June 1, 2020

Barbara Schneeman, PhD
Chair, 2020-2025 Dietary Guidelines Advisory Committee
c/o Eve Stoody, PhD
Designated Federal Officer
Center for Nutrition Policy and Promotion, Food and Nutrition Service
U.S. Department of Agriculture
3101 Park Center Drive, Room 1034
Alexandria, VA 22301

Re: Posted Nutrition Protocols and Need to Avoid Truncated Process (Docket FNS-2019-0001)

Dear Dr. Schneeman:

The Academy of Nutrition and Dietetics (the “Academy”) appreciates the opportunity to submit comments to the 2020 Dietary Guideline Advisory Committee (DGAC or the “Committee”) regarding issues and protocols relevant to the development and integrity of its forthcoming scientific report “outlin[ing] its science-based recommendations and rationale”\(^1\) for the 2020-2025 Dietary Guidelines for Americans (the “Dietary Guidelines,” “Guidelines,” or DGAs). Representing more than 107,000 registered dietitian nutritionists (RDNs), nutrition and dietetic technicians, registered (NDTRs), and advanced-degree nutritionists, the Academy is the largest association of food and nutrition professionals committed to accelerating improvements in global health and well-being through food and nutrition. Our members have helped conduct, review, and translate nutrition research for the DGAs since their inception, and will work to help consumers, industry, and schools choose meal patterns in accordance with the final recommendations of the Secretaries of the U.S. Department of Agriculture and the U.S. Department of Health and Human Services (collectively, the “Departments”).

The Academy recognizes the enormous task before it in developing the 2020-2025 DGAs and the newly required guidelines for Americans from birth to two-years-old. Below, we respectfully offer comments and recommendations related to the need for enhanced transparency throughout the DGA development process and the need to avoid arbitrarily restricting the DGAC’s time needed to satisfactorily complete its work.

A. Commitment to Science-Based Dietary Guidelines

The Academy has full confidence that, with sufficient time, the Committee can fulfill its charge to “provide independent, science based advice and recommendations to be considered by USDA and HHS in the development of the 2020-2025 Dietary Guidelines for Americans.”\(^2\) We look forward to a transparent and collaborative process for reviewing and translating the best available “science into succinct, food-based guidance that can be relied upon to help

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\(^2\) Ibid., Section 3, p.1.
Americans choose foods that provide a healthy and enjoyable diet.”3 We also look forward to ongoing engagement with the Committee as they draft and begin to finalize their conclusions and present their findings to the public.

We welcome to the opportunity to provide the below comments on timing (in addition to forthcoming comments on substantive issues raised by the Committee’s draft conclusions once available) to ensure that the Committee and Departments are able to complete their work in a manner consistent with the highest scientific standards. It is critical that health care professionals, researchers, and the public can continue to have confidence in the Dietary Guidelines by allaying any procedural concerns.

B. Delay Issuance of the Scientific Report Until October 2020

1) 2020-2025 DGAC Tasked with Substantial New Work

The Academy remains concerned about the impact of artificial, arbitrary time constraints on the guideline development process. Pursuant to the charter filed October 5, 2018, “The Committee is established to accomplish a single, time-limited task. It is expected that the Committee will complete the objectives for which it was established within two years from the date this charter is filed.” **We strongly urge the DGAC to utilize the entire two years for which it is authorized to conduct evidence reviews, analyze the results, consider its recommendations, and draft its scientific report.**

Dr. Don J. Wright, then-Deputy Assistant Secretary for Health and Director of the Office of Disease Prevention and Health Promotion, recognized the massive responsibility and “ambitious ask” this particular Committee had undertaken when he noted that “the body of evidence on the role of nutrition and disease prevention and health promotion has grown exponentially since the last committee submitted its report.”4

The DGAC has been tasked this iteration with drafting not just the scientific report similar to that which previous DGACs drafted, but in addition, has been tasked with drafting a wholly new scientific report for a new population: children from birth to 24 months. Given this additional work and the overall importance of the DGA development process, we see no reason to sacrifice quality for expediency; there is no reason why the DGAC needs to complete its work to meet an arbitrary and artificial deadline and should instead complete its work accordance with the charter in October 2020.

2) Time Constraints Present from the Outset of the Process

At the first public meeting of the DGAC (held March 28, 2019), Dr. Obbagy recognized that there were already time constraints facing the committee when she stated, “Due to time and resource constraints, NESR will not be conducting systematic reviews with input from technical expert panels, rather NESR will be conducting systematic reviews directly with the

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4 Transcript of March 12, 2020 Morning Meeting of Dietary Guidelines Advisory Committee at 3-4, Time Stamp 0:05:11; Don J. Wright. Available at [https://globalmeetwebinar.webcasts.com/viewer/landing.jsp?ei=1289826&tp_key=7df5c053f4](https://globalmeetwebinar.webcasts.com/viewer/landing.jsp?ei=1289826&tp_key=7df5c053f4).
2020 Committee.” Time constraints are understandable and often unavoidable, as with constraints arising from the Departments’ inability to work at the beginning of the process during the 35-day government shutdown in December 2018-January 2019.

Time constraints existed at the outset and were offered as the rationale leading the Departments to diverge from both their previous process for conducting systematic reviews and the National Academies’ recommendations for improving the process, yet the Departments declared their intention to complete the work of the DGAC approximately five months earlier than anticipated or necessary—and in far less time than previous Committees.

The Academy emphasizes that these time constraints are notably not a criticism of the Departments or their career staff ably assisting the Committee in its work. It is unclear why the timeline is rushed when the Committee could simply continue its work until its charter ends in October 2020. We are grateful for the contributions of these committed staff members under atypical timelines and highly unusual circumstances and underscore the recognition by members of the Committee:

- “...I can’t thank the staff enough. I know some of them must not ever go to sleep. And it’s really been helpful to us. This has been a lot of work, and I did wonder how we were going to make it through, and we have had to cut back on things, but the staff has been totally supportive and they, they work, work, work, until they get the item done.”
- “I want to really reinforce what all of you have said about the staff that we’ve been working with. Their work ethic is really incredible, and in particular, their flexibility as we pile on even more work every time we meet as a subcommittee. So, really, they’ve given us the pleasure of being able to examine this extensive evidence base and evaluate it in a way that is really exceptional.”

3) Ongoing Time Constraints Identified by Committee Members
Unfortunately, impact of time constraints on the scope and quality of the Committee’s work have become more significant as the process progressed. At the most recent March 2020 public meeting, numerous DGAC members noted impacts of the artificial time constraints, including decisions not to review all topics and scientific questions and an inability to provide draft conclusions or grades for review by the public or other committee members. Among them:

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• “Currently, we only have draft conclusion statements and grading for 2 of these, and the rest, we have draft conclusion statements, but we have not yet finished grading those, so those will not be presented today.”

• “The cancer outcomes were streamlined to focus on four types of cancers with the highest prevalence: breast, prostate, lung, and colorectal cancers. These were also examined in the 2015 review. **Given the timeline, the next advisory committee may be well-suited to explore additional cancers** for which new evidence has begun to emerge.”

• “And these are all still sort of a work in progress, too. So, to better align with criteria applied by other subcommittees, and **due to the short timeline relative to the workload volume, the subcommittee discussed and applied additional inclusion and exclusion criteria** that would both narrow and strengthen the body of evidence for the remaining questions. These additional criteria were applied prior to the completion of screening.”

• “I’m hoping tomorrow, we might have time to talk about **some of the questions that we might not be able to get to** and how we might address that in our report.”

• “**Due to the short timeframe relative to the workload volume, the subcommittee updated the following exclusion criteria to narrow and strengthen the review.** These additional exclusion criteria were applied prior to the completion of screening.”

• “Topics still under review by our subcommittee are N-6 PUFA and CVD health outcomes, dietary cholesterol and CVD health outcomes, dietary fat with a focus on food source and CVD intermediate outcomes. The next step for our subcommittee will

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9 Transcript of March 12, 2020 Afternoon Meeting of Dietary Guidelines Advisory Committee at 5, Time Stamp 0:12:02; Boushey. Available at [https://globalmeetwebinar.webcasts.com/viewer/landing.jsp?ei=1289829&tp_key=62557ab93c](https://globalmeetwebinar.webcasts.com/viewer/landing.jsp?ei=1289829&tp_key=62557ab93c). (Emphasis added.)


be to complete the topics still under review, as outlined on the previous slide, submit the review of dietary fats and CVD for peer review, and complete our draft report.”

- “It’ll end up being pretty nuanced discussion, I imagine, given the complexity of this literature.”

- “That’s why we need a little more time to do that.”

- “The other thing, Jamy, is that we, as Linda pointed out, we have yet to really finish the evaluation, given the magnitude of papers that we’re still looking at.”

- “Also, starting out with sugar-sweetened beverages, because the 2015 Dietary Guidelines included articles up to December of 2011, we focused on the literature published since January 2012 rather than going all the way back to January 2000, and again, that was partly because of where the Dietary Guidelines from 2015 left off, and partly just as a matter of reasonable workload and trying to focus our attention in the best way possible in the time that we had.”

- “Now, for added sugars and growth, size, body comp, and risk of overweight and obesity, this is a body of evidence that we’re actually not reviewing, partly—and it was partly addressed in the last by review of sugar-sweetened beverages and this outcome, so we’ve not gone further with that. And we’ve also not addressed added sugar consumption and risk of type 2 diabetes.”

- “So, as of now, we have 14 with no evidence, and I just—we just heard that there were, in the Beverages and Added Sugars subcommittee, there are a couple of questions that it appears will not be reviewed. I don’t know if there’s a systematic review or

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not, but it all—it’s all relevant for juggling assignments of the remaining reviewers and getting things done.”

- “I think it’s important to consider, for the next Dietary Guidelines, that if possible, the process would start a little bit earlier, because we’ve been rather limited in the amount of time that we’ve had to evaluate all this evidence. So, I don’t know if it’s appropriate to put into the chapter, but certainly, I think if the next Dietary Guidelines Advisory Committee could be given a little bit more time, it would be helpful in coming to some of the conclusions and evaluating the evidence.”

- “I can’t stress enough, one of the things that you mentioned, Barbara, of how helpful it was to have, at least for the B24 work group, to have some of the findings and the reviews that happened prior to the work of our committee. That was especially helpful, given the limited time that we had for—the truncated time this time around for the committee.”

- “And then, specifically, I had a question about what we do when a particular question did not actually get reviewed. So, for example, in one of our chapters, we were supposed to look at human milk and infant formula and developmental milestones and neurocognitive development, and that review did not occur due to time.”

- “I’m wondering about how you’re envisioning the whole timeline working at this point.”

4) Time Constraints Are Compounded by External Factors

Notably, the Committee identified the foregoing limitations on their ability to complete the totality of their work even before the COVID-19 pandemic and public health emergency completely altered work for the Committee, the Departments, and the public. Many committee members are health care professionals or university professors whose work has been interrupted for months. As Dr. Klurfeld noted at the most recent public meeting, career
staff at the Departments have also had their routines significantly disrupted, and government employees conducting peer review are largely working at agencies and institutes that would come to have substantial COVID-19-related responsibilities:

- “I will tell you that a number of federal agencies are beginning to tele-work for 1 day to 1 month, so that should affect timing.”

- “So, we have NIH, the National Institutes of Health, ARS, the Agricultural Research Service, FDA, the Food and Drug Administration, CDC, Centers for Disease Control and Prevention, VA, the Veterans Administration, the Department of Defense, and the Economic Research Service of USDA, are all participating in this.”

Ongoing external factors such as the COVID-19 public health emergency and the present domestic disturbances forcing the imposition of curfews upon our capital city and throughout the country have further exposed the need for the Dietary Guidelines to be relevant for all Americans, particularly those at higher health risk from the virus. The pandemic has disproportionately impacted communities, including minority communities and the majority of Americans with or at-risk of developing nutrition-related chronic conditions, such as overweight and obesity, diabetes and prediabetes, high blood pressure and other risk factors of cardiovascular disease, and compromised immunity. The disparate impact underscores the need for Dietary Guidelines that are applicable to all Americans, and we note the Committee’s repeated admonition that studies “may not be completely generalizable to the U.S. population as the result of differing participant characteristics,” with studies not adjusted for “key confounders, such as race/ethnicity.”

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30 Transcript of March 12, 2020 Afternoon Meeting of Dietary Guidelines Advisory Committee at 13, Time Stamp 0:33:10; Boushey. (Id. at 14). Available at https://globalmeetwebinar.webcasts.com/viewer/landing.jsp?ei=1289829&tp_key=62557ab93c.
The Academy agrees with Dr. Stang that the Committee should “think about dietary guidance that can apply across the life span, and that can be tailored for various racial/ethnic preferences and socioeconomic levels.”

In total, 60 percent of Americans in 2014 “had at least one chronic condition, and 42 percent had multiple chronic conditions.”

Given the extremely high prevalence of co-morbidities and overweight/obesity, the DGAs need to go beyond mere prevention and equally focus on amelioration of these conditions by leveraging a healthy food environment and food choices.

5) The Public Is Still Awaiting Substantial Information from the Committee

The Academy appreciates improvements to the dietaryguidelines.gov website for this iteration of the Guidelines, and notes the Committee Chair’s admonition that “It’s always important to keep in touch with the website, because the FAQs are updated in terms of providing the public more information, but also, that’s where you can find the protocols and information, the status reports on the work of the subcommittees, so it’s a very valuable resource.” However, we note that time constraints precluded most protocols from being developed or posted to the website until April 20, 2020, limiting public review. And, as of May 21, 2020, not a single draft conclusion has been posted, although dozens of scientific questions are marked “will not be completed.” Scientific review of the full scope of topics and questions is critically important, sufficient time for public feedback is necessary (but currently impossible), and additional time is necessary for the peer review process:

- “And I always like to emphasize that everything we’ve talked about in our public meetings is always draft until we submit that final report. The feedback we get is important.”
- “And one of the things I decided early on is that the peer reviewers should wait to receive the systematic reviews until the draft DGAC conclusions were available. So, we’ve done maybe a dozen completed reviews to date, and the flood gates will open after this meeting to get the rest of them handled.”

6) The DGAC Cannot Prioritize Speed Over Quality and Thorough Review

The public must have confidence that the Guidelines are indeed “based on the preponderance of the scientific and medical knowledge which is current at the time the report is prepared” that has not been “influenced by politics or other factors” that were noted by the National Academies.

The critical work of developing, reviewing, and drawing conclusions from
systematic reviews should not sacrifice quality for alacrity. Systematic reviews should not be developed with less-transparency or more limited engagement of experts than was previously used. Fortuitously, the DGAC’s charter provides the Committee until October to prepare and issue its Scientific Report before disbanding.

The Dietary Guidelines for Americans are simply too important to be rushed unnecessarily. Rather than arbitrarily cutting short the process, the Departments could provide additional support through a contracting process that ensures transparency and alignment with consistent methodologies, but at minimum, the Committee should take all available time allotted by the DGAC’s charter.

C. Conclusion

The Academy appreciates the opportunity to comment on the time constraints facing the Committee and the Departments and other issues of concern. We are happy to discuss these recommendations in greater detail in the near future. Please contact either Alison Steiber at 202-775-8277 ext. 4860 or by email at asteiber@eatright.org or Pepin Tuma at 202-775-8277 ext. 6001 or by email at ptuma@eatright.org with any questions or requests for additional information.

Sincerely,

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APPENDIX A

Members of the Academy of Nutrition and Dietetics’ Collaborative on the DGAs

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