PART C: METHODOLOGY

COMMITTEE APPOINTMENT

Beginning with the 1985 edition, the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) have appointed a Dietary Guidelines Advisory Committee (DGAC) of prominent experts in nutrition and health to assist in the preparation of the *Dietary Guidelines for Americans*. This Committee has been an effective mechanism to obtain a competent review of the science, recommendations from experts, and broad public acceptance of the *Dietary Guidelines*. The 2005 DGAC was established for the single, time-limited task of reviewing the 2000 edition of *Nutrition and Your Health: Dietary Guidelines for Americans* and determining if, on the basis of current scientific and medical knowledge, revision was warranted. The Committee determined that a revision was warranted and developed nutrition and health recommendations in this report to the Secretaries of HHS and USDA. The Committee was dissolved upon delivery of this report.

Nominations were sought from the public through a *Federal Register* notice published on May 15, 2003, and from Federal agencies. Prospective members of the DGAC were expected to be knowledgeable of current scientific research in human nutrition and be respected and published experts in their fields. They would be familiar with the purpose, communication, and application of the *Dietary Guidelines* and have demonstrated interest in the public's health and well-being through their research and/or educational endeavors. Expertise was sought in specific specialty areas, including, but not limited to, cardiovascular disease, cancer, pediatrics, gerontology, epidemiology, general medicine, overweight and obesity, physical activity, public health, nutritional biochemistry, nutrient bioavailability, nutrition education, and food safety and technology.

The Secretaries of HHS and USDA jointly selected individuals for membership to the DGAC. The individuals selected are highly respected by their peers for their depth and breadth of scientific knowledge of the relationship between dietary intake and health. The expertise of these individuals addresses all the relevant areas of the current *Dietary Guidelines for Americans*.

To ensure that recommendations of the Committee took into account the needs of the diverse groups served by HHS and USDA, membership included, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities. Efforts were made to ensure equitable geographic distribution and racial, ethnic, and gender representation. Appointments were made without discrimination on the basis of age; race and ethnicity; gender; sexual orientation; disability; or cultural, religious, or socioeconomic status. Equal opportunity practices, in line with HHS and USDA policies, were followed in all membership appointments to the Committee.

CHARGE TO THE 2005 DGAC

The *Dietary Guidelines for Americans* provides science-based eating and physical activity advice for healthy Americans over age 2 years. The DGAC shall advise the Secretaries of HHS and USDA whether revisions to the 2000 edition of *Nutrition and Your Health: Dietary Guidelines for Americans* are warranted on the basis of the preponderance of the scientific and medical knowledge currently available.

The Committee, whose duties are solely advisory and time-limited, will perform the following functions:

- If the Committee decides that no changes are necessary, it will so inform the Secretaries of the Departments. This action will terminate the DGAC.
- If the Committee decides that changes are warranted on the basis of the preponderance of the scientific and medical knowledge, the Committee will determine what issues for change need to be addressed.
- The focus of the Committee should be on the review of the new scientific evidence.
- The Committee shall make and submit its technical recommendations and the rationale for these recommendations in a report to the Secretaries. The Committee's focus should be its recommendations and the supporting science rather than translating the recommendations into a communication document.
- Upon the submittal of the Committee's recommendations, the DGAC will be terminated.

THE COMMITTEE PROCESS

The Committee served without pay and worked under the regulations of the Federal Advisory Committee Act. It held public meetings, announced in the *Federal Register*, in Washington, DC, in September 2003 and in January, March, May, and August 2004. Meeting summaries are available at www.health.gov/dietaryguidelines.

Written public comments were received throughout the Committee's deliberations. Those received before August 10, 2004, were shared with all Committee members. Comments with recommendations for the Committee received before May 12, 2004, are summarized in Appendix G-6. In response to a solicitation for oral comments, 31 organizations or individuals presented oral testimony during the January 28–29, 2004, meeting of the Committee. These comments are summarized in the January Public Meeting Summary (http://www.health.gov/dietaryguidelines). Comments are available for examination at the Office of Disease Prevention and Health Promotion, 1101 Wootton Parkway, Suite LL100, Rockville, MD, 20852.

To promote a fresh examination of the science base for dietary guidance, the content areas to be addressed differed somewhat from the topics of the 10 guidelines in the 2000 *Dietary Guidelines*. In particular, the workload was divided and managed by subcommittees on nutrient adequacy, carbohydrates, fats, fluid and electrolytes, energy, ethanol, and food safety. Midway through the effort, a macronutrient subcommittee was appointed to address some crosscutting topics, and a subcommittee was formed to address fruits and vegetables, grains, milk, and milk products. To aid in coordination and communication, a lead Committee member was appointed for each subcommittee, but the conclusions reached reflected the consensus of the entire group.

One or more designated staff members from HHS or USDA assisted each subcommittee.

The Science Review Subcommittee was formed to help maintain consistent standards for the reviews across subcommittees. The Subcommittee also addressed quality standards for the entire process, including consideration of the format of the report to the Secretaries, integration of the various subcommittees' work into a cohesive document, and meeting plans.

The subcommittees communicated by conference call, e-mail, and face-to-face meetings. Each subcommittee was responsible for presenting the basis for its conclusions and recommendations to the full Committee, responding to questions, and making changes if indicated. To gain perspectives for interpreting the science, some subcommittees invited experts to respond to specific questions during conference calls. The full Committee heard presentations from 12 invited experts, who addressed questions posed by the Committee in advance and responded to additional questions during the meeting. The conclusions in this report reflect the consensus of the entire Committee.

RESEARCH QUESTIONS

Each subcommittee generated an initial list of research questions that might be relevant to setting dietary guidelines. The subcommittee then set priorities based on the perceived level of importance and availability of literature. This process was iterative. Throughout the deliberations, the wording and intent of the research questions evolved, as did the need for additional questions. Available time, expertise, and resources precluded an examination of all issues related to the effects of diet on chronic disease.

SYSTEMATIC REVIEW OF THE SCIENTIFIC EVIDENCE

The DGAC relied on the published literature and, in a few instances, preprints of articles that had been accepted for publication and provided to the Committee by individual members and invited experts. Major sources of evidence were the *Dietary Reference Intake* reports prepared by expert committees convened by the Institute of Medicine (IOM). Other sources were systematic evidence-based reports such as the Agency for Healthcare Research and Quality report on omega-3 fatty acids and the World Health Organization International Agency for Research on Cancer (IARC) report on the relation between fruit and vegetable intake and cancer. In addition to these comprehensive documents, the subcommittees relied on literature searches to identify pertinent articles on research questions not addressed in any evidence-based report and to update previously published evidence reports.

TYPES OF EVIDENCE

The Committee focused on studies conducted in humans. The primary types of studies used were observational studies and clinical trials. Specific types of observational studies were cross-sectional studies, case-control studies, and cohort studies. The Committee placed greatest emphasis on results from cohort studies and trials with well-accepted, clinically relevant outcomes. Such outcomes included clinical diseases (e.g., incident cancer and myocardial infarction) and well-accepted risk factors (e.g., systolic blood pressure, low-density lipoprotein cholesterol, and weight). Meta-analyses also were considered. The majority of studies evaluated were based on adults; there were limited studies on children.

Literature Searches

Staff developed the search strategy in consultation with each subcommittee chair to meet the needs of that subcommittee. The search strategy included search parameters, search terms, search databases, and exclusion criteria (including years covered).

Typical exclusion criteria included the following: *in vitro* studies, animal studies, articles before "X" date, and drug studies. The specific exclusion criteria varied by question (e.g., questions involving cancer as an endpoint may not exclude animal studies). In some cases, additional references were identified by checking the reference lists of review articles. The years covered were influenced by the availability of evidence-based reviews that addressed the same topic. For example, the literature search regarding fiber covered only 1999 and later years because a prior IOM report covered the earlier years. Some searches were expanded if results from the initial research were meager.

Summaries of Results

The Science Review Subcommittee developed a prototype table to be used for summarizing information obtained from relevant articles for priority questions. Content included in the tables was to be concise, factual, and descriptive and to provide a basis for formulating tentative conclusions. Staff worked with the respective subcommittee chair to examine the search results and eliminate articles that were not relevant to the subcommittee's topic. They then extracted the key information and, by using the prototype, produced a table to cover key information about each question for which relevant articles were identified. See Appendix G-3 for working summary tables.

Critical Review of Studies

Subcommittee members read the tables and requested key articles. They then critically assessed study quality and relevance to the overall question being addressed. The subcommittee members, not the staff, made the decisions on study quality and on the relative value of clinical trials and observational studies. They considered these factors, along with the data summarized in the tables, in reaching tentative conclusions for consideration by the full Committee.

Preparation of Conclusive Statements

For each research question, subcommittees prepared a brief document that included a conclusion that specifically addressed the research question, a list of key sources, and a summary of key studies and findings. The subcommittee presented draft summary statements to the DGAC for consideration. Members of the Committee who were not members of the subcommittee were also assigned to review the statements and provide in-depth critical review. For especially controversial topics, the entire Committee examined the key published evidence on which a conclusion was based. At the May and August meetings, the whole Committee voted on the wording of each conclusion.

USE OF THE USDA FOOD INTAKE PATTERN AND SPECIAL ANALYSES

The Committee had access to the food pattern proposed by the USDA (*Federal Register* notice, vol. 68, no. 176, September 11, 2003, p. 53536) and to technical support data related to the pattern. This information included the following:

- A proposed daily food intake pattern that lists the daily amounts of food from each food group and subgroup for 12 age/energy groups.
- Energy levels for the proposed food intake pattern.
- Nutritional goals for the daily food intake pattern covering vitamins, minerals, and macronutrients.
- Nutrient profiles of the basic food groups and their subgroups and for additional fats, oils, soft margarines, and added sugars. The food groups and subgroups are composites that reflect the types and amounts of foods commonly consumed by Americans.
- Nutrients provided by the proposed food pattern.

At the request of three subcommittees, USDA staff used its food modeling system to conduct several types of analyses. Most of these analyses involved the modeling of the food pattern intended to meet selected specifications for nutrient intake. For example, the subcommittees requested analyses to obtain information relevant to flexibility in the choice of food to meet nutrient needs, the effects of different fat intakes on the nutrients provided by the food pattern, and the approximate number of calories needed to meet recommended nutrient intakes. See Appendix G-2 for the descriptions of these analyses and their results.

The USDA food modeling process used in these analyses was developed originally for deriving the Food Guide Pyramid. It was updated for these analyses to include nutrient goals from the IOM *Dietary Reference Intakes* report that was released in 2004 (after the *Federal Register* notice regarding the proposed food pattern) and the most recent National Health and Nutrition Examination Survey (NHANES) 1999–2000 food consumption data. The USDA food modeling process involves the following steps:

1. *Establishing nutritional goals*. Goals were obtained from the *Dietary Reference Intakes* reports for various vitamins, minerals, macronutrients, and electrolytes released by the IOM between 1997 and 2004.
2. *Establishing energy levels*. The food pattern was developed for caloric levels from 1,000 to 3,200 calories per day in 200-calorie increments. The pattern was created for each age/gender group and was deemed applicable, whether individuals were sedentary or physically active.
3. *Assigning nutritional goals to each specific food intake pattern*. The specific nutritional goals assigned to each food intake pattern were the goals of age/gender groups with sedentary energy requirements that most closely matched the caloric level. For example, the goals of females age 31 to 50 years, males/females age 9 to 13 years, and females age 14 to 18 years matched the 1,800 calories per day level. In some cases the nutrient levels in a food pattern were compared to nutritional goals for several age/gender groups. For example, at the 1,800-calorie level, three goals were specified for each nutrient: those for females age 31 to 50 years, for males/females age 9 to 13 years, and for females age 14 to 18 years.
4. *Assigning a nutrient content to each food group and subgroup*. Foods included in each of the commodity food groups or subgroups (fruits, milk, meat and beans, whole grains, enriched grains, dark green vegetables, orange vegetables, legumes, starchy vegetables, and other vegetables) are based on the food consumption of Americans, with any food that represents 1 percent or more of the consumption from that group or subgroup

included in the development of a nutrient profile. Other foods (less than 1 percent of group or subgroup consumption) are grouped with a similar food item for analysis. The nutrient profiles of each commodity group are the weighted averages of the nutrient content of foods in each food group based on consumption. The USDA Continuing Survey of Food Intakes by Individuals (CSFII) 1994–1996 was the source of food consumption data in the *Federal Register* notice, but the NHANES 1999–2000 food consumption data were used to determine new nutrient profiles for this analysis. Two-day food intakes from 14,262 individuals over age 2 years were weighted to represent the nationwide population. For example, the nutritional composition of dark green leafy vegetables reflected the nationwide consumption of foods falling into that group, which were about 53 percent broccoli and 20 percent spinach. Therefore, the nutritional value of the dark green leafy vegetable group was 0.53 of the nutritional value of broccoli, 0.20 of the value of spinach, and 0.27 other. Foods in their lowest fat form were selected for determining the nutrient profile of the milk and meat groups. For the milk group, fat-free milk was the single food item used to represent this food group. For the meat group, only the leanest cuts of meat, fish, and poultry prepared with all fat or skin removed were used. Eggs and nuts were also included in this group.

5. *Determining the daily intake amounts for each food group or subgroup*. Starting from the original Pyramid food pattern, the amounts of each food group or subgroup were increased or decreased in an iterative manner until the pattern for each calorie level achieved its nutritional goal or came within a reasonable range. A reasonable progression from pattern to pattern of the amounts recommended in each food group was maintained to make the pattern logical from an educational standpoint.

Because 12 different levels of energy intake ranging from 1,000 to 3,200 calories per day have been used, a person can select a food pattern according to his or her level of physical activity. The pattern was developed for individuals with low, moderate, or active levels of physical activity.

There are advantages to the approach used in developing this food intake pattern. One advantage is that it provides continuity with previous food guidance and allows evolution of the guidance over time to build on what consumers already understand while updating the science base. Also, the approach provides an educational tool that integrates the gamut of IOM recommendations into a food intake pattern. That is, the approach assists in converting the full set of nutrient recommendations to food-based recommendations suitable for males and females of different ages and activity levels. The process has resulted in a food pattern that meets IOM recommendations for almost all nutrients at all calorie-intake levels.

There are disadvantages to the approach, however. First, the nutrient profile of each food group and subgroup is based on Americans' current consumption of foods within that group. Because Americans may not select rich sources of certain nutrients, the nutrient profiles for a group or subgroup also may be low in that nutrient. This makes it more difficult to develop models that meet the appropriate Dietary Reference Intakes for some nutrients. For example, Americans eat very few nuts relative to other choices in the meat, poultry, fish, dry beans, eggs, and nuts group; and the nuts they tend to eat are not especially rich in vitamin E. Therefore, the nutrient profile for "nuts" and for the entire meat, poultry, fish, dry beans, eggs, and nuts group is relatively low

in vitamin E. This also is true for the types of oils that Americans tend to select; relatively few individuals use oils that are especially rich in vitamin E. When using the nutrient profiles for these food groups, it is difficult to develop a food intake pattern that meets the Recommended Dietary Allowance for vitamin E. This holds true even if only lacto-ovo vegetarian choices are made from the meat, poultry, fish, dry beans, eggs, and nuts group, by including only eggs, nuts, and legumes in the nutrient profile for this group. The same problem exists in trying to use these nutrient profiles to meet IOM recommendations for sodium and potassium because the profiles rely on current consumption and the food supply, both of which are high in sodium and low in potassium.

Second, the five basic food groups used in the modeling stemmed from historical nutritional concerns: vitamin C (fruit), vitamin A (vegetables), calcium (milk), protein (meat), and energy (grains). The original 1992 Pyramid pattern considered and evaluated 21 different diet components (i.e., vitamins, minerals, different fats, and energy). The new dietary reference intakes include standards for a total of 27 diet components (vitamins, minerals, electrolytes, essential fats, all the macronutrients, and fiber). As with the original Pyramid development, this requires the use of more than the five basic food groups to meet the dietary reference intakes. Consequently for these analyses, vegetables were broken down into the following subgroups: dark green, deep yellow, legumes, starchy, and other. Grains were divided into whole and enriched grains. Meats and legumes were not divided into subgroups, however. The amounts from several of the various subgroups increased (e.g., dark green vegetables, legumes) to meet the new nutrient recommendations.

Third, persons using this pattern need to take great care to account for the (1) fat contained in milk products and meats, (2) fats and added sugars that are a part of processed foods (such as muffins or soft drinks) and that are added when preparing or serving food, and (3) calories provided by alcoholic beverages. Otherwise, their intakes of calories and of saturated fats are likely to be too high.

Although the food modeling program was not perfect, it was a valuable tool for the Committee in determining how the food pattern could be developed that met science-based criteria for a healthful diet.

SOURCES OF NUTRIENTS IN AMERICAN DIET

Several tables found in Parts D and E of this report present food sources of nutrients consumed by Americans. These tables, adapted from tables published by Cotton et al. (2004), draw upon CSFII 1994–1996 data. To confirm that the CSFII data are still representative, a prototype analysis of 1999–2000 NHANES food consumption data was run on one key nutrient—potassium. The analytical methodology and comparison follow.

The NHANES analysis included individual consumption records that were considered reliable and met the daily minimum (acceptable) number of foods consumed. The Cotton analysis used similar data from CSFII 1994–1996. The nutrient content of the individual foods were drawn from the USDA Nutrient Composition Database Standard Reference 16.1. The two analyses incorporated similar food groupings. However, because time was short for completing the Committee's work, the prototype NHANES analysis did not disaggregate food mixtures to their basic ingredients, as the Cotton analysis did. Rather, in most cases, the most prominent

ingredient in the food mixture dictated the category in which the food was placed. For example, the coffee category includes coffee with milk or other combinations and does not break down into the coffee and milk categories, as in the Cotton article. Similarly, the tomatoes from pizza do not appear in the tomato category because they are picked up in the multi-ingredient category called egg rolls, pizza, etc. An examination of the top 10 food contributors (shown in Table C1) indicates that there may be about a 5 percent difference when using the different approaches.

A comparison of the results from the two types of analysis indicates that the percent contribution by food category to the total potassium intake did not differ substantially. The reasons for differences may be due to the placement of multi-ingredient foods or real changes in intake. In terms of potassium intake, the top 12 foods identified by Cotton et al. (2004) are found within the top 14 foods on the NHANES list, and the order does not change radically. The decision was made to use the tables from Cotton and colleagues (2004) since they were from a peer-reviewed, published article.

Table C1. Comparison of Potassium Consumption Estimated Using Data from the 1994–1996 Continuing Survey of Food Intake by Individuals and from the 1999–2000 National Health and Nutrition Examination Survey

	Cotton et al. (CSFII 1994–1996)		**NHANES 1999–2000 and SR16.1***	
Rank	**Food Group**	**(%)**	**Food Group**	**(%)**
1	Milk	10.2	Milk	10.0
2	Potatoes	8.9	Potatoes	8.0
3	Coffee	6.7	Beef	7.0
4	Beef	6.2	Coffee	5.1
5	Tomatoes	6.2	Poultry	4.0
6	Orange/grapefruit juice	4.1	Orange/grapefruit juice	3.8
7	Yeast bread	3.6	Tomatoes	3.5
8	Poultry	3.3	Dried beans/lentils	2.9
9	Dried beans/lentils	2.8	Egg rolls, pizza, other mixtures	2.8
10	Bananas	2.7	Tea	2.5
11	Corn/potato chips, popcorn	2.3	Bananas	2.4
12	Tea	2.0	Yeast bread**	2.4
	Cumulative Percentage	59.0		54.3

*USDA National Nutrient Database for Standard Reference, Release 16.1.
**Followed by consommé (include soups), then corn/potato chips and popcorn.

SUMMARY

Using results from the systematic review of the scientific literature and the food modeling exercises, the Committee evaluated and integrated the evidence into a set of conclusive statements and major conclusions regarding the components of the diet and physical activity that promote the health and well-being of Americans over age 2 years. These statements provide the basis for a set of straightforward guidelines for diet and physical activity.