

Secretaries' Science Advisory Board

MEETING SUMMARY

**Archdale Building, Ground Floor Hearing Room, Raleigh, NC
Monday, December 3, 2018
10:00 AM-12:30 PM**

The Department of Environmental Quality (DEQ) and the Department of Health and Human Services (DHHS) Secretaries' Science Advisory Board (SAB) met on Monday, December 3, 2018 at the Ground Floor Hearing Room of the Archdale Building in Raleigh, NC. SAB members in attendance were: Tom Augspurger, PhD (Chair), Viney Aneja, PhD, Detlef Knappe, PhD., Woodhall Stopford, MD, MSPH, Thomas Starr, PhD, and Betsey Tilson, MD, MPH. John Vandenberg, PhD., and Elaina Kenyon, PhD, were present via telephone. Also in attendance were DEQ Assistant Secretary Sheila Holman, Sandy Mort, PhD, DHHS Zack Moore, MD, MPH, DEQ and DHHS support staff.

I. Call to Order (Chairman Tom Augspurger)

Chairman Augspurger called the meeting to order at 10:10 am. He introduced himself, explaining that Dr. Bartram had resigned as Chair, because he was returning to England. He expressed that he was looking forward to serving the Board as Chair, and recognized Ms. Sheila Holman, DEQ Assistant Secretary.

II. Recognition of New Chair

Ms. Holman introduced Dr. Augspurger as the new Chair of the Board, giving his qualifications and expressing the pleasure both DHHS and DEQ has in having Dr. Augspurger serve as Chair. She thanked Dr. Augspurger on behalf of both DHHS and DEQ. Dr. Augspurger identified the coordination and facilitation functions of the SAB Chair, which were provided by DEQ and DHHS.

III. Ethics Statement

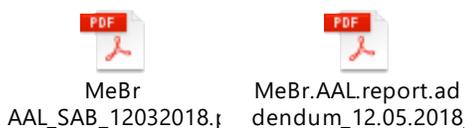
Chairman Augspurger read the ethics statement and reminded the members that if anyone had any conflict of interest to indicate so. No one expressed any conflict.

IV. Approval of Meeting Minutes for October 22nd

The meeting minutes were circulated to all members on November 20. Chairman Augspurger asked if everyone had any additional comments on the minutes; there were none, so the October minutes were approved and adopted by consensus.

V. Methyl Bromide

Dr. Sandy Mort reviewed Division of Air Quality's (DAQ) response to the three items identified by the SAB at the October 22, 2018 meeting (attached here) regarding the proposed methyl bromide Acceptable Ambient Level (AAL). DAQ provided an Addendum methyl bromide AAL report (attached) that provided additional detail on the animal-to-human extrapolation of exposure concentrations and critical endpoint concentrations in the rodent studies that were the basis of the IRIS chronic RfC and the ATSDR 2018 draft chronic MRL. The SAB suggested organizational edits to align units in Table 1's data presentation in the Addendum.



Dr. Mort also provided further discussion and text summary of the status of acute inhalation exposure levels for methyl bromide (attached). Dr. Vandenberg complimented Dr. Mort on the clarity of her explanation and stated that he is comfortable with the proposal to use the IRIS information provided. It was mentioned the public comment period on the draft ATSDR report ended on October 31, 2018, and it is not known at this time what those comments are. Dr. Mort discussed the National Research Council's (NRC) AEGL values (acute exposure guideline values) for methyl bromide in response to inquiries by the Board, identifying that no AEGL-1 value, described as an exposure concentration that would result in "non-disabling" effects to the general public or workers, was derived by the NRC because of the lack of odor or irritation properties at concentrations below the AEGL-2 value and due to the steep dose-response curve noted for methyl bromide. An AEGL-2 level is described as an exposure concentration that may result in "disabling" effects. Dr. Mort also discussed the acute inhalation value provided by the California OEHHA which is often cited as an acute exposure level, which is based on 1942 occupational study.



During the Board's discussion, members indicated they are comfortable with the source and derivation of the reference concentration. The Board re-visited the inquiry from the previous meeting regarding the averaging period and its implementation -- specifically, whether potential harmful acute exposures could occur within the 24-hour averaging period yet still comply with the AAL over the 24-hour averaging period (for example could one high concentration of concern be averaged among lower values and yet comply with the AAL and its averaging period). An illustrative hypothetical example of the 0.005 mg/m³ methyl bromide AAL and a 24-hour averaging period was offered by Dr. Augspurger, noting that if monitored hourly, no hourly measure could exceed 0.120 mg/m³ and still meet a 24-hour average guideline of 0.005 mg/m³. While there is no accepted acute reference concentration as a companion to the chronic concentration, it was noted that 0.120 mg/m³ is three-orders of magnitude less than the 1-hour acute AEGL-2 ambient level of 817 mg/m³ (referenced in Table 5 in the DAQ's Discussion of Methyl Bromide AEGL Acute Inhalation Levels document provided to the SAB), perhaps indicating that the proposed chronic reference concentration is protective of acute exposures provided it is implemented correctly.

Dr. Mort then introduced Mr. Pierre Lauffer, CSPA, DHHS DPH to discuss occupational exposure levels and exposure management for methyl bromide. Mr. Lauffer discussed the development in the 1970s of the OSHA Permissible Exposure Limit (PEL) tables designed to protect workers during an 8-hour workday and a 40-hour work week, and the plan that these tables would be periodically updated. He identified that the methyl bromide standard was not one that was updated in the 1990s and the current OSHA methyl bromide occupational level was set in 1969 and is based on research done in the 1950s-1960s. He stated there are recommendations for occupational levels that are lower than OSHA's 20 ppm regulatory limit and the NIOSH 250 ppm IDLH value (IDLH = "immediately dangerous to life and health"), noting the current ACGIH recommended 8-hour workday exposure level is 5 ppm (19 mg/m³). He also noted that NIOSH recommends wearing respirators at any detectable exposure of methyl bromide due to cancer concerns. Mr. Lauffer stated the current occupational regulatory standard in North Carolina is 25 ppm (8-hour average) with a ceiling limit of 250 ppm.

The DEQ would like to review questions posed by the EMC with DAQ staff before further SAB action on methyl bromide. Dr. Mort asked if there were any further SAB questions or feedback on the proposed AAL and averaging time. Mike Abraczinskas, DAQ Director,

answered questions by the Board regarding the proposed AAL, the permitting process, and other issues. A table of other states' methyl bromide analogous "AALs" was provided to the Board. The Board requested information on how other states derived AAL values. Dr. Augspurger thanked Mr. Abraczinskas, Mr. Lauffer and Dr. Mort for their presentations.

VI. TCE (Trichloroethylene)

The summary of public comments received during the comment period was distributed to the members (see attachments).



American.Chemical. ACC-CPTD comment
Council_TCE_emails_to NC SAB on TCE ac13Nov2018 with cov



00459506 RAD



Wikoff et al 2018 - Hart.and.Hickman_T
Risk of bias.pdf



CE_11.21.18.pdf



TCE_public.commen
ts_thru_11.20.2018.p

Dr. Mort identified that there were comments provided by three groups. The comments were:

1. A consultant identified their technology for continuous air monitoring; DEQ agreed it would be helpful for evaluating exposure levels.
2. Another consultant suggested that the response guidance may put too heavy of a burden of responsibility on contractors; Dr. Mort stated that DEQ would provide additional communication to recommend contractors and stakeholders take a proactive approach to familiarize their clients with the potential implications of TCE detections on the property before sampling begins. Dr. Mort stated DEQ would look at developing additional fact sheets to facilitate this communication between contractors and the responsible parties.
3. The American Chemistry Council (ACC) originally requested that the public comment period be extended. It submitted an extensive package (over 700 pages) that included a draft audited lab report on a rat oral TCE exposure study to evaluate fetal heart development which was sponsored by the Halogenated Solvents Industry Alliance and recently submitted to the USEPA for review.

Dr. Mort stated that the DEQ recommended that the SAB move ahead with their recommendations on the State's indoor air inhalation action levels and response guidance for TCE (a request that has been pending since June); when the draft study submitted by ACC is considered final, the staff and SAB will review it and upon receiving feedback from EPA, assess its implications to the current TCE RfC. The SAB agreed to revisit this when the study is finalized.

There was considerable discussion of this request; Dr. Vandenberg stated he did not know how long it will take EPA to review the study. It was noted the study has not been peer reviewed yet, however Dr. Augspurger noted the report contained the exposure and effects quality control data to help assess its adequacy. Dr. Vandenberg asked Chairman Augspurger to read the charge to the Board regarding TCE:

“The charge to the SSAB is to review the public health aspects of the DEQ implementation guidance for TCE to determine if it is protective and appropriate and provide recommendations to DEQ and DHHS on the action levels and implementation of the proposed guidance.”

Dr. Mort said there is not a new technical document for the Board to review; the request is to endorse the document as presented in the October meeting and the recommendations of action levels and implementation for DEQ and DHHS. In response to the public comments, there may be an additional fact sheet and plain language guidance, but no changes to the document as presented to the Board. Dr. Augspurger asked for a vote to approve the document as presented to the Board; approval was unanimous. Dr. Augspurger asked Dr. Mort to create a memo to show the Board’s approval which he will circulate to Board members before signing.

VII. GenX update

Chairman Augspurger recognized Beth Dittman from DHHS for her presentation on the EPA’s recent release of their GenX reference dose (RfD) for public comment (see attached).



DHHS update-EPA
draft GenX RfD.pdf

This presentation and EPA's report were sent to the Board before the meeting. Dr. Dorman previously recommended to Dr. Augspurger that information like this be developed and put in a plain language summary on the SAB website to explain the SAB and EPA process similarities.

Dr. Mort said DEQ's recommendation is to continue to use the DHHS July 2017 GenX Drinking Water Provisional Health Goal and when EPA's value is final, for the Board to revisit it.

Chairman Augspurger reminded the Board of Dr. Dorman's recommendation for a plain language version of the approaches and overall similarities of the EPA and SAB approaches; Dr. Tilson, Ms. Holman (on behalf of DEQ) and Dr. Zack Moore (on behalf of DHHS) agreed with the request. Dr. Moore stated DHHS hopes to have it ready for the next community meeting with DEQ.

VIII. Hexavalent Chromium (Cr6)

Chairman Augspurger reviewed the charge to the SAB regarding Cr6, saying there is no action requested of the SAB today. Dr. Mort said the updated literature review provided by the EPA to DEQ, included approximately 280 new articles published since 2008, which were grouped by EPA as *in vivo* or *in vitro* references. Dr. Mort notes approximately 55 of these had been screened as the most relevant articles and abstracts to the SAB's charge. Drs. Mort and Augspurger will review the relevant articles; Dr. Starr asked for any recent literature reviews to be made available. There was discussion on adding specificity to the SAB's charge for Cr6, such as to include mention of the threshold (cytotoxic)/non-threshold (mutagenic) aspect of the mode-of-action. Dr. Mort will modify the Cr6 charge statement and provide the update to the Board. The revised Cr6 charge is proposed as:

DEQ and DHHS request the SAB review the current hexavalent chromium toxicological science related to a linear versus a non-linear exposure response and provide recommendations to the appropriate science to be used for development of regulatory standards protective of public health and the environment for groundwater and surface water.

IX. 2019 Meeting Schedule

Chairman Augspurger said that as of now, the meeting schedule for 2019 will be every other month, the first Monday of the month, beginning on February 4, 2019. He stated the Board members will be polled as to what days of the week are best for those with teaching and other outside obligations, to keep the schedule consistent. The meetings will begin at 10:00 AM, and be held in the Ground Floor Hearing Room of the Archdale Building. The length of the meeting will be determined by the number of issues for the Board to discuss.

Future Meetings - 2019

- (i) February 4, 2019
- (ii) April 1, 2019
- (iii) June 3, 2019
- (iv) August 5, 2019
- (v) October 7, 2019
- (vi) December 2, 2019

Chairman Augspurger moved the meeting to public forum.

X. Public Forum

There were no members of the public present who wished to speak. Steve Risotto, attending remotely via WebEx, asked to clarify the American Chemistry Council's public comment and submissions regarding the TCE indoor action levels. Mr. Risotto said the rodent drinking water study results were submitted as an "audited lab report", and as such the data will not change even though marked as "draft". He noted TCE is among the top 10 chemicals that will be reviewed per the revised TSCA regulations and EPA evaluations are expected in early 2019, and he requested review of the data he provided and revisiting the SAB's decision after the review. He stated there is a manuscript in progress, and will be submitted for peer-reviewed publication by the end of 2018. Chairman Augspurger thanked Mr. Risotto for his explanation and his participation.

There being no further public comment, Chairman Augspurger thanked the Board members, DEQ and DHHS support staff and members of the public for their attendance and adjourned the meeting at 12:15 PM.