

Center for Nutrition Policy and Promotion
A Response to the National Academies of Sciences, Engineering, and Medicine Report
U.S. Department of Agriculture, Food and Nutrition Service
A Report to Congress

August 2019

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 reports that provided recommendations on how to update the process to develop the Dietary Guidelines. The following report includes a summary of the process currently in use to develop the *2020–2025 Dietary Guidelines for Americans*. The report also highlights NASEM’s recommendations and how the USDA and the U.S. Department of Health and Human Services (HHS) plan to respond to these recommendations as the Departments jointly develop the next edition of the Dietary Guidelines.

BACKGROUND

Per the National Nutrition Monitoring and Related Research Act of 1990 (7 U.S.C. 5341), the Secretaries of USDA and HHS are required to publish a report entitled “Dietary Guidelines for Americans” that provides nutritional and dietary information and guidelines for the public at least every 5 years. The Dietary Guidelines is also mandated to be based on the preponderance of the scientific and medical knowledge, which is current at the time the report is prepared.

USDA and HHS work together to meet this mandate. Each edition of the Dietary Guidelines reflects the current body of nutrition science and provides advice on what to eat and drink to promote health and reduce risk of chronic disease. The Dietary Guidelines serves as the cornerstone of Federal nutrition programs and policies, providing food-based recommendations to help prevent diet-related chronic diseases and promotes overall health.

The *2015–2020 Dietary Guidelines for Americans* is the current edition and will remain so until the next edition is released. The process to develop the 2020–2025 edition is currently underway and expected to be released by the end of 2020.

RESPONSE TO FY 19 APPROPRIATIONS DIRECTIVE

The following response is provided in chronological order of the process to establish the *2020–2025 Dietary Guidelines for Americans*. Highlighted throughout are the recommendations from NASEM’s two reports and USDA’s response.

Currently, USDA and HHS are halfway through the process of developing the *2020–2025 Dietary Guidelines for Americans*.

There are four main steps to develop the *2020–2025 Dietary Guidelines for Americans*:

- (1) Identifying topics and supporting scientific questions for the 2020 Dietary Guidelines Advisory Committee (the Advisory Committee) to address in its scientific review;
- (2) Selecting the experts to serve on the independent, external Advisory Committee;
- (3) The Advisory Committee's scientific review of the evidence; and
- (4) USDA and HHS' development of the next edition of the *Dietary Guidelines for Americans*, which takes into consideration the Advisory Committee's scientific report, as well as input from Federal agencies and the public.

NASEM has identified from both study reports, the importance of five values to improve the integrity of the process to develop credible and trustworthy guidelines:

- (1) Enhance transparency;
- (2) Promote diversity of expertise and experience;
- (3) Support a deliberative process;
- (4) Manage biases and conflicts of interest; and
- (5) Adopt state-of-the-art processes and methods.

Throughout the description of the process below, you will see how these values have been incorporated into the steps to develop the *Dietary Guidelines*.

Step 1: Identify topics and supporting scientific questions for the 2020 Dietary Guidelines Advisory Committee to address in its scientific review

USDA and HHS added a significant, new step involving public participation to the beginning of the process. For the first time, USDA and HHS identified topics and supporting scientific questions for the future 2020 Dietary Guidelines Advisory Committee to address and asked the public to provide comments. In past years, the Advisory Committee determined the topics and supporting questions. USDA and HHS added this step to promote a deliberate and transparent process, respond to feedback on the *Dietary Guidelines* development process, identify expertise needed on the Advisory Committee, help manage resources, provide opportunity for public participations in the process, and ensure the science-based review provided by the Advisory Committee addresses Federal nutrition policy and program needs.

The process used to identify topics and scientific questions was led by the USDA Center for Nutrition Policy and Promotion, and the HHS Office of Disease Prevention and Health Promotion and vetted by the USDA Acting Deputy Under Secretary of Food, Nutrition, and Consumer Services and the HHS Assistant Secretary for Health with input from Federal agencies and the public.

USDA and HHS considered each public and agency comment in relation to the following four criteria in refining the topics and questions, which were published in the *Federal Register* notice with the call for public comment:

- relevance to creating the *Dietary Guidelines for Americans*;
- importance to public health;
- potential impact on Federal food and nutrition programs; and
- avoiding duplication of Federal efforts.

This step was implemented, in part, because of NASEM's recommendation to "prioritize topics to be reviewed in each Dietary Guidelines cycle," which is elaborated below in NASEM Report 2: Recommendation 1 (see page 6).

Step 2: Select the experts to serve on the independent, external Advisory Committee

Once the topics and supporting scientific questions were finalized, USDA and HHS posted them publicly and issued a 30-day public request for nominations to the 2020 Dietary Guidelines Advisory Committee. For the first time, USDA and HHS published in the *Federal Register* notice and online the factors that would be considered by the Departments when reviewing the nomination packages. One of the factors—demonstrated scientific expertise related to one or more of the topics to be examined by the Advisory Committee—assisted USDA and HHS in identifying Advisory Committee members with expertise related to the topics and scientific questions to be addressed. As an additional change to past practice, the Federal Advisory Committee charter was posted online during the selection process, allowing the public to gain a better understanding of the specific duties of the Advisory Committee. Providing these factors publicly, along with the call for nominations and the final list of topics and scientific questions and charter, are yet more examples of the Departments evolving their process to support a transparent and deliberative process while increasing efficiency.

NASEM Report 1 - Recommendation 1: The Secretaries of USDA and HHS should employ an external third-party to review and narrow the candidate pool to a list of primary and alternate nominees. Criteria against which nominees are screened should be developed by USDA and HHS for use by the third-party.

Response: As stated above, USDA and HHS developed criteria for screening potential nominees and posted the criteria publicly online and in the *Federal Register* notice with the call for nominations. However, due to resource limitations—cost and time—USDA and HHS did not utilize a third-party for the Advisory Committee selection process. USDA and HHS did provide the public with more information than ever before online and in the *Federal Register* notice on the process to establish the 2020 Dietary Guidelines Advisory Committee.

NASEM Report 1 - Recommendation 2: The Secretaries of USDA and HHS should make a list of provisional appointees open for public comment—including short biographies and any known conflicts—for a reasonable period prior to appointment.

Response: USDA and HHS explored incorporating this recommendation. However, in concern of the provisional appointees' privacy, the Departments choose not to implement this recommendation.

There were various factors considered regarding this recommendation. One concern was the potential for public slander that could occur with requesting public comments about Advisory Committee candidates. Due to the Freedom of Information Act and other Federal provisions, comments on the slate of candidates typically cannot be kept from being made public.

NASEM Report 1 - Recommendation 3: The Secretaries of USDA and HHS should disclose how provisional nominees' biases and conflicts of interest are identified and managed by:

- a) Creating and publicly posting a policy and form to explicitly disclose financial and nonfinancial biases and conflicts;
- b) Developing a management plan for addressing biases and conflicts for the panel as a whole and individuals, as needed;
- c) Certifying that a federal ethics officer independently reviewed and judged the advisory committee's biases and conflicts of interest; and by
- d) Documenting how conflicts of interest were managed in the Dietary Guidelines Advisory Committee report.

Response: USDA and HHS agree that identifying and managing potential conflicts of interest and minimizing bias related to the Advisory Committee and its scientific review is essential. As such, the Departments agreed to implement additional steps as described below:

Advisory committee members are required to submit a Confidential Financial Disclosure Report (OGE Form 450) upon appointment. For the first time, the conflict of interest review was completed *prior to* appointing the 2020 Advisory Committee members as part of the selection process. Historically, this review was completed *after* the Advisory Committee was appointed. The process and a sample of the form used to evaluate a potential nominee's conflict of interest were described and posted online at DietaryGuidelines.gov and remain on the website for continued transparency.

In preparation for selecting the 2020 Advisory Committee, all individuals under final consideration for appointment were required to submit a Confidential Financial Disclosure Report prior to being appointed. The completed report was reviewed by USDA ethics officials with extensive expertise in this area, as USDA is the administrative lead for the 2020 Advisory Committee. The ethics officials reviewed the reports for potential conflicts of interest and impartiality concerns as defined by the Ethics in Government Act of 1978 and its implementing regulations, as well as compliance with all other pertinent Federal ethics laws and regulations. The ethics officials concluded that none of the 20 candidates that were ultimately appointed as Advisory Committee members reported any entries on their OGE Form 450 that would prevent them from being appointed and providing the complete range of duties required of a Dietary Guidelines Advisory Committee member in full compliance with the Federal ethics rules applicable to special government employees (SGE). The letter from the USDA Office of Ethics¹ about the Advisory Committee was also posted online, documenting their review.

For the first time, USDA and HHS specified information required in all nomination packages, including education, employment, peer-reviewed publications, presentations, blogs, funding sources, and other affiliations. These elements were reviewed for awareness and to support establishing an Advisory Committee with broad representation and balance across many considerations. The Departments aimed to select a membership with a mix of experience (clinicians and health professionals, epidemiologists, research scientists and trialists, and others), expertise (topic areas and points of view), and education (advanced degrees, including PhD, MD) from every region of the United States, reflecting diverse backgrounds to the extent possible.

¹ See, <https://www.dietaryguidelines.gov/sites/default/files/2019-03/DGAC%202020%20OE%20Review%20Statement.pdf>

As with previous Dietary Guidelines Advisory Committees, members of the 2020 Advisory Committee are appointed as SGEs, selected based on recognized expertise or expert knowledge relevant to the Advisory Committee. SGEs are subject to Federal employee ethics laws and regulations while serving in this role. In contrast, none of the members are appointed as “representative members”—individuals appointed to represent the points of view of outside interest groups or stakeholders. USDA ethics officials will conduct an annual review of each Advisory Committee member’s OGE Form 450 to manage potential COI throughout the proceedings.

All members of the 2020 Advisory Committee were required to go through ethics training with USDA ethics officials prior to the Committee’s first meeting. The training materials and slides are available at DietaryGuidelines.gov for public reference. All members are also required to receive annual ethics training.

The Advisory Committee will provide a summary of how it worked to manage potential conflicts of interest and minimize bias in its scientific report. The approaches the Advisory Committee will use to examine the evidence—systematic reviews (original and existing), data analyses, and food pattern modeling—are rigorous, objective and protocol-driven, and are designed to minimize bias. Information about each approach’s methodology, along with the protocols for each question being addressed, is posted to DietaryGuidelines.gov, providing transparency to the public. (For more information on the scientific review, see pages 6–10.)

The Advisory Committee’s review of the evidence is completed in a collaborative manner. Its work is not based on any one member’s expertise, nor will the final decisions for its scientific evaluation be reached on an individual-by-individual basis. The Committee will come to its conclusions together.

NASEM Report 1 - Recommendation 4: The Secretaries of USDA and HHS should adopt a system for continuous process improvement to enhance outcomes and performance of the Dietary Guidelines Advisory Committee selection process.

Response: USDA and HHS will continue to drive continuous process advancements by examining the effectiveness of process modifications, reviewing best practices, and assessing other selection processes.

The second step in the process to develop the Dietary Guidelines—selecting the experts to serve on the independent Advisory Committee—was completed with the public announcement of the Advisory Committee members. Before the Committee started its work, USDA changed the name of the Nutrition Evidence Library (NEL) to the Nutrition Evidence Systematic Review (NESR) to minimize confusion and better describe its work. Additionally, USDA launched two new websites—DietaryGuidelines.gov and NESR.usda.gov—to increase transparency and communications efforts with the public. These websites are written for a much broader audience than in the past so content is easier to understand independent of a person’s familiarity with the Dietary Guidelines or its process. These new websites and the name change are ongoing examples of USDA and HHS’s dedication to transparency and customer service.

Step 3: The independent Advisory Committee's scientific review of the evidence

NASEM's second report, *Redesigning the Process for Establishing the Dietary Guidelines for Americans*, provided recommendations pertaining to the next two steps in the process to develop the Dietary Guidelines—steps 3 and 4. USDA's responses to the recommendations from the second report are captured below. (Please note: NASEM Report 2 - Recommendation 2 is listed last to allow this congressional report to follow in chronological order.)

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. Due to time and resource constraints, the Departments responded to the recommendation to redistribute the current functions of the Dietary Guidelines Advisory Committee as follows:

For the 2020–2025 edition of the *Dietary Guidelines*, Federal scientists and Federal nutrition program experts identified and prioritized the topics and scientific questions for which the Committee is reviewing the evidence. As described in Step 1, 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 Veteran Affairs, and the Department of Defense. To finalize the list, public and agency comments were requested and considered based on the predetermined and publicly stated criteria listed online and in the *Federal Register* notice. To support ongoing strategic planning, there is a standing Interagency Committee on Human Nutrition Research Subcommittee on Dietary Guidance and a Federal stakeholder group for pregnancy and birth to 24 months.

When evaluating the evidence, Federal staff support the Advisory Committee's work to review the evidence using three scientific approaches: systematic reviews, data analysis, and food pattern modeling. The Federal support staff hold advanced degrees in nutrition, dietetics, statistics, or a related health field, and have extensive training in one of the approaches used to review the science. As such, the support staff provide methodological consultation to the Advisory Committee on the three approaches to evaluate the evidence.

The Advisory Committee’s review of the evidence is structured to include relevant studies and data that represent the full U.S. population, including people who are healthy, people who are at risk for diet-related chronic diseases, and people who have diet-related chronic diseases (e.g. obesity, type 2 diabetes, cardiovascular disease). As a result, the Advisory Committee reviews a body of scientific evidence that reflects the general U.S. population. The Advisory Committee operates as an independent group of experts to interpret the scientific evidence and draw conclusions. The Advisory Committee’s review of the evidence and conclusions are captured in its scientific report that goes to the Secretaries of USDA and HHS. This report is considered as the Departments develop the *2020–2025 Dietary Guidelines for Americans*. Thus, the Advisory Committee’s review of evidence and its scientific report that reflects the general population help USDA and HHS meet the mandate of the National Nutrition Monitoring and Related Research Act, which requires the Dietary Guidelines to include nutritional and dietary information and guidelines for the general public and that it is based on the preponderance of the scientific and medical knowledge current at the time the report is prepared.

The Advisory Committee will hold a total of five Committee meetings—all of which are open to the public. During the meetings, the Advisory Committee will discuss its plan for reviewing the science and deliberate on the scientific findings. Two Committee meetings will allow for oral public comments, and one meeting will be held outside the DC area (Houston, TX) to engage with a more diverse audience. Past practice was to invite oral public comments at one Committee meeting early in the process. The Departments introduced a second opportunity for the public to provide oral comments to the Committee as part of the ongoing effort to expand opportunities for public engagement in the process.

For future editions, the Departments will continue to work together within the time and resource constraints to consider implementation of this recommendation.

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:

- 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: For the *2020–2025 Dietary Guidelines for Americans*, NESR (formerly NEL) staff will work with the 2020 Dietary Guidelines Advisory Committee to complete systematic reviews, including the risk-of-bias assessment of individual studies. Due to time and resource restraints, NESR will not be able to conduct systematic reviews with input from technical panels. However, the process described below aligns with Recommendation 3 and reflects the five values highlighted in both NASEM reports.

The NESR team will use its rigorous, protocol-driven methodology to support the 2020 Advisory Committee to conduct systematic reviews. It is 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 general methodology for answering a systematic review question involves searching for and selecting articles; extracting data and assessing the risk of bias of results from each included article; synthesizing the evidence; developing a conclusion statement; grading the evidence underlying the conclusion statement; and recommending future research.

Use of a risk of bias tool is key to ensuring that risk of bias assessments are done consistently across studies, and that the results of the assessments are transparent. NESR is using the following risk of bias tools for systematic reviews done to support the 2020 Dietary Guidelines Advisory Committee:

- “Cochrane risk-of-bias tool for randomized trials” (RoB 2.0)² (August 2016 version) for randomized trials, including parallel group trials, cluster-randomized trials, and cross-over trials
- “Risk of Bias in Non-randomized Studies-of-Interventions” tool (ROBINS-I)³ for non-randomized trials
- “Risk of Bias for Nutrition Observational Studies” tool (RoB-NObs)⁴ for observational studies.

NESR projects are completed in a collaborative manner. The NESR team, who has expertise in systematic review methodology, also has advanced degrees in nutrition, public health, epidemiology, psychology, library science, or a related field. The 2020 Advisory Committee members include experts that are nutrition scientists, physicians, dietitians, epidemiologists, and clinicians.

The NESR team and the 2020 Advisory Committee have distinct roles in the systematic review process. The NESR team facilitates all aspects of planning, conducting, and documenting the work necessary for timely execution of the systematic reviews in accordance with NESR methodology. This includes drafting an analytic framework that describes key parts of the systematic review question (e.g., the population, food- and nutrition-related intervention or exposure, and outcomes of interest); establishing draft inclusion and exclusion criteria that specify the appropriate types of studies to review; searching for and screening studies; and extracting data and assessing risk of bias for each study included in a systematic review. The NESR team will also develop, implement, refine, and document the literature search strategies.

The role of the 2020 Advisory Committee is to review and refine the analytic framework and inclusion and exclusion criteria drafted by NESR; synthesize the body of evidence; draw conclusions that answer the systematic review question; and grade the strength of evidence supporting the conclusions.

All NESR systematic reviews conducted by the 2020 Advisory Committee will undergo a formal peer review process. Peer review will be coordinated by USDA's Agricultural Research Service (ARS). ARS will coordinate the peer-review independently, without input from the NESR team

² See, <https://www.riskofbias.info/welcome/rob-2-0-tool>

³ See, <https://www.riskofbias.info/welcome/home/current-version-of-robins-i>

⁴ See, <https://nesr.usda.gov/sites/default/files/2019-03/Risk%20of%20Bias%20for%20Nutrition%20Observational%20Studies%20Tool.pdf>

or the 2020 Advisory Committee. Once ARS has completed its peer-review of each systematic review, the 2020 Advisory Committee will then consider the peer-review comments as it finalizes the review.

NESR has previously collaborated with other expert groups to conduct a number of systematic reviews on questions relevant to the 2020 Advisory Committee's work. Therefore, when possible, NESR will work with the Committee to identify opportunities to leverage these relevant, timely, high-quality, and transparently documented existing NESR reviews.

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 remains committed to continuous quality advancement efforts to evaluate and refine processes. NESR's continuous quality advancement initiative involves 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; and expanding technological infrastructure.

When appropriate and feasible, refinements to the NESR methodology are carefully planned, tested, and adopted. Examples of process improvements that NESR has made as part of this effort to support the 2020 Advisory Committee relate 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.

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, is publicly posting the protocols for each systematic review prior to the Advisory Committee's review of evidence. Protocols have always been part of NESR's process, but this will be the first time they are being posted online prior to the evidence review. To enhance transparency, the public has been/will be notified when the protocols are online and is encouraged to provide public comment on the posted protocols. To help the public follow the Advisory Committee's review of the evidence, there is also an online tracker that provides updates on the status of each scientific question under review by the Advisory Committee. 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 each scientific approach, USDA supports ongoing continuous quality advancement efforts for food pattern modeling. Food pattern modeling is an analysis that helps us understand how changes to the amounts or types of foods and beverages in an eating pattern might impact meeting nutrient needs across the U.S. population. For the *2020–2025 Dietary Guidelines* development process, food pattern modeling exercises will test how different combinations of foods that represent variations in intakes can be integrated into a healthful diet and, dependent on findings from the systematic evidence reviews, the number and types of dietary patterns modeled.

The analytic methods and development of data inputs and constraints for food pattern modeling have been evaluated and compared 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’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. To improve public access and understanding of how food pattern modeling is used, USDA will post protocols online as they become available.

Food pattern modeling relies on food composition data from the USDA Food and Nutrient Database for Dietary Studies (FNDDS). The FNDDS provides comprehensive nutrient data on food choices of Americans. Since the last 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 will be leveraged during food pattern modeling exercises conducted to inform the development of patterns for the *2020–2025 Dietary Guidelines*. Future editions of FNDDS will integrate expanded nutrient profile data and links to related agricultural and experimental research.

Food pattern modeling explores the development of dietary patterns applicable to the American population. The current 2015–2020 edition of the *Dietary Guidelines for Americans* recognizes that there are many ways to achieve a healthful dietary pattern and highlights 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. As the 2020 Advisory Committee conducts its systematic reviews, the body of scientific evidence will determine the need to explore modeling new food patterns or to adapt current food patterns. These explorations may focus on a type of food pattern (e.g., low carb) or may be a food pattern for a particular population (e.g., toddlers).

USDA aims to increase engagement with external experts in the area of food pattern modeling through technical review as well as peer reviewed publication of the 2020–2025 USDA Food Patterns development and update. Together, these efforts will ensure that USDA’s food pattern modeling stays current with best practices, provides evidence-based eating patterns for Americans, and demonstrates USDA’s commitment to process improvement.

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, to standardize methods and criteria for establishing nutrients of concern across the Federal Government. A three-step process has been 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.

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 aim to begin to explore how to integrate systems approaches into the *Dietary Guidelines for Americans* process. Contingent on Federal funding, FNS plans to start the important process of looking at best practices regarding how the complex methodology of systems approaches can be adapted and applied to the Dietary Guidelines as effectively as possible, while ensuring that the Dietary Guidelines continues to reflect the highest scientific integrity and to contain information adaptable for consumer use.

Step 4: USDA and HHS’ development of the next edition of the Dietary Guidelines for Americans.

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: As stated above, once the 2020 Advisory Committee submits its scientific report to the Secretaries of USDA and HHS, it is taken into consideration—along with public and agency comments—as the Departments develop the *2020–2025 Dietary Guidelines for Americans*. With the release of the 2020–2025 edition, the Departments plan to provide a written explanation for decisions made in considering the conclusions from the Advisory Committee’s scientific report. This accompanying explanation will provide additional clarity and transparency to the Dietary Guidelines process.

Pursuant to the National Nutrition Monitoring and Related Research Act, USDA and HHS aim to release the *2020–2025 Dietary Guidelines for Americans* by the end of 2020 to meet the mandate to publish the *Dietary Guidelines for Americans* every 5 years.

CONCLUSION

The Departments of 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 *2020–2025 Dietary Guidelines for Americans*. Future cycles of the Dietary Guidelines will continue to re-examine NASEM’s recommendations and consider how they may be incorporated. The Departments appreciate NASEM’s review of the *Dietary Guidelines for Americans* process and their thoughtful recommendations to improve the process.

As stated throughout the report above, the *2020–2025 Dietary Guidelines for Americans* aims to meet all the requirements of the National Nutrition Monitoring and Related Research Act. USDA and HHS are working jointly in every step of the process and are on track to meet the mandate when they release the next edition of the *Dietary Guidelines for Americans*.