

August 2, 2024

Robert Vincent, MS. Ed Staff Chair, Interagency Coordinating Committee on the Prevention of Underage Drinking Substance Abuse and Mental Health Services Administration U.S. Department of Health and Human Services 5600 Fishers Lane, Room 15E45 Rockville, MD 20857 samhsapra@samhsa.hhs.gov

Re: The Interagency Coordination Committee on the Prevention of Underage Drinking Requests for Public Comments on the Alcohol Intake and Health Methodology (FR Doc. 2024-14650)

Dear Mr. Vincent and Members of the Interagency Coordinating Committee on the Prevention of Underage Drinking:

The Center for Science in the Public Interest (CSPI) respectfully submits the following comments on the methodology for the Alcohol Intake and Health Study posted by the Interagency Coordinating Committee on the Prevention of Underage Drinking (ICCPUD) in July 2024.

CSPI is a non-profit consumer education and advocacy organization that since 1971 has been working to improve the public's health through better nutrition and food safety. CSPI helped to lead efforts to pass the Nutrition Labeling and Education Act, the Healthy, Hunger-Free Kids Act (to improve school food), the Food Safety Modernization Act, and the Food Allergen Labeling and Consumer Protection Act. Most pertinent to the Alcohol Intake and Health Study, CSPI has also advocated to uphold the scientific rigor of the Dietary Guidelines for Americans (DGA) and improve alcohol labeling.¹ CSPI publishes *Nutrition Action* (NA) and is supported by the subscribers to NA, individual donors, and foundation grants. CSPI is an independent organization that does not accept any corporate donations.

We appreciate the ICCPUD's transparent and participatory process of sharing a draft methodology protocol for the Alcohol Intake and Health Study for public comment. We strongly encourage the committee to post all of the comments it receives on this protocol in a public docket.

The protocol provides high-level descriptions of four distinct research activities:

- 1. a systematic review of dietary guidelines,
- 2. a systematic review to identify meta-analyses on the link between alcohol and various health outcomes, and a process for enlisting subject area experts to select which of these meta-analyses will inform subsequent modeling studies,
- 3. modeling studies to estimate the risk relationship between alcohol use and injury, alcoholattributable burden of disease in 2022, and lifetime risk of alcohol-attributable morbidity and mortality, and
- 4. a mixed methods study to assess public understanding and reactions to data on alcohol consumption and health.

¹ Center for Science in the Public Interest. Comment on Non-Rulemaking Docket re: Labeling and Advertising of Wine, Distilled Spirits, and Malt Beverages with Alcohol Content, Nutritional Information, Major Food Allergens, and Ingredients (Docket No. TTB-2024-0002). March 29, 2024. <u>https://www.cspinet.org/sites/default/files/2024-03/CSPI%20Alcohol%20Labeling%20Written%20Comment%20to%20TTB.pdf</u>

We provide recommendations in response to the following questions posed by ICCPUD:

- Are the methods proposed scientifically valid?
- Are the risks of bias identified? Are strategies to minimize bias included?
- Are the methods proposed subject to major limitations? If so, what strategies could be employed to minimize these limitations

Are the methods proposed scientifically valid?

Recommendation 1: Provide a detailed protocol for Activity 2 (systematic review of meta-analyses) for public review

In general, we support the approach proposed by the Technical Review Subcommittee and Scientific Review Panel (SRP) to review the scientific literature and conduct mathematical modeling. However, detailed methods were not provided for Activity 2, the systematic review of meta-analyses, and we would appreciate an opportunity to review a more detailed protocol (*i.e.*, the draft research protocol that will be pre-registered on PROSPERO) to consider the full search criteria, inclusion and exclusion criteria, outcomes of interest, populations of interest (including a clear definition of "vulnerable populations"), and strategy for data synthesis.

Recommendation 2: Recruit a nationally representative sample for Activity 4

The protocol states that Activity 4 will use a convenience sampling methodology to recruit participants. Instead, the ICCPUD should recruit a nationally representative sample of adults in the United States (U.S.) who drink alcohol, given that this work will be used to inform national dietary guidelines. Furthermore, the survey should be offered in languages other than English. The proposed plan to only ask participants questions in English excludes the 8.4% of the U.S. population who have limited English proficiency.² This oversight limits the generalizability and inclusivity of the findings and of any recommendations stemming from them.

Are the risks of bias identified? Are strategies to minimize bias included?

Recommendation 3: Publicly disclose conflicts of interest (COI) for the Technical Review Subcommittee and subject matter experts involved with evidence review

We applaud the ICCPUD for selecting experts with appropriate backgrounds for the SRP and the public disclosure of their individualized COI. We urge the ICCPUD to vet and publicly disclose the names, affiliations, and COI (both actual and perceived) for both the Technical Review Subcommittee and for the additional subject matter experts recruited to help select the highest quality meta-analyses on specific topics.

Recommendation 4: Provide more information on the use of expert hypotheses about the misestimation of alcohol use in population surveys

The protocol states that "each expert [involved in selecting meta-analyses] will also be asked the degree to which they hypothesize alcohol use to be misestimated in population surveys (what fraction is due to spillage and wastage, and what fraction is due to survey and response biases) and in cohort studies." We

² U.S. Census Bureau, "Selected Social Characteristics in the United States," 2022. American Community Survey, ACS 1-Year Estimates Data Profiles, Table DP02, 2022, accessed on July 31, 2024, https://data.census.gov/table/ACSDP1Y2022.DP02?q=DP02.

recommend that the ICCPUD provide more information on how these hypotheses and other feedback from experts will be amalgamated and incorporated into the Alcohol Intake and Health Study.

As for strategies to minimize bias, we applaud the proposed use of the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach, A Measurement Tool to Assess Systematic Reviews (AMSTAR 2) checklist, and the Risk of Bias in Systematic Reviews (ROBIS) tool in the selection of meta-analyses for inclusion in the modeling studies.

Are the methods proposed subject to major limitations? If so, what strategies could be employed to minimize these limitations?

Modeling studies are inherently limited by reliance on assumptions and further limited when underlying data includes observational studies prone to confounding and other sources of bias. With that said, we appreciate that the methods outlined in the Alcohol Intake and Health Study protocol attempt to reduce bias and optimize the validity of the resulting modeling studies.

For more information, please contact:

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