

**U.S. Environmental Protection Agency
Science Advisory Board
All-Ages Lead Model Panel
Public Meeting Minutes**

Date and Time: April 23, 2020, 1:00 – 4:30 p.m.

Location: Teleconference Only

Purpose: The All-Ages Lead Model Panel discussed its review of the EPA’s All-Ages Lead Model Review Draft Version 2.0, comprising the model’s software, technical documentation, and user manual (hereafter referred to collectively as AALM 2.0). The AALM 2.0 was developed by EPA’s Office of Research and Development.

Meeting Participants:

AALM Review Panel Members*

Dr. Hugh A. Barton, Chair
Dr. Harvey Clewell
Dr. Joel M. Cohen
Dr. Deborah Cory-Slechta
Dr. Philip Goodrum
Dr. Michael Kosnett
Dr. Anne Loccisano

Dr. Steven Marcus
Dr. Clyde Martin
Dr. Isaac Pessah
Dr. Robert Phalen
Dr. Ian von Lindern
Dr. Kathleen Vork
Dr. Michael Weitzman

(*For the full Panel membership see [Roster](#)ⁱ)

SAB Staff Office

Dr. Bryan Bloomer, Designated Federal Officer (DFO)
Ms. Iris Goodman, Designated Federal Officer (DFO)
Mr. Thomas Brennan, SAB Staff Office Director
Ms. Khanna Johnston, SAB Staff Office Deputy Director

Other Attendees

See Attachment A.

Meeting Summary:

Dr. Bryan Bloomer, DFO for the AALM Review Panel, convened the meeting at 1:00 p.m. He explained that this teleconference was a public meeting and noted the compliance of the of Panel with the requirements of the Federal Advisory Committee Act (FACA) and federal ethics laws. He said the agenda had allotted time for public comments and noted there had not been any requests from the public to comment. He welcomed the AALM panelists, members of the public attending by telephone, and gave an overview of the agenda. Dr. Hugh Barton, Chair of the AALM Panel, also welcomed the Panel and thanked them for their work in reviewing the AALM

documents and model. He also thanked and members of the public attending by telephone for their interest in the AALM.

Dr. Bloomer introduced Dr. John Vandenberg and Dr. James Brown, from EPA's Office of Research and Development (ORD). Dr. Vandenberg thanked the AALM panelists. He explained that the AALM is used to support development of regulations and that he appreciated the Panel's time and effort to run the AALM, review its documentation, and to test its capabilities. Dr. Brown noted that ORD has begun addressing the Panel's initial consensus comments to update the model, had begun revisions to make the Technical Support Document and User's Manual more helpful to users, and to provide webinar training upon request.

Dr. Bloomer, DFO, reminded the Panel of their important role in conducting this peer review and turned the meeting over to Dr. Barton, Chair, AALM Panel.

Dr. Barton reviewed the criteria for evaluating the draft AALM 2.0 report:

1. Does the report adequately address the charge questions?
2. Is the information accurate?
3. Is the report clear and logically presented?
4. Are the conclusions supported by the body of the report?

Dr. Barton also summarized the three tiers of recommendation to be provided to the Agency. He noted that Tier 1 recommendations are those needed for the model to be used successfully, right now; Tier 2 recommendations are for extensions to the model needed to address specific issues; and Tier 3 recommendations are for longer-term improvements to the model. He reviewed the Charge questions and asked the committee if any clarifications were needed; none were necessary.

Question 1. Are the features of the AALM 2.0 adequately described in the *Technical Support Document*?

Question 2. Are the model features supported by peer-reviewed research findings?

Dr. Barton began the discussion of Charge Questions 1 and 2. Panelists note that AALM 2.0 is adequately described. Panelists noted that the model uses a single number for the bioavailability of lead applied for all human exposures in a given media, which distorts estimates for different sources of exposure. The Panel noted that EPA should clarify this issue for model users and agreed to substitute Dr. Kosnett's proposed language on p 14 lines 40-41. . Dr. Barton says he heard general agreement from the Panel and noted that panelists will work in small groups to make edits. He also reminds them that their role is to review the model, not to determine data quality for default values.

Discussion of Question 3 parts a, b, and c resulted in the following revisions:

-Discussion of Question 3.a., p. 16 line 42: Add the phrase "dust (deposited)" or "dust (surface)"to distinguish between the two sources.

-Discussion of Indoor Dust Load: Panelists discussed moving recommendations for indoor lead dust (p. 24, line 33 – 38) from Tier 3 to Tier 2. The panelists discussed multiple ways used to

report lead values, e.g., micrograms/square ft. vs. as lead concentration. They also discussed conversion factors and noted the AALM predicts dose, which requires more assumptions to get this value. Dr. Barton cautioned against holding up use of AALM 2.0, in order to get the data needed to do this. He summarized the discussion, saying that he heard general agreement that indoor lead dust is a Tier 2 recommendation. He also noted that EPA could address this issue in the future..

Question 3. b. Uptake / absorption parameters: The Panel discussed pages. 31- 32 and proposed alternate wording to first bullet on p32, to be provided in their edits.

Dr. Barton asked for panel recommendations regarding gastrointestinal effects. The discussion focuses on gastrointestinal motility with changes in exposure to lead; clinicians regard this as especially important for children's exposure. Panelists said this issue could be addressed by inserting into the text (rather than in recommendation) the statement "the AALM assumes that GI motility does not change with blood Pb levels." They note the text should reiterate here line 13 p 21, for clarity, the Tier 1 comment regarding bioavailability in response to Question 2. It was agreed to revise the gastrointestinal tract description by deleting bullets on lines 18 and 21, and changing the bullet on line 14 to proposed text about non-linear gastrointestinal absorption, fasting v. non-fasting, and soluble v. insoluble sources; these characteristics are fundamental to gastrointestinal modeling. They agree this is Tier 2 issue.

Question 3.c. Biokinetic parameters for distribution and elimination.

Dr. Barton asked about mass balance for bone growth in model, e.g., was the mass balance in deposition from diffusible plasma component maintained over ages? Panelists agreed these revisions are potential Tier 1 recommendations that fit within the responses to Question 3.C. Dr. Barton asked Dr. Vork to write short a paragraph about challenges associated with the model parameters, i.e., mass balance at different ages and exposures, along with similar revisions to the text for other applicable sections. Dr. Weitzman said he would draft revised for p. 36., e.g., to move bullet regarding "post-menopausal changes" to Tier 2. Dr. Barton found no objections for moving this text up to Tier 2.

The Panel discussed the AALM's "overly high" sensitivity (i.e., the ratio of change in output from change in input). One panelist noted he found no explanation in the model structure to cause such high sensitivity values, concluding that if these high values were accurate, they needed to be investigated to see how that sensitivity results from the model structure and explained in the text. The committee agrees to substitute the text of the bullet that Dr. Barton provided prior to the meeting as the only change made here. Editorial corrections needed to page 17, line 31, and page 18, line 5, will be sent to Dr. Bloomer.

Question 4. a., Predictive accuracy and reliability of AALM based on comparison to available data sets

Panelists discuss the results of simulations they ran using the AALM with respect to the draft AALM text. They discussed paragraph f., p. 39, and the potential to over-estimate occupational exposures. Dr. Barton says he hears agreement among majority of panelists to remove this paragraph. Dr. Barton asked Dr. Vork to add comments to the response to Question 4. A,

regarding concerns about predictive accuracy of the AALM, and to prepare a short paragraph for Question 4. a. based on her preliminary comments.

Question 4. b. and 4. c. Adequate verification and operation of computer code based on results comparing model predictions between applications of the AALM in distinctly differing datasets?

Dr. Barton asks if these two questions need further discussion; finds none required.

Question 5: Is the Users Guide “user friendly”? Dr. Barton noted that he and Dr. Bloomer, DFO, will respond to this question, using input from the Panel’s preliminary comments, as posted on SAB website.

Question 6: Refining specific features of the AALM to improve accuracy

The panelists discussed various options for improving accuracy, focusing on the possibility of providing “libraries,” to provide input data on exposures of children to lead from various sources. Panelists discussed adding a reference to the topic of “priming” the compartments of the model and concluded that the text needs to include a discussion of the concept of “priming” here or in Question 7.

There were no issues identified for discussion for Charge Questions 7 – 9.

Dr. Barton suggested they consider a motion from the Panel for disposition of the report: in summary, panel has discussed edits and changes to the report, with understanding that Dr. Barton will work with Dr. Bloomer to make the changes over the next few days. The motion is moved By Dr. Martin and seconded by Dr. Phalen. Dr. Barton asked if there were any objection; hearing no objections, the motion was passed unanimously. Each panelist agrees by name. Dr. Bloomer confirmed that he heard that Dr. Barton is empowered by the Panel to make revisions and to submit the report to the Administrator.

Letter to the Administrator:

Dr. Barton began the discussion of the letter to the Administrator; he noted that edits may also be made to this letter following the Quality Review. He notes that he is working with SAB SO staff to craft the draft letter: The Panel discussed the following changes:

The first page of the letter, line 32 is revised and simplified to read: “The Panel recommends the Agency make those changes, clarifications, corrections, and edits to the model...”

Additional simplifications were discussed for the second page of the Letter, with the result that only lines 1 - 4 remain, ending with the phrase “Tier 3 recommendations”; the remainder of lines 4 – 14 are deleted. Page 2 line 17, delete “Finally”.

Public comments

There were no public comments.

Dr. Bloomer summarized the steps for completing the review: Dr. Armitage, DFO for the Science Advisory Board, will transfer the report to the Board members, who will conduct the

Quality Review of the draft final report during the June 23-24, 2020, meeting of the Board. If the Board requests substantial revisions, the Board could ask that the report be returned to the Panel, though it is more likely Dr. Barton would make the requested revisions.

Meeting adjourned

Dr. Bloomer formally closed the AALM 2.0 Review at 4:30 pm Eastern Time.

Respectfully Submitted and Certified as Accurate,

_____/s/
Dr. Bryan Bloomer
DFO, SAB Staff Office

_____/s/
Dr. Hugh A. Barton
AALM Panel Chair

NOTE AND DISCLAIMER: The minutes of this public meeting reflect 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 panel members. The reader is cautioned to not 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
Tina Bahadori	EPA
Ryan Baker	Oregon Health Authority
Mary Ballew	EPA Region 1
Bryan Bloomer	EPA
Michele Burgess	EPA
Xun Che	Michigan Department of HHS
Alma Feldpausch	Ramboll
Mark Follansbee	SRC
Stiven Foster	EPA
Maria Hegstad	Inside EPA
Todd Hudson	Oregon Health Authority
Steven Jones	ATDSR
Rachel Kamiski	Get the Lead Out
Amanda Kasper	EPA
Ghassan Khoury,	EPA
Sheila Xiah Kragie	EPA
Mario Mangino	EPA
John Palmer	Ohio EPA
Zachary Pekar	EPA
Todd Phillips	EPA
Tony Pierre	MO Dept. Health & Senior Services
Andrew Podowski	EPA, Region 5
Carrie Rasik	Ohio EPA
Rosalind Schoof	Ramboll
Sofia Serda	EPA, Region 9
Jane Ellen Simmons	EPA
Barry Steffen	EPA
Marc Stifleman	EPA
Julia Tu	Ramboll

Materials Cited:

The following meeting materials are available on the SAB website (<http://www.epa.gov/sab>) at the page for the April 23, 2020 Meeting:

- 1) Technical Support Document for the All Ages Lead Model (AALM)
- 2) Users Guide for the FORTRAN Version of the All-Ages Lead Model (April 2019)
- 3) The AALM Version 2.0 Software

ⁱ Roster of SAB members

<https://yosemite.epa.gov/sab/sabpeople.nsf/WebExternalCommitteeRosters?OpenView&committee=BOARD&secondname=Science%20Advisory%20Board>
