Secretaries' Science Advisory Board

MEETING SUMMARY Archdale Building, Ground Floor Hearing Room, Raleigh, NC Monday, April 1, 2019 10:00 AM-3:00 PM

The Department of Environmental Quality (DEQ) and the Department of Health and Human Services (DHHS) Secretaries' Science Advisory Board (SAB) met on Monday, April 1, 2019 at the Ground Floor Hearing Room of the Archdale Building in Raleigh, NC. SAB members in attendance were: Tom Augspurger, PhD (Chair), Richard DiGiulio, PhD, David Dorman, DVM, Gina Kimble, PhD, Elaina Kenyon, PhD, Jaqueline MacDonald Gibson, PhD, Thomas Starr, PhD, Betsey Tilson, MD, MPH, and John Vandenberg, PhD. Also in attendance were Sandy Mort, PhD, Michael Abraczinskas (DAQ), Virginia Guidry, PhD, Zack Moore, MD, MPH, DEQ and DHHS support staff.

I. Call to Order (Chairman Tom Augspurger)

Chairman Augspurger called the meeting to order at 10:05 am. He welcomed attendees and outside presenters. He explained that Dr. Aneja was absent due to illness, Drs. Stoskopf and Knappe had conflicts, and Dr. Stopford and Mr. Tarte planned to attend via telephone.

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 February 4, 2019

The meeting minutes were circulated to all members on February 26 and March 29. Dr. Vandenberg commented that he appreciated the thoroughness and accuracy of the minutes, and he wanted to express his thanks for the staff's hard work. Chairman Augspurger asked if everyone had any additional comments on the minutes; there were none, so he asked for a motion to approve and adopt the minutes; Dr. Starr so moved, and Dr. DiGiulio seconded. The February minutes were approved and adopted unanimously by verbal vote.

IV. Methyl Bromide

Chairman Augspurger reviewed the action on methyl bromide to this point in time. He said the upper bound AAL for methyl bromide (MeBr) is unchanged from the initial October 2018 draft through the version the Board approved for public review. In October 2018 the Board

requested background on occupational levels, which was provided at the December meeting. There was no further action requested of the Board in December to allow additional coordination with the Environmental Management Commission (EMC). At the February 2019 meeting the statement on MeBr was revised, including context for how AALs are applied. An expanded table containing information on other states' values for MeBr was also provided to the Board. After the February meeting, Board comments to the revised statement as well as the other information provided were collected over a 10-day period, and the statement was published for a 30-day comment period, which ended March 27, 2019. Chairman Augspurger asked Dr. Sandy Mort to give an update on the public comments received.

Dr. Mort summarized the public comments received, which were sent to the Board members in PDF form (see attached). The summary includes the complete text of all comments and a summary table on page 2 classifying the received comments. The submitted package from the Southern Environmental Law Center (SELC) includes 1400+ pages of attachments, which was provided as separate files.



There were 40 submissions, 35 (88%) were from residents/private citizens or organizations representing citizens and were in favor of AAL proposed, or requested not allowing use of MeBr. Five responses (12%) were from fumigation operations, related trade groups, or their representatives. All were opposed to the AAL recommendation. Three requested and were granted time to present their comments to the Board. Dr. Vandenberg stated the comments received were very useful, and some addressed issues which were more the purview of the EMC, rather than this Board. Dr. Vandenberg stated he could not open the SELC attachment and asked for a summary of its contents. Dr. Mort replied that in essence the SELC stated they supported the IRIS RfC with a 24-hour averaging period. The SELC's attachments included a 2012 environmental health review, which connected MeBr to prostate cancer (referencing oral, inhalation and dermal exposure). Dr. Mort noted the ATSDR's 2018 review included a discussion of the association of MeBr to prostate cancer. The DAQ also included a discussion of cancer associations in their AAL report. The SELC comments also included concerns regarding residential exposures near agricultural use of MeBr. The other documents

included in this comment were a USDA manual, a UNEP report, and a 100-page article from California, which proposed a chronic RfC of 2 parts per billion for adults and 1 part per billion for children, which is similar to the IRIS RfC DAQ has used.

Chairman Augspurger clarified that the main toxicological or risk assessment concerns outlined in the public comments were (1) the proposed 24-hour averaging time, (2) the lack of a field instrument that could achieve detection sensitivity in the range of the proposed AAL and, (3) the interpretation of the chronic RfC. He recognized Mr. Mike Abraczinskas, DEQ's DAQ, for response.

Mr. Abraczinskas thanked the Board for their thoughtful comments; he said that once the NCSSAB puts forth a final recommendation, it then goes to the EMC for rules adoption, which is a 9-12-month process to establish the rules and regulations. A fiscal note is developed and considered by the EMC. The proposed EMC rule would be subject to a 60-day public comment period, which would include one or more public hearings, the findings would go back to the full commission for approval. He responded that an AAL is used exclusively in the permitting process, which establishes operational adherence to the AAL for the permittee. Chairman Augspurger asked if there is a public comment period for individual permits; Mr. Abraczinskas replied that there can be, depending on the type and size of the permit.

Mr. Abraczinskas noted the AALs establish protocols for operations, with respect to an annual averaging time which is specified for carcinogens and 24-hour averaging times specified for non-cancer chronic effects, and 1-hour averaging times specified for acute exposures. Dr. MacDonald-Gibson asked if a dispersion model is used and if consideration of multiple sources or operations in a localized area are considered; Mr. Abraczinskas replied that the permitting process becomes more complicated when there are larger numbers of facilities in proximity with one another, which is considered on a site-by-site basis. Dr. Starr asked how modeling output is compared to AALs; Mr. Abraczinskas replied that five (5) years' meteorological data are used in comparison and toxics modeling, and he would verify with staff that do this modeling for details. Dr. Dorman commented that the Board would like to have legislative definition of and AAL. Dr. Mort noted that her recommendation of a 24-hour averaging time was made independent of the averaging time guidance in the AAL SOPs, which were written in the 1980s-90s. Dr. Mort stated her averaging time recommendation for MeBr was based on the lack of taste or odor recognition

of exposure, delayed recognition of exposure effects for both chronic and acute exposures and the steep dose-response curve. There was more discussion of the modeling and permitting process, and in response to the question of cumulative effect of proximal locations, Mr. Abraczinskas said even though the majority of permitted facilities are clustered in southeast NC, their proximity to one another does not give rise to a concern of cumulative effect.

Chairman Augspurger recognized the representatives from ECOLAB for their presentation on MeBr (see attached).



Several Board members had questions for Mr. Marshall at the conclusion of his presentation. Chairman Augspurger thanked Mr. Marshall and Ms. Marwitz for ECOLAB's presentation. He then invited Dr. Rick Reiss of Exponent to present to the Board (see attached).



Dr. Reiss thanked the Board for the opportunity to present to the Board.

Chairman Augspurger thanked Dr. Reiss for his presentation, and invited Dr. Piccirillo to present for the Methyl Bromide Industry Panel (MBIP) (see attached).



There were many questions for Dr. Piccirillo after his presentation, and much discussion of the differences of chronic and acute exposures and how risk assessment is made, and what exactly the charge to the Board requires in terms of defining chronic and acute exposure in regard to recommending an AAL for MeBr. Chairman Augspurger thanked Dr. Piccirillo for his presentation, and stated the discussion of MeBr would continue following a lunch break. He suspended the meeting at 12:10 PM to return at 1:10 PM.

Chairman Augspurger reconvened the meeting at 1:10 PM, and recognized Dr. Sybil Burgess Murray, a citizen, to speak.

Dr. Murray thanked the Board for the opportunity to speak, and commended the Board on its work so far. She desired to speak on behalf of environmental groups; she herself has a PhD in biochemistry, and lives in southeastern North Carolina where many of the permitted MeBr log fumigation facilities are located. She said the public has a great deal of faith in the SSAB to help regulate the permitted facilities, and to safeguard the health and safety of the public. She is a member of the Brunswick Environmental Action Group, but is not speaking today on their behalf. She stated that many logging companies operate in poor, rural communities, and environmental justice is an issue for these communities and demographics, a fact of which DEQ is already aware. She stated her trust in the SSAB's judgment in establishing an appropriate AAL for MeBr, and thanked the Board for their time and attention.

Chairman Augspurger thanked Dr. Murray for her comments and said that the action requested of the Board is to come to a consensus of support for the proposed AAL for MeBr. Dr. Dorman, before he left, gave Chairman Augspurger a proposal to (1) vote on the chronic RfC which has value for permitting now independent of any subsequent acute value; and (2) clean up the document in reference to the original intent and regulatory definition of the AAL, clarifying its use in permitting, and expand the discussion of the actual exposure, whether chronic or acute. He asked for a motion regarding the AAL for MeBr. Dr. DiGiulio moved that the Board support an AAL of 5 µg/m³ chronic exposure; Dr. Tilson seconded. Chairman Augspurger asked for discussion; Dr. Kenyon said the 5 μg/m³ is a high end of values, and the Board should discuss the lower end. Dr. Vandenberg stated he was comfortable with the motion as made. Dr. Augspurger stated the EMC had requested the Board to comment on a range of risk, i.e. 2-5 $\mu g/m^3$; he said he was comfortable with a range, but would prefer to go with the 5 $\mu g/m^3$. Dr. Kenyon stated the EMC had asked the Board for a range, and that 2 μg/m³ is not unreasonable for sensitive subpopulations. Chairman Augspurger summarized the changes to both the document and the motion: (1) define AAL; (2) note 1986 history of AAL as intended to address chronic exposure; expand discussion of how an AAL is used in permitting; (3) explain the acute and chronic nature of potential methyl bromide exposures in fumigation operations; (4) note that establishing a chronic RfC has independent utility for permitting and protecting against chronic exposures and doesn't prevent derivation of an acute RfC in the future; (5) replace the IRIS RfC

definition with the more specific IRIS Chronic RfC definition; (6) add clarifying language on more confidence in the upper end of the 2-5 μ g/m³ range; (7) modify motion to indicate 5 μ g/m³ as the AAL with a range of 2-5 μ g/m³ for sensitive subpopulations. Dr. Vandenberg made the motion; Dr. DiGiulio seconded, and the motion passed unanimously by verbal vote (none opposed, no abstentions). Chairman Augspurger thanked the Board for their input, and asked that the revision be ready within two (2) weeks, with any additional changes the Board members suggest sent to Dr. Mort by Friday, April 5, 2019.

V. Hexavalent Chromium (Cr6)

Chairman Augspurger recognized Chad Thompson, PhD of ToxStrategies, Inc. of Katy TX to give his presentation on Hexavalent Chromium (Cr6) that presents a non-mutagenic mode of action and determination of an oral RfD.



The Board members had many questions for Mr. Thompson, and Chairman Augspurger thanked Mr. Thompson for his detailed presentation on Cr6.

Chairman Augspurger then read the charge to the Board regarding Cr6:

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 reflected that the Board had requested the charge narrowed, and it now specifically requests Board discussion and recommendations on a linear or non-linear mode of action. He asked members to reflect on the presentations and provide perspectives on them. The Board asked what was needed for the DWR to develop surface water and groundwater standards. Dr. Mort said a RfD or cancer slope factor is needed for the calculation of standards. Dr. Vandenberg asked if there is a timeframe the State asks for the Board's 6Cr recommendation; Dr. Mort stated that a decision on the mode of action to guide standards development would be desired as soon as possible.

Chairman Augspurger then asked Dr. Mort for her update on GenX and EPA's Cr6 update.

VI. GenX, EPA's Hexavalent Chromium update

Dr. Mort to provide the updates for GenX and Hexavalent Chromium (Cr6); see attached slides:



USEPA is responding to the draft GenX oral RfD comments and will include them with the final release of the GenX RfD sometime in 2019. Dr. Mort identified that the Netherlands in March proposed that GenX be classified as a "Substance of Very High Concern" under the REACH program. The Netherlands proposal can be found at: https://echa.europa.eu/substances-of-very-high-concern-identification.

Dr. Mort also stated EPA is completing the review of the results of their updated literature search for Cr6, and released their proposed study protocol which describes how IRIS intends to move forward in their 6Cr review.

The Systematic Review Protocol for Cr(VI) is on the IRIS website at:

https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=343950.

IRIS is holding a Public Science web-based meeting on April 24th to discuss the proposed protocol. Registration for the meeting is open until April 10th. The link to register is at: https://www.epa.gov/iris/iris-public-science-meeting-april-2019

Chairman Augspurger then opened the floor for the public forum.

VII. Public Forum

Chairman Augspurger asked if there were any members of the public present who wished to speak; there being none, he thanked the presenters for their time and information, and expressed the appreciation of the Board for the presenters' input.

Chairman Augspurger reminded the Board of the next meeting scheduled June 3, 2019 at 10:00 AM. He thanked the Board members, DEQ and DHHS support staff and members of the

public for their attendance; Dr. Vandenberg moved to adjourn, and the Chairman adjourned the meeting at 3:00 PM.

Respectfully submitted,

Louise G. Hughes

Assistant to DEQ Assistant Secretary Sheila Holman