Secretaries' Science Advisory Board

MEETING SUMMARY
Archdale Building, Ground Floor Hearing Room, Raleigh, NC
Monday, December 2, 2019
10:00 AM-4:30 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 2, 2019 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; Jamie DeWitt, PhD; Richard DiGiulio, PhD; Elaina Kenyon, PhD; Gina Kimble, PhD; Detlef Knappe, PhD; Thomas Starr, PhD and John Vandenberg, PhD. In attendance by telephone for portions of the meeting were: Phillip Tarte, MPH; Betsey Tilson, M.D., MPH. Also in attendance were Linda Culpepper (DWR); Ellen Lorscheider (DWM); Mike Abraczinskas (DAQ), Virginia Guidry, Zack Moore (DHHS), DEQ and DHHS support staff.

I. Call to Order (Chairman Tom Augspurger)

Chairman Augspurger called the meeting to order. He welcomed attendees and asked if any present, or on the telephone, wanted to comment on any agenda items; he had one reply they would like to speak. Chairman Augspurger thanked them for their interest, and indicated he would give them an opportunity to speak. Chairman Augspurger asked if there were any modifications to the meeting agenda sent on November 18th and posted on the Board webpage. There were no changes, and the agenda was approved by consensus.

II. Ethics Statement

Chairman Augspurger read the ethics statement and reminded the members that if anyone had any conflict of interest to indicate so. Dr. Jamie DeWitt explained that she has received US EPA funds for PFAS research and is currently consulted as an expert witness in PFAS/PFOA litigation. There were no other conflicts expressed.

III. Approval of Meeting Minutes for October 7, 2019

The draft meeting minutes were circulated to all members for review on November 7 and 18. Chairman Augspurger explained the adjustment to the minutes on page 5, and Dr.

Vandenberg asked for a clarification on Dr. Dorman's remarks on page 9 (see attachment for revised minutes).

Chairman Augspurger asked for any additional comments on the minutes; there were none, so he asked for a motion to approve and adopt the minutes. Dr. DiGiulio moved; Dr. Vandenberg seconded, and the October minutes were approved and adopted unanimously by verbal vote.

IV. SSAB Member Update

Chairman Augspurger welcomed Dr. Jamie DeWitt to the Board. She is Associate Professor of Pharmacology and Toxicology for East Carolina University and Adjunct Associate Professor for NC State University. She holds a Ph.D. in Environmental Science and Neural Science from Indiana University. Dr. DeWitt was appointed to the Board on November 22nd by DEQ Secretary Michael Regan and DHHS Secretary Dr. Mandy Cohen.

Chairman Augspurger informed the Board that DEQ is still in the process of hiring a toxicologist who, among other duties, will serve as Board liaison. He also informed the Board that Dr. Stopford has retired from his work with Duke, and would inform the Board of his intentions regarding continued work with the Board. He asked if there were any further changes to be expressed; there being none, he said that due to schedule conflicts, the February Board meeting will be moved to the 24th.

V. Hexavalent Chromium (Cr+6)

Chairman Augspurger introduced the topic of hexavalent chromium (Cr+6) and the discussion to further refine the Board's recommendations. Chairman Augspurger reviewed the charge, stating the Board is to provide recommendations as to what science is to be used to develop regulatory standards:

> ***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.***

He then presented the following additions/clarifications to the draft summary statements discussed at the October meeting as a basis for continued refinement of the Board's observations and recommendations:

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The goal was to edit, strike, or build upon those draft summary statements to get to a set of proposed recommendations that the Board is comfortable posting in draft for public review (to be added to the end of the draft decision memorandum the Board reviewed in October, all of which the DEQ would like the Board to post for review /comment). There was considerable discussion by the Board to the draft statements from October, and the Chairman documented the suggested edits. The following actions are to be taken:

1. Dr. Starr is to send a recent paper and report for Board review;
2. Board to review Dr. Starr's contributions to see if they appreciably change the draft summary statements;
3. Dr. Vandenberg to review the mutagenicity material he synthesized and suggest whether the Board can more clearly separate statements on drinking water versus gavage exposures. This relates mostly to draft summary statement #3, where it is said the evidence regarding the potential for mutagenic mode of action from drinking water and gavage studies are *mixed*. We will attempt to clarify whether they are mixed from grouping exposures or mixed even within similar types of exposures. This also affects draft statement summary statement #5.
4. Chairman Augspurger to circulate another iteration of the summary statements for Board review and comment before posting them for public comment.

Chairman Augspurger then broke the meeting for lunch, to return at 12:30 PM for PFAS research updates and outside presenters.

VI. Lunch

VII. PFAS Research Updates

Chairman Augspurger introduced Suzanne Fenton, PhD (NIH/NIEHS), who gave the following presentation (see attached):

NC SSAB Dec 2 2019 Fenton_V2.pdf

There were several questions from the Board for Dr. Fenton. Chairman Augspurger thanked Dr. Fenton for her informative presentation. He then turned the meeting over to Dr. DeWitt, who gave the following presentation (see attached):

DeWitt_NCSSAB_12 219.pdf

There were several questions from Board members for Dr. DeWitt. Chairman Augspurger thanked Dr. DeWitt for her informative presentation. He then introduced Rebecca Fry, PhD, who gave the following presentation (see attached):

PFAST_DEQ_Final_p df.pdf

There were several questions from the Board for Dr. Fry. Chairman Augspurger thanked all three guests for their presentations, and announced a short break.

VIII. Break

IX. PFOA/PFOS Response to Request for Comments

Chairman Augspurger reconvened the meeting and asked Bridget Flaherty to reintroduce DWR's request for comments on use of the 2016 EPA Drinking Water Health Advisory values for PFOA/PFOS as a Groundwater Quality Standard. He noted that most of the agenda attachments for the topic were copies of those from the October meeting when this item was brought to the Board's attention (including the two 2016 EPA technical support documents which are the subject of the State's proposed adoption). The new attachments are a table of other jurisdictions' PFOA / PFOS standards and the basis of their derivation (in response to a Board request in October), and a recent ATSDR overview.

Ms. Flaherty reviewed the presentation made at the October meeting (see October minutes for PDF copy of slides). She stated that currently NC has no groundwater standard for PFOS; the IMAC limit for PFOA was established in 2016 for groundwater. Chairman Augspurger thanked Ms. Flaherty for her review, and stated that before the Board discussed the request, he would open the floor to public comment. He then recognized Mr. Mike Watters for his comments.

Mr. Watters thanked the Board for the opportunity to speak. He informed the Board that contamination by PFOS/PFOA, according to his research, now spans 122 square miles. He asked the Board to act expeditiously regarding the PFOS/PFOA contamination. He recommended against adoption of 70 ng/L standards for PFOA and PFOS and stated that the current PQLs of 2 ng/L should be enforced.

Chairman Augspurger thanked Mr. Watters for his interest and comments, and opened the discussion by the Board. There was considerable discussion by the Board on DWR's request to "review and comment on use of the 2016 EPA Drinking Water Health Advisory values for PFOA and PFOS as a Groundwater Quality Standard." The Board was asked at the meeting for a more formal summary statement; Chairman Augspurger provided the following summary points and indicated he would provide these in a follow-up written summary statement for Board consideration:

- Board reviewed the 2016 EPA technical support documents for PFOA and PFOS and reviewed the technical basis for PFOA and PFOS standards in other states and other countries.
- EPA's Health Advisories were developed with rigorous scientific peer review and remain relatively current.
- The Board's only concerns were: 1) the value of reviewing mammalian toxicology studies published after those available during EPA's review (which used scientific literature through December 2015), 2) the value of examining the points of departure used in other entities' PFOA and PFOS hazard assessments, and 3) there

are many other PFAS chemicals to which people may be exposed that would remain unaddressed in setting a 70 ng/L standard for just two PFAS chemicals.

- Board voiced consensus on the establishment of a toxicological science-based standard in preference to a Practical Quantitation Level approach.
- The Board supports DWRs use of the 2016 EPA Drinking Water Health Advisory values for PFOA and PFOS as the basis for groundwater standards as a reasonable step to improve the current situation of having a much higher IMAC for PFOA of 2,000 ng/L and no standard for PFOS.
- While standards are proposed in what may be a year-long review, DWR should continue to evaluate research (with an emphasis on mammalian toxicity studies published after 2015) to determine if a lower value is warranted, and to make these chemicals a high priority for revisiting their standard(s).

There was a general consensus on these summary points. The Chairman asked the Board to review the draft summary statement to be sent following the meeting and make comments to further craft a draft recommendation to DWR on this subject.

Chairman Augspurger then announced another short break.

X. Methyl Bromide (MeBr) AAL

Chairman Augspurger reconvened the meeting to provide additional consultation to DAQ regarding methyl bromide (MeBr). He noted the specific new request from DAQ to the Board to review the Watrous 1942 paper and the California acute toxicity summary for their scientific adequacy as a basis for an acute AAL to pair with the already endorsed chronic AAL (but with a different averaging time). He asked Mr. Mike Abraczinskas (DAQ) to present the request to the Board.

Mr. Abraczinskas thanked the Board for the opportunity to present DAQ's request for further guidance on a MeBr AAL. He provided a summary of the public comment process for the EMC, which showed support for the need of rulemaking, and for the 0.005 mg/m^3 magnitude component of the chronic AAL. He further said there were public comments which objected to the 24-hour averaging time component of the chronic AAL, and some commenters suggested

that an accompanying acute AAL could establish a short term concentration not to be exceeded while simultaneously meeting the chronic AAL on more like an annual average. He discussed the exposure scenarios for log fumigation, and stated that the information provided to the Board for this meeting formed the basis for California's acute value (3.9 mg/m^3, one-hour). Board feedback is requested on those documents as well as an overall approach of deriving an acute AAL to be applied at a 24-hour averaging time and paired with the chronic AAL (0.005 mg/m^3) at a longer averaging time. He showed a chart of MeBr Comparison of Reference Values:

MeBr Comparison Values chart.pdf

Chairman Augspurger presented the following hypothetical exposure scenarios in explanation of the utility of a shorter averaging time for the chronic AAL if there was no accompanying acute AAL (a concern which could be addressed if a suitable acute AAL were available) (see attached):

Hypothetical exposure scenarios.

He then asked the Board to provide feedback on DAQ's request for comment on the Watrous (1942) study, which is the foundation of the CA, NY and NJ MeBr acute levels. There was considerable discussion by the Board on the adequacy of the Watrous study. Chairman Augspurger summarized the discussion of the study thusly: the 1942 paper is of concern because of poor quantitation of exposures; no quality assurance / quality control on the exposures; no lower bound on exposures; poor confidence in Lowest Adverse Effects Level (LOAEL); no confident No Adverse Effects Level (NOAEL); no statistics; and the observed effects of the occupational exposures were severe. One member noted the study's relevance to standard setting in that occupation exposures with humans meant no inter-species uncertainty factor was needed.

The Board also provided feedback on DAQ's request for review of the California acute level derivation document. The Board noted reliance on the Watrous (1942) study was problematic (for reasons in previous paragraph) and additional concerns including degree of

uncertainty on the extrapolated 1 hour exposure estimates from the 2 hour measures; factor of 6 for LOAEL to NOAEL extrapolation despite the appreciable uncertainty in the exposures and effects (noted above); reference to the effects as mild; and lack of sensitive subpopulation uncertainty factors. The Board concluded there were too many concerns with the California acute level based on Watrous (1942) to use it for an acute AAL in North Carolina.

There was discussion of a proposal to use the 0.078 mg/m^3 ATSDR short-term reference concentration as the 24-hour AAL to complement the chronic AAL with a modified averaging time for the chronic AAL. Dr. Vandenberg noted the 0.078 mg/m^3 value was still draft but appears unlikely to change from what he has gleaned from reviewers. He noted also that the 0.078 mg/m^3 value was designed to be applied over a 14 to 365-d period but could be applied on an acute basis (the short-term reference concentration could be applied with a 24-hour averaging time in the absence of an acute reference concentration at present -- the 0.078 mg/m^3 magnitude would be a closer match for an acute exposure duration than the 0.005 mg/m^3 chronic AAL which may be more appropriate as an annual average, in his perspective). There was support but not consensus on use of the 0.078 mg/m^3 value as an acute AAL. There was general agreement on these points: an acute AAL could provide a short-term concentration not to be exceeded while still complying with the chronic AAL (potentially allowing the chronic AAL averaging time to be adjusted depending on the magnitude and averaging time of the acute AAL); and, an acute AAL if adopted should augment rather than replace the 0.005 mg/m^3 chronic AAL already endorsed (they would work in tandem in permitting). Chairman Augspurger then opened the floor for public forum questions.

XI. Public Forum

Chairman Augspurger asked if there were any others present or on the phone who wished to comment.

There being none, he asked for a motion to adjourn. He reminded the Board and public that the next meeting is scheduled for February 24, 2019. The meeting adjourned by unanimous verbal vote.

Respectfully submitted,

Louise G. Hughes

Assistant to Sheila Holman, Assistant Secretary for the Environment, DEQ