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Comment

RE: Eligibility of red meat/beef randomized trials using FINAL cardiovascular disease-related protocols

Systematic reviews (SR) are foundational for dietary guidance and provide the opportunity to make evidence-based public health recommendations that are objective, transparent, and scientifically robust. Best practices for SR methodology aim to ensure that reviews are comprehensive and free from bias. During Meeting 5 (March 12 -13, 2020), the DGAC subcommittees introduced new SR eligibility criteria, that were designed to narrow the evidence and reduce the workload volume including study duration, and size of study group requirements across the SR protocols. Through a combination of these revised eligibility criteria and existing publication date restrictions, of the 36 randomized controlled trials (RCTs) submitted for consideration to the DGAC by the Beef Checkoff, only 4 were ultimately considered as evidence for questions related to cardiovascular disease (CVD). An additional 7 to 9 RCTs per CVD question met original evidence eligibility criteria, other than publication date, but would have been excluded by revised criteria introduced to reduce the workload volume. The final 2020-2025 DGAC SR protocols (released on April 20, 2020) leave evidence gaps that prevent the totality of the high-quality evidence on red meat's role in CVD from being considered for the 2020-2025 Dietary Guidelines for Americans.

Thank you for the opportunity to share the attached evidence overview, regarding the eligibility of red meat/beef research studies using the final systematic review protocols.

Attachments 1

BeefCheckoffCommentsonRCTs060520

Download (https://downloads.regulations.gov/FNS-2019-0001-60700/attachment_1.pdf)

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a contractor to the Beef Checkoff

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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: Eligibility of red meat/beef randomized trials using FINAL CVD-related protocols

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

The Beef Checkoff appreciates the opportunity to provide evidence regarding the inclusion and exclusion of red meat/beef research studies using the final systematic review (SR) protocols posted online on April 20, 2020.

Previously, the Beef Checkoff submitted public comments to the 2020 DGAC on 36 randomized controlled trials (RCT) relevant to the role of red meat and beef in cardiovascular health (FNS-2019-0001-41992). Using the posted protocols, and the limited time available before the DGAC comment period closes, we have endeavored to determine how much of this RCT evidence was ultimately considered for the two DGAC questions related to dietary fat and dietary patterns, respectively, and cardiovascular disease (CVD).

We previously sent a direct request for these CVD-related search strategies on October 11, 2019 and received them on April 20, 2020 as part of the final SR protocol posting. Providing search strategy details is crucial for appraisement of SR protocols. Without the transparency offered by timely availability of complete search strategies, the public has been unable to comment on available evidence for numerous protocols, until the April 20, 2020 posting of the complete and final protocols.

Systematic reviews are foundational for dietary guidance and provide the opportunity to make evidence-based public health recommendations that are objective, transparent, and scientifically robust. Best practices for SR methodology aim to ensure that reviews are comprehensive and free from bias. During Meeting 5 (March 12 -13, 2020), the DGAC subcommittees introduced new SR eligibility criteria, that were designed to narrow the evidence and reduce the workload volume including study duration, and size of study group requirements across the SR protocols. Through a combination of these revised eligibility criteria and existing publication date restrictions, of the 36 RCT submitted for consideration to the DGAC by the Beef Checkoff, only 4 were ultimately considered as evidence for questions related to CVD. An additional 7 to 9 RCTs per CVD question met original evidence eligibility criteria, other than publication date, but would have been excluded by revised criteria introduced to reduce the workload volume. The final 2020-2025 DGAC SR protocols leave evidence gaps that prevent the totality of the high-quality evidence on red meat's role in CVD from being considered for the 2020-2025 Dietary Guidelines for Americans.

Thank you for the opportunity to share the attached evidence overview, regarding the eligibility of red meat/beef research studies using the final systematic review protocols.

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BEEF
Funded by
the Beef Checkoff.

RE: Questions regarding the inclusion and exclusion of red meat/beef research studies using FINAL protocols

On April 20, 2020 the Dietary Guidelines for Americans (DGA) website was updated to include final systematic review (SR) protocols for all research questions that the Dietary Guidelines Advisory Committee (DGAC) has had sufficient time to complete.[1,2] Thirty-six randomized controlled trials (RCT) relevant to the role of red meat and beef in cardiovascular health were provided to the 2020 DGAC via public comments made by the Beef Checkoff.[3] **Using the posted protocols, and the limited time available before the DGAC comment period closes, we have endeavored to determine how much of this RCT evidence was ultimately considered for the two DGAC questions related to dietary fat and dietary patterns, respectively, and cardiovascular disease (CVD).[4,5]** To complete our review, we began by running the Pub Med search strategies provided in these two protocols.[4,5] **We directly requested these CVD-related search strategies on October 11, 2019 and received them on April 20, 2020 as part of the final SR protocol posting.**[6] Providing search strategy details is crucial for appraisement of SR protocols.[7] Without the transparency offered by timely availability of complete search strategies, the public has been unable to comment on available evidence for numerous protocols, until the April 20, 2020 posting of the complete and final protocols.[8]

Since the dietary patterns and CVD SR protocol included two distinct publication ranges for dietary patterns and macronutrient distribution diets[9], we treated these as separate questions for our review purposes. Figures 1-3 below illustrate how evidence submitted by the Beef Checkoff to the DGAC ultimately tracked through the SR process. Figures 1-3 further reflect the reconciliation of Beef Checkoff evidence versus DGAC eligibility criteria as detailed further in Table 1.

[1] https://www.dietaryguidelines.gov/work-under-way/review-science/topics-and-questions-under-review.

[2] https://www.dietaryguidelines.gov/most-popular-questions; Question – Why didn't the Committee answer all the questions, were they not given enough time to complete their work?

[3] McNeill S. https://www.regulations.gov/document?D=FNS-2019-0001-41992

[4] WHAT IS THE RELATIONSHIP BETWEEN DIETARY PATTERNS CONSUMED AND RISK OF CARDIOVASCULAR DISEASE?: SYSTEMATIC REVIEW PROTOCOL. https://www.dietaryguidelines.gov/sites/default/files/2020-04/DP-CVD-Protocol-DPSC-04-22-2020.pdf, see pgs 3-5 (eligibility criteria) and pgs 6 and 10 (search strategies).

[5] WHAT IS THE RELATIONSHIP BETWEEN TYPES OF DIETARY FAT CONSUMED AND RISK OF CARDIOVASCULAR DISEASE?: SYSTEMATIC REVIEW PROTOCOL. https://www.dietaryguidelines.gov/sites/default/files/2020-04/DFSSC_DF-CVD_Final_Protocol_4.20.2020.pdf, see pgs 4-8 (eligibility criteria) see pg 13 (search strategy).

[6] Email correspondence available upon request.

[7] Shamseer L, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ 2014;349:g7647.

[8] https://www.dietaryguidelines.gov/work-under-way/review-science/topics-and-questions-under-review "**All protocols are now final.** The protocols take into account input from the full Committee during its public meetings and public comments received throughout the Committee's work. The final protocols – which are found by clicking on the question of interest in the tables below – include those recently updated for scientific questions using systematic reviews. **Each systematic review protocol on this website now provides the literature search strategy**, the list of scientific articles included in the review, and the list of articles excluded after full-text screening, with at least one rationale for exclusion." [emphasis added]

[9] WHAT IS THE RELATIONSHIP BETWEEN DIETARY PATTERNS CONSUMED AND RISK OF CARDIOVASCULAR DISEASE?: SYSTEMATIC REVIEW PROTOCOL. https://www.dietaryguidelines.gov/sites/default/files/2020-04/DP-CVD-Protocol-DPSC-04-22-2020.pdf, see pg 4 "date of publication"

Dietary patterns and CVD (Figure 1; Table 1):

None of the 36 RCT submitted by the Beef Checkoff were included by the DGAC although, based on our review, 7 RCT would have been eligible aside from publication date restrictions and eligibility criteria added to streamline the review process.[4] Specifically,

- Eighty percent (n=29) was *excluded* based solely on publication date *prior to 2014* (Figure 1, Table 1).
    - Of this evidence, 2 RCT met all *other* DGAC eligibility criteria[10,11]
    - The remaining 5 RCT[12,13,14,15] , including the 2012 Beef in an Optimal Lean Diet (BOLD) study publication[16], would not have been excluded by originally posted protocols but were ultimately excluded based on duration and sample size criteria that were introduced at the very end of public DGAC deliberations, during Meeting 5, 8 months from when their research protocols were first discussed, in an effort to lessen "…the workload volume…"[17]
- Evidence eligible based on publication date was either not found by the DGAC search strategy[18] (n=3; includes the 2014 BOLD vascular study publication)[19,20,21]or was excluded at full text review (n=4; Figure 1, Table 1).[22]
    - Of this evidence, 2 RCT met original eligibility criteria[4] but were excluded based on criteria designed to lessen the workload volume.[17,23,24] One RCT met all eligibility criteria but was not found by the DGAC search strategy.[18,25]

[10] Davidson 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. Arch Intern Med 1999; 159:1331–1338.
[11] Hunninghake 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. J Am Coll Nutr 2000; 19:351–360.
[12] Wiebe SL, et al. A comparison of the effect of diets containing beef protein and plant proteins on blood lipids of healthy young men. Am J Clin Nutr 1984; 40:982–9
[13] Gascon A, et al. Plasma lipoprotein profile and lipolytic activities in response to the substitution of lean white fish for other animal protein sources in premenopausal women. Am J Clin Nutr 1996; 63:315–21
[14] Beauchesne-Rondeau E, et al. Plasma lipids and lipoproteins in hypercholesterolemic men fed a lipid lowering diet containing lean beef, lean fish, or poultry. Am J Clin Nutr 2003; 77:587–593.
[15] Gilmore LA, et al. Consumption of High-Oleic Acid Ground Beef Increases HDL-Cholesterol Concentration but Both High- and Low-Oleic Acid Ground Beef Decrease HDL Particle Diameter in Normocholesterolemic Men. J. Nutr. 2011; 141: 1188–1194.
[16] 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
[17] DGAC Meeting 5, March 12, 2020 Afternoon Session.
https://globalmeetwebinar.webcasts.com/viewer/event.jsp?ei=1289829&tp_key=62557ab93c Timestamp: 27:27
[18] Results of DGAC Pub Med search strategy for purposes of this evidence overview available upon request.
[19] Grieger JA, et al. Investigation of the effects of a high fish diet on inflammatory cytokines, blood pressure, and lipids in healthy older Australians. Food Nutr Res 2014; 58:20369.
[20] Daly RM, et al. Protein-enriched diet, with the use of lean red meat, combined with progressive resistance training enhances lean tissue mass and muscle strength and reduces circulating IL-6 concentrations in elderly women: a cluster randomized controlled trial. Am J Clin Nutr 2014; 99:899-910.
[21] Roussell MA, et al. Effects of a DASH-like diet containing lean beef on vascular health J Hum Hypertens. 2014;28:600-5.
[22] WHAT IS THE RELATIONSHIP BETWEEN DIETARY PATTERNS CONSUMED AND RISK OF CARDIOVASCULAR DISEASE?: SYSTEMATIC REVIEW PROTOCOL. https://www.dietaryguidelines.gov/sites/default/files/2020-04/DP-CVD-Protocol-DPSC-04-22-2020.pdf, see pgs 117, 150, 183, 232
[23] Thorning TK, et al. Diets with high-fat cheese, high-fat meat, or carbohydrate on cardiovascular risk markers in overweight postmenopausal women: a randomized crossover trial. Am J Clin Nutr 2015; 102:573–81.
[24] Hill AM, et al. Type and amount of dietary protein in the treatment of metabolic syndrome: a randomized controlled trial. Am J Clin Nutr 2015; 102:757-70
[25] Sayer RD, et al. Equivalent reductions in body weight during the Beef WISE Study: beef's role in weight improvement, satisfaction and energy. Obes Sci Prac 2017; 3:298-310.

Macronutrient distribution diets and CVD (Figure 2; Table 1):

One study of the 36 RCT submitted by the Beef Checkoff was ultimately considered by the DGAC as evidence although, based on our review, 8 additional RCT would have been eligible aside from publication date restrictions and eligibility criteria added to streamline the review process. Specifically,

- Over half the RCT evidence was *excluded* due to publication *prior to 2000* (n=19; Figure 2, Table 1).
    - Of the evidence excluded due to publication date, 3 RCT either met all *other* DGAC eligibility criteria (n=2)[4,26,27]or met all original inclusion criteria but were ultimately excluded based on criteria introduced to streamline the evidence review process (n=1).[17,28]
- Of the evidence potentially eligible by publication date, 9 RCT were excluded at title/abstract (TiAB) screening.[18]
    - Of these, 2 RCT met all DGAC eligibility criteria.[29,30] Had these RCT been passed to full-text review, based on meeting all DGAC eligibility criteria[4], they could have been included in the evidence base used to answer this research question.
- Four RCT were reviewed at full text but ultimately excluded (Figure 2).[31]
    - Of the evidence excluded at full-text review, 2 RCT were excluded based on criteria designed to refine and prioritize the evidence review process (Figure 2). One of these, the 2014 BOLD study publication, was excluded for only one reason, insufficient duration[32], but actually was not an eligible intervention/exposure for this question as all macronutrients were within the AMDR.[33]
- The study ultimately included[34] by the DGAC did not meet DGAC publication eligibility criteria for macronutrient distribution diets, i.e. published after 2013.[4]

[26] Flynn MA, et al. Serum lipids in humans fed diets containing beef or fish and poultry. Am J Clin Nutr 1981; 34:2734–2741
[27] Sayer RD, et al. Equivalent reductions in body weight during the Beef WISE Study: beef's role in weight improvement, satisfaction and energy. Obes Sci Prac 2017; 3:298-310.
[28] O'Dea, K. et al. Cholesterol-lowering effect of a low-fat diet containing lean beef is reversed by the addition of beef fat. Am J Clin Nutr 1990; 52:491-4
[29] Hunninghake 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. J Am Coll Nutr 2000; 19:351–360.
[30] Murphy KJ, et al. Effects of Eating Fresh Lean Pork on Cardiometabolic Health Parameters. Nutrients 2012; 4:711-723.
[31] WHAT IS THE RELATIONSHIP BETWEEN DIETARY PATTERNS CONSUMED AND RISK OF CARDIOVASCULAR DISEASE?: SYSTEMATIC REVIEW PROTOCOL. https://www.dietaryguidelines.gov/sites/default/files/2020-04/DP-CVD-Protocol-DPSC-04-22-2020.pdf, see pages 52, 159, 206, 223.
[32] WHAT IS THE RELATIONSHIP BETWEEN DIETARY PATTERNS CONSUMED AND RISK OF CARDIOVASCULAR DISEASE?: SYSTEMATIC REVIEW PROTOCOL. https://www.dietaryguidelines.gov/sites/default/files/2020-04/DP-CVD-Protocol-DPSC-04-22-2020.pdf, see pg. 206
[33] Roussell MA, et al. Effects of a DASH-like diet containing lean beef on vascular health J Hum Hypertens. 2014 Oct;28(10):600-5.
[34] Daly RM, et al. Protein-enriched diet, with the use of lean red meat, combined with progressive resistance training enhances lean tissue mass and muscle strength and reduces circulating IL-6 concentrations in elderly women: a cluster randomized controlled trial. Am J Clin Nutr 2014; 99:899-910

Dietary fat and CVD (Figure 3, Table 1):

Three of the 36 RCT submitted by the Beef Checkoff were ultimately considered by the DGAC as evidence although, based on our review, 4 additional RCT would have been eligible aside from publication date restrictions and eligibility criteria added to streamline the review process. Specifically,

- Over 60% (n=22) was *excluded* solely based on publication date *prior to 2010* (Figure 3, Table 1). Of this evidence, 3 RCT met all *other* DGAC eligibility criteria (Figure 3).[5]
- Of the evidence potentially eligible by publication date (Table 1, n=13), 3 RCT were included by the DGAC.[35] Four others, including the BOLD study, were found but excluded at full text review (Figure 3).[36]
    - Of these studies, one study (Thorning et al.)[37] was excluded based on criteria introduced to streamline the evidence review process.[38]
    - The lipids related publication from the BOLD study (2012) was excluded for "health status."[39] This reason for exclusion is inconsistent with the eligibility criteria for this research question which *allows* "Studies that enroll participants who are healthy and/or at risk for chronic disease, including those with obesity."[5]
    - The vascular related publication from the BOLD study (2014) was excluded based on an ineligible intervention/exposure for this research question.[39]

Systematic reviews are foundational for dietary guidance and provide the opportunity to make evidence-based public health recommendations that are objective, transparent, and scientifically robust.[40,41] Best practices for SR methodology aim to ensure that reviews are comprehensive and free from bias.[40] Sound systematic reviews evaluate the TOTAL evidence base related to a particular research question, including both observational studies and RCTs.[42,43]Randomized controlled trials, 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.[42,43]

Of the 36 RCT submitted for consideration to the DGAC by the Beef Checkoff, only 4 were ultimately considered as evidence for questions related to CVD. Nearly 20% of the RCT evidence relevant to red meat/beef and CVD was excluded by the DGAC based only on publication date (Figures 1-3). **Well-**

[35] WHAT IS THE RELATIONSHIP BETWEEN TYPES OF DIETARY FAT CONSUMED AND RISK OF CARDIOVASCULAR DISEASE?: SYSTEMATIC REVIEW PROTOCOL. https://www.dietaryguidelines.gov/sites/default/files/2020-04/DFSSC_DF-CVD_Final_Protocol_4.20.2020.pdf, see pgs. 18, 22, 23

[36] WHAT IS THE RELATIONSHIP BETWEEN TYPES OF DIETARY FAT CONSUMED AND RISK OF CARDIOVASCULAR DISEASE?: SYSTEMATIC REVIEW PROTOCOL. https://www.dietaryguidelines.gov/sites/default/files/2020-04/DFSSC_DF-CVD_Final_Protocol_4.20.2020.pdf, see pgs. 143, 174,195,155

[37] Thorning TK, et al. Diets with high-fat cheese, high-fat meat, or carbohydrate on cardiovascular risk markers in overweight postmenopausal women: a randomized crossover trial. Am J Clin Nutr 2015; 102:573–81.

[38] https://globalmeetwebinar.webcasts.com/viewer/event.jsp?ei=1289846&tp_key=af6515fc8a 1:37:00

[39] https://www.dietaryguidelines.gov/sites/default/files/2020-04/DFSSC_DF-CVD_Final_Protocol_4.20.2020.pdf See pg. 174

[40] 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.

[41] IOM (Institute of Medicine). 2011. Finding What Works in Health Care: Standards for Systematic Reviews. Washington, DC: The National Academies Press.

[42] Schulze MB, et al. Food based dietary patterns and chronic disease prevention. BMJ 2018;361:k2396.

[43] Jacobs DR, et al. Food Synergy: The Key to Balancing the Nutrition Research Effort. Public Health Rev 2011;33:507–29.

designed search strategies and study selection criteria are necessary to identify the totality of evidence relevant to research questions and aim to examine all evidence *regardless of the year published*.[7,44] The DGAC CVD-related protocols utilized 3 different publication date criteria, i.e. ≥ 2010; ≥ 2014, or between 2000-2013.[4,5] Consequently, in at least one instance,[4,25] **eligible beef RCT evidence was excluded from DGAC consideration despite being published within the past 3 years (Figure 2)**.

The totality of the evidence on red meat's role in health is not being considered for the 2020-2025 Dietary Guidelines for Americans: the 2020-2025 DGAC SR protocols created evidence gaps based on inconsistent publication date, study duration, and size of study group restrictions.[4,5] . Further, the DGAC subcommittees introduced new exclusion criteria, that were designed to narrow the evidence and reduce the workload volume during Meeting 5 (March 12-13, 2020), the Committee's last public deliberation before writing their report.[17,38] As noted by Cochrane regarding best practice in SR, "predefined, unambiguous eligibility criteria are a fundamental prerequisite for a systematic review.[45] Further, "post hoc decisions about inclusion or exclusion of studies should keep faith with the objectives of the review rather than with arbitrary rules."[45]

[44] Higgins J, et al. Methodological expectations of Cochrane intervention reviews (MECIR). Standards for the conduct and reporting of new Cochrane Intervention Reviews, reporting of protocols and the planning, conduct and reporting of updates. Version 1.07. 2018. See C35.
[45] McKenzie JE, et al. Defining the criteria for including studies and how they will be grouped for the synthesis. In Higgins J, et al (Eds). *Cochrane Handbook for Systematic Reviews of Interventions*. 2nd Edition. Chichester (UK): John Wiley & Sons, 2019. https://training.cochrane.org/handbook/current/chapter-03#section-3-2-1

Figure 1. Search and Screening Results for Randomized Controlled Trials (RCT) Submitted to the DGAC by the Beef Checkoff
What is the Relationship between Dietary Patterns Consumed and Cardiovascular Disease?

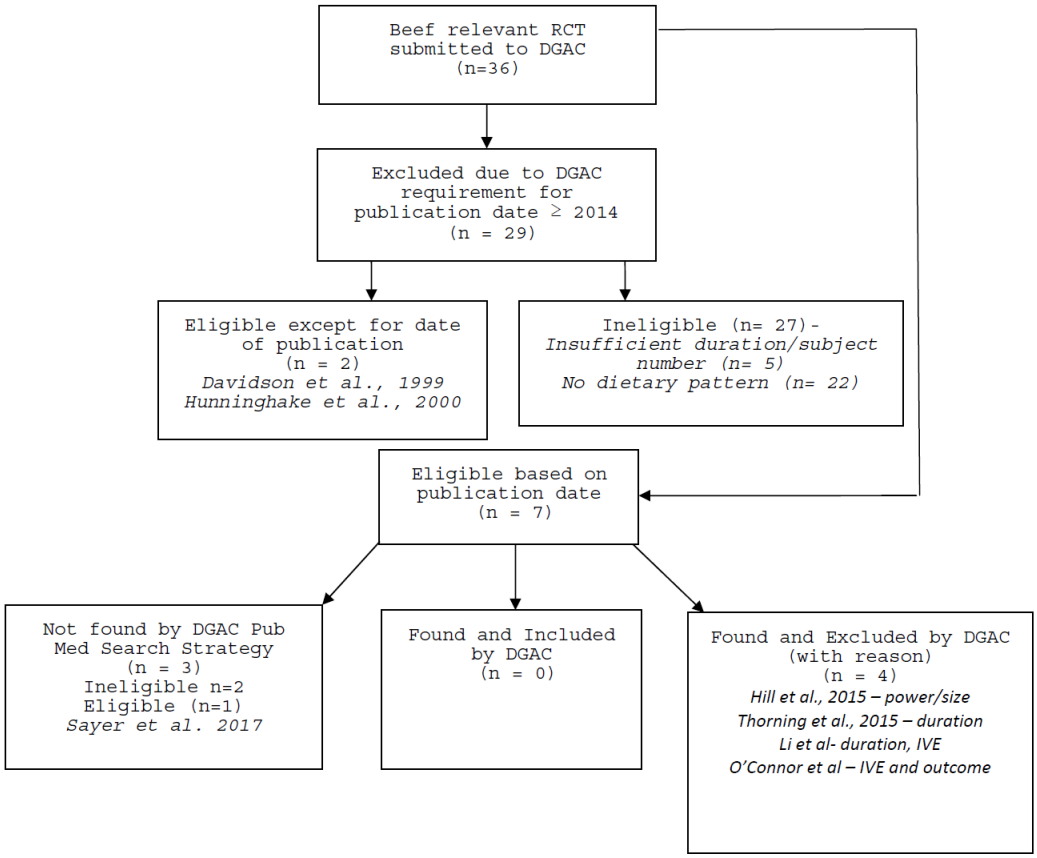

Figure 2. Search and Screening Results for Randomized Controlled Trials (RCT) Submitted to the DGAC by the Beef Checkoff
What is the Relationship between <u>Macronutrient Distribution Diet</u> Consumed and Cardiovascular Disease?

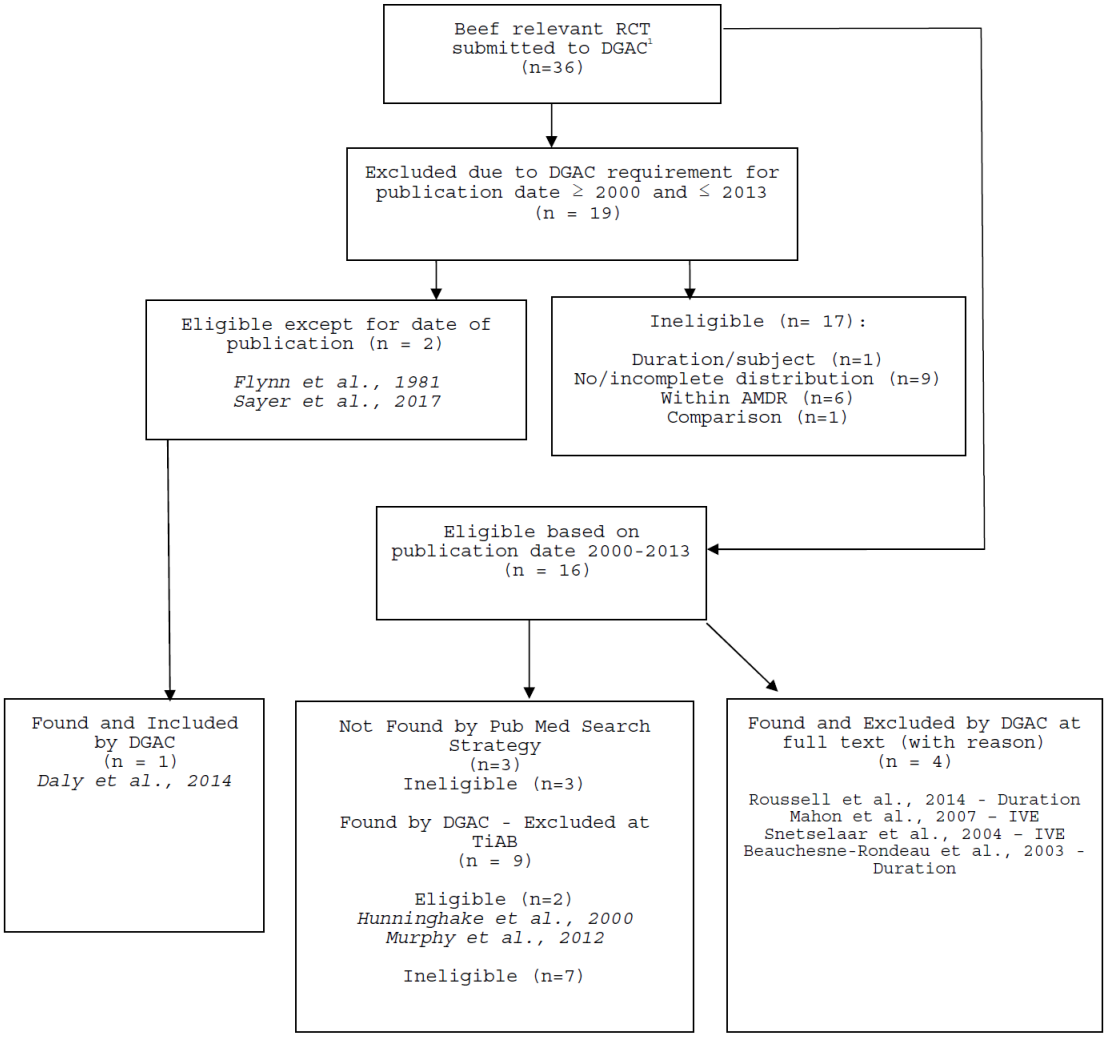

Figure 3. Search and Screening Results for Randomized Controlled Trials (RCT) Submitted to the DGAC by the Beef Checkoff
What is the Relationship between Types of Dietary Fat Consumed and Cardiovascular Disease in Adults?