


## Comment on FR Doc # 2019-04543

This is a Comment on the **Food and Nutrition Service (FNS) Notice: [Meetings: 2020 Dietary Guidelines Advisory Committee](#)**

For related information, [Open Docket Folder](#) 

### Comment

Subject: Use of Existing Systematic Reviews in 2015 - The excluded studies list of the NEL Dietary Patterns Report confirms that 70 studies, primarily randomized controlled trial (RCT) study designs, were excluded because they did not assess dietary patterns as defined for this project.

Dear Members of the 2020-2025 Dietary Guidelines Advisory Committee,

The Beef Checkoff appreciates the opportunity to provide input to the 2020 Dietary Guidelines for Americans (DGA) process. Updated evidence that lean beef can serve as the predominant protein source in Dietary Approaches to Stop Hypertension (DASH), Mediterranean and plant-forward style eating patterns will be provided to the 2020 Dietary Guidelines Advisory Committee (DGAC) in upcoming submissions. In the meantime, the Beef Checkoff is providing the attached summary, at the outset of the 2020 DGACs work, to demonstrate how a strict reliance on dietary pattern methodology can constrain the evidence for decision making.

In late 2015, a U.S. Congressional mandate initiated a review process by the National Academies of Sciences, Engineering, and Medicine (NASEM) Health and Medicine Division, to conduct a comprehensive study of the entire process used to establish the Advisory Committee for the Dietary Guidelines for Americans and the subsequent development of the Dietary Guidelines for Americans [1]. The NASEM Review Committee published two consensus reports, one provided recommendations to improve the selection of the DGAC [2], and the second provided recommendations for the review of evidence by the DGAC [3], and related support groups, including the national Nutrition Evidence Library (NEL), now the Nutrition Evidence Systematic Review (NESR) [4].

The NASEM Review Committee noted that the DGA process has not been reconsidered in a way that allows it to adapt to changes, such as those in food diversity and prevalence of chronic diseases, while also maintaining the integrity of the process [5]. The Committee further noted that, The steps used currently to evaluate the science are generally reasonable, but there are many ways in which the analyses need to be strengthened [4]. The Committee highlighted the NEL process as a key area for strengthening [4]. The attached document was submitted to the NASEM Review Committee on May 12, 2017, by the Beef Checkoff to provide evidence regarding the impact of the NEL systematic review process, as it was employed for the 2015 DGAC, on the evidence base ultimately used to inform recommendations made in the 2015 DGA.

Consistent with the goals of the DGA, the NEL systematic reviews, used to support the 2015 DGAC, were founded in research questions related to dietary patterns and chronic disease risk and prevention. However, the excluded studies list of the NEL Dietary Patterns Report [6] confirms that 70 studies, primarily randomized controlled trial (RCT) study designs, were excluded because they did not assess dietary patterns as defined for this project (see attachment). The NEL Dietary Patterns Report also resulted in the exclusion of numerous RCTs of beef in healthy dietary patterns and cardiovascular disease risk factor outcomes (see attachment).

The Beef Checkoff looks forward to reviewing the NESR systematic review protocols designed to inform the 2020 DGAC research questions. We appreciate the opportunity to provide input to the 2020 DGAC and will continue to participate throughout the 2020 DGA process. We offer our expertise for any questions the DGAC may have regarding beef in healthful diets.

#### References:

1. Consolidated Appropriations Act, 2016, Public Law 114-113, 114th Cong. (December 18, 2015), 129 Stat. 22802281.
2. National Academies of Sciences, Engineering, and Medicine. 2017. Optimizing the process for establishing the Dietary Guidelines for Americans: The selection process.

ID: FNS-2019-0001-0187

Tracking Number: 1k3-99aj-xy7k

### Document Information

**Date Posted:**

Apr 12, 2019

[Show More Details](#) 

### Submitter Information

**Submitter Name:**

Shalene McNeill, PhD, RD

**City:**

Centennial

**Country:**

United States

**State or Province:**

CO

**Category:**

Food industry

Washington, DC: The National Academies Press.

3. National Academies of Sciences, Engineering, and Medicine. 2017. Redesigning the process for establishing the Dietary Guidelines for Americans. Washington, DC: The National Academies Press.

4. About Nutrition Evidence Systematic Review (NESR), formerly the Nutrition Evidence Library (NEL). <https://nesr.usda.gov/about>

5. National Academies of Sciences, Engineering, and Medicine. 2017. Redesigning the process for establishing the Dietary Guidelines for Americans. Washington, DC: The National Academies Press. Report Highlights.

6. U.S. Department of Agriculture, Center for Nutrition Policy and Promotion, Evidence Analysis Library Division. A Series of Systematic Reviews on the Relationship Between Dietary Patterns and Health Outcomes. March 2014. Available at [https://www.cnpp.usda.gov/sites/default/files/usda\\_nutrition\\_evidence\\_flibrary/DietaryPatternsReport-FullFinal.pdf](https://www.cnpp.usda.gov/sites/default/files/usda_nutrition_evidence_flibrary/DietaryPatternsReport-FullFinal.pdf)

## Attachments (1)

---

[2017 Beef Checkoff BOLD\\_exclusion\\_comments\\_for\\_NAS Committee\\_to\\_review\\_DGA \[FINAL\]](#)

View Attachment: 

---

May 12, 2017

Ms. Meredith Young  
Keck Center  
WS718  
500 Fifth St. NW  
Washington, DC 20001

Re: Review of the Process to Update the Dietary Guidelines for Americans

To Whom It May Concern:

The Beef Checkoff appreciates the opportunity to provide comment to the “Committee to Review of the Process to Update the Dietary Guidelines for Americans” established by the Health and Medical Division of the National Academies of Science (NAS). The Institute of Medicine (IOM) of the NAS (now the Health and Medical Division) has, via a Committee on Standards for Systematic Reviews, established methodologic standards for the conduct of publically funded systematic reviews (SR) [1]. These Standards are designed to set performance expectations and promote accountability and transparency for publically funded SR so that “... observers can readily link judgments, decisions, or actions to the data on which they are based.”[1] In the context of the NAS SR standards, the Beef Checkoff would like to specifically address the SR executed by the United States Department of Agriculture (USDA) Nutrition Evidence Library (NEL) used to guide and inform the 2015 Dietary Guidelines Advisory Committee (DGAC) on dietary patterns and health outcomes and, in particular, cardiovascular disease (CVD) risk.

The DGAC is an advisory committee to USDA and the Department of Health and Human Services (HHS), yet for several key DGAC topics and related questions, the DGAC was largely advised by existing SR published in a 2014 report entitled, “A Series of Systematic Reviews on the Relationship Between Dietary Patterns and Health Outcomes” (from now on referred to as the NEL Dietary Patterns report), which resulted from the NEL Dietary Patterns Project [2, see also attachment A]. This report largely informed the conclusions for the following topics: dietary patterns and body weight/obesity; cardiovascular disease; and type 2 diabetes [3]. In contrast, topics not covered by the NEL Dietary Patterns report, such as dietary patterns and cancer and added sugars and risk of CVD, were addressed using *de novo* SR designed by the 2015 DGAC [3].

Best practices in SR recommend searching of grey-literature databases as a means to address and avoid reporting bias [1]. While it is unclear if grey literature databases such as the National Technical Information Service ([www.NTIS.gov](http://www.NTIS.gov)) were reviewed as part of the NEL SR process, use of the NEL Dietary Patterns report by the DGAC does reflect an effort by the DGAC to include grey literature in their assessment of the totality of evidence for the various

topics of interest. While the NEL Dietary Patterns report was not subject to traditional peer review<sup>1</sup>, the DGAC notes in their report that "...unlike the 2010 DGAC, the 2015 Committee was able to use existing sources of evidence to answer an additional 45 percent of the questions it addressed. These sources included existing SR, meta-analyses, or reports. The remainder of the questions, 30%, were answered using data analyses and food pattern modeling analyses." [3] The DGAC is tasked with "...developing nutrition and related health recommendations to..." the Secretaries of Health and Human Services (HHS) and of Agriculture (USDA) for use in updating *the Dietary Guidelines for Americans*. [3] At the same time, the primary stakeholders in the NEL Dietary Patterns Project were USDA and HHS [2] and the conclusions reported by the NEL Dietary Patterns report were based on objectives and methodologies implemented by USDA Center for Nutrition Policy and Promotion (CNPP) staff. [2]

In the case of questions related to cardiovascular health, "The DGAC examined research compiled in the NEL Dietary Patterns Systematic Review Project, which included 55 articles summarizing evidence from 52 prospective cohort studies and 7 randomized controlled trials (RCTs), and the 2013 AHA/ACC Lifestyle Guideline on Lifestyle Management to Reduce Cardiovascular Risk and associated National Heart, Lung, and Blood Institute (NHLBI) Lifestyle Report, which included primarily RCTs. The Committee drew additional evidence and effect size from six published systematic reviews/meta-analyses..."[3, Appendix E2.26] Due to the NEL Dietary Pattern Project interest in determining which dietary pattern methods were most useful in providing insight to health outcomes, SR questions were driven by dietary pattern assessment methodology and included the following for cardiovascular health:

- "What is the relationship between adherence to dietary guidelines/recommendations or specific dietary patterns, assessed using an index or score, and risk of cardiovascular disease?"
- Are prevailing patterns of diet behavior in a population, assessed using factor or cluster analysis, related to risk of cardiovascular disease?
- What is the relationship between adherence to dietary guidelines/recommendations or specific dietary patterns, assessed using reduced rank regression analysis, and cardiovascular disease?
- What is the relationship between adherence to dietary guidelines/recommendations or specific dietary patterns (assessed using methods other than index/score, cluster or factor, or reduced rank regression analyses) and risk of cardiovascular disease?" [2]

All these questions evaluate the relationship between *assessed* dietary patterns using various dietary pattern modeling/methodology (i.e. data driven such as cluster or factor analysis; or author defined via a pre-specified score or index). Missing from this list of questions, however, is a question designed to evaluate adherence to an *a priori assigned* dietary pattern, such as a DASH-style eating pattern, as tested in a RCT. The combined research questions and related inclusion exclusion criteria for the NEL Dietary Patterns project resulted in the questions regarding the role of CVD risk and dietary patterns being answered almost exclusively using evidence derived from cohort studies [2]. Exclusion of most, but not all, assigned dietary patterns in RCT study designs is confirmed by review of the NEL Dietary Patterns Report excluded studies list where 70 studies are excluded because they "did not assess dietary patterns as

---

<sup>1</sup> "Peer Reviewers included representatives from the following U.S. Department of Agriculture agencies:

- Food and Nutrition Science: Allison Magness, PhD, RD
- Center for Nutrition Policy and Promotion: Patricia Britten, PhD" [2, pg.v]

defined for this project” [2]. Practically, the NEL definition of dietary pattern resulted in exclusion of studies that examined individual foods in dietary patterns, adherence to fruit and vegetable recommendations, nutrients/macronutrients or food groups in dietary patterns, and DASH-style eating patterns in RCTs [2].

Use of existing NEL Dietary Patterns Projects SR also resulted in the exclusion from further DGAC consideration of numerous studies of beef in assigned healthy dietary patterns and CVD risk factor outcomes. A prime example is exclusion of key evidence regarding meat intake and CVD risk i.e. *Roussell MA, et al., 2012 Beef in an Optimal Lean Diet study: effects on lipids, lipoproteins, and apolipoproteins* (from now on referred to as the BOLD study) [4].

The NEL Dietary Pattern Project outlines the following inclusion/exclusion criteria:

- Studies published since January 1980 with subjects who were healthy or at elevated chronic disease risk from countries with high or very high scores on the Human Development Index, a measure of social and economic development, were considered;
- Study designs included in the review were randomized and nonrandomized controlled trials, including crossover studies, and prospective cohort studies;
- Cross-sectional studies, before and after studies, case-control studies, and reviews were excluded;
- Trials were required to have  $\geq 30$  subjects per arm and a follow-up of  $\geq 80$  percent;
- Studies that examined low-calorie diets and other treatment diets were excluded;
- Finally, studies were required to include a description of the foods and beverages eaten by study participants.

The NEL Dietary Patterns Report (published March 2014) originally notes the rationale for exclusion of the BOLD study to be “*sample size <30 subjects per study arm*”.<sup>2</sup> In contrast, the inclusion criteria outlined by the 2015 DGAC for *de novo* systematic reviews does not specify a minimum sample size. However, the BOLD study actually included 36 subjects per study arm. Noting that the stated rationale for exclusion of the BOLD study was incorrect, the Beef Checkoff requested clarification from CNPP about the error. A meeting with the CNPP team involved with managing the NEL process and reviewing studies was scheduled for June 18, 2014. However, between the time that the meeting was scheduled and the actual meeting (June 18), the online NEL was revised with the exclusion rationale for the BOLD study

---

<sup>2</sup> Best practices in systematic review warn against arbitrary sample size restrictions. The Agency for Healthcare Research Quality (AHRQ) advises against excluding studies based on sample size in their Methods Guide for Effectiveness and Comparative Effectiveness Reviews (AHRQ Guide). AHRQ notes the “Exclusion of small studies may exclude valuable information” and concludes that “smaller studies ... may be systematically different from larger studies ... and limiting by these characteristics for convenience may introduce a systematic bias”. Sample size is most often dictated by the need to achieve statistical power sufficient to see a predetermined effect size. If differences in a particular outcome variable can be obtained with <30 subjects per study arm, the exclusion of studies based on sample size could inadvertently omit useful evidence.

changed to state that “*All subjects were hypercholesterolemic.*”<sup>3</sup> No other study in the list of 997 studies excluded from the NEL report was excluded for this reason [2]<sup>4</sup>.

The Beef Checkoff submitted a letter on October 7, 2014, seeking clarification and provided CNPP with a list of studies of the relationship between lean red meat/lean beef and blood lipids and blood pressure that were not included in the NEL Dietary Patterns Report [see Attachment C]. Aside from the BOLD study, none of these studies were found by the NEL search strategy, i.e. they do not appear in either the included or excluded studies lists of the NEL Dietary Patterns report. In their October 17, 2014 response, CNPP stated that all of these studies did not meet the “objective criteria for inclusion in the NEL Dietary Patterns report”<sup>5</sup> and were excluded due to various reasons including incompliance with the “dietary pattern” definition; lack of information about the quantities, proportions and variety of foods and beverages consumed beyond the protein source despite the use, in some cases of well-defined diets such as the American Heart Association (AHA) Step I diet; sample size of less than 30 subjects per study arm, excess attrition as indicated by a follow-up rate of less than 80 percent; publication date; and treatment versus prevention oriented dietary intervention.<sup>5</sup> CNPP reiterated that the exclusion rationale for the BOLD study was that “all subjects were hypercholesterolemic”<sup>5</sup>.

In a follow-up letter (November 10, 2014), the Beef Checkoff requested further clarification on exclusion rationale for the BOLD study from the NEL offered in CNPP’s October 17, 2014 response was that “all subjects were hypercholesterolemic”. This appears inconsistent with other studies that were included in the NEL where all of the subjects had values for risk markers above the normal range; that is, other published research that was included in the NEL was also conducted with subjects who were at-risk for cardiovascular disease. For example, in the original DASH study published in 1997 and included in the NEL, Appel et. al., noted “Each subject had an average systolic blood pressure of less than 160 mm Hg and a diastolic blood pressure of 80 to 95 mm Hg (the mean of six measurements made during three screening visits)” [5]. Therefore, all subjects in the DASH trial were pre-hypertensive as determined by diastolic blood pressure of 80-95 mmHg [6]. Similarly, the BOLD study evaluated a healthy population with elevated chronic disease risk including subjects with LDL-C levels of between 110 and 178 mg/dl. The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) defines LDL-C of 100-129 mg/dl as near or above optimal range [7].

Furthermore, the low end of inclusion criteria from the BOLD study (110 mg/dl) is below the mean LDL-C levels in the US population (116 mg/dl) [8]. For comparison, the entry criterion for diastolic blood pressure in DASH was actually above the 2009-2010 population median of 70 mm Hg [9].

---

<sup>3</sup> The BOLD study evaluated a healthy population with elevated chronic disease risk by recruiting subjects with elevated LDL-C levels. While the BOLD authors reference their subject population as “hypercholesterolemic” in the abstract of their publication, the abstract also defines hypercholesterolemic as  $LDL \geq 2.8$  mmol/L (i.e.  $\geq 108$  mg/dl). The methods of the paper go on to further define the study LDL inclusion criteria as “2.84–4.55 mmol/L” (i.e. 108-175 mg/dL) and notes that subjects were excluded from participation if they were using cholesterol or lipid lowering medications. The mean LDL level of BOLD subjects at baseline was 139 mg/dL. Based on National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) guidelines, the BOLD subjects represent an un-medicated population with “near/above optimal” to “borderline high” LDL levels.

<sup>4</sup> See specifically Excluded Articles table found on pgs 143-212 [2].

<sup>5</sup> Correspondence date October 17, 2014. Available upon request.

In their November 24, 2014 written response, the CNPP team revised the rationale for exclusion to “health risk of the subjects”.<sup>6</sup> CNPP further indicated, the study was “interpreted as a therapeutic intervention in subjects with a therapeutic condition, hypercholesterolemia, and therefore excluded.”<sup>6</sup> While hypercholesterolemia was an exclusion criterion for the NEL Dietary Patterns report, it was not an exclusion criterion for 2015 DGAC SR. In their deliberations regarding CVD and dietary patterns, the 2015 DGAC augmented the NEL report with a NHLBI review of dietary patterns and CVD risk, which included at least one RCT with hypercholesterolemic subjects [10]. BOLD, was not published at the time the NHBLI SR was conducted. In addition, *de novo* DGAC SR had no restriction on sample size, no exclusion criteria for hypocaloric or “therapeutic” diets, included nested case-control designs, specified vegetarianism and DASH-style eating patterns as assigned dietary patterns of interest, excluded literature that was not peer-reviewed (e.g. Federal reports such as the NEL Dietary Patterns Report), and included literature published through 2014 vs 2013 for NEL Dietary Pattern SR [11; Attachment B].

The conclusions regarding cardiovascular disease risk and red meat reached by the NEL Dietary Patterns Project, i.e. “There is strong and consistent evidence that in healthy adults increased adherence to dietary patterns scoring high in fruits, vegetables, whole grains, nuts, legumes, unsaturated oils, low-fat dairy, poultry and fish; low in red and processed meat, high-fat dairy, and added sugars; and moderate in alcohol is associated with decreased risk of fatal and non-fatal cardiovascular diseases, including coronary heart disease and stroke” conflict with that reported by the Dietary Patterns Methodology Projects (DPMP). The DPMP is a collaboration between cohort researchers, independent of the NEL Dietary Patterns project, whose work provides insight on the limitations of dietary patterns methodology to make public health recommendations. The DPMP developed a protocol for a standardized methodologic approach which was followed in three parallel evaluations of four diet dietary pattern scores/indices (Healthy Eating Index 2010 (HEI-2010), Alternative Healthy Eating Index 2010 (AHEI-2010), Alternate Mediterranean Diet (aMED) score, Dietary Approaches to Stop Hypertension (DASH) score) in three cohorts (NIH-AARP Diet and Health Study (AARP study), Multiethnic Cohort (MEC), Women’s Health Initiative Observational Study (WHI-OS)) for three outcomes (all cause mortality, CVD, and cancer). Among these four dietary pattern measurement methodologies, reduced chronic disease risk began in each cohort at scores in Q2; none of the methods separated fresh red meat from processed red meat; none of the methods identified lean red meat; and the HEI, specifically, does not include a red meat (processed or fresh) factor at all. The DPMP authors note “It is important to recognize that this approach aggregates many different combinations of amounts of specific food groups and nutrients into each index score. ***To more fully evaluate the dietary intake patterns underlying each of the dietary quality index scores, multidimensional approaches would be needed.***” [12; emphasis added] Despite the limitations of the dietary patterns evaluated by the DPMP, associations between red and processed meat as individual contributors to a dietary pattern were found to be weak i.e. for all-cause mortality, CHD mortality, and cancer mortality, 3.7% (range 1-8.4%), 3.2% (range 0.8-8.8%), and 3.7% (1.2-7.8%), respectively. [13]

While the DGAC recognized the limitations of dietary patterns methodology for informing red meat intake advice, i.e. “Much of this research on eating patterns has grouped together all meats and poultry, regardless of fat content or processing, though some evidence has identified lean meats and lean poultry in healthy eating patterns.” [3], the DGAC concluded nonetheless that, “Strong evidence from mostly

---

<sup>6</sup> Correspondence dated November 24, 2014. Available upon request.

prospective cohort studies but also randomized controlled trials has shown that eating patterns that include lower intake of meats as well as processed meats and processed poultry are associated with reduced risk of CVD in adults” [3].

In summary, the DGAC was charged by CNPP to provide advice and make recommendations to inform the 2015 Dietary Guidelines for Americans and to do so using systematic review and analysis [3]. In the case of questions answered by *de novo* 2015 DGAC SR, evaluation of the latest evidence (through 2014), from a variety of study designs, testing both adherence to assessed and assigned dietary patterns, was accomplished. Reliance on the NEL Dietary Patterns report denied the DGAC the opportunity to evaluate the positive evidence for red meat in assigned healthy dietary patterns as tested in RCTs [see attachment C].

The IOM SR best practices guidance emphasizes stakeholder involvement in SR protocol development. The IOM defines stakeholders as, “... individuals who are likely to consult a specific SR to guide decision making or who have a particular interest in the outcome of an SR. This includes consumers, including patients, families, and informal (or unpaid) caregivers; clinicians, including physicians, nurses, and other healthcare professionals; payers; and policy makers, including guideline developers and other SR sponsors.” [1] The IOM SR best practice guidance makes the following recommendations for SR informing public health recommendations:

- The process of topic refinement and research question formulation should be the subject of a public comment period informed by a process document that details how topic refinement was accomplished and how research questions were formulated. [1]
- SR protocols should be made available for public review and comment. [1]
- Preliminary SR results should be made available for public review and comment so that “...observers can readily link judgments, decisions, or actions to the data on which they are based” [1] and, in doing so, provide a surrogate for peer review of grey-literature sources not otherwise evaluated by the traditional peer-review process.

The Beef Checkoff appreciates the opportunity to provide input to the NAS Committee charged with reviewing the DGA process. We looking forward to participating in future comment opportunities and offer our expertise for any questions they NAS Committee may have regarding lean beef in healthful dietary patterns.



## References:

1. Institute of Medicine (IOM). 2011. Finding What Works in Health Care: Standards for Systematic Reviews. Washington, DC: The National Academies Press.
2. U.S. Department of Agriculture, Center for Nutrition Policy and Promotion, Evidence Analysis Library Division. A series of systematic reviews on the relationship between dietary patterns and health outcomes. March 2014. Available at [https://www.cnpp.usda.gov/sites/default/files/usda\\_nutrition\\_evidence\\_flibrary/DietaryPatternsReport-FullFinal.pdf](https://www.cnpp.usda.gov/sites/default/files/usda_nutrition_evidence_flibrary/DietaryPatternsReport-FullFinal.pdf)
3. Dietary Guidelines Advisory Committee, 2015. Scientific report of the 2015 Dietary Guidelines Advisory Committee. Advisory report to the Secretary of Health and Human Services and the Secretary of Agriculture. Available at <https://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf>
4. Roussell MA, et al. Beef in an Optimal Lean Diet study: effects on lipids, lipoproteins, and apolipoproteins. *Am J Clin Nutr* 2012;95:9–16.
5. Appel LJ, et al. A clinical trial of the effects of dietary patterns on blood pressure. DASH Collaborative Research Group. *N Engl J Med* 1997;336(16):1117-24.
6. National High Blood Pressure Education Program. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. Bethesda (MD): National Heart, Lung, and Blood Institute (US); 2004 Aug. Report No.: 04-5230.
7. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. Executive Summary of The Third Report of The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, And Treatment of High Blood Cholesterol In Adults (Adult Treatment Panel III). *JAMA* 2001;285(19):2486-97.
8. Carroll MD, et al. Trends in lipids and lipoproteins in US adults, 1988-2010. *JAMA* 2012;308(15):1545-54.
9. Guo F, et al. Trends in prevalence, awareness, management, and control of hypertension among United States adults, 1999 to 2010. *J Am Coll Cardiol* 2012;60(7):599-606.
10. U.S. Department of Health and Human Services, National Heart, Lung, and Blood Institute (NHLBI). Lifestyle interventions to reduce cardiovascular disease risk. Systematic Evidence review from the Lifestyle Work group, 2013. <https://www.nhlbi.nih.gov/sites/www.nhlbi.nih.gov/files/lifestyle.pdf>
11. NEL Nutrition Evidence Library. Formerly available at: [http://www.nel.gov/template.cfm?template=sort\\_list\\_template&key=1097](http://www.nel.gov/template.cfm?template=sort_list_template&key=1097) last accessed March 01, 2017. *As of March 17, 2017 details of the 2015 DGAC NEL SR were removed from the NEL website and replaced by an overview document entitled “2015 Dietary Guidelines Advisory Committee (DGAC) Nutrition Evidence Library Methodology”. A link is provided in this document which is said to provide the detailed information for each review, however, it is unclear where. Attachment B, herein, provides information captured from the NEL website on March 01, 2017 providing the detail not evident from the recently posted overview document nor the links it contains.*
12. Liese AD, et al. The Dietary Patterns Methods Project: Synthesis of findings across cohorts and relevance to dietary guidance. *J Nutr* 2015;145:393-402.
13. Reedy J, et al. Higher diet quality is associated with decreased risk of all-cause, cardiovascular disease, and cancer mortality among older adults. *J Nutr* 2014;144:881–9.

## Attachment A – Genesis of NEL Dietary Patterns Project

Source: U.S. Department of Agriculture, Center for Nutrition Policy and Promotion, Evidence Analysis Library Division. A Series of Systematic Reviews on the Relationship Between Dietary Patterns and Health Outcomes. March 2014. Available at

[https://www.cnpp.usda.gov/sites/default/files/usda\\_nutrition\\_evidence\\_flibrary/DietaryPatternsReport-FullFinal.pdf](https://www.cnpp.usda.gov/sites/default/files/usda_nutrition_evidence_flibrary/DietaryPatternsReport-FullFinal.pdf)

To inform the design and objectives of the project, USDA’s Center for Nutrition Policy and Promotion supported a workshop titled, “Dietary Patterns Research Methods: Strengths and Limitations of Various Approaches to Inform a Systematic Review.” The workshop was held on September 1, 2011 in Alexandria, VA. The Dietary Patterns Systematic Review Management Team, Technical Expert Collaborative, and several Stakeholders attended the workshop along with invited speakers identified by the Technical Expert Collaborative.

Expert presentations included the following:

- Using factor and cluster analysis to derive dietary patterns
  - P.K. Newby, ScD, MPH, Boston University
- Using index analysis to assess dietary patterns
  - Beth Dixon, PhD, MPH, New York University
- Using reduced rank regression to identify dietary patterns
  - Angela Liese, PhD, University of South Carolina
- Dietary patterns from a clinical trials perspective
  - Larry Appel, MD, MPH, The Johns Hopkins University
- Dietary patterns from an epidemiological perspective
  - Matthias Schulze, DrPH, German Institute of Human Nutrition (via webinar)

A facilitated panel discussion followed the presentations and included dialogue related to the operational definition of dietary patterns for the purposes of this systematic review project and the appropriateness of using various research methods for answering systematic review questions related to dietary patterns and health. The Dietary Patterns Systematic Review Management Team and Technical Expert Collaborative used the discussion from this workshop to frame the approach and questions for this project.

For the purpose of this systematic review project, dietary patterns is defined as: *The quantities, proportions, variety, or combination of different foods, drinks, and nutrients (when available) in diets, and the frequency with which they are habitually consumed.*

### Objectives

The purpose of the Dietary Patterns Systematic Review project was to examine the relationship between dietary patterns and outcomes of public health concern. The initial goal of this project is to continue the work initiated by the 2010 DGAC to assess the association of several dietary patterns with blood pressure, cardiovascular disease, stroke, and total mortality. Additional objectives were identified and prioritized by the TEC with input from the Systematic Review Management Team and key stakeholders.

## Attachment B – 2015 DGAC SR Content from NEL Evidence Library Website Prior to March 17, 2017

[2015 Dietary Guidelines Advisory Committee](#) > [Dietary Patterns, Foods and Nutrients](#) > [Dietary Patterns and Risk of Cancer](#)

Search Plan and Results

### Question(s)

[What is the relationship between dietary patterns and risk of breast cancer? \(2015 DGAC\)](#)

[What is the relationship between dietary patterns and risk of colorectal cancer? \(2015 DGAC\)](#)

[What is the relationship between dietary patterns and risk of prostate cancer? \(2015 DGAC\)](#)

[What is the relationship between dietary patterns and risk of lung cancer? \(2015 DGAC\)](#)

### Date Searched

January 2014 to February 2014

### Inclusion Criteria

Inclusion criteria for the dietary patterns–cancer systematic reviews, included the following:

- Human subjects
- Subject populations from countries with high or very high human development, according to the 2012 Human Development Index (United Nations Development Programme. Human Development Report 2013, The Rise of the South: Human Progress in a Diverse World 2013. Available at: [http://hdr.undp.org/sites/default/files/reports/14/hdr2013\\_en\\_complete.pdf](http://hdr.undp.org/sites/default/files/reports/14/hdr2013_en_complete.pdf))
- Children, adolescents and adults aged two years and older
- Subjects who were healthy or at elevated chronic disease risk
- Randomized or non-randomized controlled trial, prospective cohort study or a nested case-control study
- Intervention studies with a dropout rate of 20% and a differential dropout rate of 15% between groups
- The intervention or exposure was adherence to a dietary pattern [e.g., *a priori* patterns (indices/scores), data driven patterns (factor or cluster analysis), reduced rank regression or patterns derived from other methods [Dietary Approaches to Stop Hypertension (DASH), vegetarian]
- A description of the dietary pattern(s) (i.e., foods and beverages) consumed by subjects was provided
- The comparator was different levels of adherence to a dietary pattern or adherence to a different dietary pattern
- The outcome was incidence of colorectal, breast, prostate or lung cancer.

In addition, articles were included if they were published in English in a peer-reviewed journal between January 2000 and January 2014. If an author is included on more than one primary research article that is similar in content, the paper with the most pertinent data and endpoints was included. If data and endpoints from both papers are appropriate, it was made clear that results are from the same intervention.

## Exclusion Criteria

Exclusion criteria for the dietary patterns systematic reviews included:

- Animals and *in vitro* models
- Subject populations from countries with medium or low human development, according to the Human Development Index
- Children under the age of two years
- Subjects who were hospitalized, diagnosed with disease and receiving medical treatment
- Study types including:
  - Systematic review
  - Meta-analysis
  - Narrative review
  - Before and after
  - Uncontrolled
  - Cross-sectional
  - Case-control
  - Ecological design.
- Articles were excluded if they were:
  - Not published in English
  - Published before January 2000
  - Not published in peer-reviewed journals (e.g., websites, magazine articles, Federal reports).
- If an author was included on more than one review article or primary research article similar in content, the paper with the most pertinent data and endpoints was included and others were excluded.

### 2015 Dietary Guidelines Advisory Committee

#### Nutrition Evidence Library (NEL) Systematic Reviews

The NEL website provides a detailed evidence portfolio for each of the 2015 Dietary Guidelines Advisory Committee's systematic reviews. Each evidence portfolio in the NEL contains the systematic review questions, technical abstract, conclusion statement and grade, key findings, research recommendations, evidence summaries, and search plan and results. The *Scientific Report of the 2015 Dietary Guidelines Advisory Committee* summarizes science reviews conducted using systematic review findings and other evidence-based approaches, and provides interpretations and implications related to these reviews. Information in the report was vetted by the full committee and presented at public meetings; however, more detailed supporting information on each specific systematic review is available on the NEL website. To navigate the NEL:

- Select a topic from the menu on the left to examine the evidence reviewed by the Committee
- Each topic is divided into subtopics of questions reviewed by the Committee
- By clicking on a subtopic you can access:
  - Systematic review questions - Questions formulated by the Committee, with analytical frameworks
    - Click the question to access the technical abstract, which succinctly describes the question, background, conclusion, methods and findings, or hover over the question to see the just the conclusion statement and grade
  - Full Review -
    - **Conclusion statements:** Concise statements that answer the questions based on the Committee's review of the evidence
    - **Grade:** Indicates the strength of the evidence support
    - **Key Findings:** Highlight important findings that contributed to conclusion statement development
    - **Research Recommendations:** Identify research gaps and limitations
  - Evidence summaries - A description and synthesis of the body of evidence, the NEL Risk of Bias table, research recommendations, and references
  - Search plan and results - A description of the search parameters and selection criteria used to identify peer-reviewed literature related to the topic of interest. Additionally, the final list of articles included in the review is provided, along with the articles excluded from the review, with reasons for exclusion.

Note: For 2015 Dietary Guidelines Advisory Committee and support staff membership and acknowledgments lists, see: [Membership](#) and [Appendix E-10: Dietary Guidelines Advisory Committee Report Acknowledgments](#).

Last Updated: 02/03/2015

**Attachment C: Summary of Randomized Clinical Trials evaluating diets containing lean red meat/lean beef on cardiovascular disease risk factors**

Reference citation	Study Design	Study Population	Results for Beef	CNPP Rationale for Exclusion
<b>Flynn</b> MA, et al. Serum lipids in humans fed diets containing beef or fish and poultry. <i>Am J Clin Nutr</i> <b>1981</b> ;34:2734–2741.	5 oz/d raw beef vs. poultry & fish for 3 months; crossover design	n=129 healthy adults; free-living; self-selected diets	Compared to poultry & fish diet, no changes in serum TC, TG or HDL in men; lower TG in women	Did not provide a description of the foods and beverages consumed by the subjects
<b>Flynn</b> MA, et al. Dietary “meats” and serum lipids. <i>Am J Clin Nutr</i> <b>1982</b> ;35:935–942.	5 oz/d raw beef vs. poultry & fish vs. pork for 3 months; crossover design	n=76 healthy adults free-living, self-selected diets	No differences in serum TC, TG between diets	Did not provide a description of the foods and beverages consumed by the subjects
<b>Scott</b> L, et al. Effects of a lean beef diet and of a chicken and fish diet on lipoprotein profiles. <i>Nutr Metab Cardiovasc Dis</i> <b>1991</b> ;1:25–30.	8 oz/d raw lean beef vs. chicken & fish in AHA and NCEP Step 1 diet (<30% kcal from total fat, <10% kcal from saturated fat); 11 wk study; parallel design	n=46 mild hypercholesterolemic men	Similar decreases in serum TC, LDL in both diets	Sample size was less <30 subjects per study arm
<b>Scott</b> L, et al. Effects of beef and chicken consumption on plasma lipid levels in hypercholesterolemic men. <i>Arch Intern Med</i> <b>1994</b> ;154:1261–1267.	3 oz/d cooked lean beef vs. chicken & fish in AHA and NCEP Step 1 diet (8-10% kcal from saturated fat); 13 week study; parallel design	n=36 hypercholesterolemic men; free-living	Similar decreases in plasma TC and LDL in both diets	Sample size was less <30 subjects per study arm  Did not provide a description of the foods and beverages consumed by the subjects
<b>Davidson</b> MH, et al. Comparison of the effects of lean red meat vs lean white meat on serum lipid levels among free-living persons with hypercholesterolemia: a long-term, randomized clinical trial. <i>Arch Intern Med</i> <b>1999</b> ;159:1331–1338.	6 oz/d lean red vs. lean white meat in NCEP Step I diet (<30% kcal from total fat, 8-10% kcal from saturated fat); 36 week dietary intervention; parallel design	n=191 hypercholesterolemic adults; free-living	Similar decreases in serum TC and LDL; no change in TG; HDL slightly increased in both diets	Follow-up rate was less than 80%  Did not provide a description of the foods and beverages consumed by the subjects
<b>Hunninghake</b> DB, et al. Incorporation of lean red meat into a National Cholesterol Education Program step I diet: a long-term, randomized clinical trial in free-living persons with hypercholesterolemia. <i>J Am Coll Nutr</i> <b>2000</b> ;19:351–360.	≥6 oz/d lean red vs. lean white meat in NCEP Step I diet (<30% kcal from total fat, 8-10% kcal from saturated fat); 36 week dietary interventions (76-week study); crossover design	n=145 hypercholesterolemic adults; free-living	Similar decreases in serum TC and LDL; no change in TG; HDL slightly increased in both diets	Follow-up rate was less than 80%  Did not provide a description of the foods and beverages consumed by the subjects
<b>Beauchesne-Rondeau</b> E, et al. Plasma lipids and lipoproteins in hypercholesterolemic men fed a lipid lowering diet containing lean beef, lean fish, or poultry. <i>Am J Clin Nutr</i> <b>2003</b> ;77:587–593.	≥6 oz/d lean beef vs. lean poultry vs. lean fish into an AHA diet with a high PUFA:SFA and high fiber content; 26d dietary interventions; crossover design	n=18 hypercholesterolemic men	Similar decreases in plasma TC and LDL in all three diets	Sample size was <30 subjects per study arm  Did not provide a description of the foods and beverages consumed by the subjects

<b>Melanson K</b> , et al. Weight loss and total lipid profile changes in overweight women consuming beef or chicken as the primary protein source. <i>Nutrition</i> <b>2003</b> ;19:409-414.	Beef vs. chicken as primary source of protein in individualized hypocaloric diets (19-22% protein in diets); 12 wk intervention; parallel design; weight loss study	n=61 overweight women	Similar decreases in body weight and body fat%; similar decreases in plasma TC, LDL and TG in both diets	Sample size was <30 subjects per study arm  Follow-up rate was less than 80%  Did not provide a description of the foods and beverages consumed by the subjects
<b>Hodgson JM</b> , et al. Partial substitution of carbohydrate intake with protein intake from lean red meat lowers blood pressure in hypertensive persons. <i>Am J Clin Nutr</i> <b>2006</b> ;83:780-7.	Partial substitution of carbohydrates with protein from lean red meat (with counseling from dietitian); 8 wk study; parallel design	n=60 hypertensive adults	Compared to control group, protein group had lower systolic blood pressure measurements	Sample size was <30 subjects per study arm  Did not provide a description of the foods and beverages consumed by the subjects
<b>Mahon AK</b> , et al. Protein intake during energy restriction: effects on body composition and markers of metabolic and cardiovascular health in postmenopausal women. <i>J Am Coll Nutr</i> <b>2007</b> ;26:182-189.	3 energy restricted diets: lacto-ovo vegetarian basal diet plus 250 kcal/d of either beef, chicken or carbohydrate/fat foods; control group consumed their habitual diets, weight loss study	n=54 postmenopausal overweight/mildly obese women	For all energy restricted diet subjects, fat mass, and fat-free mass similarly decreased. Loss in body mass was similar for chicken and beef groups, but significantly greater loss in fat mass than carbohydrate/fat foods and control groups. TC, LDL total and LDL similarly decreased with no differences among groups.	Sample size was <30 subjects per study arm  Did not provide a description of the foods and beverages consumed by the subjects
<b>Roussel MA</b> , et al. Beef in an Optimal Lean Diet study: effects on lipids, lipoproteins, and apolipoproteins. <i>Am J Clin Nutr</i> <b>2012</b> ;95:9-16.	28g beef vs. 113g beef vs. 153 g beef daily in a DASH-like dietary pattern and control (Healthy American Diet), 5wk dietary interventions; crossover design	n=36 hypercholesterolemic adults	Compared to control, all treatment diets decreased TC and LDL equally	All subjects were hypercholesterolemic (note: the only study outcome of interest to the NEL review was cholesterol)
<b>Roussel MA</b> , et al. Effects of a DASH-like diet containing lean beef on vascular health. <i>J Hum Hypertens.</i> <b>2014</b> ;28:600-5.	28g beef vs. 113g beef vs. 153 g beef daily in a DASH-like dietary pattern and control (Healthy American Diet), 5wk dietary interventions; crossover design	n=36 normotensive adults	Compared to control, moderate protein diet with 153g beef/d significantly decreased systolic blood pressure	Published after the search end date of August 2013

Definitions: apo = apolipoprotein; AHA = American Heart Association; BP = blood pressure; DASH = Dietary Approaches to Stop Hypertension; HDL = high density lipoprotein cholesterol; LDL = low density lipoprotein cholesterol; NCEP = National Cholesterol Education Program; P:S = polyunsaturated to saturated fatty acid ratio; PUFA = polyunsaturated fatty acids; SBP = systolic blood pressure; SFA = saturated fatty acids; TC = total cholesterol; TG = triglycerides; VLDL = very low-density lipoprotein