentative final rules for cholesterol descriptors in July 1990, and is planning to address definitions for other principal display panel descriptors in subsequent proposals. Regulations that have already been proposed will need to be reproposed under the new authority and with attention to specific provisions of the Nutrition Labeling and Education Act of 1990. The 1990 Act requires FDA to propose regulations that define certain descriptive terms and establish some reasonable control over the current proliferation of health claims.

2% LOWFAT MILK

Nutrition Information Per Serving

SERVING SIZE	ONE CUP	
SERVINGS PER CONTAINER	8	
CALORIES	120	
PROTEIN	8	GRAMS
CARBOHYDRATE	11	GRAMS
FAT	5	GRAMS
SODIUM	130	mg

Percentage of U.S. Recommended Daily Allowances (U.S. RDA)

PROTEIN	20	RIBOFLAVIN	25
VITAMIN A	10	NIACIN	*
VITAMIN C	4	CALCIUM	30
THIAMINE	6	IRON	*

*CONTAINS LESS THAN 2% OF THE U.S. RDA FOR THESE NUTRIENTS

FIGURE 1 Sample nutrition information panel for 2% lowfat milk under current FDA regulations (minimum requirements).

2% LOWFAT MILK

Serving size ..... 1 cup (8 fl oz)
Servings per container 8

Nutrition Information Per Serving

Calories	120	
Total Fat	5 g	(45 kcal)
Saturated Fat	3 g	(27 kcal)
Unsaturated Fat	2 g	(18 kcal)
Carbohydrate	11 g	
Protein	9 g	
Total Dietary Fiber	0 g	
Cholesterol	20 mg	
Sodium	120 mg	

A very good source (over 20% [standard]) of: Calcium.

FIGURE 2 Potential nutrition label incorporating the Committee's mandatory content recommendations.

2% LOWFAT MILK

Serving size ..... 1 cup (8 fl oz)
Servings per container 8

Nutrition Information Per Serving

Calories	120	
Total Fat	5 g	(45 kcal)
Saturated Fat	3 g	(27 kcal)
Unsaturated Fat	2 g	(18 kcal)
Total Carbohydrate	11 g	(44 kcal)
Complex Carbohydrate	0 g	(0 kcal)
Sugars	11 g	(44 kcal)
Protein	9 g	(36 kcal)
Total Dietary Fiber	0 g	
Cholesterol	20 mg	
Sodium	120 mg	
Potassium	430 mg	

A very good source (over 20% [standard]) of: Vitamin D, Calcium, Riboflavin, Phosphorus.
A good source (11-20% [standard]) of: Vitamin A, Vitamin B12.
Contains (2-10% [standard]): Vitamin B6, Vitamin C, Magnesium, Pantothenic Acid, Thiamin, Zinc.

FIGURE 3 Potential nutrition label incorporating the Committee's mandatory and optional content recommendations.

MACARONI & CHEESE DINNER

Serving size (as prepared) ..... 3/4 cup (50 g)
Servings per container 4

Nutrition Information Per Serving

	As Packaged	As Prepared
Calories	190	290
Total Fat	2 g (18 kcal)	13 g (117 kcal)
Saturated Fat	1 g (9 kcal)	9 g (81 kcal)
Unsaturated Fat	1 g (9 kcal)	4 g (36 kcal)
Total Carbohydrate	36 g (144 kcal)	34 g (136 kcal)
Complex Carbohydrate	30 g (120 kcal)	28 g (112 kcal)
Sugars	6 g (24 kcal)	6 g (24 kcal)
Protein	9 g (36 kcal)	9 g (36 kcal)
Total Dietary Fiber	1 g	1 g
Cholesterol	5 mg	5 mg
Sodium	425 mg	525 mg
Potassium	850 mg	900 mg

As Packaged
A very good source (over 20% [standard]) of: Niacin, Riboflavin, Thiamin.
Contains (2-10% [standard]): Calcium, Iron.

As Prepared
A good source (11-20% [standard]) of: Riboflavin, Thiamin.
Contains (2-10% [standard]): Vitamin A, Calcium, Iron, Niacin.

FIGURE 4 Potential nutrition label incorporating the Committee's mandatory and optional content recommendations for macaroni & cheese dinner, as packaged and as prepared.

The IOM study included recommendations concerning the need to improve analytical methods to provide more comprehensive nutrition information about food products. The report recommended that the agencies should allow the use of data base information for fresh food and foods sold in restaurants rather than direct laboratory analysis. This alternative would require the agencies to certify data from the USDA National Nutrient Data Bank or other appropriate sources. Methods verification and quality control are needed for analyzing samples with nonofficial methods. The IOM Committee pointed out that funding is needed for the development of improved analytical methods, establishment of programs for testing methods, development of additional standard reference materials, and expansion of the USDA National Nutrient Data bank. Specific recommendations on analytical methods were not made in either the FDA proposal or the 1990 Act.

Legal Authority

FDA's proposal states that the agency believes that it has the authority under existing statutes to require nutrition labeling on packaged foods and to expand coverage to produce and seafood. The IOM report suggested that explicit legislative authority would lay to rest any doubts that FDA and USDA have the authority to require mandatory nutrition labeling and to expand the requirement to foods that are not now covered. However, a change in the law was not viewed as imperative and the agencies could proceed under existing authority to implement the recommendations made by the Committee. The 1990 Act provides specific authority for FDA-regulated products and mandates certain information to be provided for foods that are sold with nutrition information. No legislation has been introduced to address providing comparable authority for USDA.

The Future

Having come this far in the last year, the question that now arises is: where are we and where do we go from here?

WHERE WE ARE IS: One agency (FDA) has explicit authority for nutrition labeling. However, that agency also has already proposed new regulations on the first series of rules that must now be re-proposed under the new authority. The FDA labeling format studies are currently underway. The agency has the recommendations from the IOM study as it proceeds to develop the proposed regulations for labeling issues yet to be addressed.

WHERE WE ARE GOING FROM HERE: there are certain things that need to be addressed in order for a comprehensive, harmonized system of nutrition labeling to be implemented and used effectively. The things to consider are:

1. whether comparable legislation needs to be enacted to grant USDA similar authority to that of FDA; such legislation might also include coordination of authority over certain issues, such as defining descriptors;

2. consideration should be given to whether there is a way to better coordinate the regulation of health claims made in labeling and advertising (this issue has all ready been the subject of several Congressional hearings); and

3. the development of a nutrition education program to assist consumers to effectively use new nutrition labels and other nutrition information provided at the point of purchase.

In sum, a lot has been accomplished in the last year. The substance of the recommendations among the three entities addressing changes in nutrition labeling are fairly similar. However, there are some differences that will be important to certain parties who will be affected by nutrition labeling reform. Attention to the details of the IOM report, the FDA proposals, and possible changes in USDA policy during the comment and rulemaking process will be important in determining the nutrition labeling regulations that will carry us into the 21st century. The ultimate goal of nutrition labeling reform efforts is to provide consistent, readable, understandable, and usable food labels that enable consumers to make more healthful food choices. The last year's activities in nutrition labeling have been described as a horse race with much speculation as to who would win: FDA, Congress, or the IOM Committee. We have to hope that the winners will ultimately be the American people.

References:

FDA. 1989. Food labeling; Advance notice of proposed rulemaking. Food and Drug Administration, Public Health Service, Department of Health and Human Services. Fed Reg. 54: 02610.

FDA. 1990a. Food labeling; Health messages and label statements; Reproposed rule. Food and Drug Administration, Public Health Service, Department of Health and Human Services. Fed Reg. 55: 5176.

FDA. 1990b. Food labeling; Definitions of the terms cholesterol free, low cholesterol, and reduced cholesterol. Food and Drug Administration, Public Health Service, Department of Health and Human Services. Fed Reg. 55: 29456.

FDA. 1990c. Food labeling; Reference daily intakes and daily references values. Food and Drug Administration, Public Health Service, Department of Health and Human Services. Fed Reg. 55: 29476.

FDA. 1990d. Food labeling; Mandatory status of nutrition labeling and nutrient content revision. Food and Drug Administration, Public Health Service, Department of Health and Human Services. Fed Reg. 55: 29487.

FDA. 1990e. Food labeling; Serving sizes. Food and Drug Administration, Public Health Service, Department of Health and

Human Services. Fed Reg. 55: 29517.
DHHS (U.S. Department of Health and Human Services). 1988. The Surgeon General's Report of Nutrition and Health. Government Printing Office, Washington, D.C. 727p.

IOM (Institute of Medicine). 1990. Nutrition Labeling: Issues and Directions for the 1990s. Report of the Committee on the Nutrition Components of Food Labeling, Food and Nutrition Board. National Academy Press, Washington, D.C. 355p.

NRC (National Research Council) 1989. Diet and Health: Implications for Reducing Chronic Disease Risk. Report of the Committee on Diet and Health, Food and Nutrition Board, Commission on Life Sciences. National Academy Press, Washington, D.C. 749p.

NRC (National Research Council). 1989. Recommended Dietary Allowances, 10th ed. Report of the Subcommittee on the Tenth Edition of the RDAs, Food and Nutrition Board, Commission on Life Sciences. National Academy Press, Washington, D.C. 284p.