



Responding to the National Academies of Sciences, Engineering, and Medicine Study on the Process to Update the *Dietary Guidelines for Americans*

Eve Stoady, PhD
Designated Federal Officer
2020 Dietary Guidelines Advisory Committee



**Dietary
Guidelines
for Americans**

In 2016, Congress directed a comprehensive study of the process to update the *Dietary Guidelines*

- USDA commissioned the National Academies' Health and Medicine Division (HMD) to undertake the study
- HMD convened a 14-member committee that conducted an 18-month independent study
 - Three of the members are members of the 2020 Dietary Guidelines Advisory Committee: Drs. Schneeman, Ard, and Boushey



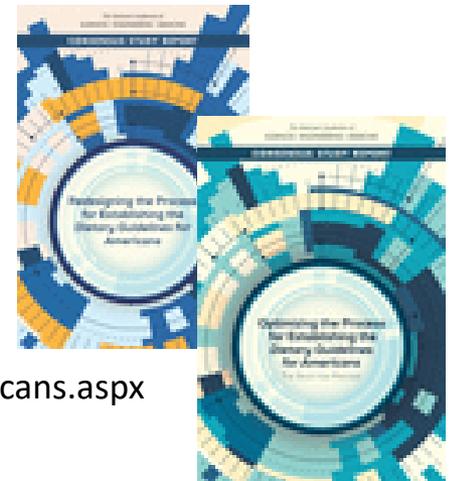
The study concluded in two reports

1. *Optimizing the Process for Establishing the Dietary Guidelines for Americans: The Selection Process*

Released: February 3, 2017

2. *Redesigning the Process for Establishing the Dietary Guidelines for Americans*

Released: September 14, 2017



<http://www.nationalacademies.org/hmd/Activities/Nutrition/DietaryGuidelinesforAmericans.aspx>



USDA and HHS thank the National Academies'
and the committee for their work and
recommendations



**Dietary
Guidelines
for Americans**

As partners, USDA and HHS have carefully considered the reports for the 2020 process

Considerations:

- Conforming with relevant laws and regulations, including:
 - Federal Advisory Committee Act
 - Federal ethics laws and regulations
- Time and resources
- Potential implications on other Federal advisory committees
 - USDA and HHS have over 400 active committees
- Input from stakeholder listening sessions in November 2017 (available at www.cnpp.usda.gov)

The reports provided overarching values and specific process recommendations

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.
5. Adopt state-of-the-art processes and methods.

USDA and HHS support these values and will continue to integrate steps to address these goals.

The first report included four recommendations for selecting the Committee (1 of 4)

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: Due to resource limitations (cost and time), USDA and HHS did not utilize a third party for the 2020 Committee selection process. USDA and HHS did:

- Develop screening criteria that was included with the call for nominations:
 - Educational background, professional experience, demonstrated scientific expertise, obligations under the FACA, and requirements regarding a balanced membership.
- Provide more information on our website on the process the Departments used to establish the Committee.

The first report included four recommendations for selecting the Committee (2 of 4)

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 of time prior to appointment.

Response: The Departments explored incorporating this recommendation. However, in the interest of the provisional appointees, the Departments choose not to implement this recommendation out of privacy concerns.

The first report included four recommendations for selecting the Committee (3 of 4)

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.

The first report included four recommendations for selecting the Committee (3 of 4, continued)

Response: Managing potential conflicts of interest (COI) and minimizing bias is essential. USDA and HHS assess and manage potential conflicts of interest and work to minimize bias using several process steps, including those outlined below:

During Committee selection

- Candidates under final consideration to the Committee submitted Confidential Financial Disclosure Report (OGE 450) *prior to* selection – typically, this is done *after* appointment.
- Completed report was reviewed by USDA ethics officials.
- For the first time, USDA and HHS requested specific information in 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 a committee with broad representation and balance across many considerations.

The first report included four recommendations for selecting the Committee (3 of 4, continued)

Response, *continued*:

During Committee service

- USDA ethics officials will conduct *annual* review of each member's OGE 450 to manage potential COI throughout the proceedings.
- Ethics training will be provided to the Committee *annually* by USDA ethics officials.
- Approaches to examine evidence are rigorous, objective, protocol-driven, and are designed to minimize bias.
- Committee will provide a summary of how it worked to manage potential conflicts of interest and minimize bias in its scientific report.

The first report included four recommendations for selecting the Committee (4 of 4)

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 report included seven recommendations (1 of 7)

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.

The second report included seven recommendations (1 of 7, continued)

Response:

Three separate groups have not been established, in part due to time and resource constraints for establishing discretionary advisory committees.

- In response to this recommendation – and to support a more deliberative and transparent process – USDA and HHS, with Federal agency and public input, identified the topics and questions prior to establishing the Committee.
- There are relevant, existing NESR systematic reviews, including those conducted by the 2015 Committee and recent pregnancy and birth to 24 months technical expert collaboratives, available for the Committee’s consideration.

The second report included seven recommendations (2 of 7)

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

Response: The Departments will respond to this recommendation as we move into this step.

The second report included seven recommendations (3 of 7)

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.

The second report included seven recommendations (3 of 7, continued)

Response:

- a. Roles and responsibilities of NESR (formerly NEL) staff and the Committee will be clearly outlined.
- b. Due to time and resource constraints, NESR will not be conducting systematic reviews with input from technical expert panels, rather NESR will be conducting systematic reviews directly with the 2020 Committee. However, relevant existing NESR systematic reviews, conducted in collaboration with external expert groups, will be available for consideration by the Committee.
- c. All systematic reviews conducted by the 2020 Committee will undergo a formal peer review process coordinated by the USDA Agricultural Research Service.

The second report included seven recommendations (4 of 7)

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.

The second report included seven recommendations (4 of 7, continued)

Response: The NESR team acknowledges that systematic review science and supporting technologies evolve continuously. 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
- Expanding technological infrastructure

The second report included seven recommendations (5 of 7)

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: The food pattern modeling team has worked to transparently document its methods and incorporated the latest dietary intake data for analyses. The topics and questions also allow for more exploration of variability in intakes across the lifespan and examination of a range of possible healthful diets based on available evidence.

The second report included seven recommendations (6 of 7)

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

Response: The data analysis team has worked to transparently document and standardize methods and criteria for establishing nutrients of concern (to be discussed at a future meeting).

The second report included seven recommendations (7 of 7)

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

Response: The Departments will continue to work to incorporate new approaches to examine the evidence – as they become available – to support science-based, credible guidance.

- USDA established the NEL (now NESR) in 2008 because systematic reviews were becoming a state-of-the-art approach for informing clinical and public health guidance.

We have done some initial exploration into systems approaches and will continue to explore this option.

Responding to the National Academies of Sciences, Engineering, and Medicine Study on the Process to Update the *Dietary Guidelines for Americans*

- Fact sheets with more information related to these recommendations are available at DietaryGuidelines.gov: Click “Resources”
- The Departments are preparing a report to Congress with our response, to be submitted later this year





DGA

Questions?

