Secretaries' Science Advisory Board

MEETING SUMMARY
Archdale Building, Ground Floor Hearing Room, Raleigh, NC
Monday, February 4, 2019
10:00 AM-12:45 PM

The Department of Environmental Quality (DEQ) and the Department of Health and Human Services (DHHS) Secretaries' Science Advisory Board (SAB) met on Monday, February 4, 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., Richard Di Giulio, PhD., Elaina Kenyon, PhD., Detlef Knappe, PhD., Thomas Starr, PhD, Phillip Tarte, Betsey Tilson, MD, MPH, and John Vandenberg, PhD. David, Dorman, PhD., Jacqueline Macdonald Gibson, PhD., Gina Kimble, PhD., Woodhall Stopford, MD, MSPH, and Michael Stoskopf, PhD., were present via telephone. Also in attendance were DEQ Sandy Mort, PhD, DHHS Zack Moore, MD, MPH, DEQ and DHHS support staff.

I. Call to Order

Chairman Augspurger called the meeting to order at 10:20 am, after explaining the meeting start was delayed due to technical difficulties.

II. 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.

III. Approval of Meeting Minutes for December 3, 2018

The meeting minutes were circulated to all members in draft on December 11, 2018 and again on January 28, 2019. Chairman Augspurger asked if anyone had comments on the minutes; he mentioned some typographical errors, but from the other members there were no other comments, so the December minutes were approved by consensus, once the errors are corrected.

IV. Methyl Bromide

Chairman Augspurger reviewed that, during the December 3, 2018 meeting, the Board received the Division of Air Quality's (DAQ) response to three items requested by the Board at the October 22, 2018 meeting regarding the proposed methyl bromide Acceptable Ambient Level (AAL). DAQ delivered to the Board an Addendum methyl bromide AAL report 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, with organizational edits to align units in Table 1's data presentation in the Addendum suggested by the Board. Chairman Augspurger stated there was no action requested of the Board on this subject in the December meeting because staff requested time to work with the EMC on additional issues. In December, the Board requested details behind derivation be added to the table of other states' standards and guidance. Chairman Augspurger then recognized Dr. Sandy Mort to present the expanded table with the other states' data and the revised report on methyl bromide.

Dr. Mort reviewed the documents provided to the Board on methyl bromide, one being the table of the other states' AALs and guidance (see attached), and the other being the revised AAL recommendation statement. She said that many states continue to use occupational levels for the basis of their AALs, as well as other methods of determining AALs. Mr. Tarte asked Dr. Mort to talk about occupational limits she indicated some states use as the basis of their air limits versus the values derived to be protective of the general public. Dr. Mort noted that historically North Carolina and other states have used occupational health levels, rather than values derived to be protective of the general public such as the IRIS chronic RfC data to determine AALs for public health. Many occupational health levels are based on science that is currently out of date and use methodologies that are not current with what we would use now for human health risk assessment, as it pertains to the general public. IRIS values are determined to be protective of the general public, or "public health", which includes all of the population: children, infants, pregnant women, people with preexisting health conditions, and the elderly; these populations may be more sensitive than those working adults for whom the occupational values are derived. Dr. Mort noted DAQ has identified the IRIS chronic RfC as a daily exposure concentration that persons in the general public may be exposed to on a daily basis over their lifetime without the expectation of adverse health effects, further noting the chronic RfC incorporates uncertainty factors that provide a "margin of safety" with the expectation the resulting value is protective of all persons. Dr. Vandenberg thanked Dr. Mort for pulling this information together, as there is not a central repository for this information. Dr. Vandenberg noted the averaging times listed in the table of other states values are highly variable, encompassing times from 15-minutes to 24-hours, noting this may be related to the expected patterns of exposure associated with log fumigation operations. He asked what was known about patterns of exposures associated with

log fumigation operations, how long it may take for the gas to disperse from the containers and what is the time domain of exposure of the public. Dr. Mort deferred to Mike Abraczinskas to respond to Dr. Vandenberg.

Mr. Abraczinskas, Director of DAQ, identified that it is anticipated that following venting from individual containers the exposure to the public would be expected to occur shortly thereafter. Mr. Abraczinskas also noted that fumigation and venting of individual or multiple containers may occur as staggered, staged or phased operations as a 24-hour operation depending on product demands and operational logistics. Dr. Vandenberg thanked Mr. Abraczinskas for the clarification. Dr. Vandenberg asked if DAQ knew the basis of the California value which does not appear to have referenced an occupational health value. Dr. Mort noted that the California OEHHA 1-hour acute value is based on a small study of occupational exposures in 1940 and involved at the time, quantitation of the exposure concentrations using a non-specific analytical method, assumptions of the length of exposure that resulted in the referenced "mild" effects (2-hours) followed by extrapolation to a 1-hour effect concentration, and the application of uncertainty factors that are less than those currently applied for human health values. Additionally, the referenced effects noted are more severe than appropriate for protection of public health. Dr. Mort noted the DAQ report includes a further discussion of the California value and DAQ's assessment that it is not appropriate for determination of a health value protective of public health. Dr. Vandenberg noted it appears as if other states reference the California value and Dr. Mort noted DAQ staff has noted their concern with the California acute value in discussions with other states who were not aware of the background and have requested additional information from DAQ.

Dr. Mort explained that the IRIS chronic RfC is the value DEQ has identified as the basis of the AAL to address public health. Dr. Viney Aneja asked why North Carolina has chosen the number it has recommended for the AAL; she replied that it is based on the IRIS chronic RfC released in 1992 and is a health value developed to be protective of the general public for repeated exposures over a lifetime. She said that ATSDR's exhaustive review of the current science in the derivation of their chronic MRL value (draft review released in 2018) supports the IRIS RfC, and it is the most current and appropriate basis for determining AAL for chronic exposure. Dr. Mort also noted that DEQ utilizes the IRIS values as the basis of public health protective values across multiple programs. Chairman Augspurger restated that the IRIS RfC is

the basis of the DAQ AAL value under discussion since October 2018. He then asked if Board members had additional questions on the table of values. Dr. Detlef Knappe asked if DAQ could answer why some states start with the same occupational health value but end up with vastly different numbers? Dr. Mort replied that she cannot speak to other states' philosophy of calculation and noted DAQ staff did the research for the table and have identified it was often difficult for them to locate person(s) within some states with a knowledge of the process that was in place when their values were derived. In her own investigation, she found the use of occupational values appears to have originated in mid-1980's when there were few, if any, EPA IRIS and Regional Screening Level values available at the time. Many of the other states' approaches appear to have followed the same approach as was used in North Carolina in the 1980s and 1990s: beginning with an occupational health level, whether it was NIOSH, ACGIH, or OSHA, because that was the number available, as IRIS values were not available for a number of these air contaminants, then applying factors based on the type of toxicity or type of effect. Dr. Vandenberg said he was part of the National Air Toxics Information Clearinghouse in the mid-1980s to gather states' data which were highly variable and you see some of that is carried through as indicated in the methyl bromide survey table with the exception in some states that use their internal capabilities to do their own derivation. He also noted IRIS focuses on deriving chronic exposure values and provides only a few acute values, with ATSDR having more focus on providing acute and other shorter-term exposure values, and this reinforces it is up to the state on how to evaluate this.

Dr. Mort said DEQ is proposing using the IRIS RfC, which is a comprehensive evaluation of the available science that goes through review by EPA's team of health scientists, through internal technical review as well as external technical review, and it is the basis of the protection of public health referenced by human health risk assessors. Dr. Starr questioned the very low number reported for North Dakota. Dr. Dorman submitted that the North Dakota value in the table was incorrect and the correct 8-hour value is 0.007 mg/m^3 according to the following link: https://deq.nd.gov/publications/AQ/policy/Modeling/Air_Toxics_Policy.pdf

Chairman Augspurger thanked Dr. Dorman for his contribution and asked Dr. Mort to review the revised methyl bromide document, which includes the history of deliberations by the Board on the subject, previously provided to the Board.

Dr. Mort reviewed the revised methyl bromide report, which combined the original report with an addendum which included the discussion, questions and answers from previous Board meetings. It also included some of the discussions ensuing after the presentations on methyl bromide to the EMC. There is limited new text; a summary of the discussion with Pierre Lauffer, Division of Public Health, and his response to the Board's request for more information regarding occupational values is included. It also includes an expanded discussion of DAQ's recommendation of the 24-hour averaging time, noting that the reference concentration represents the daily average concentration that is anticipated to not result in adverse health effects to the general population, or sensitive sub-populations. The 1992 IRIS chronic value was supported by the 2018 ATSDR review. The EMC had asked the report be revised to reflect the format referenced in the 1997 Science Advisory Board guidance document which still exists on the prior iteration of the SAB's website. Dr. Mort noted that SOP recommends a 24-hour averaging time for chronic systemic toxicants. The other science that led to the recommendation of a 24-hour averaging time was the rapid uptake and distribution of methyl bromide following inhalation exposures, the steep dose response curve, the lack of odor recognition, and a potential delay in recognition of adverse health effects following inhalation of both high and low exposure concentrations. Additionally, DAQ's literature review identified a significant subgroup of the population possesses a genetic variant that predisposes them to increased neuro-sensitivity to metabolites produced by Phase II glutathione conjugation metabolism. Noting these are the additions to the text; Dr. Mort asked if there were any questions regarding the additional text; there were none, and Chairman Augspurger asked what the agencies are asking of SAB regarding methyl bromide. Dr. Mort replied that the agencies are asking for any comments on the additional text, and to affirm support of use of the IRIS chronic RfC and a 24-hour averaging time. After comments from the Board, the methyl bromide statement will be put out for 30-day public comment period. Dr. Augspurger confirmed that the DEQ is asking for the Board's review of a work product and recommendation for a health value.

Dr. Mort also noted the EMC requested an SAB discussion of the confidence in the IRIS RfC and confirmation that the IRIS program noted having high confidence in their chronic RfC. The EMC also requested SAB provide a detailed discussion of a range of risk values, a review component mentioned in the 1997 SOP. Dr. Mort explained why, in her professional judgment, a range of risk values was not appropriate when using a public health protective chronic RfC, noting the current risk assessment science has moved away from using an occupational value that

would have a high degree of uncertainty when used as the basis for protection of public health. Instead, risk assessors reference an IRIS RfC (if available) that is derived specifically to be protective of public health over a possible lifetime of exposure. With the removal of that uncertainty, it was not seen as scientifically necessary to provide a range of risk values, because the IRIS chronic RfC is protective of public health, a single number, and incorporates a margin of safety. Dr. Mort requested the SAB provide their thoughts and feedback on range of risk.

Dr. Vandenberg asked for clarification of the GST enzyme (GSTT1) impacts on methyl bromide responses. Dr. Mort identified that a portion of the human population (thought to be somewhere between 35-70% of the population) possess this enzyme variant and those that do generate activated Phase II metabolites that increase the severity of their neurotoxic responses to methyl bromide exposures. Dr. Mort also indicated that there is a range in the severity of the response for those persons that possess this enzyme. Persons that do not have this particular enzyme will not produce the activated Phase II metabolites and will have less severe neurotoxic effects than those experienced by persons that possess the enzyme. A discussion of the influence of this genetic variant that is not present in rodents on the range of human population response is included in the report.

Dr. Vandenberg also asked for a clarification of how operationally the AAL would be applied. Mr. Abraczinskas identified AALs are used in the air quality permitting process for the applicant to demonstrate via modeling to the division they are able to comply with the AAL with the proposed operations and emissions profiles. The applicant or the DAQ can complete this modeling analysis and the DAQ verifies if the applicant provides the analysis. Mr. Abraczinskas noted with the state's risk-based approach, the applicant and the public can both have confidence that public health is protected if the applicant complies with their permit.

Dr. Mort noted that the EMC specifically mentioned a range of risk recommendation included in the AAL SOP on the prior SAB's web page and noted that her interpretation of the historical process was to recommend a range of risk values to risk managers due to the uncertainty inherent in using an occupational value for derivation of a value protective of the general public, particularly when the occupational value may not be based on the most current exposure science or have been developed using the most current risk science modeling approach. Dr. Mort noted that a member of the EMC AQC that had been involved with the SAB at the time

the procedures were developed confirmed this supposition. Dr. McDonald-Gibson asked what would be the rationale for providing a range of risks values. Dr. Augspurger suggested the prior Board's SOP may have been asking for a range of values when the Board was deriving an AAL for agency consideration, rather that reviewing a value submitted by the agency; he noted that the Board's 2017 charter includes derivation, review, and advisory / consultation roles. Dr. Starr noted in his past experience with the Board a range of risk was developed to give the EMC room to maneuver in making their risk management decision, as their decision may include influences other than risk, such as economic considerations or the number of persons potentially exposed. Dr. Augspurger noted the DAQ is requesting the Board to review their proposal for the AAL and identify if they accept the science supporting the RfC, noting the Board has the ability to provide a range of values if it considers it beneficial to the DAQ. Dr. Mort noted DEQ commonly references IRIS and EPA RfD and RfCs in their human health risk analyses and in the derivation of regulatory values, without alteration of those values. Another Board member noted the EPA definition:

> "*Reference Concentration" which is… an estimate (with uncertainty span spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark concentration, with uncertainty factors generally applied to reflect limitations of the data used."*

While the definition represents the uncertainty, the Board member noted the importance of the confidence levels expressed in the IRIS assessment for methyl bromide which includes a judgement of medium confidence because there is no NOAEL, but high confidence in the database and the chronic RfC. The chairman discussed the value in providing a range of risk, while noting it is not essential. There was agreement that range of risk includes numbers below the RfC (especially when considering the studies indicating increased neurotoxic susceptibility in segments of the human population) and this could be addressed by putting a bound on it based on best professional judgement.

Additional discussions by the board on the range of risk suggested it may be value added information to characterize the uncertainty when the Board is asked to recommend health values

derived from exposure or toxicological studies, but may not be a requirement for a consultation when the value is coming from agency staff. Dr. Mort noted that a value lower than the IRIS RfC may be considered appropriate to further protect against potential adverse effects to persons with the Phase II glutathione enzyme variant that increases their susceptibility to neurotoxic effects associated with methyl bromide metabolites, noting this increased sensitivity reduces the margin of safety that is a component of the IRIS chronic RfC. Dr. Mort noted there is not data available to provide a quantitative estimate of the increased sensitivity of this subpopulation, but suggested a factor to lower the RfC may be appropriate for this concern, such as a factor of 10 or the square root of 10.

Dr. Mort asked for the SAB to review the draft final recommendation statement in Appendix A that includes a summary statement for their approval of the methyl bromide report and DAQ's AAL recommendations, asking for any edits and/or feedback to be submitted to her by Monday, February 11, 2019. Dr. Mort noted after these final edits are included in the report, it will be posted on the SAB webpage for a 30-day public comment period that is anticipated to end in mid-March. At the conclusion of the 30-day public comment period, any additional edits deemed appropriate will be made with the final Board review to be completed in the April 2019 meeting. The final report will be presented to the EMC in its May 2019 meeting. Chairman Augspurger asked that any technical comments/edits also be copied to him so he can compile a summary of comments received and how they were handled. He thanked the Board and Dr. Mort for their consideration for the path forward.

V. TCE (Trichloroethylene)

Chairman Augspurger reminded the Board it voted unanimously in December to accept the technical documents shared by Division of Waste Management on the TCE vapor intrusion action level guidance. Dr. Mort drafted a memo to show the Board's approval, which was circulated to Board on December 11; Dr. Mort circulated the revised memo before this meeting which addressed editorial comments received from the Board. Chairman Augspurger asked for an update on TCE guidance implementation.

Dr. Mort stated said that DEQ is moving ahead with the final edits to the documents provided to the Board. There is a fact sheet in development to assist consultants' communication to responsible parties for indoor air action level exceedance, and it should be final within the

next two (2) weeks. DEQ will work collaboratively with DHHS Division of Public Health regarding responses to exceedances of the TCE indoor air action levels, to refine who/when to make coordinated contacts the with local health agencies and the impacted public. There has been such collaboration in the past when there were exceedances of TCE indoor air action levels; it has been beneficial, and DEQ appreciates the collaboration, cooperation and access to professional staff in those instances. Dr. Augspurger reminded the Board they will revisit the TCE indoor air action levels as new science is made available or as toxicological reviews are updated.

Chairman Augspurger asked if there were any questions; there were none, so he thanked Dr. Mort for that update. He then stated that due to time constraints on Board members, the updates for hexavalent chromium and GenX would be swapped on the agenda, putting GenX after the short break. Dr. Augspurger as Chair signed the Board's *Final Recommendation on the DEQ DWM TCE Indoor Air Inhalation Immediate Action Levels and Response Guidance* document.

VI. Hexavalent Chromium (Cr6)

Chairman Augspurger reminded the Board of the presentations done by DEQ and outside agencies at the prior meetings pertaining to groundwater and surface water standards. Chairman Augspurger then read the charge to the Board, refined at the December meeting:

> ***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.***

Chairman Augspurger then reminded the Board that the discussion in the December meeting included a request for critical literature reviews, which he provided to the Board before this meeting. Of the nine (9) papers provided, four (4) were from the presenters heard at the prior meetings. Chairman Augspurger opened discussion on the literature review. Dr. Starr commented that the nine papers covered a range of Cr6 toxicological science topics and approaches for deriving health goals, made extensive comments on specific articles, and

suggested presentations to the Board by authors of some of these papers, including Chad Thompson with ToxStrategies, Inc., and Anatoly Zhitkovich with Brown University.

Dr. Vandenberg updated the Board on the steps EPA is taking in review of the Cr6 science; he said on December 19, 2018 EPA updated the IRIS agenda which includes plans for Cr6, including a systematic literature review to be released in this quarter (January-March 2019), as well as a goal to release the draft IRIS assessment in the fall of 2019. This draft assessment would go through peer review. Drs. Alan Sasso and Catherine Gibbons are the contacts with EPA for updates on this process. Dr. Mort said the literature review shared with DEQ and the Board by EPA was for articles through 2017, and that EPA would share up-to-present articles with DEQ when they completed that effort.

Chairman Augspurger then referenced several articles which have been published most recently (2017 and 2018), and asked if the Board had interest in presentations from their authors at the April meeting. Dr. MacDonald-Gibson offered to speak to Julie Rager, one of the authors previously with ToxStrategies and now an assistant research professor in her department. **Dr. Mort said she would contact Dr. Zhitkovich and ToxStrategies to arrange presentations for the April meeting. Dr. Starr suggested Chad Thompson with ToxStrategies, the corresponding author of the 2018 paper. Chairman Augspurger suggested checking back with EPA before the April meeting regarding the status of their review; Dr. Mort said she would do so.** Chairman Augspurger reminded the Board, as they review the literature, that the pharmacokinetics and the mode of action are what drive the charge to the Board and the charge is relatively narrow in that regard.

Chairman Augspurger then said there would be a break, returning to the meeting at noon.

VII. GenX update

Chairman Augspurger reviewed the work on GenX done in the last meeting, with Beth Dittman's (DHHS) presentation on a plain language factsheet to explain the similarities and differences in the NC and EPA RfD derivations and the DHHS GenX Provisional Health Goal. The draft factsheet was circulated to the Board prior to the meeting. Chairman Augspurger then recognized Ms. Dittman for an update. Ms. Dittman requested the Board's comments on the

plain language factsheet. Chairman Augspurger thanked her for that update, and opened the floor for discussion.

Dr. Vandenberg said it reads very nicely; the question he had was would it be prudent to let members of the public here in Raleigh and in the Wilmington community see the document to see if it speaks to them, and get their feedback, as it is still a very technical document. He answered Dr. Betsey Tilson's question regarding EPA's release of a final RfD for GenX, saying he did not have an update to provide. Dr. Tilson said she would like to see the factsheet finalized before the EPA announces its final RfD, to allow for proactive pushout. Ms. Dittman answered Chairman Augspurger's question regarding the statement in the document that there was not enough information to indicate cancer as an endpoint for GenX noting there is one chronic carcinogenicity study that points to cancer as an endpoint, but there are not enough corroborative study results to confirm. Dr. Dorman also agreed the document is too technical for the general public to understand, and that it should be edited for general language reading level. Dr. Aneja asked regarding the air exposure effects of GenX; Chairman Augspurger replied that this document was developed as requested by the Board to specifically to illustrate the similarities and differences between EPA's draft GenX RfD and North Carolina's RfD. Ms. Dittman said there is a fact sheet that address how one may be exposed to GenX which has been used over the last year and a half, but the emphasis has been on oral exposure. Dr. Tilson suggested that an accessible language explanation be given at the beginning of the document, and keep the technical explanation, targeting the more scientific reviewer. Chairman Augspurger suggested to have the tables from the PowerPoint presentation which illustrate the science woven back into the narrative to address the technical audience. **The action item for the Board is to provide any other feedback/comments by Monday, February 11, 2019.**

VIII. Review of charter and board expectations

Chairman Augspurger then gave a brief PowerPoint presentation regarding the SAB charter and expectations of board members (see attached).

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Chairman Augspurger said it has been about 18 months since the re-forming of the Board, and the scope and expectations of this Board have expanded from those of the prior Board; his presentation explored that expansion (including other environmental media beyond air, and other technical assistance roles), the expanded charter, and priorities for 2019.

Dr. Vandenberg said that it would be helpful to the board if DEQ and DHHS provides feedback regarding whether the Board is meeting the Secretaries' goals for the Board, issues to focus on and the work being done by the Board. Dr. Mort replied that there are discussions within the agencies regarding priorities for 2019 and any changes to the SOPs they would desire. She will take these comments back to the liaisons, asking for feedback and what future topics they would like addressed, and any updates or revisions to procedures.

Dr. Kenyon said she would like for the Board to get feedback from the Secretaries and the EMC as to what they want a range of risk discussion to encompass and how they want to use it.

Chairman Augspurger then raised the issue of paper copies of meeting materials provided to the Board members; he suggested that Board members take the time to download electronic copies of meeting materials to have them available at the meeting, rather than DEQ providing paper copies. However, paper copies will be available to those Board members who specifically request them the week before the meeting.

IX. 2019 Meeting Schedule

Chairman Augspurger asked the Board members about alternate meeting days to the first Monday of the month as this was a conflict one member raised in December. The Board members answered that most find Mondays the best day; Tuesday was not as convenient for many of the Board members and was a significant conflict for two. Also, Dr. Moore had a standing conflict with Tuesdays. Chairman Augspurger said the meetings will remain on Mondays, and the next meeting is scheduled for April 1, 2019. 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

a. April 1, 2019
b. June 3, 2019
c. August 5, 2019
d. October 7, 2019
e. December 2, 2019

Chairman Augspurger moved the meeting to public forum.

X. Public Forum

Beth Markasino, president of the NC Stop GenX in Our Water group, asked to speak. She said that she is grateful to the SAB for their continued recommendations to DEQ, but she believes they have "fallen on deaf ears." She went on to state that the SAB has not been given all the information provided to the State and DEQ, that the contamination is not getting better, but worse, and Chemours is presently importing GenX waste from the Netherlands for disposal here. She asked that the SAB call upon EPA to intervene because DEQ and the State are going forward with the consent order, and Chemours is not taking responsibility for past or future contamination, including the shipment of these chemicals.

Chairman Augspurger thanked her for her comments, and said that the document the SAB created acknowledges that the science of perfluoroalkyls substances is changing rapidly and the Board will review their recommendations as needed based on new science.

There being no further public comment or agenda items or questions, Chairman Augspurger thanked the Board members, DEQ and DHHS support staff and members of the public for their attendance and adjourned the meeting at 12:45 PM.