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What are the implications for nutrient intakes when modifying the Dairy and Fortified Soy group quantities within the Healthy U.S.-Style Dietary Pattern? What are the implications for nutrient intakes when dairy food and beverage sources are replaced with non-dairy alternatives?: Food Pattern Modeling Protocol

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Table of contents

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 Dairy and Fortified Soy Alternatives group includes fluid, dry, or evaporated cow milk, including lactose-free and lactose-reduced products, as well as fortified soy beverages (soy milk), buttermilk, yogurt, fortified soy yogurt, kefir, frozen yogurt, dairy desserts, and cheeses. The 2020 Healthy U.S.-Style (HUSS) Dietary Pattern recommends 3 cup equivalents (cup eq) of Dairy and Fortified Soy Alternatives per day for individuals ages 9 years and older.[1] Recommended quantities are less for children under 9 who have lower energy as well as calcium needs. Most choices from the Dairy and Fortified Soy Alternative should be fat-free or low-fat. The exception to this is for young children 12 through 23 months, for which whole-fat milk is recommended along with options for reduced fat yogurts and cheeses, or fortified soy alternatives.

The Dairy and Fortified Soy Alternatives group does not include cream cheese, sour cream, cream, and butter, because these foods have little calcium and/or a high fat content. While this food group includes fortified soy beverages, it does not include other non-dairy alternatives marketed as “milks” that are made from plants (e.g., almond, rice, coconut, oat, and hemp “milks”), regardless of calcium fortification, because their nutritional content is not equivalent to dairy milk and fortified soy beverages.

Dairy and Fortified Soy Alternatives are sources of calcium, potassium, and vitamin D. Inadequate intakes of these nutrients are of public health concern for the general U.S. population. Additionally, most Americans do not meet the current daily quantitative serving recommendations for the Dairy and Fortified Soy Alternatives food group.[1] Reasons for consuming below recommended intakes include individuals’ dietary preferences, gastrointestinal sensitivities owing to lactose malabsorption, and milk and soy allergies.

The following food pattern modeling analyses are proposed to examine hypothetical modifications and implications for meeting nutrient goals using the HUSS Dietary Pattern when: 1) quantities of the Dairy and Fortified Soy Alternatives food group are modified from a range of 0 to the current quantities recommended in the HUSS Dietary Pattern (which ranges from 1 ½ to 3 cup eq per day), 2) proportions of potential subgroups are modified within the recommended total amount (i.e., milk [dairy and fortified soy], cheese, and yogurt [dairy and fortified soy]), 3) foods within the food group are replaced with non-dairy alternatives. The nutrient intake implications of these modifications will be examined across age groups and life stages.

The rationale for evaluating hypothetical reductions and/or modifications to this food group is supported by the prevalence lactose malabsorption, cow milk allergies, and public request.[2] Specifically, we sought to examine the potential flexibility for a recommendation that more equitably represent the range of population subgroup norms, preferences, and needs.[2] These analyses will inform whether a) nutrient goals can be achieved at daily intakes below the current recommendations (i.e., ranging from 1 ½ to 3 cup eq per day), b) recommendations for dairy subgroups (i.e., fluid milk and fortified soy, cheese, and yogurt) should be included, and c) nutrient goals can be met through intakes of non-dairy alternatives that are not currently included in the Dairy and Fortified Soy Alternatives food group. These analyses will examine hypothetical modifications and the implications on meeting nutritional goals across the lifespan. Separate protocols propose food group and subgroup modifications within the other food groups and will address any unmet nutritional goals identified in the Dairy and Fortified Soy Alternatives analyses. 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

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. [1,2] 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 questions for analysis have been identified:

> **What are the implications for nutrient intakes when modifying the Dairy and Fortified Soy group quantities within the Healthy U.S.-Style Dietary Pattern?**
>
> **What are the implications for nutrient intakes when dairy food and beverage sources are replaced with non-dairy alternatives?**

The Committee will use FPM analyses to address these questions, with support from USDA's FPM methods team. This protocol will establish the methods to model hypothetical modifications of the Dairy and Fortified Soy Alternatives group within the current HUSS Dietary Pattern and implications on meeting nutritional goals.

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, one of which is Dairy and Fortified Soy Alternatives. This food group does not contain subgroups, therefore, there are no quantitative recommendations or guidelines that discuss the amount of fluid milk/fortified soy beverage, yogurt/fortified soy yogurt, or cheese that can be accommodated in an overall healthy dietary pattern.

Due to a variety of reasons, some individuals do not or cannot consume dairy from animal sources. Beginning with the *2000 Dietary Guidelines for Americans*, calcium-fortified soy beverages were recognized as a feasible

source of calcium in the diet.[3] The *Dietary Guidelines for Americans, 2020-2025*, was the first to include both fortified soy beverages and soy yogurt as components of the Dairy and Fortified Soy Alternatives food group.[1]

The 2020 HUSS Dietary Pattern recommends 3 cup eq of Dairy and Fortified Soy Alternatives per day for individuals ages 9 years and older.[1] Recommendations for children under 9 are: 2 ½ cup eq for those 4 to 8 years 2 cup eq for those 2 and 3 years; and between 1 ½ to 2 cup eq per day for those 12 through 23 months who are no longer receiving human milk, due to lower energy and calcium needs.

The analyses in this protocol expand upon the FPM work of the 2010 Committee: *Appendix E-3.6 Milk Group and Alternatives: Food Pattern Modeling Analysis*, which explored questions related to this protocol.[4] These questions explored the impact on nutrient goals when no milk or milk products were consumed and when calcium was obtained from non-dairy sources or fortified foods. They also explored which non-dairy calcium sources or fortified foods were the most feasible alternatives to milk products for those who choose not to consume dairy foods. At the time, the non-dairy foods and beverages included were calcium-fortified soy milk, calcium-fortified rice drink, calcium-fortified orange juice, canned sardines with bones, salmon, tofu made with calcium sulfate, almonds, white beans, and dark-green leafy vegetables. Finally, they explored how the nutrients provided by the milk group would change if more low-fat and fat-free fluid milk and less cheese were consumed. The results of these analyses suggested that without the inclusion of dairy or non-dairy alternatives, there were negative implications for nutrient goals for calcium and potassium as well as several other nutrients. The comparison of non-dairy alternatives resulted in the formal inclusion of calcium fortified soy beverage (soy milk) in the food group (previously named “Milk and Milk Products”). Of note, the AI for potassium decreased after these analyses were completed—for example, the AI for females ages 19 to 30 years decreased from 4,700 mg to 2,600 mg.[5]

Past Committees have also explored the consumption of this food group in relation to health outcomes through various systematic reviews. Several systematic reviews found strong or moderate evidence in adults and older adults that consuming a healthy dietary pattern (which included low-fat dairy as a component) may reduce the risk of cardiovascular disease,[6] lung cancer,[7] and colorectal cancer,[7] and is also associated with favorable bone health outcomes.[8] Evidence also suggested that dietary patterns lower in high-fat dairy are associated with reduced risk of all-cause mortality[9] and type 2 diabetes.[10]

In addition, the 2010 Committee found moderate evidence indicating no relationship between intake of calcium and/or dairy and adiposity in children and adolescents.[11] The 2020 Committee built on this work when examining the relationship between milk intake alone and adiposity in both children and adults, finding limited evidence of no association.[12] Limited evidence suggested that higher milk intake (vs. lower) is associated with greater increase in height in children.[12] Another review found both moderate and limited evidence that lowering consumption of cow milk products during pregnancy does not reduce the risk of atopic dermatitis/eczema and asthma in the child.[13] This review also found insufficient or no evidence on the relationship between maternal cow's milk product intake during pregnancy and/or lactation and other allergy and atopic diseases. During early-childhood, limited evidence was found between the age of introduction of cow milk products, such as cheese and yogurt, and risk of food allergy and atopic dermatitis/eczema.[14] Finally, insufficient evidence was found to draw conclusions about the relationship between childhood milk intake by type of milk (i.e., milk fat content, flavor) and adiposity; the relationship between milk intake during pregnancy and birth weight outcomes; and the relationship between cow’s milk products for infants and risk of asthma or allergic rhinitis.[12,13]

In addition to this and other FPM analyses, the 2025 Committee is also planning systematic reviews to study the relationship between healthy dietary patterns and various health outcomes, the results of which may or may not include various types of dairy and non-dairy alternatives as dietary components. There are also two

planned systematic reviews on the relationships between consumption of dairy milk and milk alternatives and growth, body composition, and risk of obesity as well as for risk of type 2 diabetes.[15,16]Finally, the Committee is also considering dairy as part of the systematic review question on food sources of saturated fat and risk of cardiovascular disease. These systematic review results will be considered when the Committee synthesizes the full body of evidence to determine their overall advice on potential dietary pattern changes and/or newly recommended dietary patterns.

Current perspectives

The *Dietary Guidelines for Americans, 2020-2025*, highlighted the concern around the underconsumption of the Dairy and Fortified Soy Alternatives food group, noting that about 90% of individuals in the U.S. did not meet recommendations.[1] Furthermore, the foods and beverages generally consumed from this group were in forms with higher amounts of sodium (e.g., cheeses as part of mixed dishes such as sandwiches, pizza, and pasta dishes) and saturated fat (e.g., higher fat milks and yogurts) and can be a source of added sugars such as flavored milk, ice cream, and sweetened yogurts.[17] Data analysis used to support the development of the 2020-2025 edition showed average intakes of the food group was about 1.6 cup eq for those 2 and older, though there were notable differences between age and race and/or ethnic groups.[18]

The Dairy and Fortified Soy Alternatives food group has been identified as a separate food group because it is the primary source of dietary calcium, a nutrient of public health concern in the United States, as well as a major source of other nutrients of concern—vitamin D and potassium. Many individuals have intakes below the Estimated Average Requirement (EAR) or AI for these nutrients, with notable differences in calcium and potassium intake between race and/or ethnic groups and between persons from various socioeconomic positions.[19-26] Vitamin D intakes showed less variability between population subgroups since nearly all fall below the EAR due in part to vitamin D being a nutrient that has few dietary sources in the absence of fortification. Dairy and Fortified Soy Alternatives also provide sources of protein beyond the Protein Foods group. While most individuals meet protein needs, there are certain life stages (e.g., older adults and adolescents) when low protein intakes are a concern. The analyses in this protocol will be based on the established nutritional content of foods and beverages in the Dairy and Fortified Soy Alternatives food group.

This protocol describes a multi-phased approach to understand the implications on nutrient goals if different amounts of the Dairy and Fortified Soy Alternatives group are consumed compared to what is currently recommended or if individuals make different choices than the foods currently included in the Dairy and Fortified Soy Alternatives group.

Given that current intakes of the Dairy and Fortified Soy Alternatives group fall below recommendations, it is important to understand if nutrient goals can be met if the quantitative amount recommended in the pattern was reduced. Therefore, one of the analyses prioritized in this protocol will assess the impact on nutrient goals using the HUSS Dietary Pattern if the quantitative recommendations for the Dairy and Fortified Soy Alternatives group are incrementally reduced or if no foods and beverage are consumed from this food group—especially for nutrients/dietary components of public health concern, such as calcium, vitamin D, and potassium. Although similar analyses were conducted by the 2010 Committee, changes in population dietary intakes, FPM methodological changes, food composition database updates, and revisions to the Dietary Reference Intakes in 2011 for calcium and vitamin D, 2019 for sodium and potassium, and 2023 for energy provide support for updating these analyses with newer data.

Despite the inclusion of lactose-free dairy products and fortified soy beverages and yogurt in this food group, the public has highlighted a need to provide greater flexibility within the patterns for individuals who do not or

cannot consume dairy from animal sources, including lactose-free versions. Additionally, product innovation and consumer demand have greatly increased the availability of non-dairy alternatives available for purchase, especially when compared to products available for the analyses conducted by the 2010 Committee.[27-29] Between 2016 and 2020, sales of plant-based milk alternatives nearly doubled, reaching $2.4 billion in retail sales.[28,29] These products may or may not contain added sugars and may or may not be fortified with highly bioavailable nutrients. Therefore, these analyses will help identify any potential public health concerns if substitutions for dairy products from animal sources are made with unfortified or calorically sweetened non-dairy alternatives or if fortified non-dairy alternatives with low bioavailability are consumed. Additionally, these analyses will help determine if any non-dairy alternatives in addition to fortified soy beverages and soy yogurts, could be included as options in the USDA Dietary Patterns.

Additionally, for those who consume dairy from animal sources, the proportion of products consumed shifts across the lifespan, with less fluid milk and more cheese being consumed as people age.[30] In youth, higher- and lower-fat milk and yogurt, specifically fluid milk, are the primary contributors to dairy intake. Cheese surpasses milk as the main source of dairy as people age. Overall, yogurt contributes only about 2 percent of dairy to the diets of the U.S. population. Therefore, analyses will be conducted that shift the proportions of milk, yogurt, and cheese to determine if the addition of further guidance or quantitative subgroup recommendations could help support healthier dietary patterns lower in saturated fat and added sugars.

This protocol describes a multi-phased approach for understanding if nutritional goals can be achieved when Dairy and Fortified Soy Alternatives quantities are hypothetically modified, including reducing the quantity of the food group lower than what is currently recommended in the 2020 HUSS Dietary Pattern and when additional non-dairy alternatives are included in the food group. 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. As part of 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

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

What are the implications for nutrient intakes when modifying the Dairy and Fortified Soy group quantities within the Healthy U.S.-Style Dietary Pattern?

What are the implications for nutrient intakes when dairy food and beverage sources are replaced with non-dairy alternatives?

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 will be described in **Table 5. Protocol amendments**.

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.

Questions:

What are the implications for nutrient intakes when modifying the Dairy and Fortified Soy group quantities within the Healthy U.S.-Style (HUSS) Dietary Pattern?

What are the implications for nutrient intakes when dairy food and beverage sources are replaced with non-dairy alternatives?

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. The contribution of complimentary foods and beverages consumed by infants less than 12 months will not be included in the calculation of nutrient profiles. Around 12 months, a dietary pattern that no longer includes infant formula or human milk may be established; however, consumption of human milk in the second year of life is common and recommended by the American Academy of Pediatrics and the World Health Organization. The HUSS Dietary Pattern was tailored for children ages 12 through 23 months who are no longer receiving infant or toddler formula or human milk.[31] The work of the 2020 Dietary Guidelines Advisory Committee describes the development of the HUSS Dietary Pattern for this age group, in which the Dairy and Fortified Soy Alternatives nutrient profile modeled whole milk and reduced fat yogurts and cheeses due to the unique considerations for this life stage, such as the importance of adequate fat intake. Fortified soy beverage is also included in the nutrient profile. Additionally, the American Academy of Pediatrics recommends that unsweetened non-dairy alternatives are not recommended for exclusive consumption in place of dairy milk (with the exception of soy milk) and to consume only when medically indicated or to meet specific dietary preferences for those ages 1-5 years.[32]

The nutrient profiles examined in these FPM analyses will be applied to the 2020 HUSS Dietary Patterns for ages 2 years and older.[1] The 2020 HUSS Dietary Pattern for ages 12 through 23 months who are no longer receiving human milk or infant formula will not be re-examined as a part of this protocol.

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; 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.

These analysis questions 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 HUSS Dietary Pattern published in the *Dietary Guidelines for Americans, 2020-2025*.[1] Nutrient profiles that underlie those patterns will be updated based on the 2025 Dietary Guidelines Advisory Committees 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.[33]

Subsequent analyses will model the implications of modifications to the Dairy and Fortified Soy Alternatives food group. Specifically, analyses will test reduction and elimination of quantitative recommendations for the food group, changes to the proportion of foods included that determine the composite nutrient profile, as well as testing the implications of substituting non-dairy alternatives not currently included in the food group when assessing potential pattern modifications in meeting nutrient goals.

FPM analyses planned to answer these questions include:

- Identifying the nutritional composition and contribution of the Dairy and Fortified Soy Alternatives group in current dietary intakes, relative to the 2020 HUSS Dietary Pattern goals.
- Evaluating nutrient intake implications when the quantity of Dairy and Fortified Soy Alternatives food group in the patterns are reduced by ¼ cup eq for the 1,000, 1,200, and 1,400 calorie levels and ½ cup eq increments for the 1,600-3,200 calorie levels, starting with the current maximum quantity at calorie level of the 2020 HUSS Pattern for ages 2 and older.
- Evaluating implications on meeting nutritional goals by modifying the proportions of foods (i.e., milk, cheese, yogurt) contributing to the food group nutrient profile by creating and modeling various proportions of draft subgroups (i.e., milk, cheese, yogurt) within the Dairy and Fortified Soy Alternatives group. The process will model various draft subgroup proportions to represent potential levels of consumption. The nutritional composition and contributions of the Dairy and Fortified Soy Alternatives group in the HUSS Dietary Pattern will be examined.
- Evaluating implications on meeting nutritional goals by replacing current representative foods with a range of non-dairy alternatives not included in the food group (e.g., fortified, unfortified, unsweetened, calorically sweetened) and examining the implications of modeling varying proportions of non-dairy alternatives. Evaluating implications on meeting nutritional goals when the current fat-free representative foods for fluid milk, cheese, and yogurt are replaced with low-fat, reduced fat, and full fat choices.
- Identifying and documenting potential implications on the nutritional composition and contributions of the above analyses.

Results from these analyses will contribute to the evidence that will be used to answer the overarching FPM 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?

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 *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
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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.[1,17] 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 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.[34] 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): [1,17] 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.

Non-dairy alternatives (new for 2025): For the purposes of these analyses, non-dairy alternatives are defined as foods and beverages that may be marketed to the public as milk, yogurt, or cheese alternatives originating from plant foods (e.g., almond, coconut, pea, and oat beverages; non-dairy yogurts and cheeses). For these analyses non-dairy alternatives do not include fortified soy alternatives as they are already a component of the Dairy and Fortified Soy Alternatives food group.

Fortification (new for 2025):[35] 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.[36] 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 ≥2000 IU of vitamin A and ≥400 IU of vitamin D.[37] 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.

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 (14-18 years, 19-30 years and 31-50 years).[38] (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.[1]

Computed weight for a body mass index (BMI) of 22.5 kg/m^2 for adult males and 21.5 kg/m^2 for adult females (ages 19+ years) and median height are used to calculate reference energy levels for each age-sex group.[1] The computed weight based on the corresponding BMI is obtained using the following equation.

BMI 22.5 or 21.5 x (median height in m)^2 = computed weight in kg

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.[39,40] 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^2 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.[31,41] 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.[41,42] 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.[38,43] 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.[38]

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 1st, 2nd, and 3rd 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		
	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 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).[1,5,38,44-46] 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 [a])
Energy	Energy (EER)
Macronutrients	Carbohydrate (AMDR/RDA), Protein (AMDR/RDA), Total Fat (AMDR)
Fatty acids	Saturated Fatty Acids (DGA 2020-2025, <10% of total energy), 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 energy)
Fiber	Total Dietary Fiber (AI, 14g/1,000 calories)

[a] 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 HUSS 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 Dairy and Fortified Soy Alternatives group modifications outlined below, to examine their impacts on nutritional composition and contribution within the Dairy and Soy Alternatives group and meeting nutritional goals across the HUSS Dietary Pattern.[1]

Analysis on the nutritional contribution of the food group:

- Objective 1: Identify the nutritional composition and contribution of the Dairy and Fortified Soy Alternatives group in current dietary intakes, relative to the 2020 HUSS Dietary Pattern goals for ages 2 and older.
- Objective 2: Evaluate nutrient intake implications when the quantity of Dairy and Fortified Soy Alternatives food group in the patterns are reduced by ¼ cup eq increments for 1,000, 1,200, and 1,400 calorie levels and ½ cup eq increments for 1,600 to 3,200 calories levels, starting with the current maximum quantity in each calorie level in the 2020 HUSS Dietary Pattern for ages 2 and older.
- Objective 3: Evaluate nutrient intake implications when the Dairy and Fortified Soy Alternatives food group is removed from the 2020 HUSS Dietary Pattern for ages 2 and older.

Analyses modifying food group quantities and proportions:

- Objective 4: Evaluate implications on meeting nutritional goals by modifying the proportions of foods (i.e., milk (dairy and fortified soy), cheese, yogurt (dairy and fortified soy) contributing to the food group nutrient profile by creating and modeling various proportions of draft subgroups within the Dairy and Fortified Soy Alternatives group. The process will model various draft subgroup proportions to represent potential variations of consumption. Models will examine current intake proportions (roughly 50% “milk”, 45% “cheese”, 5% “yogurt) and proportions in ½ cup eq increments using draft subgroups, as outlined in **Table 3**. Models will use the current highest recommended level of intake (3 cup eq per day), as well as at different levels of overall dairy intake (modeled in a previous analysis).

Table 3. Proportions of draft dairy subgroups to model within the Healthy U.S.-Style Dietary Pattern

Scenario	Milk (cup eq)	Cheese (cup eq)	Yogurt (cup eq)	Milk proportion	Cheese proportion	Yogurt proportion
Milk+3/Cheese-3/Yogurt-1	3	0	0	100%	0%	0%
Milk+2/Cheese-1/Yogurt-1	2.5	0.5	0	83%	17%	0%
Milk+2/Cheese-3/Yogurt+1	2.5	0	0.5	83%	0%	17%
Milk+1/Cheese-1/Yogurt-1	2	1	0	67%	33%	0%
Milk+1/Cheese-1/Yogurt+1	2	0.5	0.5	67%	17%	17%
Milk+1/Cheese-3/Yogurt+2	2	0	1	67%	0%	33%
Milk+0/Cheese+1/Yogurt-1	1.5	1.5	0	50%	50%	0%
Current Pattern (Reference)	1.5	1.25	0.25	50%	42%	8%
Milk+0/Cheese-1/Yogurt+1	1.5	1	0.5	50%	33%	17%
Milk+0/Cheese-2/Yogurt+2	1.5	0.5	1	50%	17%	33%
Milk+0/Cheese-3/Yogurt+3	1.5	0	1.5	50%	0%	50%
Milk-1/Cheese+2/Yogurt-1	1	2	0	33%	67%	0%
Milk-1/Cheese+1/Yogurt+1	1	1.5	0.5	33%	50%	17%
Milk-1/Cheese-1/Yogurt+1	1	1	1	33%	33%	33%
Milk-1/Cheese-2/Yogurt+3	1	0.5	1.5	33%	17%	50%
Milk-1/Cheese-3/Yogurt+4	1	0	2	33%	0%	67%
Milk-2/Cheese+3/Yogurt-1	0.5	2.5	0	17%	83%	0%
Milk-2/Cheese+2/Yogurt+1	0.5	2	0.5	17%	67%	17%
Milk-2/Cheese+1/Yogurt+2	0.5	1.5	1	17%	50%	33%
Milk-2/Cheese-1/Yogurt+3	0.5	1	1.5	17%	33%	50%
Milk-2/Cheese-2/Yogurt+4	0.5	0.5	2	17%	17%	67%
Milk-2/Cheese-3/Yogurt+5	0.5	0	2.5	17%	0%	83%
Milk-3/Cheese+4/Yogurt-1	0	3	0	0%	100%	0%
Milk-3/Cheese+3/Yogurt+1	0	2.5	0.5	0%	83%	17%
Milk-3/Cheese+2/Yogurt+2	0	2	1	0%	67%	33%
Milk-3/Cheese+2/Yogurt+3	0	1.5	1.5	0%	50%	50%
Milk-3/Cheese-1/Yogurt+4	0	1	2	0%	33%	67%
Milk-3/Cheese-2/Yogurt+5	0	0.5	2.5	0%	17%	83%
Milk-3/Cheese-3/Yogurt+6	0	0	3	0%	0%	100%

Analyses modifying representative foods:

- Objective 5: Compare and contrast the nutrient composition of non-dairy alternatives with dairy foods included in the Dairy and Fortified Soy Alternatives group in the 2020 HUSS Dietary Pattern. These alternatives include various fortified, unfortified, calorically sweetened, and unsweetened non-dairy alternatives (e.g., soy, almond, coconut, and oat beverages; non-dairy yogurts and cheeses) Non-dairy alternatives selected for this analysis will be identified by first assessing the market shares of dairy alternative product categories based on Circana OmniMarket Core Outlets retail scanner data, and second by assessing the availability and usability of nutrient composition of non-dairy alternative products in USDA FoodData Central before determining which food codes will be used.
- Objective 6: Evaluate implications on meeting nutritional goals by replacing current representative foods with non-dairy alternatives not included in the food group and examining the implications of modeling varying proportions of non-dairy alternatives. Models will use draft subgroups using current intake proportions of overall dairy and alternative proportions covering a range of possible intakes when non-dairy alternatives are consumed, as outlined in **Table 4**. Non-dairy alternatives modeled will be selected in consideration of the results of Objective 5 and will also include consideration to whether single food codes from USDA FoodData Central will be modeled as the modified representative foods in the pattern and/or if a nutrient-profile composite will be developed for modeling modifications.

Table 4. Proportions of non-dairy alternatives in cup equivalents (cup eq) to model within the Healthy U.S.-Style Dietary Pattern

Scenario	Milk Alternatives	Cheese Alternatives	Yogurt Alternatives
Based on current intake of dairy from animal products	50%	42%	8%
2 cup eq "milk" **½ cup eq "cheese"** **½ cup eq "yogurt"**	67%	16.5%	16.5%
2 cup eq "milk" **1 cup eq "yogurt"**	67%	0%	33%
1.5 cup eq "milk" **1.5 cup eq "cheese"**	50%	50%	0%
1.5 cup eq "milk" **1.5 cup eq "yogurt"**	50%	0%	50%
1.5 cup eq "cheese" **1.5 cup eq "yogurt"**	0%	50%	50%
All "milk"	100%	0%	0%
All "cheese"	0%	100%	0%
All "yogurt"	0%	0%	100%

- Objective 7: Evaluate implications on meeting nutritional goals when the current fat-free representative foods for fluid milk and yogurt are replaced with low-fat fluid milk and yogurt and the fat free cheese is replaced with reduced fat <or full fat> choices.

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 and posted on DietaryGuidelines.gov.[33]

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 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. 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 groups 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 these FPM questions. Synthesis of the analyses will involve summarizing results with particular emphasis on implications for each life stage: 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 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

The first version of this protocol was published in October 2023. This revised version was published in February 2024. Amendments listing protocols changes are documented below in **Table 5**.

Table 5. Protocol amendments

Date	Protocol change	Description
February 2024	Analytic Plan	The analytic plan was revised to establish energy levels based on the updated Estimated Energy Requirements (EER) equations from the Dietary Reference Intakes for Energy report published by the National Academies of Sciences, Engineering, and Medicine in 2023.[38]

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