

# What are the implications for nutrient intakes when animal sources of foods and beverages contributing to the Dairy and Fortified Soy Alternatives and Protein Foods groups and subgroups are removed or replaced with plant sources within the Healthy Vegetarian Dietary Pattern?: Food Pattern Modeling Protocol

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## Rationale

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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.

Vegan diets may be adopted for various reasons and vary in composition, which may have implications on nutrient intakes. While current nationally representative data on the prevalence of vegetarian and vegan diets is not available and vegan food products are limited in national food composition databases, surveys estimate that the overall prevalence of vegetarian diets in the U.S. is low. Among U.S. adults, about 5% report following a vegetarian diet and 3% report following a vegan diet, which excludes all foods and beverages that originate from an animal source including dairy, meat, poultry, seafood, eggs, certain fats (e.g., lard, butter), and sometimes honey.<sup>1</sup>

The Healthy Vegetarian (H-VEG) Dietary Pattern from the *Dietary Guidelines for Americans 2020-2025* recommends food group and subgroup quantities to meet nutritional goals for individuals who consume a lacto-ovo vegetarian diet — which includes Dairy and Fortified Soy Alternatives, Fruits, Vegetables, Grains, and certain Protein Foods (i.e., Eggs; Soy Products; Nuts and Seeds; Beans, Peas, and Lentils) but excludes other Protein Foods (i.e., Meat, Poultry, and Seafood).<sup>2</sup> However, a unique vegan dietary pattern has not been examined in FPM or included in guidance since the *Dietary Guidelines for Americans, 2010*.<sup>3</sup> Supported by public interest, these FPM analyses to examine a vegan diet are part of a series of FPM analyses that will explore the potential for Dietary Patterns that more equitably represent the diverse range of population subgroup norms, preferences, and needs, including budgetary considerations.<sup>4</sup> For individuals who remove or replace food groups, such as in a vegan diet, special attention may be required to meet nutritional goals including iron, vitamin B12, DHA, iodine, vitamin D, calcium, and dietary protein. Previous FPM analyses indicate that it may be challenging for young children ages 12 through 23 months following the 2020 H-VEG Dietary Pattern to achieve recommendations for iron, potassium, vitamin E, and vitamin D, among other nutrients.<sup>5</sup>

Thus, the following FPM analyses are proposed to examine hypothetical modifications and implications on the nutritional composition and contributions of the 2020 H-VEG Dietary Pattern for ages 2 years and older when animal sources of foods and beverages contributing to the Dairy and Fortified Soy Alternatives and Protein Foods groups and subgroups are removed or replaced with plant sources. Separate protocols propose food group and subgroup modifications within the other food groups, including plant-source modifications for Protein Foods and Dairy and Fortified Soy Alternatives.<sup>6,7</sup> Results from each of these analyses will be synthesized with the results from all other FPM analyses of the 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 or if new dietary patterns are recommended.

## Introduction

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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.<sup>2,4</sup> 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 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 USDA 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 questions for analysis have been identified:

**What are the implications for nutrient intakes when animal sources of foods and beverages contributing to the Dairy and Fortified Soy Alternatives and Protein Foods groups and subgroups are removed or replaced with plant sources within the Healthy Vegetarian Dietary Pattern?**

The Committee will use FPM analyses to address this question, with support from USDA's FPM methods team. This protocol will establish the methods to model hypothetical modifications of the nutrient profiles and the Dairy and Fortified Soy Alternatives and Protein Foods quantities within the 2020 H-VEG Dietary Pattern and implications on meeting nutritional goals among individuals ages 2 years and older.

## 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 Patterns include recommended amounts to eat from five major food groups, including the Dairy and Fortified Soy Alternatives and Protein Foods groups. The 2020 H-VEG Dietary Pattern is the only Dietary Pattern currently available for a lacto-ovo vegetarian diet, which includes some animal-source foods (i.e., dairy and eggs) but excludes meats, poultry, and seafood.<sup>2</sup> Within the H-VEG Dietary Patterns intended for ages 2 years and older, the Dairy and Fortified Soy Alternatives group does not have any subgroups, and the Protein Foods group has four subgroups: Eggs; Beans, Peas, and Lentils; Nuts and Seeds; and Soy Products. Compared to the Healthy U.S.-Style (HUSS) Dietary Pattern, the H-VEG Dietary Pattern is higher in Soy Products; Beans, Peas, and Lentils; Nuts and Seeds; and Whole Grains. The USDA Food Pattern Equivalents Database (FPED) can be used to estimate the contribution of various foods and beverages to 37 food pattern components, including within the Protein Foods and Dairy and Fortified Soy Alternatives groups.<sup>8</sup>

The H-VEG Dietary Pattern recommends 2 ½ to 6 oz eq of Protein Foods per day for individuals ages 9 years and older and 1 to 2 oz eq per day for children ages 2 to 8 years.<sup>2</sup> Weekly recommendations are provided for Protein Foods subgroups, with the majority of oz eq provided by the Soy Products; Nuts and Seeds; and Beans, Peas, and Lentils subgroups. For Dairy and Fortified Soy Alternatives, the Dietary Pattern recommends 3 cup eq per day for individuals ages 9 years and older and 2 cup eq per day for children ages 2 to 8 years.<sup>2</sup>

The FPM analyses in this protocol expand and complement the work of the 2010 Committee. In the 2010 Committee's *Vegetarian Food Patterns: Food Pattern Modeling Analysis (Appendix E-3.3)*, scenarios for three plant-source food patterns, including a vegan pattern, were modeled.<sup>9</sup> The vegan pattern analysis removed all meats, poultry, fish, eggs, milk, and milk products from the base USDA Food Pattern and increased amounts

of soy products, cooked beans and peas, and nuts and seeds. All animal-source milk and milk products were replaced with calcium-fortified varieties of soy milk, rice milk, tofu, and soy yogurt. The vegan pattern was higher in dietary fiber, iron, magnesium, vitamin E, folate, and carbohydrates and lower in EPA, DHA, protein, zinc, and selenium compared to the base pattern. In addition, the vegan pattern met almost all nutrient goals at 12 calorie levels intended for the DRI age-sex groups for ages 1 year and older ( $\geq 90\%$  of the Recommended Dietary Allowance [RDA] or Adequate Intake [AI]), except for vitamin E, potassium, and choline. Of note, the AI for potassium decreased after these analyses were completed—for example, the AI for children ages 4 to 8 years decreased from 3,800 mg to 2,300 mg.<sup>10</sup> Choline, EPA, and DHA were named as potential nutrients of concern in patterns where fewer or no animal products are consumed, and fortified foods were determined to be necessary to achieve recommendations for vitamin B12, vitamin D, and calcium.

Based on the results from the 2010 Committee's FPM analyses, a vegan adaptation of the USDA Food Patterns was included in the *Dietary Guidelines for Americans, 2010*.<sup>3</sup> However, the 2015 Committee did not include a vegan adaptation of the pattern in their analyses and scientific report and, instead, analyzed a lacto-ovo vegetarian pattern since most self-reported vegetarians in What We Eat in America (WWEIA), National Health and Nutrition Examination Survey (NHANES) reported consumption of eggs and dairy.<sup>11</sup> Although a vegan adaptation of the lacto-ovo vegetarian pattern was not included, the *2015-2020 Dietary Guidelines for Americans* acknowledged that the pattern could be vegan if all dairy choices were comprised of fortified soy beverages (soymilk) or other plant-based dairy substitutes.<sup>12</sup> While the 2020 Committee introduced the H-VEG Dietary Pattern for young children ages 12 through 23 months, FPM analyses illustrate potential challenges with meeting nutritional needs for iron, potassium, vitamin E, and vitamin D, despite the use of nutrient-dense representative foods.<sup>5</sup> Restriction of additional foods or food groups or selection of less nutrient-dense foods may further impact the nutritional composition of the Dietary Pattern.

Previous systematic reviews have not specifically examined the relationship between consuming a vegan diet and health outcomes, though reviews on dietary patterns and health have included some data on vegetarian and vegan dietary patterns. Unfortunately, few studies that examine vegan diets and health outcomes are included in those reviews due to a lack of descriptive information about the foods consumed in the pattern, rather, define a vegan diet as avoidance of animal-source foods.

## Current perspectives

Intakes of plant-source food groups and subgroups—including Vegetables, Fruits, Whole Grains, and Beans, Peas, and Lentils—are below recommendations in the *Dietary Guidelines for Americans, 2020-2025*.<sup>2</sup> About 90% of individuals in the U.S. do not meet recommendations for the Dairy and Fortified Soy Alternatives group, and over 50% do not meet recommendations for intake of Nuts, Seeds, and Soy Products. In addition, over 80% do not meet recommendations for Beans, Peas, and Lentils.<sup>13</sup> Conversely, about 75% exceed or meet the intake recommendations for Meat, Poultry, and Eggs. Thus, the *Dietary Guidelines* recommends shifts within the Protein Foods group, such as selecting from the Beans, Peas, and Lentils subgroup more often, to add variety to subgroup intakes and increase the intake of dietary fiber.

The *Dietary Guidelines for Americans, 2020-2025* also identified calcium and vitamin D as nutrients of public health concern for all life stages and vitamin B12 and iron as potential nutrients of concern for some individuals consuming a vegan diet, including during pregnancy and lactation. Examples of food sources of calcium include milk, yogurt, fortified soy alternatives, and canned sardines and salmon.<sup>14</sup> Examples of food sources of vitamin D include seafood and vitamin D-fortified milk, fortified soy beverages, and mushrooms.<sup>15</sup> Vitamin B12 is only found in animal-source foods or certain fortified foods (e.g., nutritional yeast, breakfast cereals) and, thus, may be a concern when consuming a vegan diet, particularly among persons who are pregnant or lactating and older adults for whom absorption may be decreased.<sup>16</sup> Similarly, iron may be a concern for those following a vegan diet, since plant-source Protein Foods only contain non-heme iron, which is not absorbed as well by the body due to its lower bioavailability compared to heme iron and from potential interactions with other dietary components in plant-based foods, such as phytates and some polyphenols. Thus, the requirement for iron is 1.8 times higher for those who follow a vegetarian or vegan dietary pattern than those

who do not.<sup>17</sup> Healthcare providers may recommend supplementation for any of these nutrients to those at risk of deficiency. For individuals who are pregnant or lactating and follow a vegan diet, it is also recommended to discuss their needs for other nutrients such as choline, zinc, iodine, or EPA/DHA with a healthcare provider, including whether supplementation is necessary. Meeting nutritional goals for these and other nutrients is important to support growth and development during pregnancy and lactation as well as among children and adolescents. The Committee will use the data analysis scientific approach to examine the current consumption of nutrients and dietary fiber in the U.S. population.<sup>18</sup>

Nationally representative data on vegetarian and vegan diets was last collected by WWEIA, NHANES in 2009-2010 and indicated that 2% of U.S. adults consumed a vegetarian diet, with 3% of those self-identified vegetarians reporting no consumption of any animal products.<sup>19,20</sup> Current studies estimate that about 3% of all U.S. adults follow a vegan diet.<sup>1</sup>

Although the prevalence of vegetarian and vegan diets among the U.S. population is low, there is interest from the public, researchers, and subpopulations in substituting proportions of animal-source foods and beverages for plant sources to accommodate representation of cultural or religious norms (e.g., adoption of non-violence principles in Hinduism, Jainism, and Seventh-Day Adventism), dietary preferences (e.g., vegan diets for health, environmental, or moral reasons), budgetary considerations (e.g., food prices), and dietary needs (e.g., lactose malabsorption or food allergies). The 2010 Committee examined a vegan adaptation of the base food pattern, which was published in the *Dietary Guidelines for Americans, 2010*.<sup>3</sup> The 2015-2020 and 2020-2025 editions of the *Dietary Guidelines* included a lacto-ovo H-VEG Dietary Pattern only, which the *Dietary Guidelines for Americans, 2015-2020* acknowledged could be vegan if all dairy choices are comprised of fortified soy beverages or other plant-based dairy substitutes.<sup>2,12</sup>

This protocol describes a multi-phased approach for understanding if nutritional goals can be achieved for individuals ages 2 years and older when animal sources of foods and beverages contributing to the Dairy and Fortified Soy Alternatives and Protein Foods groups and subgroups are removed or replaced with plant sources within the 2020 H-VEG Dietary Pattern. Results from these analyses will be collectively synthesized by the Committee along with all other FPM analyses, including those modeling modifications of other food group and subgroup quantities to address intake variability at the food group and subgroup levels. In a separate protocol following these analyses, diet simulations will be used to examine intake variability at the individual food level. 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 will inform their recommendations for the 2025 USDA Dietary Patterns in their scientific report to the Secretaries of HHS and USDA.

## Methods

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

**What are the implications for nutrient intakes when animal sources of foods and beverages contributing to the Dairy and Fortified Soy Alternatives and Protein Foods groups and subgroups are removed or replaced with plant sources within the Healthy Vegetarian Dietary Pattern?**

## 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 or subsequent protocols.

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 will be described in **Table 7. Protocol amendments**.

## Develop an analytic framework

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

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### Question:

**What are the implications for nutrient intakes when animal sources of foods and beverages contributing to the Dairy and Fortified Soy Alternatives and Protein Foods groups and subgroups are removed or replaced with plant sources within the Healthy Vegetarian Dietary Pattern?**

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### Population:

The nutrient profiles modeled in these FPM analyses are based on dietary intake data among the U.S. population ages 12 months and older. They will be applied to the 2020 H-VEG Dietary Patterns published for children ages 2 years and older, adolescents, adults, and older adults and during pregnancy and lactation.<sup>2</sup>

### Types of analyses:

The overall FPM methodology used to develop and update the USDA Dietary 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; (5) evaluating nutrient levels in each pattern against nutritional goals; and (6) adjusting and re-evaluating the patterns to align with current or potential recommendations.

**This analysis question will focus on step 3 (establishing food groupings and food group amounts) and assess the implications of changes to step 3 throughout subsequent steps 4, 5, and 6.** Initial analyses will use existing food groups and subgroups identified in the 2020 USDA Dietary Patterns, published in the *Dietary Guidelines for Americans, 2020-2025*.<sup>2</sup> Nutrient profiles that underlie those patterns will be updated based on the 2025 Committee's analyses in answering the question: "*Should foods and beverages with lower nutrient density (i.e., those with added sugars, saturated fat, and sodium) contribute to item clusters, representative foods, and therefore the nutrient profiles for each food group and subgroup used in modeling the USDA Dietary Patterns? View the protocol developed by the 2025 Committee to answer that question.*"<sup>21</sup>

Separate analyses will model the implications of food group and subgroup modifications, including for Protein Foods and Dairy and Fortified Soy Alternatives, to accommodate plant-source Protein Foods and non-dairy alternatives within the 2020 H-VEG and HUSS Dietary Patterns. Details are available in the Committee's protocols for those questions.<sup>6,7</sup>

FPM analyses planned to answer this question include:

- Compare the nutrient profiles for the plant-source Protein Foods subgroups (Nuts and Seeds; Soy Products; Beans, Peas, and Lentils) to identify their nutritional contribution in the 2020 H-VEG Dietary Pattern. Nutrient profiles may be modified or combined for subsequent analyses in the protocol based on these results.

- Compare the nutritional composition of various plant-based meat alternatives. Examine the similarities and differences compared to the nutrient profiles for the plant-source Protein Foods subgroups in the 2020 Healthy Vegetarian Dietary Pattern.
- Evaluate the implications on meeting nutritional goals by when removing the Eggs subgroup and Dairy and Fortified Soy Alternatives group from each calorie level of the 2020 H-VEG Dietary Pattern. The nutritional composition of the Dietary Pattern will be examined.
- Evaluate the implications on meeting nutritional goals by 1) replacing Eggs with plant-source Protein Foods subgroups and/or other food groups, and 2) replacing Dairy and Fortified Soy Alternatives with fortified non-dairy alternatives. The nutritional composition of the Dietary Pattern will be examined.

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 or if additional dietary patterns should be proposed based on population norms, preferences, and needs.
- Examining modified or new dietary patterns for meeting nutritional goals compared to the DRIs, current *2020-2025 Dietary Guidelines* 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](https://ars.usda.gov/nea/bhnrc/fsrg)
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## Key definitions:

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 H-VEG Dietary Pattern.<sup>2,22</sup> The 2025 Committee will continue to consider terminology and implications of terms related to representation of population subgroups 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 Vegetarian (H-VEG) Dietary Pattern:** USDA's H-VEG Dietary Patterns for ages 12 through 23 months and ages 2 years and older provide amounts of five major food groups and subgroups including:

- Fruits
- Vegetables:
  - *Dark-Green; Red and Orange; Beans, Peas, and Lentils*<sup>a</sup>; *Starchy; and Other*
    - <sup>a</sup>. For the analyses in this protocol, Beans, Peas, and Lentils will be modeled in both the Vegetables and Protein Foods groups.
- Dairy and Fortified Soy Alternatives
- Grains:
  - *Whole Grains; Refined Grains*
- Protein Foods:
  - *Eggs; Beans, Peas, and Lentils*<sup>a</sup>; *Soy Products*<sup>b</sup>; *Nuts and Seeds*<sup>b</sup>
    - <sup>a</sup>. For the analyses in this protocol, Beans, Peas, and Lentils will be modeled in both the Vegetables and Protein Foods groups.

**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 vegetable 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.<sup>23</sup> 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 Dietary Pattern)<sup>2,22</sup>:** 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 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.

**Fortification (new for 2025):<sup>24</sup>** The addition of nutrients to a food to correct a dietary insufficiency; to restore nutrient(s) to a level(s) representative of the food prior to storage, handling, and processing; and/or to balance the vitamin, mineral and protein content in proportion to the total caloric content of the food. The terms "enriched," "fortified," or similar terms may be used interchangeably to indicate that one or more essential nutrients were added to a food unless an applicable Federal regulation requires the use of specific words or statements.<sup>25</sup> The standard of identity for milk notes that if vitamins A and D are added to milk, they shall be present in such a quantity that each quart contains  $\geq 2000$  IU of vitamin A and  $\geq 400$  IU of vitamin D.<sup>26</sup> The Dietary Guidelines for Americans, 2020-2025 notes that soy milk and yogurt included in the Dairy and Fortified Soy Alternatives food group were fortified with calcium, vitamin A and vitamin D in levels similar to dairy products.

**Soy Products (new for 2025):** Soy Products are foods made from soybeans that contribute to the Protein Foods group as a subgroup. Soy Products include tofu, tempeh, texturized vegetable protein (TVP), and processed soy products. Cooked soybeans or immature soybeans (i.e., edamame) are counted in the Beans, Peas, Lentils subgroup and do not contribute to the Nuts, Seeds, and Soy Products subgroup.

**Vegan diet (new for 2025):** For the purposes of these analyses, a vegan diet exclusively includes plant-source foods and beverages (e.g., Vegetables, Fruits, Grains, Soy Products, Nuts and Seeds, Beans, Peas, and Lentils, and Fortified Soy Alternatives) that contribute to food groups and subgroups, and excludes all animal-source foods and beverages (e.g., Dairy; Meat, Poultry, and Eggs; and Seafood) which contribute to food groups and subgroups. Animal-source ingredients that do not contribute to food groups and subgroups (e.g., gelatin, lard, honey) are not included in the calculation of the nutrient profiles and, thus, will not be identified in the Food and Nutrient Database for Dietary Studies (FNDDS) for exclusion in these analyses.

**Plant-based meat alternatives (new for 2025):** For the purposes of these analyses, plant-based meat alternatives are defined as plant-source Protein Foods that mimic animal-source Protein Foods in look, taste, feel, and nutritional contribution and are used as a meat substitute.

## Develop an analytic plan

### Establish energy levels:

Dietary Reference Intakes (DRI) formulas are used to calculate Estimated Energy Requirements (EER) for each age-sex group and for three age groups specific to pregnancy and lactation: 14 to 18 years, 19 to 30 years and 31 to 50 years.<sup>27</sup> (See **Table 1**.) EER is based on sex, age, height, weight, level of physical activity, and life stage and, during pregnancy, gestational weeks. The EERs for pregnancy account for the energy cost of tissue accretion and deposition based on pre-pregnancy BMI category and IOM recommended rates of gestational weight gain. The EERs for lactation account for the energy cost of human milk production and mobilization of postpartum tissue stores for gradual weight loss.<sup>2</sup>

Computed weight for a body mass index (BMI) of 22.5 kg/m<sup>2</sup> for adult males and 21.5 kg/m<sup>2</sup> for adult females (ages 19+ years) and median height are used to calculate reference energy levels for each age-sex group.<sup>2</sup> The computed weight based on the corresponding BMI is obtained using the following equation.

$$\text{BMI } 22.5 \text{ or } 21.5 \times (\text{median height in m})^2 = \text{computed weight in kg}$$

These BMIs correspond to the 50<sup>th</sup> 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.<sup>28,29</sup> The EER calculations for adults follow the 2020 Committee's approach to base reference weight on a BMI of 18.5 to <25 kg/m<sup>2</sup> 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.<sup>5,30</sup> For children and adolescents ages 2-18 years, median height and the 50<sup>th</sup> percentile BMI-for-age are obtained using NHANES anthropometric data and the CDC Growth Charts.<sup>30,31</sup> For young children ages 12 through 23 months, EERs from the DRI report using NHANES median weight and length are used, as these result in similar calorie levels as WHO Growth Chart data.<sup>27,32</sup> 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.<sup>27</sup>

A lower energy level (for inactive individuals) rounded to the nearest 200 calorie level and its associated pattern are determined for each age-sex group and used in evaluating the patterns against nutritional goals. (See step 2: **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 for which nutritional goals are examined in analyses**

Children (Male/Female)	Males	Females	Pregnancy (Per 1 <sup>st</sup> , 2 <sup>nd</sup> , and 3 <sup>rd</sup> Trimesters)	Lactation (Per 0-6 and 7-12 months postpartum)
1-3 years				
	4-8 years	4-8 years		
	9-13 years	9-13 years		

Children (Male/Female)	Males	Females	Pregnancy (Per 1 <sup>st</sup> , 2 <sup>nd</sup> , and 3 <sup>rd</sup> Trimesters)	Lactation (Per 0-6 and 7-12 months postpartum)
	14-18 years	14-18 years	14-18 years	14-18 years
	19-30 years	19-30 years	19-30 years	19-30 years
	31-50 years	31-50 years	31-50 years	31-50 years
	51+ years	51+ years		

## Establish nutritional goals:

Specific nutritional goal quantities for a 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 dietary fiber are based on DRI reports released between 1997 and 2023 and on quantitative recommendations in the current *Dietary Guidelines for Americans, 2020-2025* (DGA).<sup>2,10,16,27,33</sup> The macronutrients, fatty acids, vitamins, and minerals that are considered nutritional goals for these analyses are specified in **Table 2**. Because the dietary patterns are designed as a framework for achieving a healthy dietary pattern, the goals are the Recommended Dietary Allowance (RDA) amounts for nutrients having an RDA. The Adequate Intake (AI) is used as the nutrient goal when an RDA is not established.

**Table 2. Nutritional goals for analyses**

Food Component	Specific Nutrients (and Source of Goal <sup>a</sup> )
Energy	Energy (EER)
Macronutrients	Carbohydrate (AMDR/RDA), Protein (AMDR/RDA), Total Fat (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 (RDA), Vitamin C (RDA), Vitamin D (RDA), Vitamin E (RDA), Vitamin K (AI), Thiamin (RDA), Riboflavin (RDA), Niacin (RDA), Vitamin B6 (RDA), Folate (RDA), Vitamin B12 (RDA), Choline (AI)
Minerals	Calcium (RDA), Copper (RDA), Iron (RDA), Magnesium (RDA), Phosphorus (RDA), Potassium (AI), Sodium (CDRR), Zinc (RDA)
Added Sugars	Added Sugars (DGA 2020-2025, <10% of total calories)
Dietary Fiber	Total Dietary Fiber (AI, 14g/1,000 calories)

<sup>a</sup> AI = Adequate Intake, AMDR = Acceptable Macronutrient Distribution Range, CDRR = Chronic Disease Risk Reduction Level, DGA 2020-2025 = *Dietary Guidelines for Americans, 2020-2025*, RDA = Recommended Dietary Allowance

## Establish food groupings and amounts:

Food groups and subgroups in the USDA H-VEG Dietary Pattern for ages 2 years and older (published in the *Dietary Guidelines for Americans, 2020-2025*) will be used in these analyses, along with the Protein Foods and

Dairy and Fortified Soy Alternatives modifications outlined below, to examine their impacts on meeting nutritional goals across the Dietary Pattern.<sup>2</sup>

Analysis on the nutritional contribution of the plant-source Protein Foods subgroups:

- Objective 1: Compare the nutrient profiles for the plant-source Protein Foods subgroups (Nuts and Seeds; Soy Products; Beans, Peas, and Lentils) to identify their nutritional contribution in the 2020 H-VEG Dietary Pattern. Nutrient profiles may be modified or combined for subsequent analyses in the protocol based on these results.
- Objective 2: Compare the nutritional composition of various plant-based meat alternatives. Plant-based meat alternatives for this analysis will be selected by assessing the availability and usability of product nutrient composition data in USDA FoodData Central before determining which food codes will be used. Examine the similarities and differences compared to the nutrient profiles for the plant-source Protein Foods subgroups in the 2020 H-VEG Dietary Pattern.

Analyses modifying nutrient profiles and food group/subgroup quantities:

- Objective 3: Evaluate the implications on meeting nutritional goals by when removing the Eggs subgroup and Dairy and Fortified Soy Alternatives group from each calorie level of the 2020 H-VEG Dietary Pattern. The nutritional composition of the Dietary Pattern will be examined.
- Objective 4: Evaluate the implications on meeting nutritional goals by 1) replacing Eggs with plant-source Protein Foods subgroups and/or other food groups, and 2) replacing Dairy and Fortified Soy Alternatives with fortified non-dairy alternatives. These analyses will model hypothetical scenarios to represent potential quantities of consumption within vegan diets. The nutritional composition of the Dietary Pattern will be examined.
  - Ingredients that do not contribute to food groups and subgroups (e.g., gelatin, lard, honey) will not be identified in the FNDDS database for exclusion in this analysis.
  - The Protein Foods group will comprise subgroups for Beans, Peas, and Lentils; Soy Products; and Nuts and Seeds in the Dietary Patterns. Based on the analysis results from objective 1, the nutrient profiles may be modified or combined.
  - The Dairy and Fortified Soy Alternatives group will utilize a nutrient profile that includes fortified non-dairy alternatives and excludes animal-source dairy. The proportions of fortified non-dairy milk, yogurt, and/or cheese will be determined based on the analysis results from the Committee's protocol examining modifications to the Dairy and Fortified Soy Alternatives group.<sup>6</sup>
  - Several scenarios to be modeled using the 2020 H-VEG Dietary Pattern's 1,400 calorie level as an example, along with the quantities from each food group and subgroup, are described in **Table 4**.

**Table 3. Cup equivalents (cup eq) of fortified non-dairy alternatives and ounce equivalents (oz eq) of plant-source Protein Foods subgroups per week<sup>a</sup> to be modeled when Eggs and Dairy and Fortified Soy Alternatives are replaced within the 1,400-calorie level of the 2020 Healthy Vegetarian (H-VEG) Dietary Pattern (Objective 4)<sup>b</sup>**

Scenario	Total Fortified Non-Dairy Alternatives (Plant Source)	Eggs (Animal Source)	Soy Products (Plant Source)	Nuts and Seeds (Plant Source)	Beans, Peas, and Lentils (Plant Source)	Total Protein Foods (All Subgroups)	Proportion from Animal-Source Food Groups/ Subgroups	Proportion from Plant-Source Food Groups/ Subgroups
<b>Current Pattern (Lacto-Ovo Reference)</b>	17.5	3	4	3	4	14	7%	90%
<b>Vegan 1 (Eggs redistributed as Soy Products)</b>	17.5	0	7	3	4	14	0%	100%
<b>Vegan 2 (Eggs redistributed as Nuts and Seeds)</b>	17.5	0	4	6	4	14	0%	100%
<b>Vegan 3 (Eggs redistributed as Beans, Peas, and Lentils)</b>	17.5	0	4	3	7	14	0%	100%
<b>Vegan 4 (Eggs redistributed among all plant-based Protein Foods subgroups)</b>	17.5	0	5	4	5	14	0%	100%
<b>Vegan 5 (Eggs and Soy Products redistributed as Beans, Peas, and Lentils)</b>	17.5	0	0	4	11	14	0%	100%

<sup>a</sup> The H-VEG Dietary Pattern recommends a daily amount from the Dairy and Fortified Soy Alternatives food group and weekly amounts for the Protein Foods subgroups. However, for the purposes of this analysis, the daily amount for Dairy and Fortified Soy Alternatives (2 ½ cup eq for the 1,400-calorie pattern) was converted into a weekly amount for Fortified Non-Dairy Alternatives to align with the weekly Protein Foods subgroups recommendations being examined.

<sup>b</sup> This table shows just one example of several scenarios that will be modeled.

## Determine the amounts of nutrients that would be obtained by consuming various foods within each group:

The anticipated energy and nutrient content, or nutrient profile, of each food group and subgroup will be determined based on the synthesis of results of the planned 2025 analyses to answer the question:

*Should foods and beverages with lower nutrient density (i.e., those with added sugars, saturated fat, and sodium) contribute to item clusters, representative foods, and therefore the nutrient profiles for each food group and subgroup used in modeling the USDA Dietary Patterns?*

The results of those analyses will determine if a “composite” system will be used to determine the nutrient profiles, or if a revised approach will be used which removes foods and beverages lower in nutrient density from contributing to the development of healthy dietary patterns.

For more information on the work planned for this question, view the protocol developed by the 2025 Committee on [DietaryGuidelines.gov](https://www.dietaryguidelines.gov).<sup>21</sup>

## Evaluate nutrient level in each pattern against nutritional goals:

Using the revised nutrient profiles that apply to young children less than 2 years and the population 2 years and older, the nutrients provided by amounts recommended in the *Dietary Guidelines for Americans, 2020-2025* from each food group (and oils) are compared to the age, sex, and life stage-specific goals (usually at least 90% of the RDA or AI).

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

Any nutritional 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. Calories from all food groups, subgroups, and oils, termed “essential calories,” will then be summed, and the remaining calories up to the calorie limit for the pattern will be used to set limits on calories for other uses.

## Conduct analyses

The USDA FPM methods team, in collaboration with 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 by population, with results described for each age-sex group and life stage (e.g., pregnancy and lactation). Depending on the available data, subsequent analyses may be based on population subgroups, race and/or ethnicity, and/or socioeconomic position.

## Synthesize analyses

The Committee will describe, compare, and combine the evidence from all FPM analyses conducted to answer this FPM question. Synthesis of the analyses will involve summarizing results with particular emphasis on

implications for each life stage: infants, children, adolescents, adults, older adults, and individuals who are pregnant or lactating. Implications for each of the existing USDA Dietary Patterns or rationale for new pattern development, including energy levels, will also be included.

The analyses from 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 FPM 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 model 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 4**.

**Table 4. 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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