USDA Fails to Fully Implement National Academies' Advice for Bringing "Transparency," "Rigor" to the Dietary Guidelines

• nutritioncoalition.us/news/usda-fails-to-fully-implement-natl-academies-recs-for-transparency

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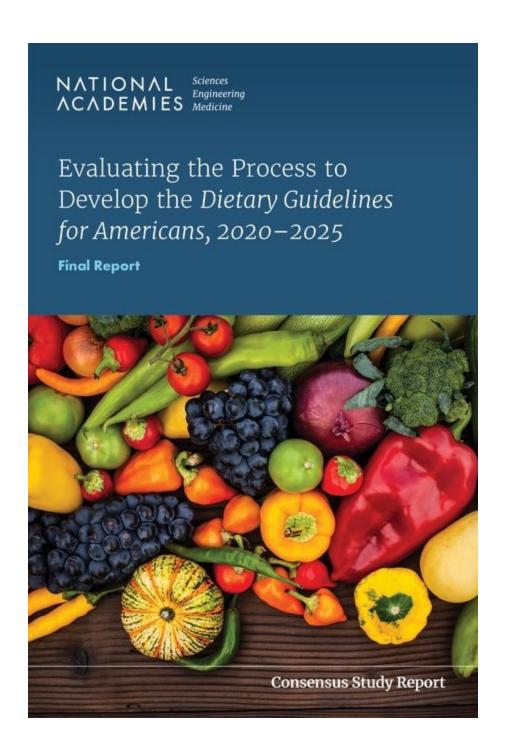
By, Nina Teicholz

Congress has spent seven years and 2 million dollars trying to improve the rigor and transparency of the U.S. Dietary Guidelines for Americans (DGA), our nation's top nutrition policy. In 2015, Congress funded the National Academies of Sciences, Engineering, and Medicine (NASEM) to conduct the first-ever outside peer-review of the guidelines process, a commission that resulted in the NASEM <u>issuing 11 recommendations</u> in 2017 to the U.S. Department of Agriculture (USDA), the agency that oversees that process. Following up on this work, the NASEM this year <u>issued a report</u> concluding that the USDA had not fully implemented even one of these 11 recommendations. Each of these reports cost taxpayers \$1,000,000.

In its 2017 peer-review, NASEM warned that "Current methods need[ed] to be strengthened to better support the development of credible and trustworthy DGA." And: "To develop a trustworthy DGA, the process needs to be redesigned."

Since the DGA process has only been partially redesigned, we can assume that the guidelines still fall short of being either trustworthy or credible.

With respect to the process for reviewing the science, which is the key component that assures a reliable outcome, the NASEM, in its most recent report ("NASEM 2023"), concluded that "the proposed analytic and methodologic improvements to the *DGA* process had largely not yet been achieved." (p. 98)



The NASEM 2023 report states, "[the] remaining obstacles compromise the integrity, transparency, deliberative process [of systematic review protocols], and leave open the possibility of introduction of bias into the...systematic review process." This in turn, "decrease[s] the transparency and rigor of the decision-making process."

Overall, the NASEM concludes: "Given the expectations of the 2017 report committee, an important implication of these conclusions is that **opportunities remain to improve the deliberative nature**, transparency, rigor, and integrity of the *DGA* process as well as the ability of the *DGA* to address the needs of the diverse U.S. population." (p.99)

These problems are not just some future danger. The last iteration of the guidelines, in 2020, for instance, excluded the entire scientific literature on weight loss and made key recommendations for which the science was 7-to-8 years out of date. These are serious issues for the guidelines.

Clearly a lack of reliable nutrition policy is no small predicament for a country where at least 60% of Americans have been diagnosed with a diet-related chronic disease and up to 93% have some cardio-metabolic health problem, according to <u>a recent estimate</u>.

Congress has been concerned since 2015

Members of Congress have evidently been concerned for some time. In 2015, when originally commissioning the NASEM to review the Dietary Guidelines, <u>language</u> in the appropriations report included the following:

Questions have been raised about the scientific integrity of the process in developing the dietary guidelines and whether balanced nutritional information is reaching the public. The entire process used to formulate and establish the guidelines needs to be reviewed before future guidelines are issued. It is imperative that the guidelines be based upon strong, balanced science and focus on providing consumers with dietary and nutritional information that will assist them in eating a healthy and balanced diet. At a minimum, the process should include: full transparency, a lack of bias, and the inclusion and consideration of all of the latest available research and scientific evidence, even that which challenges current dietary recommendations."

That same year, there was a rare hearing of the House Full Committee on Agriculture, focused exclusively on the Dietary Guidelines.



HHS Secretary Sylvia Burwell and USDA Secretary Tom Vilsack testify for 2 hours before the House Full Committee on Agriculture (Vilsack is now serving his second term as USDA Secretary)

Representative Mike Conaway, Chair of the Committee asked:

"Serious questions have been raised about the overall oversight of the overall DGAC process... Hopefully, the next time the question will be asked: Are the guidelines themselves contributing to the problem?"

The NASEM's answer to that question was: Quite possibly. Among its many comments about the shortcomings in the transparency and scientific rigor of the guidelines, it stated: "Without...changes, present and future dietary guidance will not be applicable to a large majority of the general population."

First-Ever Peer Review of the Dietary Guidelines—2017

The NASEM's eleven recommendations in 2017 for the USDA were delivered in a two-part report:

1. <u>Part One</u> ("2017a"), with 4 recommendations, on the process for selecting the expert appointees that review the science for the guidelines, called the Dietary Guidelines Advisory Committee (DGAC).

2. <u>Part Two</u> ("2017b"), with 7 recommendations, on the process for reviewing the science that underpins the DGA.

These recommendations would likely have simply sat on a shelf collecting dust, had Congress not required that the USDA report on its progress, which <u>it did in 2019</u>. At that point, two years had passed since the original recommendations, yet none had been fully implemented—or there was insufficient information to make a judgement. The Nutrition Coalition, which had been instrumental in requiring the USDA report as well as the original NASEM reports, published a scorecard to illustrate the USDA results.

NASEM 2023 report on USDA: No Recs Fully Implemented

Apparently unsatisfied, Congress returned to NASEM again, this time asking for a formal evaluation of USDA progress in complying with the 11 recommendations. The result was the 2023 NASEM report, which concluded the following:

On NASEM 2017b: None of the recommendations were fully implemented.

- 3 were "substantially" implemented. Our view: Only 1 of these was "substantially" implemented; 1 was "partially" implemented and 1 was "minimally" implemented. See our reasoning below.
- 2 were partially implemented implemented. Our view: Only 1 of these was "partially" implemented; the other was not implemented. See below.
- 2 were not implemented.

Therefore, in our view, the more accurate scorecard for USDA compliance is:

- 1 substantially implemented.
- 2 partially implemented.
- 1 minimally implemented.
- 3 not implemented.

The NASEM 2023 report did not report on <u>any of the recommendations</u> made in 2017a, which focused on the appointment of the guidelines' expert advisors. A strong recommendation here was the requirement to disclose and manage conflicts of interest (COI) on this committee—clearly an important issue, since 95% of the 2020 DGAC was found by <u>an analysis</u> to have at least one tie with a food or pharmaceutical company, and 50% had 30 such ties or more. Despite this strong NASEM recommendation, the USDA did disclose the COI for either the 2020 or 2025 committees (The latter was recently announced).

Non-disclosure of conflicts of interest on the DGAC creates distrust around the entire DGA process and undermines the public's faith and confidence in the guidelines. As the NASEM 2023 authors wrote, "...improved transparency and reduce[d] possible conflicts of interest... are needed to establish public trust in the DGA."

Detailed Findings on USDA Compliance with NASEM Recommendations

The following is from the NASEM 2023 "Final" Report. To make matters more confusing, the NASEM also issued a "Midcourse" Report in 2022, which provided some findings not included in the final report, as well as much more detail generally. All of the NASEM quotes below are from the 2023 Final Report unless otherwise stated.

NASEM Recommendation #1:

NASEM finding: Partially Implemented

Our View: Not Implemented

The report itself states that each of these recommendations was not implemented.

"The [NASEM] committee found that the components of recommendation 1 were not implemented as proposed"

<u>Original Recommendation:</u> The USDA-HHS Secretaries should redesign the Dietary Guidelines for Americans (DGA) process to prioritize topics to be reviewed in each DGA cycle, and redistribute the current functions of the Dietary Guidelines Advisory Committee to three separate groups:

- a. Dietary Guidelines Planning and Continuity Group to monitor and curate evidence generation, to identify and prioritize topics for inclusion in the DGA, and to provide strategic planning support across DGA cycles;
- b. Technical expert panels to provide content and methodological consultation during evaluation of the evidence; and
- c. Dietary Guidelines Scientific Advisory Committee to interpret the scientific evidence and draw conclusions.

NASEM found that for **recommendation 1a:** Not implemented. The report explains that the recommendation came too late in the 2020 process.

For **recommendation 1b**: Not implemented. The report explains that the recommendation came too late in the 2020 process.

For **recommendation 1c**: Not implemented. The report explains that the recommendation came too late in the 2020 process.

Key Quote:

"Overall, the committee concluded that full implementation of recommendation 1 is essential if the guiding principles of the 2017 National Academies report are to be achieved. This would provide improved transparency and reduce possible conflicts of interest, which are needed to establish public trust in the *DGA*." (Midcourse Report, p. 8)

NASEM Recommendation #2:

NASEM finding: Substantially Implemented

Our View: Partially Implemented

<u>Original Recommendation:</u> The USDA-HHS Secretaries should provide the public with a clear explanation when the DGA omit or accept only parts of conclusions from the scientific report.

Two well-known instances where the DGA did not follow advice from the scientific report are in the areas of sugar and alcohol. In both cases, the DGAC called for further restrictions, which the DGA did not adopt.

Background: the DGA policy document is written by USDA-HHS political appointees, based on the scientific report. These appointees often do not follow the scientific report to the letter, and many observers have speculated that these divergences are due to the influence of lobbying by corporate or other interests.

The 2020 DGA explained that it did not impose more severe restrictions on sugar and alcohol, because in its view, the "preponderance of scientific evidence" did not support these changes. However, the NASEM Midcourse report points out that the "preponderance of evidence" was not defined, and the DGA did not provide any detail on how its interpretation of the evidence differed from that of the scientific report. Further, the DGA did not explain why its recommendations differed from advice in the scientific report in other ways, such as on iron and folic acid supplementation for pregnant women (See NASEM Midcourse Report, Appendix D).

Based on the above, our interpretation of this recommendation is that it was only partially implemented.

NASEM Recommendation #3:

Summary of findings: Partially Implemented

A key concern here is that USDA employees, in directing every aspect of the scientific reviews including drawing the conclusions, clearly usurped the role of the Dietary Guidelines Advisory Committee, which is required by the Federal Advisory Committee Act to perform its role independently.

<u>Original Recommendation:</u> The Secretary of USDA should clearly separate the roles of USDA Nutrition Evidence Library (NEL) staff and the Dietary Guidelines Scientific Advisory Committee (DGSAC) such that:

- a. The NEL staff plan and conduct systematic reviews with input from technical expert panels, perform risk-of-bias assessment of individual studies, and assist the DGSAC as needed.
- b. The NEL systematic reviews are externally peer reviewed prior to being made available for use by the DGSAC.
- c. The DGSAC synthesizes and interprets the results of systematic reviews and draws conclusions about the entire body of evidence.

The NASEM found that **recommendation 3a** was partially implemented, even though technical expert panels were not implemented, and the USDA did not achieve a "clear delineation of roles [between USDA staff and the expert DGAC] in order to minimize the introduction of bias and allow for an objective, evidence-based reviews."

The NASEM found that **recommendation 3b** was partially implemented, because although peer-review was undertaken, the reviewers were not outside experts. Instead, they were employees of USDA-HHS, the same agencies that issue the Dietary Guidelines—which is an inherent conflict of interest.

The NASEM found that **recommendation 3b** was partially implemented.

Our View: Not Implemented

Although the DGAC was supposed to act independently in synthesizing and interpreting the results of systematic reviews, in fact USDA employees were also involved. Achterberg et al., found that USDA employees conducted 43 systematic reviews for the 2020 DGA. These employees went so far as to issue conclusion statements for the "Pregnancy and Birth to 24 Months Project" before the 2020 expert committee was even publicly convened. These reviews were published in a USDA-funded supplement of an academic journal, authored by USDA—HHS officials directly involved in the DGA. The 43 systematic reviews on these topics undertaken by USDA employees, without DGAC oversight, can be contrasted to 11 reviews (about one-fourth of the reviews on these topics) conducted with DGAC

involvement. Moreover, <u>a paper</u> by six 2020 DGAC members acknowledge that USDA officials were responsible for "developing conclusions and advice based on the evidence." This high level of involvement by the USDA is clearly contrary to the NASEM recommendations. Achterberg et al. explains why this relegation of the DGAC to the sidelines does not comply with the Federal Advisory Committee Act.

Key NASEM quote: "A clear separation of function between [USDA] and the DGAC was not evident in the 2020 DGAC Scientific Report. This raises serious concerns about both transparency and conflict of interest." (NASEM Midcourse Report, p. 10)

NASEM Recommendation #4:

Summary of findings: Substantially Implemented

Our View: Minimally Implemented

<u>Original Recommendation:</u> The secretary of USDA should ensure all [USDA] Nutrition Evidence Library (NEL) systematic reviews align with best practices by:

- a. Enabling ongoing training of the NEL staff,
- b. Enabling engagement with and learning from external groups on the forefront of systematic review methods,
- c. Inviting external systematic review experts to periodically evaluate the NEL's methods, and
- d. Investing in technological infrastructure.

This is arguably the **most important set of recommendations**, because they address the **rigor of the systematic review process.** A rigorous process yields reliable, reproducible results that the public can depend upon. A non-rigorous process does not.

The NASEM found that for **recommendation 4a**, not enough information was provided to judge, and the information that was provided was not convincing: "The committee found that this information did not describe a systematic approach." Not enough information to evaluate.

The NASEM found that for **recommendation 4b**, the methods used by USDA to improve its methods "were unclear." Not enough information to evaluate.

The NASEM found that for **recommendation 4c**, "it was unclear to the committee whether NESR training practices are sufficient to ensure updating of these practices" and that "further documentation...[is] needed"." Not enough information to evaluate.

The NASEM found that for **recommendation 4d**, there was "only limited evidence" of investments or requests for funding for technological infrastructure." Limited evidence of adoption.

Separately, the NASEM Midcourse Report states that "the evidence base included in the systematic reviews [for the 2020 Guidelines] was current." However, this statement refers only to new reviews conducted for the 2020 DGA. Reviews from previous years, including those on the the USDA "Dietary Patterns," which are the centerpiece of DGA advice, relied on data no later than 2013. Achterberg et al. documents how the evidence in these reviews was 7-8 years out of date when the 2020 DGA was published.

The NASEM also observes that the lack of data on minority and low-income populations. Often, reviews included vast-majority of studies not on US populations:

"This issue was not always identified as a limitation of the source literature. For example, in the review titled *Dietary Patterns and Growth, Size, Body Composition, and/or Risk of Overweight or Obesity: A Systematic Review for children,* 10 of the 12 studies included were from countries outside of the United States (Australia, Portugal, the Netherlands, the United Kingdom). However, this systematic review [inaccurately] report indicated 'Generalizability: The study participants, interventions and/or exposures, comparators, and outcomes examined in the body of evidence are applicable to the U.S. population." (Midcourse Report, p. 94)

Key NASEM quote: "Both full implementation of this recommendation and maintaining best practices for conducting systematic reviews for population-level nutrition guidelines **are critical for sustaining the rigor and integrity, and thus the trustworthiness, of the DGA.** (Final Report, p. 10)

NASEM Recommendation #5:

Summary of findings: Not implemented

<u>Original Recommendation:</u> The Secretaries of USDA and HHS should enhance food pattern modeling to better reflect the complex interactions involved, variability in intakes, and range of possible healthful diets.

The committee found that some refinements were made to the food pattern modeling, but that "the analytic methods used did not change" and outside experts "were not employed to support the food pattern modeling," as recommended. "Enhancement of food pattern modeling is still needed…"

Key NASEM quote: "...partial implementation of this recommendation presents serious concerns about adequate rigor of the guidelines given the diversity of food patterns in the U.S. population. Moreover, this is an important missed opportunity to create a better informed and more useful product. " (Midcourse Report, p. 12)

NASEM Recommendation #6:

Summary of findings: Substantially Implemented.

<u>Original Recommendation:</u> The Secretaries of USDA and HHS should standardize the methods and criteria for establishing nutrients of concern.

The committee found that "some enhancements" to the process took place but that there was a distinct lack of transparency about these changes: "the federal agencies have not publicly documented the descriptive data analyses commonly used across previous DGACs. The report also found shortcomings in the "arbitrary thresholds proposed to identify nutrients of concern" and says this topic "require[s] further evaluation..." On the whole, however, the NASEM reports had only "minor concerns remaining."

NASEM Recommendation #7:

Summary of findings: Not implemented

<u>Original Recommendation:</u> The Secretaries of USDA and HHS should commission research and evaluate strategies to develop and implement systems approaches into the DGA. The selected strategies should then begin to be used to integrate systems mapping and modeling into the DGA process.

The committee found **none of recommendation 7 was implemented as proposed.** For this recommendation, the NASEM found "no discernable planning or implementation activities other than requests for additional funding." (Midcourse Report, p. 14)

Key Quotes:

- The committee concluded that the full implementation of recommendation 7 "could have significantly affected the rigor and integrity of the 2020–2025 DGA."
- "Ultimately, the use of systems approaches and methods could substantially improve the rigor, integrity, and thus trustworthiness of future editions of *DGA*." (Final Report, p. 11)