



August 13, 2020

Mr. Brandon Lipps  
Deputy Under Secretary for Food, Nutrition & Consumer Services  
U.S. Department of Agriculture  
1400 Jefferson Drive, SW  
Washington, DC 20250

CAPT Paul Reed, MD  
Deputy Assistant Secretary for Health, Medicine and Science  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

**RE: Scientific Report of the 2020 Dietary Guidelines Advisory Committee (FNS-2020-0015)**

Dear Mr. Lipps and Captain Reed:

Wine Institute is pleased to submit these comments on the Scientific Report of the 2020 Dietary Guidelines Advisory Committee (“the Report”) on behalf of our more than 1,000 member wineries and affiliated businesses. Wine Institute is the public policy trade association of California wine and our members are responsible for more than 80% of the wine grown and produced in the U.S. Nationally, more than 10,000 wineries, the vast majority of which are small, family-owned businesses, produce some of the most highly value-added agricultural products in the country, while creating approximately 998,000 jobs.

The responsible and sustainable production, marketing and consumption of wine has been at the very heart of Wine Institute’s existence throughout our 86-year history. As such, our members have always recognized the importance of the DGA and the need to ensure consumers have accurate, science-based information to guide their decisions about alcohol consumption. Wine Institute’s website contains the following statement, based upon the 2015-2020 Dietary Guidelines for Americans:<sup>1</sup>

- If alcohol is consumed, it should be in moderation – no more than one drink per day for women and up to two drinks per day for men – and only by adults of legal drinking age, preferably at mealtime.
- There are some people who should not consume beverage alcohol at all. Those who are under 21, women who are pregnant, or have a medical or family history of concern for example. Any person who has concerns about consuming alcohol should consult with their healthcare provider.

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<sup>1</sup> Available at: <https://wineinstitute.org/our-work/responsibility/social/>

Wine Institute has always supported the Dietary Guidelines for Americans as helpful and practical guidance for healthcare professionals and adult Americans who choose to consume alcohol. The DGAC Charter exists for the very purpose of protecting the validity and consumer acceptance of government guidelines such as the DGA. In order to accomplish this, the Charter states that any significant change in DGA guidance must be based on new scientific evidence establishing a “clear preponderance of evidence.”<sup>2</sup> In the Report, the DGAC has recommended that your agencies change the guidance for alcohol consumption in men from a limit of two drinks per day to a limit of one drink per day. However, this conclusion has not been made based on a preponderance of evidence, and the DGAC does not appear to follow its own pre-established processes and provides no transparency in how conclusions were reached. We write today to express our concern that the DGAC has departed from the process it set up to provide transparency and an evidence-based approach to DGA guidance.

## **I. THE DGAC DID NOT FOLLOW CLEARLY ESTABLISHED PROTOCOLS AND FAILED TO TRANSPARENTLY EXPLAIN HOW IT ARRIVED AT ITS RECOMMENDATIONS**

The work of the 2020 DGAC and the drafting of the report were guided by the 2020 DGAC Charter as well as a comprehensive set of protocols designed to ensure the DGAC bases its recommendations on a transparent and scientifically rigorous review of science. Key to the DGAC’s recommendations are systematic reviews that follow the USDA Nutrition Evidence Systematic Review (NESR) process. Each of the reviews are conducted with assistance by USDA NESR staff, and reviews must follow a specific protocol designed to ensure the guidelines contained in the Charter and spelled out in the Methodology chapter of the report are adhered to. An analysis of the evidence included in the DGAC/NESR systematic review (hereinafter “the Review”) for alcoholic beverages demonstrates a purposeful exclusion of decades of relevant scientific work and a lack of the required preponderance of evidence supporting a change in the recommendation for men. Wine Institute is concerned that the lack of transparency and departure from scientific protocols will affect the credibility of the recommendations in the scientific community, with the public and within the industry.

### **a. The Review did not follow the methods established by DGAC**

In the final protocol established by DGAC prior to the Review, the date of publication for included studies was 2010-2020. Thus, the Review ignored decades of scientific evidence. While systematic reviews conducted for health agencies under tight regulatory deadlines often cannot review every piece of evidence, the gold standard Institute of Medicine systematic review guidance recommends a thorough and documented approach to identifying a “comprehensive and unbiased set of the relevant studies” to include in a review (IOM, 2011)<sup>3</sup> The Review on alcoholic beverages does not describe why study inclusion was limited to that published in the last 10 years, and if and how previous agency reviews (including those conducted by other agencies) or peer-reviewed review articles were considered and synthesized with the findings of the more recent literature.

A highly respected expert within the scientific community already has noted the significance of these omissions. Dr. Eric Rimm is Professor of Epidemiology and Nutrition and Director of the Program in Cardiovascular Epidemiology at the Harvard T.H. Chan School of Public Health and served on the 2010 DGAC as Chair of the Alcohol Subcommittee. After the release of the recent DGAC report, Dr. Rimm commented publicly that, “they [the 2020 DGAC] ignored all research before 2010 and were very

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<sup>2</sup> 2020 Dietary Guidelines Advisory Committee Charter. Available at <https://www.dietaryguidelines.gov/sites/default/files/2019-03/DietaryGuidelinesAdvisoryCommitteeCharter-10-05-18.pdf>

<sup>3</sup> Institute of Medicine. 2011. *Finding What Works in Health Care: Standards for Systematic Reviews*. Washington, DC: The National Academies Press.

dismissive of observational studies of alcohol and chronic disease, even though this represents the only way to study alcohol and long-term health... There are no long-term clinical trials of alcohol."<sup>4</sup> The decision not to consider this information in making the recommendation to cut guidance on daily consumption for men warrants close scrutiny by your agencies as you draft the final DGA.

Additionally, the Review only looked at the relationship between alcohol and all-cause mortality, specifically excluding additional questions that USDA and HHS originally asked it to consider. Included among these is the link between alcohol consumption and the risk of cardiovascular disease (CVD). The report attributes the failure to address the questions asked to time constraints and a desire to prioritize the systematic review of all-cause mortality. The justification of a "lack of time" is difficult to understand given the fact that the Review did include analysis of issues outside the prescribed protocol. And the decision not to conduct a systematic review of the additional medical questions and particularly of the relationship between alcohol and CVD is all the more notable given that the report readily acknowledges a strong body of scientific evidence in this area. The DGAC states in the report:

The 2010 Dietary Guidelines Advisory Committee conducted a review on the topic of alcohol intake and coronary heart disease, and concluded that "strong evidence consistently demonstrates that compared to non-drinkers, individuals who drink moderately have lower risk of coronary heart disease." **Since that time, observational studies and meta-analyses of observational studies have affirmed the "J-shaped curve" for coronary heart disease and ischemic stroke demonstrates higher risk among those who do not consume alcohol compared with those who consume low volumes of alcohol...**<sup>5</sup> [emphasis added]

These departures from the methodological protocol set in advance of the Review raise concerns regarding the transparency of the process and adherence to the pre-established guidance.

**b. The Review did not establish a preponderance of new evidence to support a change in guidance**

In addition to the departures in methodology and transparency, the change in guidance for men does not appear to be supported by a preponderance of the scientific evidence that the committee did review. The Review included a total of 60 studies. Based on these studies, the weight of the evidence indicates that consumption levels of up to 2 drinks/day for men (and in some studies, 3 drinks per day) is associated with no increased risk of all-cause mortality or in some cases, a reduced risk of all-cause mortality. The evidence thus does not demonstrate a lower risk of all-cause mortality for men consuming 1 drink/day relative to men consuming 2 drinks per day. While the Review purports to have conducted evidence synthesis considering consistency of results, quality of each individual study, and other critical factors, the Report does not discuss how the DGAC incorporated these considerations into its overall conclusions. This is a critical oversight because, as an example, inconsistencies across studies (i.e., differences in the presence or absence of an association or in the magnitude of effect) may be partially or wholly due to differences in methodological design and/or rigor.

**c. The DGAC failed to evaluate alcohol within the context of dietary patterns**

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<sup>4</sup> Frank, Mitch. "U.S. Dietary Guidelines Panel Takes Aim at Moderate Wine Drinkers." *Wine Spectator*. Aug. 5, 2020.

<sup>5</sup> Dietary Guidelines Advisory Committee. 2020. *Scientific Report of the 2020 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Agriculture and the Secretary of Health and Human Services*. U.S. Department of Agriculture, Agricultural Research Service, Washington, DC., Part D, Ch. 11, p. 17

In their letter of transmittal to USDA and HHS, the co-chairs of the DGAC note that the committee focused on two major themes to inform their work, one of which was the importance of dietary patterns. The executive summary of the report states the DGAC:

...has made dietary patterns a centerpiece of its report. This emphasis acknowledges the reality that people do not consume nutrients or foods in isolation but in various combinations over time. It also reflects growing evidence that components of a dietary pattern may have interactive, synergistic, and potentially cumulative relationships that can predict overall health status and disease risk more fully than can individual foods or nutrients.<sup>6</sup>

The chapter on alcohol ignores this emphasis and simply fails to consider any research on alcohol in the context of dietary patterns. This is inexplicable, particularly as alcohol in the context of dietary patterns is discussed elsewhere in the report. In Part D, Chapter 8 on Dietary Patterns the committee conducted a systematic review of evidence on dietary patterns associated with decreased risk of CVD and found strong evidence that, “regular consumption of nuts and legumes and **moderate consumption of alcohol also are shown to be components of a beneficial dietary pattern in most studies** [emphasis added].”<sup>7</sup> The failure to consider research on alcohol within dietary patterns in the chapter on alcohol further demonstrates the lack of evidence for the recommendation to cut the alcohol consumption guidance for men in half.

## II. CONCLUSION

As noted at the outset, this year’s DGAC report includes the recommendation to significantly change the guidance in the DGA to limit drinking for men from up to two drinks per day, to no more than one drink per day. Unfortunately, the report fails to present a complete picture of the DGAC’s work with respect to alcohol because so much of it was conducted outside of the scope of the DGA Charter and the general protocols of the systematic review. However, it is abundantly clear that the evidence presented in the report in no way meets the standard established by the Charter for changing long-standing guidance such as this. The lack of adherence to pre-approved scientific methods and protocols jeopardizes the long-standing credibility associated with DGAC recommendations.

We urge you to review the recommendation to change the guidance on alcohol consumption for men and to preserve the current recommendations in the 2015-2020 DGA based upon the strength of the scientific evidence that continues to support that recommendation.

Sincerely,



Robert P. Koch  
President and CEO

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<sup>6</sup> Dietary Guidelines Advisory Committee. 2020. *Scientific Report of the 2020 Dietary Guidelines Advisory Committee*. Part A, p.2

<sup>7</sup> Dietary Guidelines Advisory Committee. 2020. *Scientific Report of the 2020 Dietary Guidelines Advisory Committee*. Part D, Ch. 8, p. 14.