

Do simulated diets that meet the updated USDA Dietary Patterns and reflect variation in dietary intakes achieve nutrient adequacy? Food Pattern Modeling Protocol

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Rationale

Food pattern modeling (FPM) is a methodology used to a) illustrate how hypothetical changes to the amounts or types of foods and beverages in a dietary pattern might affect meeting nutrient needs, and b) assist in defining quantitative dietary patterns that reflect the evidence for health-promoting diets synthesized from systematic reviews, while meeting energy and nutrient needs. The quantitative dietary patterns that emerge specify the recommended amounts of foods and beverages from each food group and subgroup, with the intention that individuals and programs will select the recommended amounts from the wide variety of nutrient-dense foods and beverages included in each group. This flexible framework is intended to allow inclusion of the widest variation in foods and beverages possible as dietary selections are based on many factors, including affordability, access, individual dietary requirements and preferences, and traditions.

As a part of continuous quality advancement between the work of the 2020 and 2025 Dietary Guidelines Advisory Committees, the Food Pattern Modeling methods team, which is composed of staff with expertise in FPM methodology and the Dietary Guidelines process, explored methodologies used by international counterparts to understand how other research groups have considered intake variability in diverse populations. The results of that evidence scan revealed that the addition of simulated diet methodologies may provide another opportunity to consider intake variability in addition to existing rigorous FPM methods. Currently, FPM considers a broad range of intakes by developing composite food group nutrient profiles reflecting actual dietary intakes of the U.S. population. Diet simulations also considers a broad range of intakes, but instead of using a composite nutrient profile based on proportional consumption and the nutrient profile of representative foods, this method models hundreds or thousands of individual foods in different combinations to meet the dietary pattern. The energy and nutrient composition of all foods are considered when simulated diets are assessed for meeting nutritional goals as outlined in this protocol (see Table 2). The addition of this systems science approach allows the Dietary Guidelines Advisory Committee to examine and refine the proposed dietary patterns to ensure the final pattern(s) recommended to the Departments are inclusive of a broader range of dietary intakes.

This protocol describes an analytic approach to evaluate the proposed dietary patterns, considering variability in the selection and consumption of predominantly nutrient-dense foods and beverages. The approach uses simulations to construct daily dietary intakes from different combinations of individual foods and beverages in the amounts that meet food group and subgroup recommendations across the life stages. Analyses will be conducted for the overall U.S. population and for identified population groups, specifically American Indian and Alaska Native populations, providing an opportunity to consider the variation in dietary practices across the country.

The analyses in this protocol are supported by public interest that dietary patterns recommended in the *Dietary Guidelines for Americans* address the wide variation in dietary practices in the United States. While the long-term goal is to simulate foods and beverages that are integral to all the various foodways in the United States, in this cycle there is an opportunity to simulate foods and beverages from American Indian and Alaska Native populations. This analysis is also an opportunity to be responsive to public comments that included a call for *Dietary Guidelines* to be inclusive of American Indian and Alaska Native populations by emphasizing the traditional foods of these populations in the *Dietary Guidelines* and federal programs. The analyses in this protocol are also responsive to a recommendation by the National Academies of Science, Engineering, and Medicine to apply system science approaches, such as simulation, to FPM to account for variability in food consumption.¹ Results from these analyses will be synthesized with the results from all other FPM analyses of the Dietary Guidelines Advisory Committee, along with related data analysis findings and systematic review evidence, before determining if the final advice to the Departments will include suggested changes to the USDA Dietary Patterns. The conclusions drawn by the Committee will inform their recommendations for the 2025 USDA Dietary Patterns in their scientific report to the Secretaries of HHS and USDA.

Introduction

To prepare for the development of the *Dietary Guidelines for Americans*, 2025-2030, the U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) identified a proposed list of scientific questions based on relevance, importance, potential impact to federal programs, and avoiding duplication, which were posted for public comment.^{2,3} The Departments appointed the 2025 Dietary Guidelines Advisory Committee (Committee) in January 2023 to review evidence on the scientific questions. Their review forms the basis of their independent, science-based advice and recommendations to HHS and USDA, which is considered as the Departments develop the next edition of the *Dietary Guidelines*. These questions were refined and prioritized by the Committee for consideration in their review of the evidence.

The Committee will be asked to answer the following question using Food Pattern Modeling (FPM) analyses:

Considering each life stage, should changes be made to the USDA Dietary Patterns (Healthy U.S.-Style, Healthy Mediterranean-Style, and/or Healthy Vegetarian); should additional Dietary Patterns be developed/proposed based on:

- Findings from systematic reviews, data analysis, and/or FPM analyses; and
- Population norms (e.g., starchy vegetables are often consumed interchangeably with grains), preferences (e.g., emphasis on one staple grain versus another), or needs (e.g., lactose intolerance) of the diverse communities and cultural foodways within the U.S. population?

Changes to Dietary Patterns may include modification to the amounts of food groups/subgroups and/or recategorization of food groups/subgroups, as well as subsequent changes to energy available for other uses, including for added sugars.

As part of that process and to address the overarching FPM question, the following question for analysis has been identified:

Do simulated diets that meet the updated USDA Dietary Patterns and reflect variation in dietary intakes achieve nutrient adequacy?

The Committee will use simulation analysis to address this question, with support from USDA's Food Pattern Modeling (FPM) methods team and a USDA contractor. The protocol will establish methods to use simulation to construct daily diets for U.S. populations from different combinations of individual foods and beverages in the amounts recommended across the life stages. The protocol will also describe methods to evaluate the simulated intakes for meeting energy and nutrient requirements and dietary recommendations to reduce the risk of diet-related disease.

Historical perspectives

The 2020 USDA Dietary Patterns are designed to reflect health promoting dietary patterns and meet the known nutrient needs of the age-sex groups for which they are targeted, within calorie constraints. The Dietary Patterns include recommended amounts to eat from five major food groups — Vegetables, Fruits, Grains, Dairy and Fortified Soy Alternatives, and Protein Foods — and ten subgroups. Figure 1 shows an example of one of the three 2020 USDA Dietary Patterns, the Healthy U.S.-Style Dietary Pattern. The recommended amounts are provided at the level of the food group and subgroup with the intention that individuals and programs will select the recommended amounts from the wide variety of nutrient-dense foods and beverages included in each group. These dietary selections are based on many factors, including affordability, access, individual dietary requirements and preferences, and traditions.

Figure 1. 2020 USDA Dietary Pattern - Healthy U.S.-Style Dietary Pattern for Ages 2 and Older

Healthy U.S.-Style Dietary Pattern for Ages 2 and Older, With Daily or Weekly Amounts From Food Groups, Subgroups, and Components

CALORIE LEVEL OF PATTERN ^a	1,000	1,200	1,400	1,600	1,800	2,000	2,200	2,400	2,600	2,800	3,000	3,200
FOOD GROUP OR SUBGROUP ^b	Daily Amount [©] of Food From Each Group (Vegetable and protein foods subgroup amounts are per week.)											
Vegetables (cup eq/day)	1	1 1/2	1 1/2	2	2 1/2	2 1/2	3	3	3 1/2	3 1/2	4	4
				V	egetable	Subgroup	s in Wee	kly Amou	unts			
Dark-Green Vegetables (cup eq/wk)	3/2	1	1	1 1/2	1 1/2	1 1/2	2	2	2 1/2	2 1/2	2 1/2	2 1/2
Red and Orange Vegetables (cup eq/wk)	2 1/2	3	3	4	5 1/2	5 1/2	6	6	7	7	71/2	71/2
Beans, Peas, Lentils (cup eq/wk)	1/2	3/2	3/2	1	1½	1½	2	2	2 1/2	2 1/2	3	3
Starchy Vegetables (cup eq/wk)	2	3 1/2	3 1/2	4	5	5	6	6	7	7	8	8
Other Vegetables (cup eq/wk)	1 1/2	2 ½	2 1/2	3 ½	4	4	5	5	5 1/2	5 1/2	7	7
Fruits (cup eq/day)	1	1	1 1/2	1 ½	1 ½	2	2	2	2	2 1/2	2 ½	2 1/2
Grains (ounce eq/day)	3	4	5	5	6	6	7	8	9	10	10	10
Whole Grains (ounce eq/day)d	1 1/2	2	2 ½	3	3	3	3 1/2	4	4 1/2	5	5	5
Refined Grains (ounce eq/day)	1 1/2	2	2 1/2	2	3	3	3 1/2	4	4 1/2	5	5	5
Dairy (cup eq/day)	2	2 ½	2 ½	3	3	3	3	3	3	3	3	3
Protein Foods (ounce eq/day)	2	3	4	5	5	5 1/2	6	6 1/2	6 1/2	7	7	7
				Pro	tein Food	s Subgro	ups in W	eekly Am	ounts			
Meats, Poultry, Eggs (ounce eq/wk)	10	14	19	23	23	26	28	31	31	33	33	33
Seafood (ounce eq/wk)e	2-3	4	6	8	8	8	9	10	10	10	10	10
Nuts, Seeds, Soy Products (ounce eq/wk)	2	2	3	4	4	5	5	5	5	6	6	6
Oils (grams/day)	15	17	17	22	24	27	29	31	34	36	44	51
Limit on Calories for Other Uses (kcal/day) ⁹	130	80	90	100	140	240	250	320	350	370	440	580
Limit on Calories for Other Uses (%/day)	13%	7%	6%	6%	8%	12%	11%	13%	13%	13%	15%	18%

Patterns at 1,000, 1,200, and 1,400 kcal levels are designed to meet the nutritional needs of children ages 2 through 8 years. Patterns from 1,600 to 3,200 kcal are designed to meet the nutritional needs of children 9 years and older and adults. If a child 4 through 8 years of age needs more energy and, therefore, is following a pattern at 1,600 calories or more, his/her recommended amount from the dairy group should be 2½ cup eq per day. Amount of dairy for children ages 9 through 18 is 3 cup eq per day regardless of calorie level. The 1,000 and 1,200 kcal level patterns are not intended for children 9 and older or adults. The 1,400 kcal level is not intended for children ages 10 and older or adults.

Note: Additional details on each group and subgroup in the Healthy U.S.-Style Dietary Pattern can be found on pages 145-146 of Dietary Guidelines for Americans, 2020-20252

In the United States, quantitative dietary patterns are developed to meet nutritional goals using a composite nutrient profile for each food group and subgroup. These nutrient profiles reflect the proportion at which foods and beverages are consumed in the population. However, to ensure that the resulting nutrient profiles are made up of nutrient-dense foods and beverages, each food reported as consumed is assigned a representative food that reflects the most nutrient-dense version of the food or beverage. For example, fat-free cow milk is the nutrient-dense representative food for all whole fat, reduced-fat, and fat-free cow milk consumed and, as the representative food, its energy and nutrient content is used to represent all three types of milk in the calculation of the weighted nutrient profile for Dairy and Fortified Soy Alternatives.

The analyses in this protocol will assess whether the dietary patterns proposed by the 2025 Committee meet nutritional goals irrespective of which nutrient-dense foods and beverages are consumed from each food group and subgroup. The assessment is accomplished by using simulation analysis to construct daily diets to meet the proposed dietary pattern using different combinations of foods and beverages, prioritizing foods lower in saturated fat and added sugars. The energy and nutrient content of the aggregated simulated diets for each age-sex group will be assessed relative to nutritional goals to determine if revisions to the proposed dietary patterns are warranted.

The methods proposed in this protocol build on methods used in Canada and Australia to evaluate and refine quantitative dietary patterns developed using a compositive nutrient profile system. In Canada, Katamay and colleagues constructed 500 daily simulated diets for each age-sex group following a previously developed food intake pattern and dietary statements such as choosing foods with little or no added fat, sugar, or salt.4 The nutrient content of the simulated diets was assessed relative to Dietary Reference Intakes (DRIs) to inform refinements to the original food intake pattern. A second Canadian study used diet simulation to validate the classification of foods and beverages for consistency with the Canadian Food Guide.⁵ In Australia, researchers used simulations to construct 100 7-day diets for each population group to assess the recommended pattern of a foundation diet that did not include foods and beverages with higher fat, sugar, or alcohol.⁶ As in the Canadian studies, the nutrient content of the simulated diets conducted by Australian researchers was assessed to refine the dietary patterns. In all three studies, the probability of selection of individual foods and beverages to construct simulated diets was based on reported consumption patterns in national or provincial surveys.

Current perspectives

Dietary practices vary across the U.S. and are influenced by many factors, including food cost and access, individual dietary requirements and preferences, and cultural traditions. Given this variability, it is important to understand if nutritional goals are met when the recommended dietary patterns are tailored to different situations, preferences, and traditions of individuals or groups.

To advance FPM methods to address variability in dietary intake, the FPM team examined the methodologies of international counterparts to understand how other research groups have considered intake variability in diverse populations. The review identified simulated diet methodologies as an opportunity to evaluate and refine dietary patterns developed using existing FPM methods for intake variability. For example, existing rigorous FPM methods consider a broad range of intakes by developing composite food group nutrient profiles reflecting actual dietary intakes of the U.S. population. Diet simulations also consider a broad range of intakes, but instead of using a composite nutrient profile based on proportional consumption and the nutrient profile of representative foods, diet simulation models hundreds or thousands of individual foods in different combinations to meet the recommended dietary pattern. The energy and nutrient composition of all foods are considered when simulated diets are assessed for meeting nutritional goals. The addition of this systems science approach allows the Committee to examine and refine proposed dietary patterns to ensure the final pattern(s) recommended to the Departments are inclusive of an even broader range of dietary intakes.

This protocol describes the approach to evaluate the implications on nutritional goals if different combinations of individual foods and beverages are consumed to meet the recommended amounts for each food group and subgroup. The approach will be applied to the overall U.S. population by age-sex group using national dietary intake data. The approach will also be applied to the American Indian population and the Alaska Native population using only foods and beverages identified as integral to or included in the cuisine of these populations by experts with appropriate professional and lived experience. Conducting diet simulation using foods and beverages consumed by American Indian and Alaska Native populations involves a method under development by the Committee. Developing and piloting this method is consistent with the Committee's commitment to advance the inclusion of diverse foodways in the Dietary Guidelines process and responsive to public comments calling for Dietary Guidelines to be inclusive of American Indian and Alaska Native populations by emphasizing the traditional foods of these populations in the *Dietary Guidelines* and federal programs. Conducting this pilot does not increase or address representativeness of the dietary patterns for all tribal organizations or the many different population groups in the U.S., but it tests a process to expand representativeness of the proposed patterns to be more inclusive and is a starting point for future work.

Results from the analyses conducted in this protocol will be collectively synthesized by the Committee along with all other FPM analyses, including those modeling modifications of food group and subgroup quantities, to address intake variability at the food group and subgroup levels. As part of the iterative FPM process, findings from these and other analyses may prompt the development of subsequent protocols to address any identified nutrient inadequacies and answer the overarching FPM question. The conclusions drawn by the Committee, along with findings from systematic reviews and data analysis, will inform their recommendations for the 2025 USDA Dietary Patterns in their scientific report to the Secretaries of HHS and USDA.

Methods

This section presents an overview of the methods, or the process, that will be used by the Committee to answer the question:

Do simulated diets that meet the updated USDA Dietary Patterns and reflect variation in dietary intakes achieve nutrient adequacy?

Develop a protocol

A FPM protocol is the plan for how USDA's FPM methodology will be used to conduct specific FPM analyses. The protocol is established by the Committee before the analysis is conducted. The protocol describes the components of the FPM process, including the analytic framework, analytic plan, analysis synthesis, conclusion development, and future research recommendations. It is developed through Committee discussion of the strengths and limitations for various analysis types and exercises to identify the most appropriate and relevant methods to answer each FPM question. FPM is an iterative process; thus, results from initial analyses may inform refinement of this protocol or subsequent protocols for other research questions.

When reviewing questions or topics addressed by prior Committees, the Committee uses the previous analytic framework, plan, and protocol to inform and refine their current approaches. Any changes to this protocol would be described as in Table 3. Protocol amendments. The Diet Simulations Protocol is new to the Dietary Guidelines FPM process and is being implemented for the first time by the 2025 Committee.

Develop an analytic framework

An analytic framework represents the overall scope of the FPM analyses, including the population, type of analyses, and data sources identified to answer the question. It also includes the definitions of key terms.

Question:

Do simulated diets that meet the updated USDA Dietary Patterns and reflect variation in dietary intakes achieve nutrient adequacy?

Population:

The simulation analyses conducted for this protocol are based on dietary intake data among the U.S. population ages 12 months and older to evaluate the proposed dietary patterns for the variety of foods and beverages consumed by age groupings of 1-3, 4-8, 9-13, 14-18, 19-30, 31-50, and 51+ years.

Types of analyses:

The overall FPM methodology used to develop and update the USDA Food Patterns includes six steps: (1) identifying appropriate energy levels for the patterns; (2) identifying nutritional goals for the patterns; (3) establishing food groupings and food group amounts; (4) determining the amounts of energy and nutrients that would be provided by consuming various foods within each food group or subgroup; and (5) evaluating nutrient levels in each pattern against nutritional goals. Finally, (6) adjust and re-evaluate the patterns to align with current or potential recommendations.

This analysis question will focus on step 5 (evaluating nutrient levels in each pattern against nutritional goals). In other FPM analyses, step 5 addresses whether the food group and subgroup quantities and their associated nutrient profiles meet nutritional goals for each age-sex group. Simulation analyses will evaluate the proposed dietary patterns recommended by the 2025 Committee in meeting nutritional goals considering variability in the selection of individual foods and beverages.

Analyses planned in this protocol include:

- 1. Simulating individual foods and beverages from Food and Nutrition Database for Dietary Studies (FNDDS) to construct 500 7-day diets for each age (or age-sex) group to meet the dietary pattern for age groups 1-3, 4-8, 9-13, 14-18, 19-30, 31-50, and 51+ years.
- 2. Identifying the frequency in which individual foods and beverages were included in the diet simulations for each age group.
- 3. Calculating the percentile distributions of energy and nutrient content for the simulated diets for each age-sex group.
- 4. Identifying the mean, median, minimum, and maximum energy, nutrient, and dietary component level across the simulated diets for each age-sex group.
- 5. Calculating the percentage of simulated 7-day diets that fall below the Dietary Reference Intakes' (DRIs) Estimated Average Requirement (EAR) for each nutrient by age-sex group.
 - a. For nutrients that do not have an EAR, compare the median nutrient content for the simulated diets to the DRIs Average Intake (AI) by age-sex group.

- 6. Calculating the percentage of simulated 7-day diets that fall outside of the Acceptable Macronutrient Distribution Range (AMDR) for carbohydrates, protein, and total lipid content for each age-sex group.
- 7. Calculating the percentage of 7-day diets with a nutrient content above the Tolerable Upper Intake Level (UL) and a sodium content above the Chronic Disease Risk Reduction Intake (CDRR) value by age-sex group.
- 8. Calculating the percentage of simulated 7-day diets that contain more than 10 percent of energy from saturated fatty acids by age-sex group for individuals ages 2 years and older.
- 9. Calculating the percentage of simulated 7-day diets that contain more than 10 percent of energy from added sugars for individuals ages 2 years and older. For individuals ages 12 through 23 months, the percentage of simulated 7-day diets that contain added sugars will be calculated.
- 10. Repeat analyses described in items 1 through 9 using foods and beverages identified as integral to and included in the cuisine of American Indian populations. For this analysis, larger age groupings may be
- 11. Repeat analyses described in items 1 through 9 using foods and beverages identified as integral to and included in the cuisine of Alaska Native populations. For this analysis, larger age groupings may be

Results from these analyses will contribute to the evidence that will be used to answer the overarching FPM question. This process will include:

- Synthesizing the above analyses with all other food group and subgroup modification analyses to determine if changes should be made to the USDA Dietary Patterns to account for variability in dietary practices in the U.S.
- Examining modified or new dietary patterns for meeting nutritional goals compared to the DRIs, current Dietary Guidelines for Americans, 2020-2025 recommendations, potential recommendations of the 2025 Committee, and simulated diet analyses.
- Developing conclusion statements based on all FPM analyses informing the overarching FPM question and in consideration of related systematic review conclusions and data analysis findings.
- Making research recommendations to inform future work on this topic.

Data Sources:

- What We Eat in America, NHANES 2017-2018, individuals 1 years and over, days 1 and 2, weighted to produce nationally representative estimates. Available: ars.usda.gov/nea/bhnrc/fsrg
- FNDDS 2017-2018: U.S. Department of Agriculture, Agricultural Research Service. 2020. USDA Food and Nutrient Database for Dietary Studies 2017-2018. Available: ars.usda.gov/nea/bhnrc/fsrg
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Key definitions:

Note: Key definitions in this protocol include existing definitions used by the 2020 Dietary Guidelines Advisory Committee and/or published in the Dietary Guidelines for Americans, 2020-2025, such as definitions operationalized in the HUSS Dietary Pattern.² The 2025 Dietary Guidelines Advisory Committee will continue to consider terminology and implications of terms related to health equity and/or communication to the public. Future revisions to existing definitions and new working definitions for 2025 will be noted.

Food Groups and Subgroups in the Healthy U.S.-Style (HUSS) Dietary Pattern: USDA's HUSS Dietary Pattern for ages 2 years and older provides amounts of five major food groups and *subgroups* including:

- Fruits
- Vegetables:
 - Dark-Green; Red and Orange; Beans, Peas, and Lentils a; Starchy; and Other
 - a. Beans, Peas, and Lentils are typically modeled as Vegetables in the HUSS Dietary Pattern but can also be counted toward the Protein Foods group. For the analyses in this protocol using the HUSS Dietary Pattern, Beans, Peas, and Lentils will only be modeled in the Vegetables food group.
- Dairy and Fortified Soy Alternatives
- Grains:
 - Whole Grains and Refined Grains
- Protein Foods:
 - Meats, Poultry, and Eggs b; Seafood; Nuts, Seeds, and Soy Products
 - b. For the HUSS Dietary Pattern for ages 12 through 23 months, there are separate subgroups for 1) Meats and Poultry and 2) Eggs.

Oils: Oils are sources of essential fatty acids and include canola, corn, olive, peanut, safflower, soybean, and sunflower oils. Oils also are naturally present in nuts, seeds, seafood, olives, and avocados. The fat in some tropical plants, such as coconut oil, palm kernel oil, and palm oil, are not included in the oils category because they contain a higher percentage of saturated fat than do other oils.

Added sugars: Added sugars are either added during the processing of foods or are packaged as sweeteners (e.g., a bag of table sugar). Added sugars include sugars (free, mono- and disaccharides), sugars from syrups

and honey, and sugars from concentrated fruit or vegetables juices that are in excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type. Naturally occurring sugars, such as those in fruit or milk, are not defined as added sugars. Specific examples of added sugars that can be listed as an ingredient include brown sugar, corn sweetener, corn syrup, dextrose, fructose, glucose, high-fructose corn syrup, honey, invert sugar, lactose, malt syrup, maltose, molasses, raw sugar, sucrose, trehalose, and turbinado sugar.

Limits on calories for other uses (as defined in the HUSS Pattern):^{2,8} Foods are assumed to be in nutrient-dense forms, which are lean or low-fat and prepared with minimal added saturated fat, added sugars, refined starches, or sodium. If all food choices to meet food group recommendations are in nutrient-dense forms, a small number of calories remain within the overall limit of the pattern (i.e., limit on calories for other uses). The amount of calories depends on the total calorie level of the pattern and the amounts of food from each food group required to meet nutritional goals. Calories up to the specified limit can be used for added sugars, refined starches, saturated fat, and/or alcohol (for nonpregnant adults of legal drinking age only), or to eat more than the recommended amount of food in a food group.

Item Clusters: Identified groupings of the same or similar foods or beverages that make up each food group and subgroup. Item clusters are used to calculate the weighted average consumption for use in calculating a nutrient profile for each food group and subgroup used in USDA FPM.

Nutrient-Dense Representative Foods: For the purpose of USDA's FPM, each item cluster is assigned a nutrient-dense representative food which are those foods or beverages that represent the forms with the least amounts of added sugars, sodium, and saturated fats. The nutrient composition of the nutrient-dense representative food is used to represent the nutrient composition of the entire item cluster when calculating the nutrient profile for a food group or subgroup.

Nutrient-Dense Foods and Beverages: Nutrient-dense foods and beverages provide vitamins, minerals, and other health-promoting components and have little added sugars, saturated fat, and sodium. Vegetables, fruits, whole grains, seafood, eggs, beans, peas, and lentils, unsalted nuts and seeds, fat-free and low-fat dairy products, and lean meats and poultry—when prepared with no or little added sugars, saturated fat, and sodium—are nutrient-dense foods.

Nutrient Profiles: The proportional nutrient composition from the item clusters that represent each food group and subgroup from the variety of foods in each food group in their nutrient-dense forms. The nutrient profiles are based on a weighted average of nutrient-dense forms of foods (i.e., a composite of nutrient-dense forms of foods and beverages within a food group or subgroup). The weighted average calculation considers a range of food choices in the United States, but in nutrient-dense forms and results in a food pattern that can be adapted to fit an individual's preferences.

Simulation: Simulation is a systems science method that has been defined as "a mathematical model that describes or recreates computationally a system process." In USDA FPM, simulation is used to create computationally thousands of daily diets that meet the recommended dietary pattern by randomly selecting foods and beverages from a set of food and beverage items using a predefined probability of selection for each item.

Develop an analytic plan

Establish energy levels:

Dietary Reference Intakes (DRI) formulas are used to calculate Estimated Energy Requirements (EER) for each age-sex group¹⁰ (See **Table 1**.) EER is based on sex, age, height, weight, level of physical activity, and life stage and, during pregnancy, gestational weeks.

Computed weight for a body mass index (BMI) of 22.5 kg/m² for adult males and 21.5 kg/m² for adult females and median height are used to calculate reference energy levels for each age-sex group.² The computed weight based on the corresponding BMI is obtained using the following equation:

These BMIs correspond to the 50th percentile (median) for reference weight among 19-year-old males and females based on the 2005 DRI for energy and the 2000 CDC Growth Charts. 11,12 The EER calculations for adults follow the 2020 Committee's approach to base reference weight on a BMI of 18.5 and <25 kg/m² but are enhanced to incorporate median heights for each age-sex group using updated NHANES data instead of using one median height for all adult males and one median height for all adult females. 13,14 For children and adolescents ages 2-18 years, median height and the 50th percentile BMI-for-age are obtained using NHANES anthropometric data and the CDC Growth Charts. 14,15 For young children 12 through 23 months, EERs from the DRI report using NHANES median weight and length are used, as these results in similar calorie levels as WHO Growth Chart data. 10,16 These weight, height/length, and BMI assumptions for estimating energy levels in FPM align with those being used in the Committee's data analysis work. The use of median height/length also aligns with the DRI for energy report.¹⁰

A lower energy level (for inactive individuals) rounded to the nearest 200 calorie level and associated pattern is determined for each age-sex group and used in evaluating the patterns against nutritional goals. (See Establish nutritional goals.) The 2020 USDA Dietary Patterns for ages 12 through 23 months are established to meet the EER for those ages. For ages 2 years and older, the 2020 Dietary Patterns generally are not age- or sex- specific. However, the 2020 Dietary Patterns at 1,000, 1,200, and 1,400 calorie levels are designed to meet the nutritional needs of children ages 2 through 8 years. Patterns from 1,600 to 3,200 calories are designed to meet the nutritional needs of children 9 years and older and adults. The 1,000 and 1.200 calorie level patterns are not intended for children 9 years and older or adults, and the 1.400-calorie level is not intended for children ages 10 years and older or adults. Individuals may require a calorie level that is higher or lower than the calorie level associated with each population-level age-sex group.

Table 1. Age-sex groups included in simulation analyses

Children (Male/Fe male)	Males	Females
1-3 years		
	4-8 years	4-8 years
	9-13 years	9-13 years
	14-18 years	14-18 years
	19-30 years	19-30 years
	31-50 years	31-50 years
	51+ years	51+ years

Establish nutritional goals:

Specific nutritional goals for each dietary intake pattern are set according to energy intake level and based on the DRI age-sex group(s) for which the pattern is designed. Goals for total energy, fat, protein, carbohydrates, 3 fatty acids, 12 vitamins, 8 minerals, added sugars, and fiber are based on DRI reports released between 1997 and 2023 and on quantitative recommendations in the current Dietary Guidelines for Americans, 2020-2025.^{2,10,17-19} The macronutrients, fatty acids, vitamins, and minerals are specified in **Table 2**. Because the simulated diets are designed as a framework for evaluating the variability in energy and nutrient intakes in a population, the goals include a low percent (<10%) of simulated diets below the EAR amounts for nutrients having an EAR. This differs from use of the RDA in developing the dietary pattern as an intake for individuals to achieve. When an EAR is not established, the Adequate Intake (AI) is used to evaluate the simulated diets, with the nutritional goal being a median nutrient content for simulated diets at or above the Al. Nutritional goals also include a low percent of simulated diets exceeding the UL for nutrients or CDRR for sodium; a low percent of simulated diets outside the AMDR for carbohydrate, protein, and total lipid content; less than 10 percent of energy from simulated diets from saturated fatty acids and added sugars; and the median energy content at or below the Estimated Energy Requirements for the age-sex group. The lowest energy level (for inactive individuals, determined in step 1) rounded to the nearest 200 calorie energy level and associated pattern is determined for each age-sex group and used in evaluating the simulated diets against nutritional goals.

Table 2. Nutritional goals for simulation analyses

Food Component	Specific Nutrients (and Source of Goal ^a)				
Energy	Energy (EER)				
Macronutrients	Carbohydrate (AMDR/RDA), Protein (AMDR/RDA), Total Lipid (AMDR)				
Fatty acids	Saturated Fatty Acids (DGA 2020-2025, <10% of total calories), 18:2 Linoleic Acid (AI), 18:3 Linolenic Acid (AI)				
Vitamins	Vitamin A (EAR), Vitamin C (EAR), Vitamin D (EAR), Vitamin E (EAR), Vitamin K (AI), Thiam (EAR), Riboflavin (EAR), Niacin (EAR), Vitamin B6 (EAR), Folate (EAR), Vitamin B12 (EAR), Choline (AI)				
Minerals	Calcium (EAR), Copper (EAR), Iron (EAR), Magnesium (EAR), Phosphorus (EAR), Potassium (AI), Sodium (CDRR), Zinc (EAR)				
Added Sugars	Added Sugars (DGA 2020-2025, <10% of calories)				
Fiber	Total Dietary Fiber (AI, 14g/1,000 calories)				

^a AI = Adequate Intake, AMDR = Acceptable Macronutrient Distribution Range, CDRR = Chronic Disease Risk Reduction Intake, DGA 2020-2025 = Dietary Guidelines for Americans, 2020-2025, EAR = Estimated Average Requirement

Establish the food groupings and amounts used in the evaluation:

The food group and subgroup amounts recommended by the 2025 Committee for the proposed dietary patterns for ages 12 months and older are evaluated considering variability in dietary intake across the age groups.

Establish criteria for the foods and beverages included in diet simulation:

The Dietary Guidelines for Americans recommends consuming primarily nutrient-dense foods to meet the amounts recommended for food groups and subgroups in a dietary pattern. The diet simulation analyses also focus on nutrient-dense foods to construct daily diets of different combinations of foods and beverages in the amounts recommended. For this protocol, nutrient-dense is defined as foods lower in saturated fat and/or added sugars.

Criteria are established to identify foods and beverages higher in saturated fat and added sugars among all foods and beverages in FNDDS that contribute to a food group or subgroup. The foods and beverages identified are then selected with a lower probability in the random selection of foods and beverages in simulation.

The criteria to identify foods higher in saturated fat and foods higher in added sugars are based on the proposed Food and Drug Administration (FDA) criteria for determining eligibility for foods and beverages to bear a Dietary Guidance Statement* but with less restrictive saturated fat criteria for meats, cheese, and soy alternatives of cheese based on Canada's Food Guide Classification System. † Less restrictive saturated fat and added sugars criteria for larger standard portion sizes are also applied based on Canada's Food Guide Classification System. In addition, Canada's Food Guide Classification System has been previously used to identify foods and beverages included in diet simulations.

The following criteria are applied to the Food and Nutrition Database for Dietary Studies (FNDDS) to identify foods and beverages defined as high in saturated fat and/or added sugars per standard portion amount consumed (e.g., Reference Amount Customarily Consumed or portion most frequently or typically consumed):

For foods and beverages with a standard portion ≤30 grams:

>25% of the Daily Value (>5 g) of **saturated fat** per standard portion[‡] for meats, cheese, and soy alternatives of cheese; >10% of the Daily Value (>2 g) of **saturated fat** per standard portion for all other foods and beverages

OR

>10% of the Daily Value (>5 g) of **added sugars** per standard portion

Exceptions: For fats and oils: higher in saturated fat is defined as >30% of total fat from saturated fat; saturated data criteria are not applied to nuts and seeds. Other exceptions may be applied and will be reported in the final analyses.

For foods and beverages with a standard portion >30 grams:

>25% of the Daily Value (>5 g) of **saturated fat** per standard portion for meats, cheese, and soy alternatives of cheese; >15% of the Daily Value (>3 g) of **saturated fat** per standard portion for all other foods and beverages

OR

>15% of the Daily Value (>7.5 g) of **added sugars** per standard portion

Exceptions: For fats and oils: higher in saturated fat is defined as >30% of total fat from saturated fat; saturated fat criteria are not applied to nuts and seeds. Other exceptions may be applied and will be reported in the final analyses.

^{*} Draft Guidance for Industry: Questions and Answers About Dietary Guidance Statements in Food Labeling (fda.gov)

^{† 2019-}canada-food-guide-food-classification-system-development-validation.pdf

[‡] Canada's Food Classification System is based on Reference Amounts and FDA Draft Guidance is based on Reference Amounts Customarily Consumed

Establish the probability of selection of food and beverages in diet simulation analyses:

The probability that each individual food and beverage will be randomly selected in the simulation analysis to construct daily diets will vary by nutrient-density with respect to saturated fat and added sugars. For nutrient-dense foods and beverages (not identified as higher in saturated fat or added sugars), the probability of selection will be equal. For foods and beverages identified as higher in saturated fat and/or added sugars, the probability of selection will be lower than the probability of nutrient-dense foods. An exception to setting a lower probability of selecting foods higher in saturated fat will be applied for children ages 12 through 23 months to include in simulated diets items such as whole fat dairy and soy products.

Disaggregate multi-ingredient foods to individual ingredients:

Multi-ingredient foods are disaggregated into individual component ingredients, which are assigned to their respective food group or subgroup to be included in the random selection of foods and beverage in diet simulation.

Simulate dietary intake data to randomly select foods and beverages to meet proposed dietary patterns:

Simulation of individual foods and beverages, including the ingredients of mixed-ingredient foods, is conducted to construct at least 500 7-day diets for each age or age-sex group. Each simulated daily diet will meet the amounts per food group and subgroup recommended in the proposed dietary pattern for the age-sex group. For each age or age-sex group, the random selection of foods and beverages in appropriate amounts will be among all food and beverages included in FNDDS that contribute to a food group or subgroup. Some foods and beverages considered not appropriate for a specific age group (e.g. foods that are choking hazards for young children) will be removed before constructing simulated diets for the age group.

For the simulations of foods and beverages identified as integral to and included in the cuisine of American Indian populations and in the cuisine of Alaska Native populations, foods and beverages included in FNDDS and coded as "integral to the cuisine" or "eaten but not integral to the cuisine" by experts with professional and lived experience in each culture will be simulated to meet the amounts per food group and subgroup recommended in the proposed dietary pattern for the age-sex group. Food and beverages identified as "never consumed as part of the cuisine" will be excluded from simulation analyses. The simulation will be conducted separately for the American Indian population and for the Alaska Native population. For these analyses, larger age groupings may be necessary.

Calculate the energy and nutrient content distributions of the simulated diets for each age-sex group:

The percentile distributions of energy and nutrient content of simulated diets for each age-sex group will be determined using the composition data for each food and beverage included in the 3,500 daily simulations per age-sex group.

Evaluate the energy and nutrient content of simulated diets against nutritional goals:

The energy and nutrient distributions of simulated diets for each age-sex group are compared to the age, sex, and life stage-specific goals (for example, no more than 10% of simulated diets below the EAR for a nutrient or a median nutrient content at or above the AI).

The percentile distributions are evaluated against all nutritional goals to answer the question:

"Do simulated diets that meet the updated USDA Dietary Patterns and reflect variation in dietary intakes achieve nutrient adequacy?"

The results of those analyses will determine if the proposed dietary patterns will be revised to meet nutritional goals when variety of dietary selections is considered.

Iteration and re-evaluation of the patterns to align with current or potential recommendations:

Any nutrient goals that were not feasible to meet within the structure of the dietary patterns will be identified and potential health impacts will be considered by the Committee. Food group amounts and modifications will be based on expert judgement of which food groups could most reasonably provide the nutrients when goals were not met. New food groups and subgroups may be modeled to aim towards achieving a potential recommendation reflected in the systematic reviews. All modifications to food groups or subgroups will be balanced within energy constraints. To reduce possible bias in modifying food group amounts, food group and subgroup amounts in the patterns will be evaluated against usual intake distributions and limited to amounts between median and 95th percentiles of usual intakes, or in the case of overconsumed components, between the median and the 5th percentiles of usual intake.

Conduct analyses

The USDA contractor, in collaboration with the USDA FPM Methods Team and the Committee, will use the analytic framework and analytic plan as a guide for conducting analyses and preparing tables and reports describing the analytic results for each analysis.

The first level of analysis will be for the U.S. population age 12 months and older with results described for each age-sex group. A subsequent analysis will be based on foods and beverages identified as integral to and included in the cultural cuisines of American Indian and Alaska Native populations. For these analyses, age groups may include a wider range of ages. Depending on the available data, subsequent analyses may be based on other population groups.

Synthesize analyses

The Committee will describe, compare, and combine the evidence from all FPM analyses conducted to answer these FPM questions. Synthesis of the analyses will involve summarizing results with particular emphasis on implications for each life stage. Implications for each of the existing USDA Dietary Patterns or rationale for new pattern development, including energy levels, will also be included.

The analyses related to each individual protocol, along with the results of simulated diet analyses, related systematic review evidence, and related data analysis findings will be considered together in answering the primary question.

Develop conclusion

The Committee will review and discuss the synthesis of the analyses to develop conclusion statements for each FPM question. Conclusions from this protocol will be used along with conclusions from all other food pattern modeling protocols, the graded conclusions of any related systematic review, and related data analysis findings to collectively inform the Committee's advice on the development or refinement of healthy dietary patterns.

Recommend future research

The Committee will identify and document research gaps and methodological limitations throughout the FPM process. These gaps and limitations will be used to develop research recommendations that describe the research, data, and methodological advances that are needed to strengthen the process to test and develop

healthy dietary patterns. Rationales for the necessity of additional or stronger research may also be provided with the research recommendations.

Protocol amendments

No amendments to the protocol have been made at this time. Any future amendments will be documented below in Table 3.

Table 3. Protocol amendments

Date	Protocol change	Description
N/A	N/A	N/A

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The Committee members are involved in: establishing all aspects of the protocol, which presents the plan for how they are planning to examine the scientific evidence, including the development of an analytic framework and analytic plan; synthesizing analysis results; and writing conclusion statements. The analytic framework and plan provide details about the types of analyses that will be conducted, synthesized, and from which conclusions will be drawn to inform subsequent FPM questions and the Committee's advice on the development or refinement of healthy dietary patterns. The FPM Methods Team, with assistance from Federal Liaisons and Project Leadership, supports the Committee by facilitating, executing, and documenting the work necessary.

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