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Comment on FR Doc # 2019-12806

The is a Comment on the **Food and Nutrition Service** (FNS) Notice: <u>Meetings: 2020 Dietary Guidelines Advisory Committee</u>

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Comment

RE: Concerns and Questions Related to the Assessment of Evidence and Recognition of Evidence Limitations

The Beef Checkoff appreciates the opportunity to submit questions and concerns related to how evidence is being evaluated as part of the 2020-2025 Dietary Guidelines for Americans (DGA) process, including potential limitations with those assessments. The Beef Checkoff is a producer-funded marketing and research program, which includes a significant commitment to supporting nutrition research to better understand beef's role in healthy diets.

As the NASEM Review Committee noted, "Taking the limitations of evidence sources into account is crucial for building guidelines that are based on the totality of scientific evidence [1]." The attached overview addresses several concerns related to the strength of the evidence being evaluated as part of the DGA process, including: limitations of dietary pattern evidence to inform individual food recommendations; the need for consistency in the application of evidence grades, particularly recognizing the possible risk of bias in evaluating individual studies and the collective evidence base for a particular Research Question; the need for consistent evidence grade definitions; and a clear discrimination of graded conclusions, as compared to research observations.

Thank you for the opportunity to share the attached concerns and questions, to help ensure the DGA is based on the totality of the evidence and best practices for evidence reviews and conclusions. The strength of evidence criteria and evidence grading rubric as presented by Julie Obbagy, PhD, RD at Meeting 1 outlined for the 2020 DGAC allow for recognition of the evidence limitations and resulting uncertainty surrounding dietary guidance resulting from their review process, and we look forward to the thoughtful consideration of these factors in the 2020 DGAC's final report.

[1] NASEM, 2017. Redesigning the process for establishing the Dietary Guidelines for Americans.

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Category:
Food industry

Attachments (1)

Beef Checkoff Strength of Evidence Comments 032620

View Attachment: [PDF]

National Cattlemen's
Beef Association
a contractor to the Beef Checkoff

March 25, 2020

Barbara Schneeman, PhD
Chair, 2020-2025 Dietary Guidelines Advisory Committee

Ron Kleinman, MD
Vice-Chair, 2020-2025 Dietary Guidelines Advisory Committee

CC: 2020-2025 Dietary Guidelines Advisory Committee Members
    U.S. Department of Agriculture
    U.S. Department of Health and Human Services
    Brandon Lipps, Deputy Undersecretary for Food and Nutrition Consumer Services

RE: Concerns and Questions Related to the Assessment of Evidence and Recognition of Evidence Limitations

Dear Members of the Dietary Guidelines Advisory Committee (DGAC):

The Beef Checkoff appreciates the opportunity to submit questions and concerns related to how evidence is being evaluated as part of the 2020-2025 Dietary Guidelines for Americans (DGA) process, including potential limitations with those assessments. The Beef Checkoff is a producer-funded marketing and research program, which includes a significant commitment to supporting nutrition research to better understand beef's role in healthy diets.

As the NASEM Review Committee noted, "Taking the limitations of evidence sources into account is crucial for building guidelines that are based on the totality of scientific evidence."[1] The attached overview addresses several concerns related to the strength of the evidence being evaluated as part of the DGA process, including: limitations of dietary pattern evidence to inform individual food recommendations; the need for consistency in the application of evidence grades, particularly recognizing the possible risk of bias in evaluating individual studies and the collective evidence base for a particular Research Question; the need for consistent evidence grade definitions; and a clear discrimination of graded conclusions, as compared to research observations.

Thank you for the opportunity to share the attached concerns and questions, to help ensure the DGA is based on the totality of the evidence and best practices for evidence reviews and conclusions. The strength of evidence criteria and evidence grading rubric outlined for the 2020 DGAC allow for recognition of the evidence limitations and resulting uncertainty surrounding dietary guidance resulting from their review process,[2] and we look forward to the thoughtful consideration of these factors in the 2020 DGAC's final report.

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[1]National Academies of Sciences, Engineering, and Medicine. 2017. Redesigning the process for establishing the Dietary Guidelines for Americans. Washington, DC: The National Academies Press. doi: https://doi.org/10.17226/24883.
[2] https://www.dietaryguidelines.gov/day-1-nutrition-evidence-systematic-review

Incomplete Assessment of Evidence and Recognition of Evidence Limitations:
Evidence Overview and Supporting Citations

The 2020 DGAC has addressed the research questions at hand using systematic review methodology, which is designed to evaluate evidence totality.[1] However, research questions provided to the 2020 DGAC were framed in the context of dietary patterns,[2] thus reducing the available evidence for consideration to primarily one type of research design, i.e. observational.[3] Thus, while the totality of evidence regarding certain dietary patterns and health outcomes has been reviewed by the 2020 DGAC, the collective evidence base for many health outcomes is broader than that considered by only dietary pattern studies, and includes a robust evidence base of randomized controlled trials (RCTs), which can demonstrate cause and effect relationships.[4] Randomized controlled trials provide less biased evidence, and are both foundational and complementary to inform recommendations on individual food groups.[3] Yet this evidence is not readily being considered by the current DGAC focus on observational evidence. In fact, Vice Chair of the 2020 DGAC Dr. Ron Kleinman noted that the DGAC's approach may lead to discordant conclusions from existing systematic reviews and it will be important that the DGAC's final report "…comment not only on what methodologies we used but on the limitations of those methodologies."[5] Public comment from nutrition expert organizations mirror those of Dr. Kleinman with the Academy of Nutrition and Dietetics noting, regarding dietary patterns as a framework for generating public health recommendations, that "It is important, however, to recognize and articulate the limitations of this approach and accordingly, support the DGAC in presenting the findings in a manner consistent with the systematic reviews' most accurate interpretation."[6]

Limitations of Dietary Pattern Evidence

Limitations of observational nutrition studies on foods and dietary patterns are well recognized and include: unclear contribution of individual foods to observed dietary pattern associations; lack of standardized food grouping; lack of generalizability across populations; varying scoring systems for the same named dietary patterns; long-term variability of intake; unknown correlation between food intake and exploratory substitutions; measurement error; and the semiquantitative nature of dietary data.[3] **Dietary pattern evidence also lacks the ability to inform individual food recommendations and, in particular, for red meat where nutritionally distinct foods such as fresh and processed red meat are considered collectively rather than independently.[7]** Discussion among the DGAC Committee during Meeting 5 echoed these limitations with Dr. Linda Van Horn noting inconsistences and concerns as far as trying to align some of the patterns with differences across scoring systems, type of diet data collected, and foods included, "elaborates about the difficulty of coming up with a standardized method to make meaningful conclusions from all these different dietary patterns studies."[8]

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[1] https://www.dietaryguidelines.gov/most-popular-questions How is the Committee reviewing the evidence?
[2] https://www.dietaryguidelines.gov/most-popular-questions How will all aspects of the diet be addressed during the 2020 Committee's scientific review?
[3] Schulze MB, et al. Food based dietary patterns and chronic disease prevention. BMJ 2018;361:k2396.
[4] Maki K et al. Limitations of Observational Evidence: Implications for Evidence-Based Dietary Recommendations. Adv. Nutr. 2014;5:7-15.
[5] https://globalmeetwebinar.webcasts.com/viewer/event.jsp?ei=1289829&tp_key=62557ab93c timestamp: 2:57:50
[6] Tuma, P. Comment on FR Doc # 2019-12806. ID FFNS-2019-0001-7171.
[7] Gifford C et al. Broad and Inconsistent Muscle Food Classification Is Problematic for Dietary Guidance in the U.S. Nutrients 2017, 9, 1027; doi:10.3390/nu9091027
[8] https://globalmeetwebinar.webcasts.com/viewer/event.jsp?ei=1289829&tp_key=62557ab93c timestamp: 1:23:43

Consistent Application of Evidence Grades

The debate between Subcommittees during Meeting 5 regarding the assignment of evidence grades for evidence that is largely observational in nature was recognized and highlights the importance of certain aspects of the DGAC process. Specifically, the importance of consistency across Subcommittees in strength of evidence (SOE) assessments for various research questions.[9] The discussion led by the Chair of the Dietary Fats and Seafood Subcommittee is a useful example as she announced that based on feedback from other members of the 2020 DGAC, draft conclusions regarding seafood intake and neurocognitive health and development were being revised. This feedback resulted in the downgrading of the SOE for all of the draft conclusion statements presented by this Subcommittee in January from an evidence grade of "moderate" to a grade of "limited" based on feedback that included "…the evidence base being solely prospective cohort studies and modifying the language so as not to imply a treatment effect."[10] **This feedback and related SOE downgrade illustrates the challenges of making strong dietary recommendations with only partial evidence, i.e. based on an only observational evidence base.[9]**

During Meeting 1, criteria used to assign SOE grades for conclusions to DGAC research questions were described in detail, and included assessment of risk of bias (ROB) in individual studies, using three "state of the art" ROB tools, along with assessment of the ROB, consistency, directness, precision and generalizability in the collective evidence base.[11] Yet it is unclear how consistently these criteria are being applied between the subcommittees.[9] For example, during Meeting 5 the Chair of the Beverages and Added Sugars Subcommittee summarized[12] multiple SOE factors as part of the collective result of evidence on the relationship between alcohol consumption and all-cause mortality, noting factors such as high attrition [e.g. ROB], difference in assessment methods [e.g. consistency], poor generalizability [e.g. generalizability], no assessment of compliance [e.g. ROB], short study duration [e.g. ROB] while, in contrast, the Dietary Fats and Seafood Subcommittee did not report on these factors.[10] **Risk of bias assessments for individual studies and the collective evidence base allows consideration of strengths and limitations to resulting recommendations.[13] It is expected that in the DGAC's final report, the assessment of each study's ROB, and the SOE evaluation of each collective evidence base will be presented to aid understanding of the grades assigned to the DGAC's conclusions.**

Consistent Evidence Grades Definitions

It was announced during Meeting 4 that existing NESR conclusions regarding maternal health outcomes and dietary patterns would be carried forward as 2020 DGAC conclusions. During Dr. Donovan's presentation, the existing NESR conclusion regarding maternal dietary patterns and gestational age at birth was presented, i.e. "*Limited but consistent* evidence suggests that certain dietary patterns during pregnancy are associated with a lower risk of preterm birth and spontaneous preterm birth"[14] [emphasis added]. However, during Meeting 1 Dr. Obbagy outlined four evidence grades – strong, moderate, limited, and grade not assignable.[11] We request clarification on how conclusion statements from existing NESR SR will be aligned to be consistent with conclusions statements and evidence grades for the 2020 DGAC process. **In other words,**

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[9] https://globalmeetwebinar.webcasts.com/viewer/event.jsp?ei=1289829&tp_key=62557ab93c timestamp: 2:39:00

[10] https://globalmeetwebinar.webcasts.com/viewer/event.jsp?ei=1289846&tp_key=af6515fc8a timestamp: 1:30:30

[11] https://www.dietaryguidelines.gov/day-1-nutrition-evidence-systematic-review

[12] https://globalmeetwebinar.webcasts.com/viewer/event.jsp?ei=1289852&tp_key=6cf027ef9d timestamp: 03:00

[13] National Academies of Sciences, Engineering, and Medicine. 2017. Redesigning the process for establishing the Dietary Guidelines for Americans. Washington, DC: The National Academies Press. doi: https://doi.org/10.17226/24883.

[14] https://www.youtube.com/watch?v=LRHw6gtwLL8&feature=youtu.be timestamp: 2:35:11

will the 2020 DGAC grade "limited" be substituted for NESR "limited but consistent" grade in the conclusion above, and others like it, to provide consistency with the current DGAC process?

Clear Discrimination of Graded Conclusions versus Research Observations
In the 2020 DGAC draft conclusion statement for the relationship between dietary patterns consumed and all-cause mortality, a series of ungraded sub-bulleted observations are listed following the conclusion statement.[15] Are the ungraded sub-bullets intended as part of the conclusion statement or are they intended to reflect an evidence synthesis summary rather than a conclusion statement? We request clarification on how, if at all, these sub-bulleted statements will be presented in the final 2020 DGAC report.

Summary
In closing, systematic reviews are foundational for evidence-based dietary guidance and provide the opportunity to make evidence-based public health recommendations that are objective, transparent, and scientifically robust.[13,16] Best practices for systematic review methodology aim to ensure that reviews are comprehensive and free from bias.[16] Comprehensive evaluation of the evidence base related to a particular research question requires review of evidence from a broad range of high quality study designs, including randomized controlled trials (RCTs) and observational studies.[13,16,17] In their report regarding the redesign of the process to establish the DGA, the **NASEM Review Committee made the following observation, "Taking the limitations of evidence sources into account is crucial for building guidelines that are based on the totality of scientific evidence."[13] The SOE criteria and evidence grading rubric outlined for the 2020 DGAC allow for recognition of the evidence limitations and resulting uncertainty surrounding dietary guidance resulting from their review process,[11] and we look forward to the thoughtful consideration of these factors in the 2020 DGAC's final report.**

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[15] https://www.youtube.com/watch?v=2RnX37Xoz18&feature=youtu.be timestamp: 34:13
[16] IOM (Institute of Medicine). 2011. Finding What Works in Health Care: Standards for Systematic Reviews. Washington, DC: The National Academies Press.
[17] Shamseer L, et al. 2015. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ 2015;350:g7647.