

**U.S. Environmental Protection Agency  
Science Advisory Board  
Summary Minutes for the Public Meeting held on  
July 18, 2022 and July 20, 2022**

**Meeting Participants:**

Chartered Science Advisory Board (SAB) Members

Dr. Alison C. Cullen, Chair	Dr. Angela Leung
Dr. C. Marjorie Aelion	Ms. Lisa Lone Fight
Dr. David T. Allen	Dr. Lala Ma
Dr. Florence Anoruo	Dr. John Morris
Dr. Joe Arvai	Dr. Enid Neptune
Dr. Barbara D. Beck	Dr. Sheila Olmstead
Dr. Roland Benke	Dr. Austin Omer
Dr. Tami Bond	Dr. Gloria Post
Dr. Mark Borsuk	Dr. Kristi Pullen-Fedinick
Dr. Sylvia M. Brouder	Dr. Amanda D. Rodewald
Dr. Jayajit Chakraborty	Dr. Emma J. Rosi
Dr. Aimin Chen	Dr. Jonathan M. Samet
Dr. Weihsueh Chiu	Dr. Lianne Shepherd
Dr. Ryan Emanuel	Dr. Genee Smith
Mr. Earl W. Fordham	Dr. Daniel O. Stram
Dr. John Guckenheimer	Dr. Peter S. Thorne
Dr. Steven P. Hamburg	Dr. Godfrey Arinze Uzochukwu
Dr. Selene Hernandez-Ruiz	Dr. Wei-Hsung Wang
Dr. Elena G. Irwin	Dr. June Weintraub
Dr. David Keiser	Dr. Sacoby Wilson
Dr. Mark W. LeChevallier	Dr. Dominique van der Mensbrugghe

Please see roster for full listing of the Chartered SAB Members.<sup>1</sup>

Board Liaisons

Dr. Daniel Schlenk, TSCA SACC  
Dr. Deanna Scher, Chair, Children's Health Protection Advisory Committee  
Dr. Shirlee Tan, Incoming Chair, Children's Health Protection Advisory Committee  
Dr. Paul Gilman, Board of Scientific Counselors

Designated Federal Officer

Dr. Thomas Armitage, Designated Federal Officer (DFO)

Other Attendees

See Attachment A.

## **Meeting Summary:**

The Chartered Science Advisory Board held a public meeting by video conference on July 18 and July 20, 2022. Dr. Thomas Armitage, Designated Federal Officer (DFO) for the Chartered SAB, convened the meeting at approximately 1:00 p.m. (Eastern Time) and provided an opening statement. He noted that the SAB is an independent expert advisory committee chartered under the Federal Advisory Committee Act (FACA) to provide advice to the EPA Administrator. Dr. Armitage noted that SAB meetings are held in public, with advance notice given in the Federal Register.<sup>2</sup> Dr. Armitage indicated that there was one public speaker scheduled to present comments during the public comment period at the meeting. He noted that all meeting materials were posted on the SAB website and minutes would be certified by the SAB Chair and posted on the SAB website as well. He further noted that public access to the meeting had been provided through a YouTube webcast and a telephone conference line. Dr. Armitage then reviewed the FACA and the ethics requirements observed by the SAB noting that one SAB member, Dr. Barbara Beck, had recused herself from the discussion of the per- and polyfluoroalkyl substances (PFAS and PFOS) SAB report scheduled on Wednesday, July 20, 2022. Dr. Armitage asked those listening to the webcast to send him an e-mail to let him know of their attendance and then took the roll.

Mr. Thomas Brennan, Director of the SAB Staff Office, also welcomed and thanked SAB members for their work and for their compliance with federal ethics requirements.

Dr. Alison Cullen, SAB Chair, welcomed SAB members and reviewed the meeting agenda.<sup>3</sup> She indicated that the items on the agenda for the first day of the meeting included a quality review of the SAB draft report: *Review of the EPA's Draft Fifth Contaminant Candidate List (CCL-5)* as well as discussion of recommendations received from the SAB work group for review of science supporting EPA decisions. She indicated that a quality review of the SAB draft report titled *Review of EPA's Analyses to support EPA's National Primary Drinking Water Rulemaking for PFAS* would occur on the second day of the meeting, Wednesday, July 20, 2022.

## **Public Comments**

Dr. Cullen stated that the SAB would hear public comments. She indicated that a list of registered public speakers<sup>4</sup> had been posted on the SAB website. She then asked Mr. Stephen Risotto of the American Chemistry Council (ACC) to present his comments.

Mr. Steven Risotto said the ACC supports the development of national drinking water standards for PFOA and PFOS but is deeply concerned about EPA's draft approach to developing a Maximum Contaminant Level (MCL) for these two substances. He indicated that ACC's concerns were based on two main issues: (1) the data from the Faroe Islands are not appropriate basis for human health risk assessment for either PFOA or PFOS and (2) if the Agency's conclusion is that PFOA is a "likely" carcinogen, then the MCL goal should be set at zero, consistent with EPA's long-standing policy. Further details of Mr. Risotto's comments may be found in his written comments<sup>5</sup> posted on the meeting webpage.

## **Quality Review of Draft Review of the EPA's Draft Fifth Contaminant Candidate List (CCL 5)**

Dr. Cullen indicated that the SAB would next conduct a quality review of its report on EPA's draft Fifth Contaminant Candidate List (CCL 5). Dr. Cullen noted that quality review of SAB panel and committee reports is a key function of the chartered SAB. She indicated that the Board must make a determination about the quality of all draft reports. She indicated that the SAB would: (1) hear a brief introduction from Dr. June Weintraub, Chair of the SAB panel that developed the CCL5 report; (2) hear comments from SAB members designated as lead reviewers; (3) hear a brief response from Dr. Weintraub; (4) hear any additional comments from SAB members; and (5) vote on disposition of the draft report.

Dr. Cullen noted that the quality review discussion would focus on four questions that are the responsibility of the chartered SAB:

1. Whether the original charge questions to the SAB Panel were adequately addressed;
2. Whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the SAB Panel's report;
3. Whether the SAB Panel's report is clear and logical; and
4. Whether the conclusions drawn or recommendations provided are supported by the body of the SAB Panel's report.

Dr. June Weintraub, Chair of the SAB Drinking Water Committee Augmented for the CCL-5 Review, presented an overview of the Panel's report as shown in her slides posted on the meeting webpage.<sup>6</sup> Dr. Weintraub discussed the Panel's meetings and listed the three documents reviewed by the panel covering chemical contaminants, microbial contaminants and the contaminant information sheet. Dr. Weintraub reviewed the legal basis for the EPA's identification of a list of contaminants known or anticipated to occur in public drinking water systems and which may require regulation under the Safe Drinking Water Act. She noted that every 5 years, EPA is required to identify a list of contaminants that are currently not subject to regulation but may require regulation under the Safe Drinking Water Act (SDWA). She further indicated that the EPA must then select a minimum of five contaminants to undergo determination to ascertain whether they should be regulated under primary drinking water regulations. Dr. Weintraub then summarized EPA's charge questions to the SAB and the Panel's key recommendations as shown in her presentation slides. She indicated that the Panel had asked EPA to clarify the types of occurrence data that were included or rejected for consideration in development of the Draft CCL 5. She noted that the Panel had recommended that EPA clarify the reason that expert opinion weighed heavily in the identification of microbial contaminants for the Draft CCL 5. In addition, Dr. Weintraub indicated that the Panel had asked for clarification of the criteria used to identify information for making determinations, including dates of sampling and publication of results. She also noted that the Panel had provided recommendations regarding the consideration of sensitive populations. Dr. Weintraub said that, in general, the

Panel supported the consideration of groups of compounds but had asked for a rationale explaining why EPA had listed some compounds as groups. Dr. Weintraub noted that, in particular, the Panel had asked EPA for information on the criteria for grouping individual PFAS chemicals. Dr. Weintraub presented a full list of Panel recommendations found in her presentation slides.

#### Lead Reviewers' Comments on CCL5 Draft Report

Dr. Cullen thanked Dr. Weintraub for her presentation and called upon the lead SAB reviewers to summarize their comments on the draft report. The written quality review comments from SAB reviewers on the CCL5 draft report<sup>7</sup> are available on the SAB webpage.

Dr. Barbara Beck said the draft report was clear and logical. She offered some specific comments on the scientific basis of the manganese (Mn) discussion. She indicated that the cross-sectional studies on which health effects of manganese in drinking water depend cannot be used to draw conclusions on causality. Dr. Beck noted that the draft report had not provided support for moving MN from the draft to the Final CCL 5. More specifics may be found in Dr. Beck's written comments posted on the meeting webpage.

Dr. Cullen summarized written comments from Dr. Aimen Chen in his absence.

Dr. Gloria Post offered some technical information on 1,4-Dioxane and manganese as shown in her written comments posted on the meeting webpage. Dr. Post presented data showing that 1,4-Dioxane occurs frequently in drinking water and has been found at levels exceeding the EPA health-based Reference Concentration. Dr. Post cited a World Health Organization 2021 publication which updated a provisional health-based guideline value of 80 µg/L. Dr. Post questioned the Panel's recommendation to "list the criteria for screening chemical contaminants from the initial universe of contaminants to form the Preliminary Contaminant Candidate List (PCCL) (i.e. before the point-based scoring is applied)." Dr. Post questioned whether it was possible for EPA to provide a table that listed the specific PFAS chemical considered given that more than 4,000 PFAS chemicals had been manufactured and used.

Dr. Kristi Pullen-Fedinick said that the charge questions had been adequately addressed and she did not see any technical errors or omissions in the draft report. She also indicated that the draft report was clear and logical but occasionally found the need to reference what the tiers of recommendations in the report meant. She identified several places in the report where there was language recommending that EPA consider expanding the definition of PFAS, but she wasn't sure whether this was a tier 1 or tier 2 recommendation. Dr. Pullen-Fedinick indicated that the Panel's conclusions in Section 2.3.1 could be clarified. She also noted that the meaning of the phrase "carried from" in the report was not clear.

Dr. Peter Thorne said the charge questions had been adequately addressed and he did not find any technical errors. He noted that it was not clear why EPA's text on *Legionella pneumophila* had been found to be insufficient. Dr. Thorne questioned the rationale for specifically listing

saxitoxins. Dr. Thorne suggested the report could include more specific text indicating what EPA could do to replace the U.S. Geological Survey monitoring efforts. Dr. Thorne also indicated that the manganese discussion could be clarified.

Dr. Cullen thanked the lead reviewers for their comments and called for further discussion on disposition of the report. She indicated that the SAB had to decide whether the report needed further review by the full SAB or a subset of the SAB or if any further changes should be made through discussion between the Panel Chair and SAB Chair.

D. Cullen asked Dr. Weintraub if she wanted to respond to the lead reviewers' comments. In response, Dr. Weintraub said the draft report could include additional information about manganese although she did not expect it to change the Panel's recommendations. With respect to 1,4-Dioxane, Dr. Weintraub said the Panel was trying to say that EPA's screening should capture some additional information. Dr. Weintraub said that most of the lead reviewers' comments could be resolved by editing and adding information to the report.

Dr. Beck said that most of her comments and Dr. Post's comments could be addressed by adding additional information. Dr. Post agreed that most of her comments could be addressed by adding additional text because she wasn't questioning the Panel's conclusions. Dr. Pullen-Fedinick said consideration could be given to removing a recommendation on *Campylobacter*.

Dr. Cullen called for a motion on disposition of the report. She indicated that the SAB should consider whether the report should be revised and returned to the lead reviewers or the entire SAB for approval. Dr. Hamburg moved to approve the report with revisions and empower the lead reviewers to approve the final report, with any interested SAB members being allowed to join in. Dr. Thorne seconded the motion. By a voice vote, the motion passed. Dr. Cullen thanked the Panel for their hard work.

#### Discussion of Recommendations Received from the SAB Work Group for Review of Science Supporting EPA Decisions

After a break, Dr. Cullen called the Board's attention to the July 5, 2022 memo<sup>8</sup> (posted on the meeting webpage) summarizing recommendations of the SAB Work Group for Review of Science Supporting EPA Decisions regarding planned EPA regulatory actions. Dr. Cullen noted that the Work Group had met on May 27, 2022 and June 24, 2022 to recommend whether the full SAB should consider further review of the following planned actions:

1. National Emission Standards for Hazardous Air Pollutants (NESHAP): Gasoline Distribution Technology Review and Standards of Performance for Bulk Gasoline Terminals Review (RIN 2060-AU97)
2. Federal Recreational Water Quality Criteria Applicable to Certain Waters in New York (RIN 2040-AG08)
3. Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights (RIN 2040-AG17)
4. New Source Performance Standards Review for Industrial Surface Coating of Plastic Parts for Business Machines (RIN 2060-AV23)

5. Renewable Fuel Standard (RFS) Program: Alternative Renewable Identification Number (RIN) Retirement Schedule for Small Refineries (RIN 2060-AV72)
6. Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act – Safer Communities by Chemical Accident Prevention (RIN 2050-AH22)
7. Designating PFOA and PFOS as CERCLA Hazardous Substances (RIN 2050-AH09)
8. Federal Implementation Plan for Prong 1 and Prong 2 Infrastructure Requirements (“Interstate Transport”) for the 2015 8-Hour Primary Ozone NAAQS (RIN 2060-AV51)

Dr. Cullen summarized these eight proposed rules and the reasons the Work Group had found that SAB review of the science supporting them was not warranted. In each case, the SAB voted to approve the Work Group’s recommendation.

Dr. Cullen thanked SAB members for discussing the Work Group’s memorandum and asked members if they had additional comments. Dr. Deanna Scher returned to the subject of the CCL-5 draft report. She noted that the report contained a recommendation calling for further explanation of the “sensitive populations” that had been considered when developing the list of chemical contaminants. She indicated that it might be useful for the lead SAB reviewers to consider how “sensitive populations” had been addressed in the report and whether there were opportunities to expand the subject.

Dr. Beck asked whether written comments from the American Chemistry Council would be available. Dr. Armitage said that Mr. Risotto’s written statement would be posted on the SAB website and also noted Mr. Risotto had registered to provide additional oral comments at the second comment period on July 20, 2022.

Dr. Mark LeChevallier asked why EPA had issued a health advisory for PFAS chemicals in advance of the SAB review. He asked whether the Agency would address the timing of the health advisory in its presentation on July 20, 2022. Mr. Brennan said that senior officials from the Office of Water would be at the SAB meeting on July 20, 2022 and would address this point.

### **July 20, 2022: Meeting Continued**

Dr. Armitage reconvened the meeting at approximately 1:00 p.m. (Eastern Time) on July 20, 2022. He indicated that the meeting was a continuation of the July 18, 2022 SAB meeting and took the roll. Dr. Cullen then welcomed members and reviewed the agenda for the day. She indicated that the SAB would hear a presentation from the Office of Water (OW) on Drinking Water Health Advisories for PFAS Chemicals and that the SAB would conduct a quality review of the draft SAB report titled *Review of EPA’s Analyses to Support EPA’s National Primary Drinking Water Rulemaking for PFAS*.

### **EPA Presentation on Drinking Water Health Advisories for PFAS Chemicals**

Dr. Cullen introduced two speakers from EPA’s Office of Water (Mr. Eric Burneson, Director of the Standards and Risk Management Division in EPA’s Office of Ground Water and Drinking

Water and Ms. Elizabeth Behl, Director of the Health and Ecological Criteria Division in EPA's Office of Science and Technology) and asked them to begin their presentation on Drinking Water Health Advisories for PFAS Chemicals

The presentation followed the slides<sup>9</sup> posted on the meeting webpage. Mr. Burneson reminded members that EPA had provided four draft documents for SAB review:

1. Proposed Approaches to Derive the Maximum Contaminant Level Goal (MCLG) for PFOA
2. Proposed Approaches to Derive the MCLG for PFOS
3. Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per and Polyfluoroalkyl Substances
4. Analysis of Cardiovascular Disease Risk Reduction as a Result of Reduced PFOA and PFOS exposure

He noted that charge questions had been submitted for each of these documents and that the EPA would consider the SAB's input as the Agency developed the proposed PFAS MCLGs and drinking water regulations. Ms. Behl described the interim updated Health Advisories that EPA had issued for PFOA and PFOS. She indicated that Health Advisories were likely to remain below the minimum reporting level of 4 ppt. Ms. Behl discussed the four PFAS Health Advisories released thus far. She directed members to the Safe Drinking Water Act (SDWA) website where supporting documents could be found. Mr. Burneson returned to finish the presentation slides, covering next steps with the PFAS roadmap.

Dr. Cullen thanked the speakers for their presentation and called for questions from SAB members. In response to a question from Dr. Uzochukwu, Mr. Burneson described the program for approval of laboratories that conduct chemical analyses. He indicated that further information on approved laboratories was available on the SDWA website. In response to a question from Dr. Guckenheimer, Ms. Behl said she did not think there was unusually high uncertainty associated with PFAS and PFOS science. In response to a question from Dr. LeChevallier, Ms. Behl explained that EPA had issued interim Health Advisories because analysis showed that the 2016 health advisory of 70 ppt was orders of magnitude higher than what was needed. She indicated that the EPA was working to develop MCLGs that would incorporate the SAB's recommendations.

Mr. Burneson noted that, as indicated in the questions and answers on the SDWA website, EPA may remove the interim health advisories when the SAB recommendations were incorporated into new MCLGs.

Dr. Hernandez-Ruiz asked whether there were talking points to address possible public confusion given the probability of a MCLG lower than minimum reporting levels. Mr. Burneson directed her to the SDWA website for community fact sheets.

Dr. Post noted that Health Advisories were based on non-cancer effects and reference doses but the MCLGs were also developed on the basis of cancer effects. She commented that MCLGs for

likely carcinogens would be probably be zero and that if PFOA remained a likely human carcinogen, that could affect the MCLG. Ms. Behl stated that OW would have documents available to support the MCLG for both cancer and non-cancer effects.

Dr. Neptune asked whether there was information available on possible advances in detection that would allow better monitoring approaches.

Mr. Burneson said that measuring at the level of parts per trillion (ppt) was an advance in monitoring technology and that the EPA was focusing on how to conduct more and better monitoring given the thousands of PFAS chemicals. He noted that there were a number of contaminants for which analytical methods were a limiting factor for monitoring. He noted that the EPA's mixtures methodology was under review by SAB. In response to a question from Dr. Hernandez-Ruiz, Mr. Burneson said that 75% of laboratories can achieve a parts per trillion (ppt) measurement with 90% confidence.

Dr. Post said that the EPA should emphasize that Interim Health Advisories apply to short-term as well as lifetime exposure. Ms. Behl indicated that the technical fact sheet on the SDWA website captures this point.

There were no further questions. Dr. Cullen thanked EPA staff and indicated that the SAB would next conduct a quality review of the SAB draft report titled *Review of EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS*.

#### Quality Review of Draft SAB Report, Review of EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS

Dr. Cullen indicated that the SAB would: (1) hear a brief introduction from Dr. Weihsueh Chiu, Chair of the SAB panel that developed the PFAS report; (2) hear comments from SAB members designated as lead reviewers; (3) hear a brief response from Dr. Chui; (4) hear any additional comments from SAB members; and (5) vote on disposition of the draft report.

After reminding SAB members of the questions to be addressed in a quality review, Dr. Cullen asked to Dr. Chiu to summarize the panel's findings.

Dr. Chiu thanked the panel for its work and presented the findings in the draft report. Dr. Chiu's presentation slides<sup>10</sup> may be found posted on the meeting webpage. Dr. Chiu said the purpose of the PFAS review documents was to support development of the MCLG. He indicated that these documents synthesized available toxicological and epidemiological data. Dr. Chiu presented the panel's main conclusions. He indicated that the Panel had called for more transparency and completeness in deciding which studies were eligible for inclusion in EPA's analysis of the data. He also noted that the Panel had found there were studies in the 2016 analysis that should be included in the present analysis. In addition, he indicated that the panel had provided specific recommendations for non-cancer hazard identification, cancer hazard identification, toxicokinetic modeling, reference dose (RfD) derivation and relative source contribution. With respect to EPA's Draft Framework for Estimating Noncancer Health Risk Associated with Mixtures of PFAS, Dr. Chiu presented the panel's recommendations on dose additivity assumptions, hazard index approach, relative potency factor and mixture benchmark dose



(BMD). Dr. Chiu presented an overview of the cardiovascular disease (CVD) risk reduction analysis which formed the basis of EPA's estimates of CVD reduction and he summarized the panel's recommendations on EPA's approach. Dr. Chiu's summary of the recommendations included comments on EPA's meta-analysis, life table approach and the Artherosclerotic Cardiovascular Disease (ASCVD) model.

Dr. Cullen thanked Dr. Chiu for his presentation and asked the lead reviewers to summarize their comments on the draft report. The written quality review comments<sup>11</sup> from SAB reviewers on the PFAS report are available on the SAB meeting webpage.

Dr. Aelion said she did not find technical errors or omissions and found the panel's draft to be clear and logical. She noted that the panel's criticism of EPA's decision to exclude literature published in 2016 should be emphasized. Dr. Aelion said it was important to identify the endpoints that may be relevant for future research. Dr. Aelion agreed with the panel's recommendation to use a probabilistic framework for determining uncertainty factors for derivation of the RfD (draft report, p. 70).

Dr. Borsuk said that the charge questions had all been addressed except 2B where he noticed the panel did not provide recommendations for modelling approaches. He questioned what the Panel meant by "broadened to recommend the need for scientific input and review in general."

Dr. Hernandez-Ruiz had no comments.

Dr. van der Mensbrugghe said that the report met the SAB's quality review criteria (in the four quality review questions). As indicated in his written comments posted on the meeting webpage, he noted that the draft report could take a stronger position on the justification for the CVD analysis. He noted that the report clearly stated that "elevated serum cholesterol is one of the better-established effects of exposure in humans." He asked whether the Panel was suggesting that EPA re-evaluate the evidence for not having the ability to develop a CVD-based RfD or whether the Panel had found that the focus of EPA's work should be on the PFAS link to cholesterol levels. He stated that if there is a PFAS to cholesterol to CVD link, one could undertake a detailed benefit-cost analysis that would show the relevant trade-offs. He further noted that the draft report highlighted some of the challenges in incorporating more population heterogeneity in the analysis - for example the risk of CVD changes with age, and that the ASCVD model had limited parameterization across age and sub-populations. He indicated that the heterogenous response and the desire to address it could be stressed more broadly.

Dr. Weintraub stated that the Panel's report was well-written. She offered some suggestions for adding sub-headers for organizational improvement.

Dr. Chiu responded to the lead reviewers' comments. In response to Dr. Aelion, he said he would scrutinize the letter to make sure her points were highlighted. With regard to Dr. Borsuk's comments, he indicated that he would make sure the recommendations on modelling ALT were clearly stated. He noted that an approach for evaluating the effects of mixtures is to determine weighted averages. He further noted that a concern of one reviewer who works at the state level was that in some cases, states might be implementing this guidance on their own using their own

review of the literature for the particular PFAS of concern. He indicated that he would look at the report to determine how to incorporate Dr. Weintraub's suggestions for headers and sub-headers.

Dr. Cullen thanked the lead reviewers for their comments and, after a break, called for comments on the draft report from other SAB members.

Dr. Samet commented that there should be a broader statement in the SAB report to stress that, in EPA's analysis, there was a lack of systematic review based on a protocol. He noted that, although the panel pointed out flaws concerning transparency, selection, and evaluation, there may be a need for the SAB to make a cross-cutting statement indicating that EPA's documents do not represent the state of the practice around information gathering. Dr. Morris voiced support for including a stronger statement about the lack of a systematic review.

Dr. Brouder commented that a systematic review of the literature should be conducted using clear inclusion and exclusion criteria. Dr. Chiu said the chartered SAB should consider whether Dr. Samet's suggested statement should be included in the letter to the Administrator as an overarching issue.

Dr. Guckenheimer said he did not find clear-cut statements from EPA that explained why a change in PFOA and PFOS standards was the appropriate next step nor did he see any indication of cost-benefit analysis being considered. Dr. Post indicated that the PFOA/PFOS numbers had been drastically reduced from 2016 due to the availability of new data showing effects on humans. Dr. Olmstead said the complete cost-benefit analysis was not available and that the panel was not asked to review it. Dr. Chiu noted that mechanistic data was also missing. Dr. Cullen asked whether it would be appropriate to itemize the missing pieces in the SAB report. Dr. Chiu responded to Dr. Cullen, indicating that the SAB the panel had suggested that EPA focus on four endpoints rather than every possible endpoint.

Dr. Cullen repeated Dr. Samet's suggestion of indicating in the letter to the Administrator that EPA's documents had methodological flaws and urging that these problems be addressed with revisions that represent the state-of-practice for gathering and using evidence for decision-making. Dr. Morris recommended that Dr. Samet's statement be included in the letter to the Administrator and Dr. Brouder agreed. A member asked for a qualifying sentence such as: "despite all the problems, the Panel agreed with overall conclusions." In response, Dr. Chiu said the panel had agreed with EPA's conclusion on PFOA, the likely carcinogen. He also noted that the panel agreed that the four endpoints (liver, immune, low birth weight, cardiovascular) had the strongest evidence supporting a causal relationship. SAB members commented that they did not support adding the qualifying sentence concerning overall conclusions.

In response to a question from Dr. LeChevallier, Dr. Chiu said the panel had not discussed the Health Advisories EPA had issued in July.

Dr. Post reminded SAB members that the Reference Dose (RfD) for non-cancer effects would likely remain below the reporting level of 4 ppt. Therefore, if PFOA was detectable, it would exceed the reference dose. Dr. Neptune asked whether EPA had enough time to conduct a systematic review following typical protocols.

Dr. Samet reiterated his recommendation that the lack of a systematic review should be acknowledged. Dr. Cullen said the SAB might consider adding a sentence indicating that the review documents did not constitute a “systematic review.” Dr. Post acknowledged EPA had not followed certain aspects of systematic review but she indicated that some parts of EPA’s analysis were consistent with systematic review.

Dr. Guckenheimer indicated that the most important question to be considered was whether the review documents formed a basis for setting Health Advisories for EPA. Dr. Weintraub expressed concern that a blanket critique about the lack of “systematic review” would not be useful, given EPA’s timeline for completion of its work, and would not serve the current rulemaking process. She suggested that it would be better to give EPA specific feedback for revision of their report.

Mr. Brennan reminded SAB members they would have another opportunity to look at a proposed rule when it was developed through the regulatory process. Dr. Chen (who sat on the PFAS Review Panel) said that EPA’s review wasn’t perfect but it was quite extensive and key papers had been used to derive MCLG. He said that he doubted the additional work suggested by SAB members would result in changes in derivation of MCLG.

Dr. Anoruo commented that in issuing health advisories, EPA was taking a precautionary approach. Dr. Hernandez-Ruiz expressed concern that the general public might not understand why EPA had issued an advisory level that can’t be measured. She said the Administrator needed to be informed about levels that can be measured. Dr. Borsuk commented that SAB members were guessing about what EPA might or might not be able to do in the timeframe for completion of the work. Dr. Aelion said she hoped EPA would read the quality review comments. She commented that the panel’s report could be more forceful.

Dr. Post responded to Dr. Hernandez-Ruiz, pointing out that PFOA/PFAS chemicals bioaccumulate over a lifetime in human blood. She indicated that human studies show bioaccumulation in blood at very low exposures. She noted that it was very common to have EPA set a minimum health goal below enforceable standards. She noted that people had PFAS in their blood even if their drinking water is not contaminated.

SAB members asked EPA staff to provide a brief overview of how drinking water standards were set. Mr. Burneson provided an overview of the process used to establish a national primary drinking water regulation. He indicated that for PFAS chemicals, EPA made a determination to regulate in March 2021 and was now working on a health-based MCLG which would be set at a level at which there are no adverse effects for humans. He noted that the SDWA did not use the term “systematic review” but established specific requirements to ensure the rigor of EPA’s health-effects analysis. He noted that, in addition to proposing an MCLG, EPA had to propose an enforceable standard, the MCL, which required consideration of a number of additional factors. He indicated that the EPA was required to set the MCL as close as feasibly possible to the MCLG, considering the availability of treatment technologies. He indicated that the SDWA required the EPA to evaluate all regulatory options for enforceable standards. He indicated that EPA prepares an economic analysis that includes both quantified and unquantified costs as well

as mortality and morbidity and the EPA Administrator has to determine if benefits justify the costs. He noted that additional analyses would be performed to determine the affordability of the technology for small water systems.

Dr. Cullen thanked Mr. Burneson for his comments and indicated that the SAB should discuss disposition of the PFAS report. To begin the discussion on the disposition of the report, Dr. Cullen called for a motion. She indicated that it was clear there should be some edits in the report, but the SAB needed to decide whether the revised report should be returned to the full SAB or just the lead reviewers for approval. Dr. Samet introduced a motion to: include a statement in the letter to the Administrator indicating that EPA's documents had methodological flaws and urging that these flaws be addressed, incorporate other revisions discussed into the SAB report, and to return the revised SAB report to the lead reviewers (but not to the full SAB) for approval. Dr. Cullen indicated that it would also be useful to identify pieces of the analysis that were not available to the panel for review. Dr. Cullen called for a voice vote and the motion was approved.

Dr. Cullen indicated that the SAB would next hear clarifying public comments. The DFO noted that one person had registered to provide clarifying comments.

#### Clarifying Public Comments

Mr. Stephen Risotto, American Chemistry Council provided clarifying public comments. Mr. Risotto stated that, earlier comments of EPA staff notwithstanding, the central issue for the SAB to consider was whether the MCL goals in EPA's documents were set at levels where no known human effects occur, allowing for an adequate margin of safety. He commented that the studies from Faroe Islands, the basis of the proposed goals, did not report adverse effects. He indicated that the evidence was not clear and, as a result, the National Toxicology Program had said there is low confidence that PFOA or PFOS leads to infectious disease or a lower ability to respond to infectious disease. He noted that the Faroe Island studies did not conclude that vaccine antibodies were reduced to levels approaching those that provide basic immunity. He commented that, while a 2018 publication by Jorgenson et. al., suggested that many children had concentrations below the clinically protective level, no children had levels at or below those identified by WHO and CDC. He noted, moreover, that the models were not capable of establishing PFOA and PFOS antibody levels considered to be protective. He commented that the Faroe Islands studies did not provide evidence of adverse effects on human health. He indicated that similar criteria should be assessed for other health endpoints that have been identified.

Dr. Cullen thanked Mr. Risotto for his comments.

#### **Meeting Summary:**

Dr. Cullen summarized the actions taken by the Board at the meeting. She noted that the Board had approved the two reports submitted for quality review subject to revisions. She indicated that the panel chairs would work with the panel DFOs to revise the reports in response to quality review comments and that the revised reports would be sent to the lead reviewers for approval.

The revised reports would then be sent to the SAB chair and Panel chair for final approval. Dr. Cullen also noted that the Board had discussed and approved recommendations submitted by the of the SAB Work Group for Review of Science Supporting EPA Decisions. Dr. Cullen then thanked all the members of the SAB for their work and asked if there were any final questions or comments from members. There were no further questions or comments.

Meeting Adjourned

Dr. Armitage adjourned the meeting at approximately 4:10 p.m. (Eastern time).

**Respectfully Submitted and Certified as Accurate,**

/s/

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Dr. Thomas Armitage

Designated Federal Officer

/s/

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Dr. Alison Cullen, Chair

Science Advisory Board

Date: August 12, 2022

NOTE AND DISCLAIMER: The minutes of this closed meeting reflect briefly the diverse ideas and suggestions offered by committee members during the course of deliberations within the meeting. Such ideas, suggestions, and deliberations do not necessarily reflect definitive consensus advice from the Committee members. The reader is cautioned not to rely on the minutes to represent final, approved, consensus advice and recommendations offered to the Agency. Such advice and recommendations may be found in the final advisories, commentaries, letters, or reports prepared and transmitted to the EPA Administrator following the public meetings.

Attachment A: Additional meeting participants in attendance or who requested the teleconference call-in number.

Name	Affiliation
Ryan Albert	EPA
Hannah Albertus-Benham	
Elizabeth Behl	EPA
Anna Belova	ICF
Thomas Brennan	EPA, SAB Staff Office
Eric Burneson	EPA
Mary Butow	New Hampshire Department of Environmental Services
Brian Chalfant	Pennsylvania Department of Environmental Protection
Lesley Chuang	DLA Piper
Paige Coleman	Integral
Jennifer Corack	U.S. Navy
Laura Cummings	Southeast Morris County MUA
Steve Davies	Agri-Pulse
Lois Elliott Graham	Michigan EGLE
Susan Euling	EPA
Zaida Figueroa	EPA, SAB Staff Office
Colleen Flaherty	EPA
Kesha Forrest	EPA
Shannon Garcia	U.S. Air Force Civil Engineer Center
George Gardenier	EPA
Joseph Haney	Texas Commission on Environmental Quality
Esther Haugabrooks	Coca-Cola Company
Lesley Hay Wilson	Sage Risk Solutions
John Hilbert	VPRA
Brittany Jacobs	EPA
Khanna Johnston	EPA, SAB Staff Office
Aaryn Jones	EPA
Christine Julias	Geosyntec Consultants, Inc.
Jordan Kari	Water Quality Association
Carolyn Kilgore	EPA, SAB Staff Office
April Kluever	U.S. Office of Management and Budget
Grace Kuan	State of Michigan
Anthony Lacey	EWG
Alexis Lan	EPA
Wendy Linck	State Water Resources Control Board
Casey Lindberg	EPA
Laura Lockard	State of DE DNREC

Vivek Mathrani  
Paul McGuire  
Ed Monachino  
Angela O'Brien  
Janet Petruska  
Jeff Ramey  
Stephen Risotto  
Pat Rizzuto  
James Robinette  
Sue Shallal  
Theresa Slifko  
Lameka Smith  
Holly Stallworth  
Bailey Taylor  
Katie Tippin  
Nicole Tucker  
Ying Wang  
Nadine Weinberg  
Deirdre White  
Morgan Willming  
Kimberly Wilson  
Bilgen Yuncu

Cal-EPA DTSC  
Hedgerow Hill Corp  
RTI International  
Zone 7 Water Agency  
Texas Commission on Environmental Quality  
TRC Companies  
American Chemistry Council  
Bloomberg Law's Environment Desk  
Arkansas Dept of Energy and Environment  
EPA, SAB Staff Office  
Metropolitan Water District of Southern California  
EPA  
EPA, SAB Staff Office  
Arkansas Dept of Energy and Environment  
U.S. Navy  
EPA  
WSP  
ERM  
ASDWA  
Integral  
EPA  
TRC

## Materials Cited:

The following meeting materials are available on the SAB website at the page for the July 18, 2022 meeting:

[https://sab.epa.gov/ords/sab/f?p=114:19:22302214671965:::RP,19:P19\\_ID:975](https://sab.epa.gov/ords/sab/f?p=114:19:22302214671965:::RP,19:P19_ID:975)

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<sup>1</sup> Roster

<sup>2</sup> Federal Register Notice Announcing the Meeting

<sup>3</sup> Meeting Agenda

<sup>4</sup> Registered Public Speakers (PDF)

<sup>5</sup> Comments from Stephen P. Risotto, American Chemistry Council

<sup>6</sup> Presentation from Dr. June Weintraub on the Review Conducted by the SAB CCL5 Committee

<sup>7</sup> SAB members' Quality Review Comments on the SAB Draft Report: Review of the EPA's Draft Fifth Contaminant Candidate List (CCL 5) – as of July 17, 2022

<sup>8</sup> Preparation for Chartered Science Advisory Board (SAB) Discussion of Recommendations Received from the SAB Work Group for Review of Science Supporting EPA Decisions

<sup>9</sup> EPA Presentation on Drinking Water health Advisories for PFAS Chemicals

<sup>10</sup> Presentation from Dr. Weihsueh Chiu on the Review Conducted by the SAB PFAS Review Panel

<sup>11</sup> SAB members' Quality Review Comments on the SAB Draft Report: Review of EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS – as of July 17, 2022