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Comment on FR Doc # 2019-12806

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Comment

RE: Best Practices Methodology of Systematic Review for Nutrition Research

The Beef Checkoff appreciates the opportunity to provide evidence related to the systematic review methodology that will be used to develop the 2020-2025 Dietary Guidelines for Americans (DGA). 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 outlined in the attached evidence overview, systematic reviews are foundational for evidence-based dietary guidance.

First, sound systematic reviews allow for the evaluation of the total evidence base related to a particular research question, including both observational studies and randomized controlled trials (RCTs). To that end, it is imperative that both research questions and study selection criteria are created in a way that will help identify a wide variety of study designs, which then allows for the full evidence base to be examined.

In addition, the nutrition research community has noted that observational dietary pattern methods cannot make discernments that are essential for individual food recommendations, which are often included in the DGAs. Further, observational evidence often relies on assessments that lack standardized methods to identify patterns and which use subjective labels that generalize and bias food categories (e.g. Southern dietary pattern). A simplified name to label a pattern does not necessarily capture the full range of foods in a dietary pattern. It is important that a systematic review reflect and examine all possible dietary patterns, including the range of healthy patterns for fat, carbohydrate and protein intake as defined in the well-established and widely recognized Acceptable Macronutrient Distribution Range (AMDR).

In short, evidence from RCTs, where meat types and intakes are independently evaluated and more clearly defined, provide less biased evidence, and are both foundational and complementary to observational data, to inform recommendations on individual food groups such as meat.

Thank you for the opportunity to share the attached evidence overview for consideration as the Committee examines Topics and Questions that are relevant to evaluating the role of beef in healthy diets.

Attachments (1)

[Beef Checkoff Methodology Comments FINAL 061919](#)

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Category:

Food industry

June 19, 2019

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, Acting Deputy Undersecretary for Food and Nutrition Consumer Services

RE: Best Practices Methodology of Systematic Review for Nutrition Research

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

The Beef Checkoff appreciates the opportunity to provide evidence related to the systematic review methodology that will be used to develop the 2020-2025 Dietary Guidelines for Americans (DGA). 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 outlined in the attached evidence overview, systematic reviews are foundational for evidence-based dietary guidance.

First, sound systematic reviews allow for the evaluation of the total evidence base related to a particular research question, including both observational studies and randomized controlled trials (RCTs).^{2,3,9-11} To that end, it's imperative that both research questions and study selection criteria are created in a way that will help identify a wide variety of study designs, which then allows for the full evidence base to be examined.

In addition, the nutrition research community has noted that observational dietary pattern methods cannot make discernments that are essential for individual food recommendations, which are often included in the DGAs.^{11,13,28} Further, observational evidence often relies on assessments that lack standardized methods to identify patterns and which use subjective labels that generalize and bias food categories (e.g. Southern dietary pattern).^{23,28} A simplified name to label a pattern does not necessarily capture the full range of foods in a dietary pattern. It's important that a systematic review reflect and examine all possible dietary patterns, including the range of healthy patterns for fat, carbohydrate and protein intake as defined in the well-established and widely recognized Acceptable Macronutrient Distribution Range (AMDR).

In short, evidence from RCTs, where meat types and intakes are independently evaluated and more clearly defined, provide less biased evidence, and are both foundational and complementary to observational data, to inform recommendations on individual food groups such as meat.^{11,26,27}

Thank you for the opportunity to share the attached evidence.



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Best Practices Methodology of Systematic Review for Nutrition Research

Evidence Overview and Supporting Citations

In late 2015, Congress mandated that the National Academies of Sciences, Engineering, and Medicine (NASEM) evaluate the process used to update the Dietary Guidelines for Americans (DGA) (1). Of two consensus reports published by the NASEM Review Committee, one provided recommendations regarding the review of evidence by the Dietary Guidelines Advisory Committee (DGAC) (2). In this report the NASEM Review Committee confirmed that, “the DGA have to be based on the highest standards of scientific data and analyses to reach the most robust recommendations (2).”

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 (2, 3). Best practices for systematic review methodology aim to ensure that reviews are comprehensive and free from bias (3). 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 (2-4). **When conducting systematic reviews, formulating research questions and creating study selection criteria that aid in the identification of a variety of study designs promotes evaluation of a comprehensive evidence base (2).**

Many of the research questions to be examined by the 2020 DGAC, much like the 2015 DGAC, are focused on the relationship between dietary patterns consumed at each stage of life and various health outcomes (5, 6). While dietary patterns can be directly tested in RCTs, systematic reviews designed to inform the 2015 DGAC relied almost exclusively on dietary patterns identified in observational data (5, 7). As noted in our earlier comment, at least 70 RCTs, including those demonstrating the role of beef in healthy dietary patterns and cardiovascular disease risk factor outcomes, were excluded from the evidence base considered by the 2015 DGAC because they “did not assess dietary patterns as defined for this project (8).” Representing only one type of diet data, observational dietary pattern methods provide only a fraction of the evidence regarding food consumption and health outcomes thus denying the opportunity for these results to be interpreted within the total body of evidence and may result in implementation of recommendations based on erroneous conclusions (9-11).

Three recently published systematic reviews by Nutrition Evidence Systematic Review (NESR) (12), regarding dietary patterns before and during pregnancy and maternal health and pregnancy outcomes, have also resulted in an evidence base populated almost exclusively with evidence derived from studies using three specific dietary pattern methods, i.e. indices and scores, cluster or factor analysis and reduced rank regression (13-15). A brief review of the list of excluded articles for the NESR systematic review titled “Dietary Patterns before and during Pregnancy and Risk of Gestational Diabetes Mellitus” (NESR GDM) finds many that do not use the three methods of dietary pattern identification, yet provides evidence regarding relevant outcomes and dietary macronutrient distributions and/or food group intakes (14). Examples of potentially relevant exclusions, include RCT evidence of lower carbohydrate with higher total protein (16) and observational evidence of higher animal protein with lower carbohydrate (17) diets associated with improved pregnancy outcomes. While DGA dietary patterns do not include “animal protein” as a food group, protein foods, and animal and plant sub-groups, are inherent in the 2015 DGA patterns and recommendations (18). **Evidence of an association between animal protein and**

GDM can inform recommendations, even if not identified via specified dietary pattern methods, and is consistent with review of the totality of available evidence. The NESR study selection criteria resulted in the inclusion of 11 publications, representing 3 unique populations, resulting in an evidence grade of “limited” (14). Based on this limited evidence, NESR concluded that dietary patterns protective against gestational diabetes are, in part, lower in red and processed meats (14).

Studies included in the NESR GDM systematic review provide useful examples of previously identified limitations of using epidemiologic studies to assess dietary effects of meat and meat product consumption on health outcomes (16-20). Specifically, observational evidence regarding red and processed meat in dietary patterns has been limited and confounded by dietary survey groupings that are too broad or inaccurate to study specific meat effects (20-22) and interpretation of red or processed meat intake based on common, but unstandardized, dietary pattern names, such as Western or prudent, as low in red or processed meat (5, 13, 19, 23-25). **Evidence from RCTs, where meat types and intakes are independently evaluated and more clearly defined, provide less biased evidence, and are both foundational and complementary to inform recommendations on individual food groups such as meat (11, 26, 27). Dietary pattern methodology lacks the discernment needed to make individual food group recommendations, thus further confounding advice for red meat intake derived from dietary pattern methodology alone (11, 28).** Science-based dietary guidance must rely on systematically reviewing the totality of relevant evidence (2, 9).

In their report regarding the redesign of the process to establish the DGA, the NASEM Review Committee made the following observations, “The dual challenge faced in developing the DGAC Scientific Report, and subsequently the DGA recommendations, is to properly assess the quality and interpret the results of studies available, and to use them appropriately in drawing conclusions about the body of evidence. Taking the limitations of evidence sources into account is crucial for building guidelines that are based on the totality of scientific evidence (2).” Reliance on dietary pattern evidence, which lacks standardized methodology and pattern names, may contribute to erroneous conclusions regarding the role of red and processed meat in a healthful diet including, in the case of GDM, missing potential benefits of nutrient-dense animal protein intake (14, 16, 17). Systematic evaluation of the complete evidence base is essential and increases the public’s confidence in evidence-based guidelines and recommendations (2). The Beef Checkoff appreciates the opportunity to participate in the 2020 DGAC process and acknowledges the importance of best practices methodology of systematic review for dietary guidance.

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