

**U.S. Environmental Protection Agency
Science Advisory Board
Multimedia Multipathway Multireceptor Risk Assessment (3MRA)
Modeling System Panel**

Committee: Multimedia Multipathway Multireceptor Risk Assessment (3MRA) Modeling System Panel of the U.S. Environmental Protection Agency's Science Advisory Board (SAB). (See attached Roster)

Date and Time: November 24, 2003 from 1-5 p.m., Eastern Time (See attached Federal Register Notice)

Location: Science Advisory Board, Room 6450Z, Ariel Rios North, 1200 Pennsylvania Ave, Washington D.C.

Purpose: The purpose of the conference call was to allow the Panel to make progress on their draft report of their review of the 3MRA Model System and supporting documentation.

Materials Available: In addition to the materials distributed before or at the October 28-30, 2003 face-to-face meeting, the Panel, the Agency and Public had received the original and revised agendas for this conference call, draft minutes for the October 28-30, meeting, a revised draft response to Question #1; new or rethought materials from Carlisle, deFur, Foran, Merrill, Thibodeaux and Travis; and an additional write-up on water balance provided by Bob Ambrose of EPA. Other materials prepared by individual panelists as contributions to the rewrites of questions 1, 2, 3, and 4 were received, but not circulated in advance of the meeting. Similarly, the DFO received, but had not distributed CDs from ORD with the results of an uncertainty analysis for seven chemicals. All these materials will be distributed, but it was not possible to do so before the meeting. No additional written public comments were made available before this conference call.

Attendees: Foran joined the call at 1:30; Eschenroeder was unable to participate. Because Drs. Murarka and Thibodeaux would have to miss parts of the conference call, some adjustments to the schedule were made to include them for critical discussions. All other panelists attended the full conference call. A list of participants, including the Agency and the Public, is attached to these minutes.

Summary

At 1 :00, SAB DFO Kathleen White opened the meeting. She called the roll of the Panel, expected Agency staff, and the public. She made the following points:

1. Welcome to the conference call. This is the seventh meeting in a series of eight (or possibly more) face-to-face and conference call meetings at which a specially formed panel of the EPA Science Advisory Board will review the 3MRA Modeling System. The eighth call will be December 15 from 1-5.

Since the last meeting, there has been one preparatory meeting of the panelists charged with coordinating the revised responses to the charge questions: DePinto, Merrill, Murarka, and Theis on November 11. This meeting was about the mechanics of revising the responses. No Agency staff were present, but the DFO was and her notes will be appended to minutes for this conference call.

2. The activities of the Science Advisory Board are governed by the Federal Advisory Committee Act, other government regulations (such as those on conflict of interest) and SAB policies.

With the permission of those present the DFO skipped the following items which most had heard on the previous conference calls and face-to-face meetings and all could read in the minutes of those meetings.

3. In accordance with those policies, this panel was formed using a widecast (FR dated April 11), a short list was posted June 20, and, after consideration of the comments received and the review of confidential financial disclosure statements, the current panel was formed. All panelists have completed a course on government ethics prepared especially for Special Government Employees, like themselves. The panelists introduced themselves at the first conference call and their biosketches are available at the SAB website. In the interests of saving time, the introductions will not be repeated on today's call.
4. She referred those present to the SAB website (www.epa.gov/sab) for materials relating to the 3MRA review and about panel formation.
5. All materials available to the Panel will be available to the public. Individuals wishing to be on the DFO's distribution list for materials relating to this review should send an email to that effect to the DFO (white.kathleen@epa.gov) who will add them to her list.
6. Public comment is accepted at SAB meetings. Written public comments are encouraged, but opportunities for brief oral comments are also scheduled. David Case of the Environmental Technology Council will provide brief oral comments this afternoon introducing a written public comment, prepared by AMEC Earth & Environmental, for ETC which is in the mail to the panelists.
7. All consensus drafts, and possibly earlier drafts, will be available to the public and the Agency.

8. As part of the SAB's routine process for insuring the quality of the reports it provides to the Agency, after the Panel is satisfied with its report, it will be sent to the Executive Committee for review before being transmitted to the Administrator.

Because this is a conference call, she asked that people use the mute button if they were not speaking and identify themselves before they do speak. She asked panelists, if they would be away from their usual addresses Tuesday or Wednesday, to send her the correct address for FedExing by 2:00. SAB Staff will FedEx the CDs from EPA to the Panel today. The material will be available at a website

At 1:08, Theis welcomed the panel and introduced the agenda. Although the Panel had hoped to review its revised draft at this conference call, quite a bit of new or rethought material came in that should be discussed by the Panel and many panelists were not able to meet the original November 14 deadline which meant that the question integrators were unable to revised their sections by November 21. Therefore, this conference call focuses first on the new or rethought material, then on presentations by the Agency on newly sent (or soon to be sent) materials, and finally on the revised draft response to Question 1.

After ascertaining that the relevant Agency staff (Cozzie & RTI support) were present, Theis began the Presentations and Discussions of New or "Rethought" material at 1:15 with Thibodeaux's discussion of the GSCM model. This model is not a legacy model and was developed especially for 3MRA. (Thibodeaux's comments are attached.)

Thibodeaux summarized what he thinks the GSCM is about in terms of theory and process development. It seems to be made up of layers, each of which is a really neat solution of a partial differential equation, starting with a uniform concentration. Material diffuses out in all directions. There is an air interface at the top and a release at the bottom. Figure #1 shows his understanding of a release from a single layer in contact with the air region, which yields a bell shaped curve with the air discharge shown as shaded. There is something similar for groundwater, but this is folded back on itself and reintroduced in the next iteration. Dave Cozzie and Keith Little confirmed this understanding is correct.

Thibodeaux has two major concerns with the model. One is a lack of process realism reflected in the diffusion out of the top and bottom, which is not really mechanistically correct because. when the chemical passes the phase boundary, it doesn't behave with a bell shaped curve. The other is tying all three phases together and assuming all three are always at equilibrium, which causes some problems with terminal boundary conditions. The GSCM is a traditional model with assumptions traditional in groundwater (where it is probably sound) but in this situation where the column is short and the masses high, he's not sure this is the right approach.

The relevant text from his comments is, "In summary there are two theoretical problems with the GSCM. First, the quasi-analytical solution requires two imaginary semi-infinite soil sections located top and bottom the soil column to act as surrogate sinks for the diffusive and advective mass transport. Secondly, the application of the LEA in the relative short soil column forces the concentration profiles in air, water and solid particles near the two interfaces to have parallel profile shapes. Both theoretical problems work together to fabricate a quantitative chemical release model that is at odds with the known scientific fate and transport processes operative at the interfaces and within this multi-phase system."

This causes some problems which the developers tried to patch up with a reasonable approach.

Thibodeaux listed five assumptions from pages 6-7 of his comments.

- 1) The volatilization loss is assumed proportional to the total mass loss by the ratio of gas-phase diffusivity to the total effective diffusivity. See Equation 2-23 in 1996 document. Is there experimental evidence for this assumption in a chemical three phase system at equilibrium?
- 2) The developer assume that mass is not lost across the top boundary due to diffusion in the aqueous phase in the soil. In making this "assumption" the developers are tacitly acknowledging that the governing equation (Equation 2-8 in the 1996 document) is theoretically incorrect. While it is true no aqueous diffusion occurs this assumption is in effect a correction imposed on the computational algorithms. In fairness, the developers they do acknowledge that a more rigorous treatment would be desirable.
- 3) An implied assumption is made that numerical diffusion can be avoided completely by using Equation 2-26 for computing the integration time step. No supportive arguments are offered to justify this assumption.
- 4) The model developers assume that a "reflective" soil column source below the actual soil column is an appropriate procedure for transforming the zero concentration boundary condition to a zero flux boundary condition (BC). The parameter used to accomplish this is defined as "bcm"; the model user must specify it over the range is 0 to 1. The "reflective" source concept is widely used and accepted in simplistic air dispersion modeling for plumes that contact the ground surface and when a zero flux BC is desired. By doing this the developers are introducing another correction into the chemical transport computational algorithm. Based on the solution to the governing equation (See Equation 2-16) a zero boundary is already applied to each layer in the soil column. How do the modelers justify arbitrarily imposing a non-zero B.C. on the stack of layers that form the waste/soil column? This bcm parameter plays a major role in controlling the chemical diffusive rates emerging from the bottom of the column. Based on what information does the user select a value of bcm to specify in the algorithm? (See page 2-10). To the 3MRA reviewers it appears to be an adjustable parameter. It is unclear to the reviewers whether the bottom layer concentration, C_{TO} , (See the sentence below Equation 2-26.) which quantifies the chemical mass convected (i.e., leachate) out the lower boundary is in anyway adjusted by the choice of the bcm. It seems that it should. All these factors both diffusive and

advective, taken together, effect the mass of chemical delivered to the vadose zone below the waste soil column. This mass enters the ground water pathway module which in turn delivers a concentration to receptors using water wells or surface waters for their water supplies

5) In the solution to the governing equation the superposition solution requires a sequential approach. The developers prioritize the processes with diffusion first, followed by decay and then advection. They acknowledge that systemic error could result from this choice. And that the size of the error would be dependent on the relative loss rates associated with the three processes. The ordering of processes needs to be investigated numerically to resolve the issue of the assumed ordering. This GSCM limitation appears on page 2-12.

Relative to #4, Keith Little said there is no loss due to diffusion to the vadose zone. Thibodeaux agrees advective loss is much more important than diffusion. He thinks the GSCM is a placeholder. It gives answers which tend to be in the right direction. There will be some leakage out the top and the bottom. He knows this is the first version, there is work ongoing, and it will be updated in the future. However, as of now, he is not sure it is giving the right answers, or even the right magnitudes of answers.

deFur asked Thibodeaux to expand. Thibodeaux responded that the processes are not handled in a state-of-the-art way. There are other know processes, particularly particle diffusion which can contribute to enhanced release from the top and cracking which can lead to rapid down infiltration.

This asked EPA to respond to the theoretical chemical mass transfer and the chemical equilibrium assumptions. Dave Cozzie asked to have the question made more clear. This said now we have a statement from a panel member saying neither assumption is scientifically valid. This creates a problem in going forward with the review. Dave Cozzie said the SAB had recommended EPA look into the soil risk model and they contracted with one of its developers. One of the constraints was that the module run quickly and they made some simplifications. After the peer review, they looked at some other choices. OSW's Zubair Saleem spoke of a model they looked at to replace GSCM, which EPA agree is not state-of-the-art. They went as far as they could with the resources they had. EPA looked at several models (EPACMTP, PRIZM, GSCM, Hydrus – associated with Van Genuchten at the USGS salinity lab – and others). But they are not able to substitute at this time. The lab validation for GSCM turned out pretty well. If they get the funding, they will probably go to the Hydrus model.

This asked whether EPA could assure the Panel that the GCSM that it is functioning “well enough”. Mr. Merrill asked about the comparisons. He can see why certain models would be abandoned as too computationally intensive. ORD's Robert Ambrose asked whether the testing might demonstrate that GCSM is adequate until they can put HYDRUS on line. Keith Little responded that the testing was of the verification type, to see that the model did what it was intended to do. During a different project, there was some broad-scale validation in terms of reproducing observed dioxin

half lives. He thinks there was also some bench scale testing done. Keith Little agrees with Thibodeaux that GSCM is not state-of-the-science, he is not aware that it produces any sort of gross error.

This says it is one thing to say something is not state-of-the-art-science. It is something else to say it is not scientifically defensible. Perhaps we could deal with the chemical equilibrium assumption. There has been a lot about this in the literature and guidelines have been developed on when it is good enough. EPA responded that they had not explicitly considered the literature in choosing to make that assumption. Zubair Saleem referred the Panel to the Ada study where the results came out very good. Thibodeaux agreed that the results were quite good and that it is one of the best tests. There is no problem with a well done 1980 study, which this was. It had three columns, with the GSCM being only 7.5 cm. He thought it was a good test of the module, but not particularly a test of the GSCM.

A Panelist asked if OSW was going to replace GSCM before calculating exit levels. It is a difficult question to answer. The EPA scientists do not have heartburn over the numbers which they are getting with GSCM.

At 1:43 EPA/OAR's Barnes Johnson suggested Keith Little speak about why he feels comfortable with what has been done, briefly summarizing the testing that has been done and the behavior of the model and why he thinks that the use of the model is reasonable, given the restraints. This agreed and noted that the Panel had a great deal of comfort with the legacy models. Anything to improve the comfort level of the Panel with this newer model would be useful at this time.

Keith Little said, first, the charge at the outset was to get modules that were pretty honest to the science and also ran very quickly. The need to run quickly precluded the use of something like HYDRUS and led to the GSCM approach. It has been verified extensively to show that it does what it was intended to do. There are no bugs. He is unaware (based on dioxin half-life studies) that there are any unreasonable results. He got involved after it was developed and, like the Panel, can see places where it could be improved. He has no problem with viewing GSCM as a place-holder, but sees no reason to think it is not producing reasonable results.

Saleem said that they were investigating HYDRUS in part because of the desire on some people's parts to use the model for site specific applications. Little said that a finite compartment model was looked at as an alternative to the GSCM and reviewed. The reviewer thought it would do the trick, but was troubled that it didn't have a rigorous transport solution.

Thibodeaux spoke of simpler compartment models, which have a long history of use.

Ambrose wondered if they could run a few quick tests of the GSCM against a legacy model to see if they could elucidate the size of the disagreement. DePinto was thinking something along the same lines, and perhaps simpler. He thought could it would probably be possible to test those two assumptions by running the model with very simple configurations and, perhaps, even compare it to analytic solutions, depending on how we set up the scenario. At the very least they could look at the effect of relative transport effects and see if we are in a situation where the GSCM is a reasonable assumption. Theis asked the Panel whether they remained unconvinced that the GSCM is appropriate for setting exit levels.

Thibodeaux noted that EPA thinks it gives fairly reasonable results – and they do -- he doesn't have any numerical data to show it doesn't. Another Panelist asked if it was reasonable to ask EPA to show the Panel to demonstrate that. Carbone mentioned that Thibodeaux had mentioned the JURY model in his write-up and asked if that would be a good comparison. The question was asked, "How close do we have to be?" Boissevain asked when the HYDRUS model would be available for this application? Salleem says HYDRUS is available, but the integration (the "handshakes") with the other models has not been established.

Salleem says the Ada lab results represent one of the few cases where they have lab validation of the model. These are the Schmelling and Jewitt AWMA presentation and more detailed report circulated earlier.

Brown returned to Ambrose's suggestion that there might be one or two quantitative comparisons that the Agency could provide to the Panel. Theis said that the goal is to demonstrate that, compared to a model which is theoretically complete, the GSCM gives answers that are close enough. Cozzie thinks the Agency staff needs to huddle about what they could do that would be quick and responsive. Theis thinks, one way or another, a new summary point will emerge from this. Any input the Agency can provide will help the Agency.

ACTION #1: EPA will respond to Thibodeaux's review by December 15. If EPA wants to bounce off their proposal the DFO could involve Thibodeaux and anyone else who wants to comment in giving feedback. (Merrill and DePinto are among the interested.)

ACTION #2: Theis will draft a new summary point based on this input which will say something like this, "The panel is concerned about GSCM . . . for the following reasons . . . therefore the Panel recommends that GSCM not be used to set exit levels until a more . . . has been substituted." This could change based on new evidence from EPA. Although the Panel seemed pretty comfortable with this approach, one panelist thought EPA should have a choice of providing a more sophisticated modeling framework or demonstrating the existing framework is good enough to use.

Carbone was especially concerned with the use of the module to set exit levels in a regulatory setting; his other concerns for that context are mass balance and results that pass the straight face test. Before EPA uses it for regulation, people need to be comfortable that the results are in the ballpark of reality. How to do this seems somewhat up in the air. Saleem noted that open-ended recommendations are difficult to implement.

This said there have been two sticking points so far. One is the Agency's policy on not doing uncertainty analysis on the effects, which the Panel is addressing by saying they think a different policy would be better. The other one is the GSCM. At this time, the Panel is not comfortable enough to pass off on the GSCM. He thinks the Panel can become comfortable with it. In the meantime, he wants the Panel to continue work on Draft #2. He hopes, after they see the additional EPA input, that they will be able to do so.

At 2:10, This asked deFur to summarize his views. At the face-to-face meeting, he left the Panel with a paragraph on whether the decision to use population risks was a departure from EPA policy; if it is, he doesn't think this is the right time to do it. His longer piece of writing addressed other issues as well. This asked that the Panel address the embedded policy issues in 3MRA.

Smith spoke of an EPA May 1997 incineration report with population risks by sector calculated in it as well as various risks to various kinds of individuals. He has heard informally for years that the Agency was interested in going to more population-based approaches to risk assessments, in part so they could consider populations affected by multiple sources. deFur said EPA has made no qualms about calculating population risks for site-specific situations; they do it all the time under Superfund. But this isn't a site-specific situation, it is a national rule.

Barnes Johnson reflected that he hears a concern from the Panel that EPA decision makers will be forced to consider a new risk metric in the context of a future rulemaking. The concern is that EPA is doing this through the vehicle of a model. He referred back to his closing presentation at the October 28-30, 2003 meeting. He assured the Panel that EPA managers did not invest millions into 3MRA without having a very good understanding of the nature of the risk metric and what it brings to the table in terms of having to think about national risk problems in new ways. This is not new to OSW. Beginning with the toxicity characteristic that was based on MC analysis across multiple sites a decade ago. As GIS has become more available, OSW decision-makers have lived through an evolutionary process that has made them comfortable with this metric. This is one of the reasons they have so many sub analyses, so the model can get at special populations, such as children. 3MRA does not represent a new policy. Across the Agency, population based risk modeling for decisions is a common practice, partly because of the need to do cost-benefit analyses. EPA does look at distributions of individual risks across the population as opposed to MEI approaches.

deFur appreciates that, but is unpersuaded.

Babendreier spoke of deFur's dilemma and observed that a national regulation is a place-based risk analysis constructed at the national level.

Merrill said he was not as versed in how EPA has used population based approaches, but has *Hazardous Waste TSDF - Background Information for Proposed RCRA Air Emission Standards.* June, 1991. EPA-450/3-89-023a,b,c. PB91-233577. In Appendix E of that document, the Human Exposure Model calculates a population-weighted risk value. In his view, this document shows that EPA (Office of Air Quality and Planning and Standards, and Office of Air and Radiation) were using population-based risk analysis over 10 years ago. This document was prepared when EPA was looking at air exposures. It looks at population weighted risk assessment, just like 3MRA. This is a concrete example which, in his view, demonstrates that the 3MRA is not a departure from established Agency practice.

This asked for the sense of the Panel: is 3MRA a shift or an extension? Boissevain thinks it is part of an evolution. People have a level of comfort in doing this when all the variables have associated distributions. Thibodeaux said, the question of policy aside, he doesn't see anything wrong with the 3MRA approach. If it is a policy shift, it looks logical to him. deFur had used the formulation, "If this is a policy shift, this isn't the correct place for it." He thinks the examples people have raised are place-based. When you change your procedures and assumptions, in effect a policy has changed . . . so that the technology outruns the policy. It can happen in one office without the others being aware of it.

Murarka thought that the 3MRA modeling system needs to have the capability to do the assessment at the population level and, as long as it is properly done, he is comfortable with it. He thinks we could discuss the modeling system and its capability separately from how the results, in conjunction with current or changed EPA policy, are used. He thinks the modeling is properly done. This agreed. The use of 3MRA is just part of a more complicated process of carrying out policy. He asked if the Panel can craft a consensus point that reflects that the Panel recognizes that there is a difference between how well the model runs and how it is used. Foran referred to the summary statements crafted at the last meeting and suggested they could be revised. If 3MRA is only a component of making decisions about exit levels, then the summary points need to be more sharply focused because establishing exit levels includes much more than just 3MRA. This then does lapse into what deFur was talking about. Murarka thinks this will happen as part of preparing Draft #2.

This thinks the Panel as a whole does not think 3MRA represents a shift in policy, but the new technologies could actually lead to subversion of environmental protection. He thinks this is worth a new consensus point. A panelist reflected that he hears the Panel saying it knows that there are places where the 3MRA approach has

been used, there has been an evolution in the uses of the population approach, which is also a kind of shift.

Carlisle thinks risk assessors have known and acknowledged for years that they use some metric (like MEI) which is supposed to be the highest end and have always known there was a distribution of risk, but didn't know where it was. It used to be addressed in the uncertainty section of a risk assessment. It was always there. Now this technology with MC has become available and we are trying to quantify it. It is a shift in our level of knowledge, but it is not something new.

Stubblefield also believes risk assessment has had a continuum in the use of tools. To the extent we can use tools that reduce uncertainty, we should. The 3MRA approach is not very new, but still takes things a step forward, reducing uncertainty (on the fate side). He remains concerned on the effects side. He's not sure how germane or important it is that the Panel talk about this.

Murarka said that the typical risk assessment is done on MEI. That's one of the assumptions in the risk assessment guidelines. The 3MRA uses more of the available science to look at all the people living near the source. In essence, the very conservative or deterministic MEI basic calculation has been replaced or extended by a more applicable risk assessment. In that sense, 3MRA has made an improvement in the direction in which EPA should go. Is this a policy shift? Or just a change in ability? He believes 3MRA uses the right science in the right way to do the right thing.

Boissevain said that, in dealing with populations, risk communicators tell people to verbalize that a risk (such as 1 in a million) should be applied to a population.

This follows EPA pronouncements pretty regularly, but when he looks at EPA policy, he thought it was stated long ago and that 3MRA is just the computer version of what has always gone on. But his opinion doesn't matter, if the Panel wants to make a statement, that's what should happen. If there is a connection between science and policy, maybe they should.

Travis thinks the idea of protecting the MEI always had a 95% concept in it because they didn't use the most outrageous scenario. He doesn't want to get into whether it is a policy change or not, but there are policy issues in it. He has some worries over 95% of the population at 95% of the sites. What happens to the other 5%? But that's policy. For the last 5-10 years, review panels have been urging that models consider uncertainty and variability. Once you implement that advice, you are forced towards protecting a certain percentage of the population.

Barnes Johnson said that EPA has the same concern, as did their managers. They tried to express who those people might be who were less protected. That's why they are able to set the percentages as high as 99% and also why they designed

outputs that let you look at who isn't protected. As a practical matter, you can't go to the end of the tails. This is why there is the flexibility questions in the charge.

ACTION #3: deFur will draft a new consensus point which reflects this issue.

On a slightly different subject, the chair would prefer not to re-write the consensus points developed with such effort in October. Murarka thinks some need to be changed because they are unsupported; GSCM is a case in point. Travis thinks several could be better written. Murarka thinks the Panel should resist the urge to edit them willy-nilly. This is quite concerned that the Panel not say one thing in one place and something else, elsewhere.

There was a long discussion of what to do when information is missing or when new data becomes available. Using the best that is available today, making decisions, and being prepared to change them later is not unique to 3MRA. It might be able to make a clear statement about what the minimum data base requirement might be to calculate an exit level. This brought the Panel to a discussion of Foran's new material – the boldened paragraph on page 2 of his write-up which ends with a recommendation that 3MRA should not be used in the decision-making process, **“Presently, there is no validation, nor has any determination been made of the ability of 3MRA to accurately predict risks associated with chemical exit levels. Nor has a determination been made of whether 3MRA provides conservative (over-protective) estimates of exist level-associated risks to humans and ecosystems. The comments provided below suggest that, in at least some cases, risks to human health and the environment are not conservative (may be under-protective). In these cases, chemicals may be released to the environment and cause adverse effects to humans and ecosystems. There will be no opportunity to recall these chemicals once they are released; therefore, the management system that is designed to develop chemical exit levels must not rely exclusively on 3MRA where it has the potential to underestimate risks. Rather, 3MRA should be used in concert with other conservative screening mechanisms and tools to predict chemical fate and transport and human and ecological risks, ensuring that initial decisions regarding risks to human health and the environment are fully protective and preferably over-protective. Opportunity should then be provided to stakeholders to refine estimates of fate, transport, and effects using 3MRA and other appropriate tools. Data and analysis from these refined assessments may then be used, after appropriate peer review, to modify exit levels in either direction. Until such a comprehensive chemical management system is developed, articulated, and peer reviewed, 3MRA should not be used in the decision-making process.”**

Foran said this was a fairly general concern that goes to the issue of whether 3MRA is over or under protective. He doesn't know which. There are components that render it under-protective, so he has some concerns. This paragraph is somewhat of a catch-all. Stubblefield has some concerns in this area as well. There are mixed areas of uncertainty in how the model is run. He thinks the model should start with conservative assumptions, then change as data becomes available. He agrees there should be flexibility for the risk manager to make decisions about acceptable risk. He is

just not as comfortable on the effects side. But 3MRA is a mix. If it were consistently conservative, you would at least know where you stood.

This reads Foran's para a little differently. He assumes public comment will take care of, "Opportunity should then be provided to stakeholders to refine estimates of fate, transport, and effects using 3MRA and other appropriate tools," and, "Data and analysis from these refined assessments may then be used, after appropriate peer review, to modify exit levels in either direction." He would like the Panel to focus on the last sentence.

Murarka thinks the modeling system can and should be used. Travis agrees because all of risk assessment is riddled with bad data and we have to go ahead and make decisions. Stubblefield tends to agree and says the para he gave to Theis (incorporated into Draft 2 of Q1) is along those lines. Smith thinks that by using 3MRA you provide a stimulation for improving it. Murarka wonders if we can simply recognize 3MRA is still evolving and strongly encourage EPA to continue to use it and improve it.

Carbone remarked that we have talked today about the GSCM and the inconsistencies, mass balance, and a myriad of things that the Panel has not seen any data for. He agrees that risk assessments are largely done with incomplete data sets. Given that, we do take some safeguards that the risk assessments are reasonable. We compare, validate, ask things to pass the laugh test. He fears the Panel is ready to suggest 3MRA be used without getting those assurances. Is the model biased or conservative in terms of the exposure side? He's not certain. Just because it is big and complex doesn't mean it is verified. Whether or not it is ready for prime time, it is clearly moving in the right direction.

Carlisle shares Foran's concern about the mix of assumptions that are conservative or the opposite. He echoed Carbone's comment about exit levels. A matrix table or something that would allow the Panel to do a laugh test. He thinks this is necessary for an overview. He'd like to see some numbers that relate to

Murarka said a single waste producer can petition to have a waste de-listed. So there has been case-by-case laborious de-listings.

Babendreier mentioned the CD containing the uncertainty analyses for the seven chemicals should provide a basis for a laugh test by the Panel. Carbone agrees EPA is taking those steps, but until he's seen it, he's not ready to advocate using it.

Foran also brought up another point from his comments on page 1, which goes to something DePinto brought up, the issue of effects beyond the 2km diameter, **"However, the 3MRA system does not address the potential for adverse effects in humans or ecosystems (and their components) beyond a 2 kilometer radius around the WMU. Therefore, it does not predict transport of chemicals beyond this critical region, nor does it predict the accumulation of chemicals in ecosystems and the attendant risks to human**

health and the environment associated with transport and accumulation beyond the 2 km critical region. Before the 3MRA systems is implemented, guidance must be developed to ensure that the fate, transport, and effects of chemicals that are to be managed via chemical exit levels are assessed and do not result in longer range transport and adverse effects beyond the 2 km region near a WUM. Such an assessment does not necessarily need to be conducted within the 3MRA modeling system, but must be conducted before chemical exit levels are established.“ Theis had taken this into account in his revisions of the response to Question 1 and , after reading that text to the Panel, asked if it captured the concern. It seemed that it did. A Panelist, perhaps Carlisle, thought it could be strengthened by a discussion of overlapping plumes and another noted it would be exacerbated for persistent and bio-accumulative toxics.

The Panel took a break from 3:30 to 3:40 and then experienced technical difficulties and were switched to a different conference call line. Due to the shortening time remaining, the chair asked to have Agency input first.

Bob Ambrose spoke to his write-up on air to canopy mass balance, first asking if there were questions. He had laid out a fairly simple set of geometries and assumptions. One key is the initial set-up of the screening problem, which is reasonably simple. There is a constant vapor pollution emission from a waste management unit (WMU) with a circular area of interest around it. He allowed an original concentration around the WMU and calculated the average concentration to the end of the area, partition to the leaves, compare to mass, and compare to the amounts emitted. He started by looking at simpler geometries and found a rectangular area with wind going in a single direction gave the same answers as this more complicated one. When you divide the mass in the leaves by the mass emitted you get delta. (Please refer to his write-up for further information.) He concluded that for the area of interest (2km) there was no mass balance problem for air-to-canopy. He believes that, if you went out far enough, there would at some point need to have air-to-canopy partitioning as part of the atmospheric mass balance; but at the local scale, it does not appear to matter. Thibodeaux congratulated Ambrose on these calculations and thinks, given this analysis, that the Panel might have been overly concerned.

At 4:05 Justin Babendreier spoke of the uncertainty analysis done for seven chemicals and now being distributed to the Panel. There are two read files on the CD to help the Panelists access the material. He explained some of the details of accessing the material on the CD and will be available for technical support. He hopes these materials will help the Panel understand how EPA is dealing with uncertainty.

In about a week EPA will have this up on a website for public access. They will provide this site to the DFO who will forward the information to the public.

Murarka had to leave at 4:10

At 4:15 Nadine Weinberg of ARCADIS provided a few brief spontaneous public comments on behalf of the HWIR consortium.

1. The model is most likely over-conservative because EPA's goal is to be protective. This can be seen in the toxicity values and modifying factors as well as many of the exposure assumptions. While it is true that these get refined as more data becomes available, right now they are very conservative.

2. As to when the model can be used for regulatory purposes, the Consortium would like the Panel's report to be very clear about when it can be used. First, the peer review comments should be addressed, especially with regard to verification and validation. Second, is the mass balance study; this should be incorporated as it goes through the model. Finally, the completion of the sensitivity analysis is very important to the regulated community so they know what the critical parameters are where they might provide additional information.

3. The Panel's tier analysis of the modules is important to helping the public understand the complexity and strengths of the modeling system. The 3MRA is only as strong as its weakest module.

4. EPA should incorporate the most recent data. Most of the data about the WMUs is twenty years old.

Theis had a question about the HWIR that pre-dated 3MRA. Did that come about because industry wanted relief from what they thought was overly stringent regulation? She didn't know. Some members of the regulated community would like to see exit levels if they were not so conservative that they provide no relief.

At 4:20, the Panel returned to Foran's concerns. Theis referred the Panel to a summary point currently under question 2C calling and suggested, "The Panel recommends that the minimum characteristics for carrying out a risk analysis be documented, that the data be updated . . . at regular intervals " and asked whether Foran would be satisfied. Foran thought that was reasonable and would like to see what those requirements are. Maddalena spoke to the context for the original text. While he agrees with the edit Theis suggested, he doesn't want the original thought (and associated paragraph) to be lost.

At 4:30, Theis asked Merrill and Carlisle to summarize their points for the Panel. Babendreier has a brief set of responses to the Merrill questions. Merrill has an evolution of what the Panel has seen before, so he yielded to Babendreier. A full 2-D approach is not feasible due to lack of input data and computational capacity limitations. Nevertheless, Babendreier thinks he hears the Panel saying the 2D analysis has to be done. Merrill said that he is not advocating a full 2D, but suggested a focused 2D. Not all chemicals and all scenarios, a very focused 2D. There was further detailed

Attachments (hardcopy)

1. Agenda for the meeting
2. List of attendees
3. Committee roster
4. Federal Register Notice
5. New and Rethought Comments of Panelists
6. Air-to-Canopy Mass Balance from EPA
7. Thibodeaux's comments on the GSCM
8. Chair's emailed approval of the final minutes

NOTE: The CDs will be found with the records for the December 15 conference call.