Questions from the committee to Evaluate the process to develop the *Dietary Guidelines for Americans*.

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What are your perceptions and/or insights into the barriers (time and/or cost) of implementing the seven 2017 NASEM recommendations?

- Now that you have gone through the 2020 DGAC process, do you feel that any of the seven 2017 recommendations may either need to be modified or may not be necessary?

What has been implemented from the 2017 recommendations?

- 1a Topic comment period was implemented; various mechanisms are available for planning and continuity.
- 1b Use of technical working groups by the 2020 DGAC
- 1c The DGAC interpreted scientific evidence and drew conclusions
- 2. Rationale provided for change in quantitative recommendation on limits for added sugars and alcohol for men
- 3. The roles of the NESR staff and the DGAC were clearly separated.
- 4. The NESR staff provided outstanding expertise in systematic review methodology and maintaining the integrity of the process
- 5. Food pattern modeling: 6-24 month methodology
- 6. DGAC established a framework for nutrients of public health concern
- 7. DGAC emphasized the importance of evaluating systems approaches

Now that you have gone through the 2020 DGAC process, do you feel that any of the seven 2017 recommendations may either need to be modified or may not be necessary?

- Modification for consistency with Federal policy and resources
- Meeting the need for continuity and planning across cycles:
  - Topics identified by the 2020 DGAC in Future Directions
  - Monitoring by federal working groups
  - Learning from the comment period on topics for the DGA
  - Monitoring and updating of evidence by NESR staff

From your perspective, what is really needed to improve the integrity of the *DGA* process and, thus, the product?

- Progress has been made based on the values from the 2017 report (continue to build upon this progress)
  - Transparency
    - Availability of draft protocols, draft conclusions, extra public meetings…
  - Diversity of expertise and experience
    - Committee members breadth of expertise and experience
    - Membership expanded to 20 members
    - Utilized work of the TECs
  - Deliberative process
    - Enhancement of evidence review, including peer review
  - State-of-the art methodology
    - Systematic review process suited to food-based recommendations
  - Manage bias and conflict of interest
    - Re-design of the committee selection process

Schneeman et al. *Adv Nutr* 2021;12:1051-1057

In your opinion, did the recommendations of 2017 NASEM report influence the workings of the DGAC that you co-chaired?

- Perspective: Impact of the National Academy of Sciences, Engineering, and Medicine Report on the Process for the 2020 Dietary Guidelines Advisory Committee; *Adv Nutr* 2021;12:1051-1057.
- Examples:
  - Topic identification
  - Working group reports for B-24 and pregnancy populations
  - New topics (e.g. frequency of eating, dietary patterns & all-cause mortality, B-24, pregnancy, lactation)
  - Use of current authoritative reports (DRIs for sodium and potassium; FDA action on *trans* fatty acids)
  - Additional staff with expertise in systematic reviews
  - Framework for nutrients of public health concern
  - Understanding the rationale for limits on added sugars and alcohol

From an external perspective, there did not appear to have been a separation of functions between the NESR and DGAC as recommended in the 2017 NASEM report. From your recent perspective of chairing the 2020 DGAC, was there adequate separation of functions? If so, why? If not, why not?

- The separation between NESR and the DGAC was clear and functioned well.
  - DGAC finalized the analytical framework for search criteria
  - NESR conducted the literature search for the Systematic Reviews and risk of bias assessment
  - DGAC evaluated evidence, graded its strength, and drafted conclusion statements
  - The Systematic Reviews and draft conclusions were peer reviewed by Federal scientists.
  - The DGAC finalized conclusion statements and prepared summary statements with advice to the Secretaries.

. Many kinds of data are used in the development of the DGAC Scientific Report. Is there a flowchart or logic model available that visually represents all of the data inputs and how the DGAC incorporates this information into their Scientific Report?

DGAC Review of Evidence on Relationship between Diet and Health

- Defining characteristics: the use of 3 approaches to examine the evidence, the creation of transparent protocols before the evidence review began, and the development of scientific review conclusion statements.

- Each of these approaches has its own rigorous, protocol-driven methodology, and plays a unique, complementary role in examining the science.
  - www.dietaryguidelines.gov

Data Analysis
A collection of analyses that uses national data sets to help us understand the current health and dietary intakes of Americans. These data help make our advice practical, relevant, and achievable. *The Committee conducted more than 150 analyses of Federal data sets. (NHANES, NHANES/WWEIA,, USDA Nutrient Database for Dietary Studies, USDA Food Pattern Equivalents Database, National Health Interview Survey, Surveillance Epidemiology and End Results (NCI)*

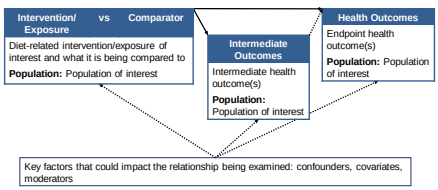
Food Pattern Modeling
Analysis that helps us understand how changes to the amounts or types of foods and beverages in a pattern might impact meeting nutrient needs across the U.S. population. *Several food pattern modeling analyses were completed, and representing for the first time, the 6 through 24 months life stage.*

NESR Systematic Review
Research project that answers a question on diet and health by searching for, evaluating, and synthesizing all relevant, peer-reviewed studies. *More than 270,000 citations were screened and nearly 1,500 original research articles included in 33 original systematic reviews. Peer reviewed.*

NESR Scientific Review Protocols

- **The Committee created a protocol for each question before it examined any of the scientific evidence.**
- Developed before the scientific review begins, a protocol is a plan for how one of the scientific approaches will be used to examine evidence related to one question (e.g., inclusion/exclusion criteria for study design and date of publication).
- For the first time in the DGA process, draft protocols were posted online for public comments to the Committee before they were finalized.
- NESR systematic review protocols include:
  - Analytic framework (PICO, key terms, confounders)
  - Inclusion and exclusion criteria
  - Literature search strategy
  - Literature search and screening results
  - Lists of included and excluded articles
- DGAC was responsible for protocol development, grading of the evidence, development of the scientific conclusion statements and recommendations.

Components of a NESR Analytic Framework



Key definitions

[Term] – [definition]
[Term] – [definition]
[Term] – [definition]

NESR Scientific Review Protocols

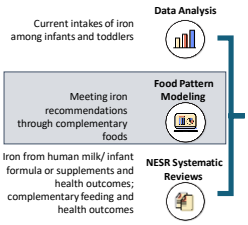
- NESR analysts extracted data from each included study to answer the systematic review question
  - Study design
  - Participant characteristics
  - Measurement methods
  - Analysis
  - Results
  - Funding source
- NESR analysts used 3 risk of bias tools to assess how well each included study was designed and conducted:
  - "Cochrane risk-of-bias tool for randomized trials" (RoB 2.0) for randomized trials
  - "Risk of Bias in Non-randomized Studies-of-Interventions" tool (ROBINS-I) for non-randomized trials
  - "Risk of Bias for Nutrition Observational Studies" tool (RoB-NObS) for observational studies
- The risk of bias assessment was considered when synthesizing and grading the evidence

- ✓ Bias arising from the randomization process
- ✓ Bias in selection of participants into the study
- ✓ Bias due to confounding
- ✓ Bias in classification of interventions or exposures
- ✓ Bias due to deviations from intended interventions or exposures
- ✓ Bias due to missing outcome data
- ✓ Bias in measurement of the outcome
- ✓ Bias in selection of the reported result

From Conclusion Statements to Advice

The Committee looked across all of the conclusion statements – the totality of our scientific review – to develop overarching advice for USDA and HHS to consider as the Departments develop the 2020-2025 Dietary Guidelines.

Example: From Conclusion Statements to Advice to Guidance



Committee's Advice: "Provide foods that are rich in iron and zinc, either intrinsically (e.g., meats) or due to fortification (e.g., iron fortified infant cereal), particularly during the second 6 months of life among breastfed infants… Iron requirements are lower in the second year of life than during infancy but a good source of iron is still needed."

Dietary Guidelines Key Recommendation: "Encourage infants and toddlers to consume a variety of foods from all food groups. Include foods rich in iron and zinc, particularly for infants fed human milk." [+ supporting text]

- What are the limitations of the data sources used in this report and how are these limitations managed?

Future Directions*: Enhancements for developing evidence to support recommendations

- For past DGA cycles the DGAC has, at times, relied on existing, published systematic reviews, and evaluation is needed of whether those systematic reviews should be re-examined and updated with the current methodology and with protocols more relevant to the DGAs and whether to include meta-analyses
- Ensure national surveillance systems expand diversity and sample size of underreported populations, and incorporate additional foods and beverages from diverse populations. Further, national surveillance systems should incorporate survey questions that query participants on food and beverage intake in the context of socioeconomic status, food security status, cultural food traditions, and religious or ethnic food "rules"
- Include biomarker data that are national in scope to adequately describe the nutritional status of Americans, particularly those who are currently underrepresented in national data
- Improve dietary assessment methods that can more accurately estimate energy intakes feasible for use in Federal surveillance and monitoring
- Harmonize the Federal sampling framework with the Dietary Reference Intakes (DRI) age groups, and develop clear definitions of life stages. (the sampling frameworks and age groupings do not align with the DRI age groupings, complicating data analysis and interpretation)

*Part E DGAC report

Future Directions*: Enhancements for developing evidence to support recommendations

- Implement surveillance systems to gather more information about the contextual aspects of food and beverage intake, such as the frequency and/or timing of food and beverage consumption..
- Continue the ongoing Federal initiative to expand research on human milk composition and how it relates to maternal and infant health. Update USDA databases to establish a reference or standard human milk composition profile that incorporates data from diverse populations and across lactation, with consideration of how milk composition may be influenced by maternal diet and other factors
- Enhance surveillance systems to enable linkage of parent-child or other family member intakes within surveys and link surveillance systems that collect data about infant feeding and health outcomes..
- Updates to existing DRIs are urgently needed for many nutrients for all age-sex groups and life stages to better characterize potential risk of dietary inadequacy and excess. The growing interest in low carbohydrate diets as well as the need to understand metabolic responses to different fatty acids indicates the importance of updating the DRIs for macronutrients. In addition, the availability of the Chronic Disease Risk Reduction Intake (CDRR) framework for the DRIs will be useful in examining appropriate recommendations for all of the macronutrients and subcategories within each classification.

*Part E DGAC report

Questions about staffing and resources

- Key points:
  - Staffing for DGAC critical to the volume of work
  - Is DGPCG an extra layer? What alternatives exist for planning and continuity?
    - Recommendations from the DGAC (Future Directions)
    - Input from federal partners that use the DGA in program development (what currently exists?)
    - Use the topic comment period to identify emerging issues
  - Current use of technical working groups in the interim between DGA cycles has been effective.
    - TECs addressed nutrition recommendation in the B-24 age groups, pregnancy and lactation and Food Pattern Modeling

Additional Questions

- What, in your opinion, are the most important factors that affect the public's perception of the integrity of the *Dietary Guidelines for Americans*?
- In your opinion, how would the 2017 NASEM recommendations, if implemented fully, have affected the rigor and integrity of the process and guidelines?