In 2016, Congress appropriated funds to the U.S. Department of Agriculture (USDA) to engage the National Academies of Sciences, Engineering, and Medicine (NASEM) to conduct a comprehensive study of the process used to establish the Dietary Guidelines for Americans. The study culminated in two reports¹ that provided recommendations on how to update the process to develop the Dietary Guidelines. In several cases, these recommendations supported or confirmed work USDA and HHS already had underway. This response highlights recommendations in the second NASEM report and how USDA and the U.S. Department of Health and Human Services (HHS) responded to these recommendations as the Departments jointly developed the Dietary Guidelines for Americans, 2020-2025.

The four steps below outline the process used to develop the Dietary Guidelines for Americans, 2020-2025:

1. Identify topics and supporting scientific questions for the 2020 Dietary Guidelines Advisory Committee (the Advisory Committee) to address in its scientific review;
2. Select experts to serve on the independent, external Advisory Committee;
3. Advisory Committee reviews the scientific evidence and develops its scientific report; and
4. USDA and HHS develop the next edition of the Dietary Guidelines, taking into consideration the Advisory Committee’s scientific report, as well as input from Federal agencies and the public.

NASEM’s second report, Redesigning the Process for Establishing the Dietary Guidelines for Americans, provided recommendations pertaining to steps 1, 3, and 4. Responses from USDA and HHS to the recommendations from the second report are provided below.

(Note: NASEM Report 2 - Recommendation 2 is listed last to allow the responses to follow in chronological order in line with the Dietary Guidelines development process.)

REPORT 2 - Recommendation 1: The secretaries of the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (HHS) should redesign the Dietary Guidelines for Americans (DGA) process to prioritize topics to be reviewed in each


DGA cycle, and redistribute the current functions of the Dietary Guidelines Advisory Committee to three separate groups:

- a) Dietary Guidelines Planning and Continuity Group to monitor and curate evidence generation, to identify and prioritize topics for inclusion in the DGA, and to provide strategic planning support across DGA cycles;
- b) Technical expert panels to provide content and methodological consultation during evaluation of the evidence; and
- c) Dietary Guidelines Scientific Advisory Committee to interpret the scientific evidence and draw conclusions.

Response: In USDA and HHS’s review of this recommendation, it was determined that carrying out this recommendation as written would require the establishment of two or more discretionary Federal advisory committees. Since the 1985 edition of the Dietary Guidelines, a discretionary Federal advisory committee has been re-established every five years to provide advice to USDA and HHS for their use in developing the next edition of the Dietary Guidelines. At any given time, the Federal government maintains approximately 1,000 Federal advisory committees. There is an extensive process to request a Federal advisory committee, and Departments have an annual budget for Federal advisory committees. In short, establishing a new Federal advisory committee is a time-intensive process, and depending on other priorities and activities within the Departments, a new committee may not be possible within the desired timeframe and Department budgets. For the 2020 process, USDA and HHS were not able to establish an additional Federal advisory committee and addressed this recommendation to redistribute current functions of the Dietary Guidelines Advisory Committee by utilizing Federal nutrition scientists, existing Federal committees, and Nutrition Evidence Systematic Review (NESR) technical expert collaboratives as described below.

In response to Recommendation 1a, for the 2020 process, Federal scientists and Federal nutrition program experts from USDA and HHS identified and prioritized the topics and scientific questions that were examined by the Committee. The list of topics and questions was informed by experts from across the Federal government including scientists, nutritionists, and program specialists from USDA, HHS, the Department of Veterans Affairs, and the Department of Defense. To finalize the list, public and agency comment were requested and

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2 Discretionary advisory committee means any advisory committee that is established under the authority of an agency head or authorized by statute. An advisory committee referenced in general (non-specific) authorizing language or Congressional committee report language is discretionary, and its establishment or termination is within the legal discretion of an agency head. Other types of advisory committees include independent Presidential advisory committees, non-discretionary advisory committees, and Presidential advisory committees. For more information, see FACA Final Rule (102-3.25) (Available at: http://www.gsa.gov/portal/mediайл/218007/fileName/FACAFinalRule_R2E_NZ_0Z5RDZ-i34K-pR.action).
considered based on the predetermined and publicly stated criteria listed online and in the Federal Register notice.

To support ongoing strategic planning, USDA’s Center for Nutrition Policy and Promotion (CNPP) and HHS’s Office of Disease Prevention and Health Promotion (ODPHP) have staff who continuously support the Dietary Guidelines process and plan for future editions. These staff work with other Federal nutrition scientists in standing committees, including the Interagency Committee on Human Nutrition Research Subcommittee on Dietary Guidance and the Dietary Guidance Review Committee to identify and prioritize topics for inclusion in the Dietary Guidelines process, and to provide strategic planning support across Dietary Guidelines cycles.

In regards to 1b, USDA’s NESR has completed a number of systematic reviews in between Dietary Guidelines cycles to address high priority topics relevant to Advisory Committee work. These projects were completed with support from Technical Expert Collaboratives (TECs), which are groups of 7-8 leading subject matter experts on the topics being addressed in the reviews. When possible, Advisory Committees have used these relevant, timely, high-quality, and transparently documented existing NESR reviews in their review of evidence.

For example, in response to growing interest in the inclusion of infants and toddlers into the Dietary Guidelines, beginning in 2012, USDA and HHS undertook a series of projects to identify topics and scientific questions and conduct systematic reviews related to diet and health for individuals who are pregnant and for infants and toddlers. In particular, the Pregnancy and Birth to 24 Months (P/B-24) Project systematic reviews, led jointly by USDA and HHS, were completed in 2018. USDA’s NESR team conducted systematic reviews for the P/B-24 Project with the support of TECs, which included subject matter experts internal and external to the Federal government. A Federal Expert Group, a broadly representative group of Federal researchers and program leaders, also provided input throughout the P/B-24 Project. The 2020 Advisory Committee was able to use a number of the P/B-24 systematic reviews to answer the scientific questions they were tasked with addressing.


USDA Nutrition Evidence Library and Dietary Patterns Technical Expert Collaborative. A series of systematic reviews on the relationship between dietary patterns and health outcomes. 2014; Available at: https://nesr.usda.gov/dietary-patterns-systematic-reviews-project-0

Also in regards to 1b, prior to convening the Advisory Committee, Federal staff supported food pattern modeling analyses, documented and refined the process for identifying nutrients of public health concern, and initiated discussions regarding data analyses. The intent of each of these activities was to conduct prework in advance of the Advisory Committee so that the Committee could initiate their review at their first meeting. As example activities, Federal staff updated background files with the latest data to support food pattern modeling and initiated analyses specific to pregnancy and lactation. Staff from ODPHP and CNPP also collaborated with Federal colleagues at the Food and Drug Administration to discuss processes used to identify nutrients of concern and health claims. Finally, the data analysis team, including Federal staff from USDA’s Agricultural Research Service (ARS) and HHS’s Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH), met to coordinate data needs, including NHANES analyses.

For 1c, USDA and HHS provided substantial staff and contractor support before and during the process to support the Advisory Committee’s scientific review. This staff support allowed the Advisory Committee to focus on: (1) drawing conclusions and (2) integrating the evidence to provide advice to the Departments. While staff supported analyses, the conclusions presented in the Advisory Committee’s report are those of the Advisory Committee. Additionally, the Departments requested that the Advisory Committee provide advice to the agencies in the “summary” sections of each of the science-based chapters of its report. Also, for the first time in the Dietary Guidelines process, the Advisory Committee’s final meeting focused on its draft report. This meeting allowed for discussion and deliberation by the full Advisory Committee before submitting its report to the Secretaries of USDA and HHS. In these ways, the Departments supported separation of roles and responsibilities to allow the Advisory Committee to focus on drawing conclusions and preparing advice for the Departments.

In line with the recommendation to distribute responsibilities, there is also separation of the evidence review conducted by the Advisory Committee and the development and publication of the Dietary Guidelines by USDA and HHS. This approach is in line with best practices in guideline development, which includes organizing an effective guideline development group and use of evidence to inform recommendations.

REPORT 2 – Recommendation 3: The secretary of USDA should clearly separate the roles of USDA Nutrition Evidence Library (NEL) staff and the Dietary Guidelines Scientific Advisory Committee (DGSAC) such that:

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a) The NEL staff plan and conduct systematic reviews with input from technical expert panels, perform risk-of-bias assessment of individual studies, and assist the DGSAC as needed.

b) The NEL systematic reviews are externally peer reviewed prior to being made available for use by the DGSAC.

c) The DGSAC synthesizes and interprets the results of systematic reviews and draws conclusions about the entire body of evidence.

Response: NESR (formerly known as NEL) reviews were completed in a collaborative manner between the NESR team and the Advisory Committee. The NESR team of scientists has expertise both in systematic review methodology and in nutrition, public health, epidemiology, psychology, library science, or a related field. The Advisory Committee members hold advanced degrees in medicine or science and included experts that are nutrition scientists, physicians, dietitians, epidemiologists, and clinicians.

The NESR team used its rigorous, protocol-driven methodology to support the 2020 Advisory Committee to conduct systematic reviews. NESR’s methods are designed to promote transparency, minimize bias, and ensure the public availability, via NESR.usda.gov and peer-reviewed publications, of systematic reviews that are relevant, timely, and high quality. NESR’s methodology is based on and aligns with that of other systematic review organizations, such as Cochrane, the Agency for Healthcare Research and Quality, and other U.S. and international entities that conduct systematic reviews to inform public health guidance. NESR’s general methodology for answering a systematic review question involves developing a protocol; searching for and selecting articles; extracting data and assessing the risk of bias of results from each included article; synthesizing the evidence; developing conclusion statements; grading the evidence underlying the conclusion statements; and recommending future research.

The NESR team and the 2020 Advisory Committee had distinct roles in the systematic review process. The NESR team facilitated all aspects of planning, conducting, and documenting the work necessary for timely execution of the systematic reviews in accordance with NESR methodology. The role of the 2020 Advisory Committee was to develop systematic review protocols, synthesize evidence, and develop and grade conclusions. A protocol is a plan for how a specific systematic review will be conducted using NESR’s methodology. Each protocol included the analytic framework and inclusion and exclusion criteria. The NESR team then developed and implemented the literature search strategy, screened the literature search results using the Advisory Committee’s inclusion and exclusion criteria, and extracted data and assessed risk of bias for each study included in the systematic review. Then, the Advisory Committee synthesized the body of evidence; developed conclusion statements that answered the systematic review question; and graded the strength of evidence supporting the conclusions.
New to the 2020 process, the Departments added a step for peer review of the systematic reviews conducted by the Advisory Committee. This step was added in response to recommendations from NASEM as well as stakeholder comments, and in acknowledgement that peer review is a best practice for conducting systematic reviews. Per the Advisory Committee’s charter, peer review was coordinated by the Co-executive Secretary from USDA’s Agricultural Research Service (ARS), which developed a peer-review process analogous to that used for academic journal articles. Each systematic review was peer reviewed by 2 Federal scientists. In total, 47 Federal scientists from USDA, HHS (including the NIH, CDC, and the FDA), Department of Defense, and the Department of Veterans Affairs participated in the process.

The peer review process was anonymous and confidential. Peer reviewer comments were provided to the Advisory Committee and to the NESR team. NESR reviewed the comments, addressed editorial comments, and proposed edits for the Advisory Committee to review in response to substantive comments. Substantive comments were reviewed and discussed by the Advisory Committee, and revisions were made to the systematic review, as needed, based on the Advisory Committee’s discussion. For example, edits to improve clarity and better explain the rationale for decisions made by the Advisory Committee in developing conclusion statements and grading the strength of the evidence were made.

Detailed information on the Advisory Committee’s peer review and its review of the evidence is documented in its scientific report, which is available on DietaryGuidelines.gov.

REPORT 2 – Recommendation 4: The secretary of USDA should ensure all Nutrition Evidence Library (NEL) systematic reviews align with best practices by:

a) Enabling ongoing training of the NEL staff,

b) Enabling engagement with and learning from external groups on the forefront of systematic review methods,

c) Inviting external systematic review experts to periodically evaluate the NEL’s methods, and

d) Investing in technological infrastructure.

Response: Systematic review science and supporting technologies evolve continuously. The field of nutrition science is also progressing in areas related to the design, conduct, and analysis of food- and nutrition-related research. Therefore, to ensure that the methods NESR uses to conduct systematic reviews continue to align with best practices, NESR engages in a robust continuous quality advancement effort to evaluate and refine processes. NESR’s continuous quality advancement initiative involves all of the strategies noted in the NASEM recommendation, including enhancing staff knowledge and skills through ongoing training and
professional development; leveraging the expertise of and collaborating with methodologists from other leading systematic review organizations, such as Cochrane and the Agency for Healthcare Research and Quality; periodic evaluation of NESR’s methods by systematic review experts and nutrition scientists, including the two NASEM Committees examining the Dietary Guidelines process; and expanding its technological infrastructure.

When appropriate and feasible, refinements to the NESR methodology are carefully planned, tested, and adopted. Examples of process improvements that NESR made prior to supporting the 2020 Advisory Committee related to 1) tools and processes for assessing risks of bias of primary research, 2) criteria for grading the strength of evidence underlying the conclusion drawn in NESR systematic reviews; and 3) technology to support efficient and accurate searching for and screening of studies, as well as data extraction.

One example of how NESR evolved its methods to align with best practices related to the posting of protocols. A recent best practice in the field of systematic review methodology is to publicly post protocols prior to initiating the review of evidence. NESR, in conjunction with the 2020 Advisory Committee, publicly posted the protocols for each systematic review prior to the Advisory Committee’s review of evidence to enhance transparency and encourage the public to provide comments. Protocols have always been part of NESR’s process and had been discussed at public meetings of the 2010 and 2015 Advisory Committees, but this was the first time they were posted online prior to the evidence review. Prior to reviewing and synthesizing any evidence, the Advisory Committee established protocols designed to capture the most appropriate, relevant, and direct body of evidence to answer each question. Protocols also were presented and discussed at Advisory Committee meetings. Any revisions to protocols that occurred during the course of the Advisory Committee’s work were documented, posted online, and presented at meetings. The literature search plan (i.e., search terms) and screening results (i.e., flow chart, included and excluded articles) were added to the protocols online as they were finalized.

More information about the NESR’s methodology and continuous quality advancement initiative can be found on its website at NESR.usda.gov. The NESR methodology used to support the 2020 Dietary Guidelines Advisory Committee is also documented in the methodology section of the Advisory Committee’s Scientific Report, available at DietaryGuidelines.gov.

By aligning with current best practices, NESR’s continuous quality advancement initiative promotes efficiency and resource management and ensures the ongoing high quality and credibility of NESR work.
REPORT 2 – Recommendation 5: The secretaries of USDA and HHS should enhance food pattern modeling to better reflect the complex interactions involved, variability in intakes, and range of possible healthful diets.

Response: Similar to the other scientific approaches used in the Dietary Guidelines process, USDA and HHS support ongoing continuous quality advancement efforts for food pattern modeling. Food pattern modeling helps explain how changes to food-based dietary recommendations could potentially affect Americans’ ability to meet their nutrient needs. For the Dietary Guidelines for Americans, 2020-2025 development process, food pattern modeling was used to answer a portion of the topics and supporting scientific questions the Advisory Committee examined. These questions looked at:

- The ability to meet nutrient recommendations for each stage of life through variations in USDA Food Patterns.
- Development of two USDA Food Patterns for ages 12 through 23 months.
- The relationship between added sugars consumption and achieving nutrient and food group recommendations.

Federal staff have evaluated the analytic methods and development of data inputs and constraints for food pattern modeling and compared them to methods used in the development of guidance in other countries, as well as other modeling exercises described in scientific publications. This effort is part of USDA and HHS’s commitment to drive continuous process advancements and adopt best practices. The data inputs and constraints are the foundation for food pattern modeling, and when compared to external examples, they align with best practices and exceed expectations for transparent documentation. For the first time, the Advisory Committee, with support from Federal staff, developed a protocol with an analytic framework that described the overall scope and approach that would be used to answer each food pattern modeling question and an analytic plan that detailed the data and subsequent analysis to be conducted. Food pattern modeling protocols were posted online for public review and presented and discussed at its meetings.

Food pattern modeling relies on food composition data from the USDA Food and Nutrient Database for Dietary Studies (FNDDS) and Standard Reference (SR). The FNDDS and SR provide comprehensive nutrient data on food choices of Americans. Since the previous edition of the Dietary Guidelines, additional foods have been added to FNDDS to better reflect the current food supply and the increased variability of what Americans are eating. This increased variability was leveraged during food pattern modeling exercises conducted to inform the development of patterns for the Dietary Guidelines for Americans, 2020-2025. Future editions of FNDDS will integrate expanded nutrient profile data and links to related agricultural and experimental research.
The *Dietary Guidelines* food pattern modeling process divides food groups and subgroups into item clusters and selects one representative food for each item cluster. Food group and subgroup nutrient profiles are calculated based on the proportion that each item cluster contributes to food group and subgroup intakes within a population, using the nutrient profile of the item cluster’s representative food. To account for variation in eating patterns across different age groups, a new approach was employed to describe the food group and subgroup nutrient profiles used in analyses. In the past, nutrient profiles were calculated using intake data for all individuals ages 2 and older. In the 2020 process, differences in food intake by life stage were taken into account for infants and toddlers under age 2, ages 2 to 3 years, 4 to 18 years, 19 to 70 years, and 71 years and older. Thus, a food group and subgroup nutrient profile specific to each life stage was calculated and then used to estimate the anticipated nutrients and other food components in the patterns, improving the relevance of food pattern modeling for each life stage.

The goal of food pattern modeling is to develop dietary patterns applicable to the American population. The 2015-2020 edition of the *Dietary Guidelines* recognized that there are many ways to achieve a healthful dietary pattern and highlighted three dietary patterns that have demonstrated health benefits: (1) the Healthy U.S.-Style Eating Pattern, (2) the Healthy Mediterranean-Style Eating Pattern, and (3) the Healthy Vegetarian Eating Pattern. The 2020 Advisory Committee explored the need to add or modify the USDA Food Patterns based on its systematic reviews. The Advisory Committee decided to carry forward the three USDA food patterns with demonstrated health benefits and expanded the Healthy U.S.-Style and Healthy Vegetarian Eating Patterns to meet the needs of toddlers from 12 through 23 months.

USDA and HHS plan to continue advancing the food pattern modeling process through a variety of activities, including engagement with external experts. These efforts will ensure that the *Dietary Guidelines* food pattern modeling process stays current with best practices, provides evidence-based dietary patterns for Americans, and demonstrates USDA and HHS’s commitment to process advancement.

More information about the food pattern modeling used to support the 2020 Dietary Guidelines Advisory Committee is available in the methodology section of the Advisory Committee’s Scientific Report and online-only supplementary materials, available at DietaryGuidelines.gov.

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REPORT 2 – Recommendation 6: The secretaries of USDA and HHS should standardize the methods and criteria for establishing nutrients of concern.

Response: USDA and HHS have explored other Federal processes for evaluating potential nutrients of concern, like FDA’s Evaluation Process of Public Health Significance of Essential Vitamins and Minerals\(^7\), to standardize methods and criteria for establishing nutrients of concern across the Federal government. A three-step process was established to identify nutrients of public health concern: (1) estimate U.S. population intake levels for essential vitamins and minerals as compared to Dietary Reference Intakes; (2) if possible, consider biological endpoints such as biochemical indices of nutritional status with valid cut-points; and (3) consider scientific evidence on the relationship between nutrient inadequacy or excess and clinical health consequences.

Similar to the NESR systematic review and food pattern modeling processes, a protocol for identifying nutrients of concern was developed with the 2020 Advisory Committee and posted to DietaryGuidelines.gov for public input before any data was reviewed and synthesized. The protocol was also presented and discussed at Advisory Committee meetings. The protocol included the analytic framework that described the three-step process used to identify nutrients of public health concern and the analytic plan that detailed the data and subsequent analysis to be conducted. This method was further standardized through the Scientific Report of the 2020 Dietary Guidelines Advisory Committee, available at DietaryGuidelines.gov, and publication in the peer-reviewed literature\(^8\).

REPORT 2 – Recommendation 7: The secretaries of USDA and HHS should commission research and evaluate strategies to develop and implement systems approaches into the DGA. The selected strategies should then begin to be used to integrate systems mapping and modeling into the DGA process.

Response: USDA and HHS recognize the importance of exploring how to integrate systems approaches into the Dietary Guidelines process. CNPP has sought funding to do so each fiscal year since 2018, but has yet to secure any funds. Contingent on funding, the Departments plan to start the important process of examining best practices for adapting the complex

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methodology of systems approaches and applying it to the Dietary Guidelines as effectively as possible, while ensuring that the Dietary Guidelines continues to reflect the highest scientific integrity and contain information adaptable for public health and consumer use.

REPORT 2 - Recommendation 2: The secretaries of USDA and HHS should provide the public with a clear explanation when the DGA omit or accept only parts of conclusions from the scientific report.

Response: USDA and HHS support this recommendation, which aligns with the value of transparency. USDA and HHS developed the Dietary Guidelines for Americans, 2020-2025 by relying on the scientific advice in the Advisory Committee’s report, consultation with subject matter experts within Federal agencies, as well as comments from these agencies and from the public. Information detailing the step-by-step process to develop the Dietary Guidelines for Americans can be found on DietaryGuidelines.gov.

Any revisions to previous editions of the Dietary Guidelines must have sufficient scientific justification, and by law, must be based on the preponderance of scientific and medical knowledge current at the time. The Dietary Guidelines for Americans, 2020-2025 includes nearly all of the science-based recommendations of the 2020 Dietary Guidelines Advisory Committee, including new dietary advice for infants and toddlers. With the release of the 2020-2025 edition, the Departments made clear, through a written response that was posted to DietaryGuidelines.gov, decisions related to certain recommendations from the Advisory Committee’s scientific report that were not carried forward into the Dietary Guidelines for Americans, 2020-2025. The response provided additional clarity and transparency to the Dietary Guidelines process.

CONCLUSION

USDA and HHS have thoroughly considered all the recommendations from both NASEM reports and incorporated as many of them as possible in the process to develop the Dietary Guidelines for Americans, 2020-2025. Future cycles of the Dietary Guidelines will continue to re-examine the NASEM reports and consider how they may be incorporated as part of overall process advancement efforts. The Departments appreciate NASEM’s review of the Dietary Guidelines process and their thoughtful recommendations to improve the process.

The Dietary Guidelines for Americans serves as the cornerstone of Federal nutrition programs and policies, providing food-based recommendations to help prevent diet-related chronic diseases and promote overall health. According to the National Nutrition Monitoring and Related Research Act of 1990, the Dietary Guidelines is mandated to reflect the preponderance of scientific evidence, and is published jointly by USDA and HHS every five years.

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