August 12, 2020

Mr. Brandon Lipps  
Deputy Under Secretary for Food, Nutrition & Consumer Services  
U.S. Department of Agriculture  
1400 Jefferson Drive, SW  
Washington, DC 20024

Captain Paul Reed, M.D.  
Deputy Assistant Secretary for Health, Medicine & Science  
U.S. Department of Health and Human Services  
330 C St., SW  
Washington, DC 20416

Submitted electronically to: https://www.regulations.gov/docket?D=FNS-2020-0015

Dear Mr. Lipps and Captain Reed,

The Beer Institute (BI) and the Brewers Association (BA) are trade associations representing US brewers, beer importers, and industry suppliers, large and small. There are more than 8,000 breweries in the US today, including at least one in every Congressional district. Overall, the US beer industry contributes more than $328B in economic output, which is equal to 1.6% of US GDP. The industry supports 2.1M American jobs and pays $58.6B in tax revenue. But the work of the beer industry does not stop with brewing and selling beer. America’s beer industry is also a critical partner to our nation’s farmers, supporting more than 38,000 agricultural jobs which pour almost $5 billion into our nation’s economy.

The beer industry supports agricultural jobs in every state. The primary ingredients of beer include water, yeast, hops, and fermentable grains—包括 barley, corn, rice, rye, wheat, oats, sorghum, and spelt. Barley is the most widely used grain in beer production and each year barley farmers plant 3.5 million acres of barley.

The beer industry supports sound science and objective examination of the science to inform the American public about the consumption of alcohol. BI and BA submit these comments in response to Chapter 11 of the report of the 2020 Dietary Guidelines Advisory Committee (2020 DGAC) relating to alcohol. Chapter 11 conflicts with and goes beyond the scope of the 2020 DGAC charter and has no place in informing current nutritional policy in the United States. BI and BA urge the agencies to reject the recommendations of Chapter 11 and continue with the current guidance to Americans regarding alcohol consumption.

Summary

The preponderance of the scientific evidence supports continuation of the alcohol consumption guidelines from the 2015 Dietary Guidelines for Americans. The agencies should not rely on Chapter 11 of the 2020 Dietary Guidelines Advisory Committee Scientific Reports, particularly its recommendation for a change in the consumption guidelines for the following reasons:
1. The recommendation to change the consumption guidelines for men conflicts with the requirements of the 2020 DGAC Charter.
2. The authors of Chapter 11 place unwarranted reliance on out-of-scope Mendelian Randomization (MR) studies to support the recommendation to reduce the consumption guidelines for men.
3. The authors of Chapter 11 did not meet DGAC charter standards for transparency nor strengthen the science base of the process and proposed recommendations.
4. The recommendation to reduce consumption guidelines for men violates the DGAC charter because it deviates from and does not build upon prior Dietary Guidelines.

Instead of adopting the flawed and conclusory statements and recommendations of Chapter 11, we respectfully ask the agencies to include the following simple, scientifically supported statements in the 2020 Dietary Guidelines for Americans:

- If alcohol is consumed, it should be in moderation – up to one (1) alcohol drink-equivalent per day for women, and up to two (2) per day for men. This consumption guideline is consistent with the 2015 Dietary Guidelines for Americans.
- One alcohol drink-equivalent has 14 g (0.6 fl oz.) of pure alcohol. The following are reference beverages that are one alcohol drink-equivalent: 12 fluid ounces of regular beer (5% alcohol), 5 fluid ounces of wine (12% alcohol), or 1.5 fluid ounces of 80 proof distilled spirits (40% alcohol). This definition of a drink-equivalent is also consistent with the 2015 Dietary Guidelines for Americans.
- If you choose to drink alcohol, know the differences between the types, sizes, and alcohol content of alcohol beverages in the market so you may understand and keep track of how much alcohol you are consuming. The 2015 Dietary Guidelines for Americans includes this same guidance.
- Do not consume alcohol beverages on an empty stomach. Food slows the absorption rate of alcohol beverages. If you choose to consume alcohol beverages, eat food before or while drinking. Also, stay hydrated (with water or other non-alcohol beverages) when consuming alcohol beverages. This is practical, prudent advice to add to the 2020 Dietary Guidelines.
- Discuss any concerns about alcohol beverage consumption with your healthcare provider. There are some people who should not consume alcohol beverages at all. Examples include, but are not limited to, those who are under 21, women who are pregnant, or those that have a medical or family condition or history of concern. This recommendation is consistent with the language of the 2015 Dietary Guidelines for Americans.

**Background**

Section 301 of Public Law 101-445 (7 U.S.C. § 5341) directs USDA and HHS to jointly publish at least every five years a report providing nutritional and dietary information and guidelines for the general public, “based on the preponderance of scientific and medical knowledge current at the time of publication.”

Before USDA and HHS publish a new set of Dietary Guidelines, the agencies set up and ask for input from a Dietary Guidelines Advisory Committee (DGAC). A DGAC does not write the Dietary
The role of any DGAC is to supply independent, science-based advice and recommendations for USDA and HHS to consider when those agencies write new Dietary Guidelines.

**Dietary Guidelines Best Practices**

With publication of the 2015 Dietary Guidelines for Americans, there were questions about potential biases amongst some members of the 2015 DGAC, limited transparency for the whole process, and inadequate scientific bases for some statements and recommendations adopted in the 2015 Dietary Guidelines. To address these concerns, Congress mandated a review of the process for developing the Dietary Guidelines for Americans. That review, conducted by the National Academies of Sciences, Engineering, and Medicine (NAS), resulted in two reports, one on best practices for selecting a Dietary Guidelines Advisory Committee and a second on best practices regarding other aspects of processes for developing Dietary Guidelines. Based on NAS report recommendations and with the goal of establishing a more transparent, inclusive, and science-driven process, USDA and HHS added some new steps to the 2020 Dietary Guidelines Advisory Committee (2020 DGAC) selection process and updated best practices for reviewing nutrition science and developing guidance and recommendations for the 2020 Dietary Guidelines. These comments focus on whether the 2020 DGAC followed those best practices in developing Chapter 11 of its report published on July 15, 2020.

**2020 DGAC Charter**

The purpose of the 2020 DGAC was to review scientific evidence for USDA and HHS to consider in developing the 2020 Dietary Guidelines. No DGAC operates without a charter and other controls. The 2020 DGAC charter limited the committee’s work to specific topics and scientific questions for which the agencies sought advice. This limitation extended to DGAC subcommittees, to wit, “[s]ubcommittees will limit their review and advice to dietary guidance for human nutrition on the topics and scientific questions specified with the department.” The purpose of limiting the 2020 DGAC’s work to specified topics and scientific questions was to “promote transparency, respond to feedback on the Dietary Guidelines development process, identify expertise needed on the Committee, help manage resources, and ensure the advice provided by the Committee addresses Federal nutrition policy.” The Charter also specified that recommendations advanced by the 2020 DGAC must match the “preponderance of scientific and medical knowledge current at the time of the publication.” Finally, the Charter took note of the advisory nature of the 2020 DGAC’s work.

The 2020 DGAC Charter outlined three acceptable approaches to examination of the scientific evidence on the specific topics and questions presented for review: data analysis, food pattern modeling, and Nutrition Evidence Systematic Review (NESR) systematic reviews. Each approach has its own rigorous, protocol-driven method and plays a unique, complementary role in examining the science. Not every topic or scientific question calls for the same approach. The type of information needed to answer a specific scientific question determined which approach the 2020 DGAC used to review the evidence. Whatever approach or approaches the 2020 DGAC used to examine the scientific evidence, however, two overarching standards applied: limit bias and strive for wholly objective review and recommendations based on a preponderance of the scientific evidence.

---

1 The alcohol consumption guidelines recommended by the 2015 DGAC did not receive criticism.
The attached highlighted transcript shows that the 2020 DGAC received a full and complete briefing on the Charter, the procedures required for review of scientific evidence, and the need to ensure that recommendations match the “preponderance of scientific and medical knowledge current at the time of the publication.” There was also a reminder that each edition of the Dietary Guidelines builds on the previous edition with scientific justifications for any recommended changes based on the preponderance of the science identified, not a limited subset of that science, or science falling outside set parameters.

**Nutrition Evidence Systematic Review**

Nutrition Evidence Systematic Reviews (NESR) developed by USDA’s NESR team play an important role in development of each edition of the Dietary Guidelines. NESR systematic reviews evaluate scientific evidence on topics relevant to Federal programs and policies. They also serve as an important safeguard against confirmation bias, which is the tendency to distort evidence-based decision-making by searching for, interpreting, favoring, and recalling information that confirms or supports one’s prior beliefs or values.

The NESR team supported the 2020 DGAC in examining the science by supplying state-of-the-art systematic reviews of the topics and scientific questions raised by the agencies. Each systematic review followed rigorous, protocol-driven method, including:

- developing a protocol,
- searching for and selecting articles,
- extracting data and assessing the risk of bias of results from each included article,
- synthesizing the evidence,
- developing conclusion statements,
- grading the evidence underlying each conclusion statement, and
- recommending future research.

NESR analysts worked jointly with DGAC members to set up inclusion and exclusion criteria tailored to the systematic review question addressed. The goal was to ensure that the evidence reviewed by DGAC members was:

- applicable to the U.S. population, including those who are healthy and/or those at risk of chronic disease,
- relevant to public health nutrition policies and programs, and
- rigorous from a scientific perspective.

Criteria were also set up for study characteristics, such as:

- study design,
- language,
- publication status,
- health status of study subjects,
- publication date,
- country in which the study was conducted,
• subject age,
• independent and dependent variables,
• study duration, and
• group size.

Although the NESR team tailored criteria to the unique characteristics of each systematic review question, it also applied standard criteria. These standard criteria align with common practice within the field of systematic review. NESR analysts also graded evidence presented in every systematic review to allow for development of statements or recommendations with sound evidentiary support. Because the U.S. Dietary Guidelines reflect important Federal policy, which many others carefully review and consider, it is essential that statements and recommendations in the Dietary Guidelines be valid, evidence-based, and free of intellectual bias and conflicts of interest to the greatest extent possible. For that reason, Dietary Guidelines generally only include statements or recommendations with “strong” or “moderate” evidentiary support as graded by NESR analysts.

**Alcohol-Related Questions**

In Fall 2018, even before selecting the 2020 DGAC, USDA and HHS identified eight (8) alcohol-related questions for which they sought review and advice. The questions called for examination of the relationship between alcohol consumption and --

1. growth, size, body composition, and risk of being overweight and obesity,
2. risk of cardiovascular disease (CVD),
3. risk of cancer,
4. neurocognitive health,
5. all-cause mortality,
6. infant developmental milestones, including neurocognitive development (lactation),
7. post-partum weight loss (lactation), and
8. human milk composition and quantity.

The Beverages and Added Sugars Subcommittee (Subcommittee), formed as part of the 2020 DGAC, was responsible for reviewing these eight (8) questions and examining the related science using NESR systematic reviews and data analysis On March 28, 2020, the Subcommittee announced that it was self-limiting its work to only one (1) of the original eight (8) questions: the relationship between alcohol consumption and all-cause mortality.\(^2\) Again, a NESR systematic review would provide the graded science for the Subcommittee to use in addressing this single issue.

The NESR systematic review on alcohol consumption and all-cause mortality was published on April 20, 2020. There was no indication of any deviation from the standard protocol other than a time span limitation requested by the Subcommittee. The original protocol called for a systematic review of

\(^2\)During its presentation of summary recommendations on June 17, 2020, the Subcommittee explained that it “[p]rioritized all-cause mortality over CVD and cancer as outcomes for NESR systematic review due to time constraints, and because alcohol and CVD had been reviewed by DGAC before.”
studies published over twenty years (between 2000-2020). Citing “time constraints,” the Subcommittee asked NESR to reduce the review period to only a ten-year period (2010-2020).

The NESR systematic review on alcohol consumption and all-cause mortality was robust and included mostly prospective cohort studies. On May 26, 2020, Subcommittee posted the science it would reference from that NESR systematic review. Without question, the referenced science supported continuation of the current consumption guidelines for alcohol: up to one drink per day for women and up to two drinks per day for men.

Things changed on June 17, 2020, just weeks later, when the Subcommittee presented publicly the summary recommendations reflected in the attached PowerPoint presentation. The Subcommittee gave different and arguably inconsistent answers to the question of whether the science on alcohol consumption and all-cause mortality warrants any change in the current consumption guidelines. First, the Subcommittee said the current consumption guidelines, present in the Dietary Guidelines since 1990, align with “an early and influential meta-analyses on alcohol and all-cause mortality.” Second, the Subcommittee said the current consumption guidelines “constitute reasonably low risk.” Inexplicably, the Subcommittee then announced, “[h]owever, more recent evidence justifies tightening guidelines for men in particular.” The “tightening” was a recommendation to reduce to one (1) drink per day the consumption guidelines for men.

That “more recent evidence” did not come to light until publication of the full DGAC report on July 15, 2020. It turned out to be eighty (81) references that were not part of the NESR systematic review protocol on alcohol consumption and all-cause mortality. Basically, the Subcommittee disregarded the NESR systematic review protocol, which included sixty (60) graded studies, and instead, relied heavily on ungraded, out-of-scope references (mainly Mendelian Randomization studies not dealing with all-cause mortality). Based on these ungraded, out-of-scope references, the Subcommittee presented what it called “evidence-based advice” to USDA and HHS to reduce the consumption guidelines for men.

Alcohol is discussed in Chapter 11 of the July 15 DGAC report. Chapter 11 includes the previously described recommendation to change the consumption guidelines to one drink per day for men. The recommendation does not meet the standards of the 2020 DGAC Charter and is otherwise seriously flawed from a scientific and methodological standpoint.

5. **The preponderance of the evidence as shown by the NESR systematic review supports keeping the current consumption guidelines for men.**

In Chapter 11, the authors summarize the findings of the NESR systematic review as follows: "among those who drank alcohol, most studies found lower risk among men consuming within ranges up to 2 drinks per day and women consuming ranging up to 1 drink per day compared to those drinking higher amounts" (emphasis added). The authors then set this evidence aside and presented a completely different recommendation: reduce the consumption guidelines for men to 1 drink per day. Notably, only one study in NESR systematic review considered the difference in consuming 2 versus 1 drink per day.
in men, with alcohol intake at one time-point.\textsuperscript{3} This one study, which measured self-reported alcohol intake on a single occasion, does not rise to the moderate/strong level of science typically used for recommendations and certainly does not constitute a “preponderance of the evidence.” The preponderance of the evidence as shown by the NESR systematic review supports keeping, not changing, the consumption guidelines for both men and women.

Of the sixty (60) studies from the NESR systematic review, thirty-three (33) supplied risk estimates for men. Reduced risk was associated with drinking levels that varied from a range defined as <10g/day to 60g/day, depending on the study. Twenty-eight (28) of these thirty-three (33) studies reported a higher risk of mortality for nondrinkers than for light-to-moderate drinkers; two (2) studies showed results that were not statistically significant; and two (2) studies included current drinkers only. Twelve (12) of the studies separated former drinkers from nondrinkers while another six (6) found a lower risk among light-to-moderate drinkers.

Since 1990, the Dietary Guidelines have included consumption guidelines based on levels at which risk to drinkers and non-drinkers is equivalent. The authors of Chapter 11 rejected this approach and instead, discounted or disregarded the evidence shown in the NESR systematic review in favor of out-of-scope science supporting their preferred outcome: an absolute risk approach to consumption guidelines.\textsuperscript{4}

It bears note that the preponderance of evidence as shown by the NESR systematic review, supports a finding that risk for male drinkers versus male non-drinkers does not increase until alcohol consumption exceeds two drinks or 28g/day. In putting forth the recommendation to reduce consumption guidelines for men to one (1) drink per day, Chapter 11 of the DGAC report deviates significantly from the preponderance of scientific evidence.\textsuperscript{5}

6. The recommendation to change the consumption guidelines for men conflicts with the requirements of the 2020 DGAC Charter.

The 2020 DGAC Charter requires recommendations to match the “preponderance of scientific and medical knowledge current at the time of the publication.” The recommendation to reduce the consumption guidelines for men falls short of this requirement, because it is based on a select and arguably non-representative group of evidence outside the NESR systematic review on alcohol and all-
cause mortality. In other words, it is a recommendation based on far less than a “preponderance of the scientific and medical knowledge.”

Recommendations to change Federal nutrition policy must have unbiased support that represents the totality of scientific evidence, not limited science, or questionable science. Per the 2020 DGAC charter, there are three types of acceptable scientific support for DGAC recommendations: data analysis, food pattern modeling, and/or Nutrition Evidence Systematic Review (NESR) systematic reviews.

The original NESR systematic review protocol on alcohol and all-cause mortality included research spanning a twenty-year period (2000-2020). Citing “time constraints,” the subcommittee writing Chapter 11 decided to look at research from only half this period (2010-2020). Worse still, while the Subcommittee said it did not have time to review the first ten years of scientific evidence as planned in the original NESR protocol, it did have time to search for and locate eighty-one (81) references outside the NESR protocol. Disregarding science from the original NESR systematic review protocol on the one hand and accepting out-of-scope science on the other hand neither meets the requirements of the 2020 DGAC charter nor basic standards for systematic reviews of science to support Federal nutrition policy.6

7. The authors of Chapter 11 place unwarranted reliance on out-of-scope Mendelian Randomization (MR) studies to support the recommendation to reduce the consumption guidelines for men.

The authors of Chapter 11 formulated their recommendation to reduce consumption guidelines for men based on Mendelian Randomization (MR) studies, not on all-cause mortality, but on cardiovascular disease, certain cancers, and other out-of-scope topics. The NESR systematic review on alcohol and all-cause mortality included only one MR study. MR studies are observation studies that employ genetic data to infer relationships between exposure to lifestyle factors and chronic disease. Like other forms of observational epidemiology, MR studies present meaningful challenges in term of both reproducibility and interpretation of results. The use of genes as a proxy for estimating the effects of alcohol consumption on chronic disease is relatively new and subject to criticism because failure of replication is common. For this reason, expert researchers question the reliability of MR studies over high quality, reproducible epidemiology in assessing the association of alcohol consumption with health effects such as cardiovascular disease.7 The one MR study on alcohol in the NESR systematic review showed that older men who regularly consume excessive amounts of alcohol have higher mortality, but found no evidence of progressive increase in mortality hazard with increasing amounts of alcohol use up to six drinks daily.8 In other words, the study authors found an increased risk for older men at 6+ drinks per day but did not say whether lower regular intake is either harmful or protective. The authors of Chapter 11 only referenced this study in passing. They then held up fourteen (14) other MR studies, all outside

---


the NESR systematic review and none related to all-cause mortality, as superior to the weight of the other scientific evidence on alcohol and all-cause mortality found through that review. It makes no sense for the Subcommittee to cite time restrictions to limit its work and the NESR systematic review protocol and then rely on studies falling outside the NESR systematic review, including fourteen (14) MR studies, as the evidence base for a recommendation to reduce the consumption guidelines for men. If the Subcommittee had time to search the literature for additional MR studies, meta-analyses, and modeling studies on cardiovascular disease and cancer (i.e., topics not prioritized and thus out-of-scope), they could have used that time to implement the entire NESR systematic review protocol and develop recommendations based on a preponderance of the graded evidence within the scope of that systematic review protocol.

8. The authors of Chapter 11 did not meet DGAC charter standards for transparency nor strengthen the science base of the process and proposed recommendations.

After widespread complaints about the process followed for the 2015 Dietary Guidelines, the agencies worked diligently to establish standards in the 2020 DGAC charter for identification and examination of science to reduce and manage sources of bias and conflicts of interest, improve timely opportunities for engagement by all interested parties, enhance transparency, and strengthen the science base of the 2020 Dietary Guidelines process and proposed recommendations.

The authors of Chapter 11 subverted these standards. First, they deviated from the science found in the NESR systematic review. Second, they published science supporting continuation of the current consumption guidelines yet only weeks later claimed the same science supports a different consumption guideline for men. Their approach was neither transparent nor designed to supply prompt opportunities for engagement by all interested parties. The Subcommittee provided no citations during its June 17, 2020 presentation, and no opportunity for public comment on its surprise recommendation prior to release of the DGAC report on July 15, 2020.

Third, the authors addressed questions in Chapter 11 that were beyond the questions specified by the agencies and presented their review and recommendations in an imprecise manner, leaving many to question the actual scientific basis for their conclusions. For example, Chapter 11 includes a conclusory statement that “drinking less is generally better for health than drinking more,” as well as the unsupported declaration that “alcohol consumption is positively associated with 3 types of cancer.” The authors describe these statements as “evidence-based,” but present them without context, reference, or the proper level of evidentiary support as required by the 2020 DGAC Charter.  

Fourth, the authors included incomplete and quite misleading references to third party sources. For example, the authors cite a statement from the American Cancer Society’s Guideline on Diet and

---

9Nutrition research merits the same rigor used in understanding other domains in which science is used, but daily interactions with food and cultural practices surrounding diet seem to lead to widespread nutritional beliefs based on conjecture, anecdote, and intuition more than sound science. Many individuals have beliefs about foods and nutrition that are not necessarily grounded in empirical evidence, and such beliefs, when held by scientists, likely influence the lens through which they report their findings. See Brown AW, Ioannidis JP, Cope MB, Bier DM, Unscientific Beliefs about Scientific Topics in Nutrition. Advances in nutrition (Bethesda, Md.). 5. 563-5. 10.3945/an.114.006577 (2014).
Physical Activity to wit, “it is best not to drink alcohol,” without disclosing the full guideline which is, “[p]eople who choose to drink alcohol should limit their consumption to no more than 1 drink per day for women and 2 drinks per day for men.”

9. The recommendation to reduce consumption guidelines for men violates the DGAC charter because it deviates from and does not build upon prior Dietary Guidelines.

During instruction on the 2020 DGAC Charter, agency representatives reminded each member that each edition of the Dietary Guidelines builds on the previous edition with scientific justifications for any recommended changes based on a preponderance of the science identified, not a limited subset of that science, nor science falling outside set parameters. Chapter 11 of the DGAC report deviates significantly from guidance included in the Dietary Guidelines since 1990 by emphasizing levels at which risk is lowest, not levels at which risk to drinkers and non-drinkers is equivalent.

Given these breaches of both process and protocol as well as the science disclosed as part of the NESR systematic review, the agencies should not adopt the recommendation to lower the consumption guidelines for men, especially as the recommendation leaps over decades of clear science and sound public policy.

Recommendations

Instead of adopting the flawed and conclusory statements and recommendations of Chapter 11, we respectfully ask the agencies to include the following simple, scientifically supported statements in the 2020 Dietary Guidelines for Americans:

- If alcohol is consumed, it should be in moderation – up to one (1) alcohol drink-equivalent per day for women, and up to two (2) per day for men. This consumption guideline is consistent with the 2015 Dietary Guidelines for Americans.

- One alcohol drink-equivalent has 14 g (0.6 fl oz.) of pure alcohol. The following are reference beverages that are one alcohol drink-equivalent: 12 fluid ounces of regular beer (5% alcohol), 5 fluid ounces of wine (12% alcohol), or 1.5 fluid ounces of 80 proof distilled spirits (40% alcohol). This definition of a drink-equivalent is also consistent with the 2015 Dietary Guidelines for Americans.

- If you choose to drink alcohol, know the differences between the types, sizes, and alcohol content of alcohol beverages in the market so you may understand and keep track of how much alcohol you are consuming. The 2015 Dietary Guidelines for Americans includes this same guidance.

- Do not consume alcohol beverages on an empty stomach. Food slows the absorption rate of alcohol beverages. If you choose to consume alcohol beverages, eat food before or while

---

drinking. Also, stay hydrated (with water or other non-alcohol beverages) when consuming alcohol beverages. This is practical, prudent advice to add to the 2020 Dietary Guidelines.

- Discuss any concerns about alcohol beverage consumption with your healthcare provider. There are some people who should not consume alcohol beverages at all. Examples include, but are not limited to, those who are under 21, women who are pregnant, or those that have a medical or family condition or history of concern. This recommendation is consistent with the language of the 2015 Dietary Guidelines for Americans.

Respectfully submitted,

Jim McGreevy  
Beer Institute, President and CEO

Bob Pease  
Brewers Association, President and CEO

Enclosure: DGAC Meeting #1 Transcript