

U.S. Environmental Protection Agency
Science Advisory Board
Multimedia Multipathway Multireceptor Risk Assessment (3MRA)
Modeling System Panel
Minutes of Public Conference Call Meeting February 6, 2004

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: February 6, 2004 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 discuss its third draft report.

Materials Available: In addition to the materials distributed before the January 16, 2004 conference call meeting, the Panel, the Agency and Public had received the agenda for this conference call, draft minutes for the January 16 conference call meeting, the third draft report with reader's note, executive summary and appendices, a revised Appendix I with accompanying paragraph for consideration for inclusion in the body of the report, a revised Appendix Q2c3, and Agency comments on the third draft.

Per the Panel's agreement, individual exchanges relating to particular parts of the report were not circulated to all. However, all these materials will be available in the FACA file and can be distributed on request. No additional written public comments were made available before this conference call.

Attendees: All panelists participated in this call. A list of participants, including the Agency and the Public, is attached to these minutes.

Summary

The following assignments resulted from this meeting:

1. The following people need to write and provide input to Theis and the chapter coordinators:

Carlisle, Merrill, and Stubblefield to Murarka
Thibodeaux to DePinto

DFO will draft Introduction

2. All materials are due to Theis no later than February 12.
3. Theis will revised the responses so that they sound like they were written by a single author by February 20
4. DFO will distribute Draft #4
5. Panelists will reserve time on their calendars to review Draft #4.
6. The next call will be February 27, 2004.
7. Schedule call March 12 1-3 to confirm final language (Call was actually held March 18)
8. Merrill is rewriting text on recommendations #4 and #5 in the discussion of Monte Carlo recommendations in Section 2c, page 9 and 10.

The Panel suggested extending MCA to include uncertainty and variability of toxicity factors, deleting Appendix 2B2, and eliminating redundancy in 2c.

The following is a more chronological and detailed account of the meeting.

At 1 :00, SAB DFO Kathleen White opened the meeting. After reporting that panelist Eschenroeder and EPA staff David Cozzie, Stephen Kroner, and Zubair Saleem would be joining the call late, she called the roll of the Panel, expected Agency staff, and the public. (The list of attendees is attached.)

After welcoming those present, she reminded them that this is the tenth meeting of a specially formed panel of the EPA Science Advisory Board will review the 3MRA Modeling System. The last one will be February 27. She said that Nadine Weinberg of ARCADIS had requested time for public comment, then asked the permission of those present to forego repeating information that has been given at previous conference calls and face-to-face meetings and simply include it in the minutes. That permission was granted and the material appears here:

1. Since this Panel began its work, the SAB has reorganized. In the past, as part of the SAB's routine process for insuring the quality of the reports it provides to the Agency, the Panel's report would have been sent directly to the Executive Committee for review before being transmitted to the Administrator. In the new structure what was the Executive Committee is now a larger body called the Board; that Board has the option of using a Quality Review Committee to review and provide input on important SAB products. Former EEC chair, now Board Vice Chair, Domenico Grasso will work with SAB Deputy Director for Science

Tony Maciorowski to organize that review using existing members. or those additional people likely to be involved in it.

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.
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. The SAB website (www.epa.gov/sab) has 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. .
7. All consensus drafts, and possibly earlier drafts, will be available to the public and the Agency.

At 1:09 Theis thanked the Panel for their hard work in producing the third draft of the report. The purpose of today's call is to go through the third draft in order. He has flagged areas where some clarification is needed and would like to raise those in sequential fashion. Because some areas are raised in more than one area, when you raise a question on one page, it may impact others as well. He encouraged people to speak up.

Carbone, Maddalena and Merrill have emailed him some suggested edits to the response to Question #1.

Beginning with Question 1, focusing on the bottom of page 1, para beginning "From a regulatory perspective, " he proposes adding national, to read as follows, "From a regulatory perspective the model provides decision makers a valuable tool and is an important step forward. The panel acknowledges that 3MRA can be used today to aid decision makers in making the intended regulatory decisions for establishing **national**

exit concentrations.” The purpose of the addition is to help distinguish between national and site-specific applications.

DePinto said there is a small conflict between this statement and one in the response to question 3 where he says there is a little more to be done before it can be used. Carbone thinks there is a dichotomy in the report where, in some places, we say it is ready for regulatory use while in other places the Panel raises some potentially serious concerns that suggest the model might not be ready for use. Thibodeaux thinks the use of the word “can” does not necessarily mean “ready”; it could mean, “If you are foolish enough to use it right now, go right ahead.”

Theis heard no objections to the use of the word national. With regard to whether it can be used today, he added some text at the top of page 2, “The panel therefore stresses the need for the Agency to make clear that 3MRA is to be used in conjunction with other tools and factors that also affect the setting of regulatory standards (e.g. economic implications, stakeholder input, etc.). “

DePinto said his concern was the use of the word “today” and asked for the Panel’s sense.. DeFur thinks that, if it ready to use today, it doesn’t need further updating. Boissevain says this is especially. Maddalena thinks “today” is OK in the context of the following “however” clause. Brown thinks it depends on whether you think 3MRA is a static or dynamic product. He agrees with Maddalena that it is ready to use today. Smith suggested, “could be used virtually immediately.” DePinto says that the current version could be used to aid. Murarka suggested, “The model can be used in its current state recognizing the limitations and the recommendations made in this report for ongoing development.” Carlisle thinks we need to make very clear whether there are any recommendations that are necessary pre-conditions for using it.

Theis suggested that the Panel set this side for now and the wording will be changed later to reflect any recommendations that are pre-conditions.

He turned to the sentence, “However, it must be recognized that the model is built on limited data, conservative assumptions, and is the product of a collection of submodels, most of them extant legacy models, thus any regulatory decisions that rely on 3MRA may reflect the uncertainty, conservatism, and the limitations of these models” He does not feel that all the assumptions are conservative. DeFur agreed. (At this time the DFO had to go off-line to resolve a conference call problem)

When the DFO returned Thibodeaux discussed what the GSCM did a good job with (leaching) and what it did not (volatilization) and testing was done at laboratory scale. Done carefully, Murarka thinks a short column gives very good insights, although the problem of scaling up remains. Theis asked whether this has to be resolved before 3MRA can be used to aid decision-makers. Theis asked whether it would work well with the current set of chemicals, but might fail with more volatile chemicals and Thibodeaux expressed some concern with some chemicals on the current list. Theis asked what the

remedy would be. Thibodeaux is struggling with models for volatilization for a particular site; good volatilization models are not available.

Theis asked the Panel to generate a specific recommendation with the GSCM. He feels they have dealt adequately with ISCM, thanks to Maddalena. He would like the sense of the Panel on the use of 3MRA as it relates to GSCM. Brown asked, "Is there an alternative?" If there isn't, we have to stick with GSCM and encourage improvement. Travis thinks the Panel is saying current state of the art isn't good enough. Thibodeaux says there isn't another model. Carbone spoke of the LEACH M model from Cornell. Thib said they are comparing it to HYDRUS, which is much like GSCM. Thibodeaux thinks that EPA is aware of the Panel's reservations and is comfortable with the use of "can" in the first sentence Theis raised. Theis asked whether they should make a parallel recommendation that, as 3MRA is used, GSCM has to be validated. Travis wants more specifics about volatilization, its' impact on leaching and recommend that, over the long term, EPA should improve the quality of the model.

As a separate point, Thibodeaux would like to raise the issue of metrics. Brown says Beck says you use other things in conjunction with metrics and include metrics where you can. Theis confirmed that Thibodeaux was referring to data matching metrics. Smith (?) raised a question about the tense of the action, suggesting "will be incumbent upon". Theis will turn this language into a recommendation.

Theis moved discussion to text at the bottom of page 2, the second to last sentence, "In addition, the science within 3MRA does not currently provide a mechanism to adequately assess ecological impact. As such, the use of protective criteria as benchmark comparative values, as are used in 3MRA, **may** not adequately characterize risk in ecological populations. " He confirmed that the benchmark values were water quality criteria. Carlisle, who had written on 95% of the people 95% of the time, and thought the situation for ecosystems was slightly different. Stubblefield confirmed it was 95% of the species in the data base, 95% of the time. Carbone mentioned that Foran had written that the WQCs were not as protective as that language would imply. Foran is not comfortable with the word protective and prefers, "The use of criteria as"

Theis wonders if more explanation is needed here. Travis thinks it needs to be changed and has problem with the sentence above it, "The panel is concerned about the lack of sophistication, in comparison with transport fate, and exposure, of the treatment of toxicity in 3MRA, i.e. toxicological parameters in 3MRA are represented with a single parameter rather than a probability distribution." DeFur and Travis think it should be made more clear. DeFur said it was an exposure analysis, with risk just being a look-up analysis. Stubblefield noted that there are also differences in the rigor of the numbers, for example, those that come from the GLI and Oak Ridge numbers which have uncertainty factors built into them. DeFur made a small, but not unimportant point, at the top of page three he would prefer "ecological endpoints" to "ecological populations".

Travis wants the Panel to say what is inadequate, not just assert that it is inadequate. Murarka thought this could be done by references to other portions of the report rather than by expanding the summary text.

It appears Stubblefield sent out materials which never reached Murarka, Theis, White or other intended recipients. Part of this was the paragraphs he wrote in DC. He will re-forward it and the recipients will acknowledge receipt. This is especially important to the response to Question 2

Theis would like to remove critical from this sentence, "Therefore, it does not predict transport of chemicals beyond this **critical** region, nor was it designed to address the attendant risks to human health and the environment associated with long range transport and accumulation." and got no arguments.

There was a brief clarification with Maddalena.

Theis asked the panelists to raise any other issues in Q1. Carlisle, Maddalena and Travis favor deleting this sentence, "Lacking this, the panel recommends that sensitivity analysis for the dose-response for candidate chemicals should be performed." A panelist said you can work the exposure side very far, but the model still requires you to compare it to an effects threshold and if you have a lot of uncertainty there, you still have a problem. Travis has done sensitivity analysis on full models and has found that toxicity parameters are the most sensitive. Smith had the same experience and Carlisle agrees. Brown thinks this should be said. Boissevain noted the model has the capability to incorporate distributions for toxicity. Smith thinks it would be valuable to document the uncertainty, even if you later ignored it. Theis thinks there is no harm in re-iterating the importance of including the dose-response in the sensitivity analysis. Maddalena says there are two things here – inclusion of pathways in the sensitivity analysis and consideration of dose response it be considered in the uncertainty analysis. Theis will recast accordingly

Brown is not clear what "this" means in, "The panel recommends that the Agency demonstrate, through appropriate analysis, that **this** approach achieves the level of protection intended." Theis and Maddalena had different ideas. Theis also thinks this is a place where the distinction between national and site-specific applications is important. Brown asked whether they should ask EPA to provide a rationale for pathways not included. Foran said the rationale for not doing dermal, was not that it was unimportant, but that we didn't know how to do it.

Smith spoke to the revised Appendix I developed by Boissevain and Smith and the paragraph for the text intended for question 2a, in which case the Appendix will become an appendix to the response to question 2. The issue remains of whether to speak about it at all in the response to question 1 and, if so, how. Boissevain noted that EPA has asked what they are supposed to do with the analysis she and Smith did. Smith seems concerned with giving credit to the Agency for what they have achieved.

Theis thinks it reflects accurately that what the EPA did in creating 3MRA was take modules with varying degrees of sophistication and pulled them together. He likes the use of the word “sophistication” and he thinks it is an excellent explanatory document.

Maddalena observed that from this sentence, “Perhaps the most complex issue that the panel has faced in evaluating the 3MRA modeling system has been that of validation.” onward, there are no recommendations. He suggested that, after the Panel describes what EPA is doing, they should say the Beck approach is the right way to go. He sent text to the chair. He would like to go on at the end and say what the Panel is recommending, that EPA continue with this work. He asked DePinto to respond because this relates to the response to Question #3. Brown agrees with Maddalena and has drafted notes which he will share with Theis.

Maddalena says EPA has done a very good job on the first three and is working on the fourth. “The Panel believes that the final stage . . . is the most demanding . . . it is premature for the Panel to make . . . steps are appropriate . . . with emphasis on . . .” Theis said it sounds fine, except for the problem of what this means about the use of the model at this time. Smith spoke about use while these steps are taken.

The Panelists had no further comments or questions on the response to Question #1.

At 2:10 Theis turned the Panel to consideration of the response to question 2, beginning with this paragraph:

Another issue as to the consistency in the use of available science arises in the air module. The meteorological community and EPA have recently advocated the substitution of a new air dispersion model, AERMOD, for applications otherwise calling for ISC3. AERMOD has been thoroughly tested and documented over recent years and may be formally adopted as a recommended model by the Agency now. AERMOD can default to the input structure of ISC3; however, it is designed to accept better resolution of input data than that required by ISC3. Hence, a hierarchy of input complexity should be established depending on which model is chosen and what data sets are available.

Theis asked if it was the Panel’s assertion that ISC should be replaced with AERMOD. Maddalena said not. Theis asked if the comparison of AERMOD and ISC was significant or not. Smith thinks ISC will be shown to be better for site-specific analyses, but burdensome for national level analyses. Therefore, he is not sure which would come out better. Schwede said that recent analysis has revealed problems with the deposition algorithms in AERMOD. It does not yet have formal status as a “status model” for Agency use, although people think this will happen in time.

Murarka asked if the whole paragraph should be removed. Theis thought it should just be modified. He thinks Smith's comment is very important. Murarka thinks the way it is written gives a different impression – it sounds like AERMOD is accepted and there and 3MRA is weak because it doesn't use it. This is not the case. Maddalena fears this paragraph waters down a later recommendation that 3MRA be set up to incorporate new knowledge; the AERMOD situation is just a case of that. Theis asked if this should become an example in the response to question 1 where updating should occur, then asked if it should just be struck. There seemed to be agreement it should be modified and moved.

Maddalena clarified that, "In a coupled computer environment, any choice of time step results in enormous compromises.," meant linked model environment, not Supermuse.

Brown and Smith made a modification to include "hourly meteorological record" for list.

Foran had an issue in the first paragraph. There were some language changes agreed to in December that didn't make it into this draft. He would like the word reasonable dropped from, "Nevertheless, the panel believes that the choices made about what science to include in 3MRA modeling system were consistent and reasonable" Murarka said they would say, "consistent and reproducible."

On page 2 of 2a, everyone agreed to delete, "As to providing a mechanism for reproducing results, it will be necessary to conduct a formal round robin inter-comparison of results generated by different users. This exercise needs to follow a well planned protocol much in the same way that inter laboratory comparisons are structured for chemical analysis of environmental samples. The results should be widely publicized to the stakeholder community in a comprehensive report."

Smith and Boissevain suggested relating to converting Appendix I to draft 3 to an appendix to 2a and inserting some text after the first paragraph and above "Comments on Consistency" to reference it. The next draft will adopt the numbering scheme suggested by Dave Merrill which will make this Appendix 2a or 2a-1.

Smith suggested an amendment to, "In order to ensure sound science there should be instituted a continuing effort to assess the additional uncertainties attendant to these compromises. "

Murarka said Carbone had a comment at the end of page 1, going into page 2. Partitioning into the foliage of plants of high K_{oc} materials where the plants would become a sink. Ambrose's presentation discounted that possibility. Brown had a similar concern, that the implication was that this was documented using 3MRA which is not the case. Either the analysis should be referenced, or this should be linked to the response to question 3. Theis and Carbone think the whole para could come out. There was agreement that this para would be deleted:

Earlier peer reviews stressed that the 3MRA prototype, a non-relativistic system, maintains mass balance, and the current documentation asserts

that this is accomplished. In order to inspire user confidence there should be an optional output in the modeling system that provides the mass balance information at each step. It would sum up all of the mass left in each medium with corrections for intended inflows and outflows in the form of a balance sheet. Mass creation is immediately identifiable in this diagnostic output. Let's look at one example of this possible pathology: There will be mass creation when partitioning is performed by simple empirical relationship. Examples of this are the large air-to-plant partition coefficients that multiply ambient air concentration to obtain plant tissue concentrations. If this rubric is followed, one finds that there is more contaminant stored in the plants than was ever emitted from the source. This was analyzed by and documented by one of the panel members. Without doubt there are other examples of such mass creation that can be discovered by the mass balance tests.

In the para beginning, "Even though the panel recognizes that the model was developed specifically for agency use," Brown suggested ending with, " and run the model and then verify their results against **Agency simulation outcomes.**"

Maddalena asked what the Panel's recommendations were regarding integrating legacy models. He thinks it would be very hard to do what is said at the end, "Breaking up the modules in the 3 MRA modeling system is not an option at this point, but a multilevel online diagnostic scheme could eliminate these concerns about the obscuration of the process. Such a scheme would provide intermediate output; for example soil concentrations at selected receptors at selected times." Theis agrees it is difficult, but doesn't think it is needed for national level applications. It has some value for site-specific applications. He thinks what the Panel is trying to get at is making the model more transparent and asked the Panel if they want to qualify this – should it be done, must it be done? Murarka thinks that breaking up the modules is not an option at this point and the rest (" but a multilevel online diagnostic scheme could eliminate these concerns about the obscuration of the process") should be deleted, then a suggestion made that a mechanism should be sought to provide an intermediate outcome and state what the value is of that. Theis wants to be sure they don't stumble into a recommendation that must be done that is unrealistic to do. Brown asked what breaking up the modules mean. Murarka responded that that it was looking at the output one module provided as input to the other. Brown thinks the FRAMES architecture makes this possible and this is how the TRIM comparison with 3MRA was done. Murarka thinks users cannot get there, although Agency might be able to. Babendreier pointed the Panel to comments from EPA which pointed out the specific capabilities.

Theis wonders if this discussion actually belongs in Q1 or Q4 instead of Q2. Brown recommends Q4, Merrill agrees the thrust is on documentation, not integration. He is also struck by the additional work they saw by Karl Castleton so it seems like some of that work, with a little dusting off

Theis moved the discussion to the response to question 2b, page 3, the last full paragraph, there was general agreement that the last sentence was vague. This sentence is, "In many cases, the 3MRA system does not appear to incorporate recent scientific information and methods and, as a result, selection of exit levels may not be based on an adequate understanding of the impacts of chemical exit levels." Boissevain thinks her concerns are said more clearly elsewhere and can be deleted elsewhere. Theis doesn't think this sentence belongs here, even if it was clarified. Murarka thinks the understanding comes from methods, data and the scientific basis. Any caveats on those could be incorporated here. Theis asked if this sentence means the Panel doesn't like how ecological risk is handled, that is discussed elsewhere. If it means something else, he needs to know what that is. Murarka favors dropping it, most of the Panel seemed content with that. Stubblefield and Foran just wanted to be sure that the concepts are covered.

Brown favors beefing it up because the Agency is looking for suggestions for improvements and if Stubblefield and Foran would provide some positive suggestions that would be good. Stubblefield will draft something on the ecotox side on the use of newer methodologies that are being developed today to take the place of ambient water quality criteria. Travis thinks that's fine, but saying "does not incorporate recent scientific information and methods" is too broad. It ought to say exactly where the problem is. Foran thinks that the Appendices can be referenced. Carlisle reminded people that it has to be clear if this is a required change before the model can be used or a suggested future improvement.

Foran reminded the Panel that there are some changes agreed to in December that didn't make it in. He is also anxious that changes, like from conservative to pragmatic, will also make it into Q1. Theis believes that they will eliminate duplication again.

There was a break from 3:05 to 3:15

The chair turned the Panel's attention to the middle of page 5, "Additional Considerations for 3MRA modeling system," both the paragraph beginning, "There does seem to be flexibility" and the one beginning "Another potentially missing assessment," refer to site-specific applications and it should be made clear that is so. A Panelist and Boissevain spoke of high end populations. Another said this was not structural to the 3MRA – all you would have to do is include a distribution for the population of interest. Brown thought there were distributions that reflect their patterns, but others thought the question was the choice of distribution for the exposure factors. Theis asked, then, how should the second para be stated. Carlisle offered to re-write, incorporating some references. Foran referenced Carlisle's Appendix on exposure duration and found it sympathetic to what needs to be brought out here, "The failure to include . . . distorts . . . such as farmers." A panelist said they would have to look at volume 4 to see if these are missing. Boissevain is willing to look into this.

Steve Kroner of OSW said that, for one particular receptor group (farmers) they truncated the distribution at the high end. That is an example of where they excluded a

subpopulation. A Panelist responded that he, too, had looked at the exposure factor handbooks and found that the standard ones are not representative of subsistence farmers and native Americans. Carlisle has the lead and was cautioned to get rid of the word "potentially"

Brown, who authored Appendix 2B2, is happy to see it go and no one objected.

There being no more comments on 2b, discussion moved to 2c which focuses on setting national risk based exit levels, which is why the MCA is discussed here, beginning on page 7. All of the material from the beginning of on page 7, beginning with **Monte Carlo Analysis -- Discussion** to page 9 is also in the Appendix. Where do we want it? It talks about percent protection. It has an explanatory graph for percent sites protected, then it goes on to talk about what is not addressed in the MCA. Murarka, Smith and Merrill think it should stay in the body. Carbone is concerned about the length and density and whether it will lose the EPA managers. Therefore, he urges Merrill to make the discussion less technical, to emphasize the implications of the way EPA has done the MCA, and what it does not provide. Maddalena tried to clarify whether both an appendix and the text should be kept. Merrill thinks so, but that some redundant material could be eliminated. He hears Carbone say the body, as it stands, is still too much. This thinks it is dense because it is complicated and he doesn't want to short-change the analysis. Carbone said, on second thought, the body of the report could outline the Panel's position, then reference the Appendix. Smith wondered whether an outline type approach would work. Merrill thought it could be re-arranged by beginning with a para supporting the use of MCA, articulate four issues that aren't included that we temper the statement with, and then give the five recommendations, then have the discussion below and detailed in the Appendix. Murarka will take a shot at this and run it past Merrill.

Regarding recommendations, the Panel found the first one confusing and it will be rewritten. The third draft reads, "1. The Panel recommends reconsidering the use of the "pseudo 2-D" terminology. Given that the "two dimensions" of risk analysis in 3MRA appear to revolve around dual protection metrics of population protection and percent of sites meeting this population protection, the Panel suggests using terminology that more accurately reflects these dual protection criteria (e.g., "Dual Population Protection" MCA). Furthermore, as described in response the Charge Question 4, the Panel recommends that the documentation describing the Monte Carlo Analysis in 3MRA be significantly revised in order to describe the analysis more succinctly."

The second will be altered from recommends to suggests and will acknowledge the work EPA is already doing. The third draft reads, "2. The Panel recommends that the Agency consider modifying the method of processing the MCA results. The Panel finds the current approach lacks transparency, and also appears to discard valuable information. See Appendix Q2c.2 for further details. We do understand from the Agency, that this proposed change may impact the storage requirements for the MCA results."

The Panel agreed on the third recommendation as currently worded, "3. The "resolution" of the modeled Cw range should be addressed. In some instances, two orders of magnitude separate Cw intervals, and this will inevitably lead to crude interpolation of the exit levels (with unknown biases). One possible approach to do this would be to conduct an initial set of model runs in order to

determine an approximate Cw range for the exit concentrations. Once an approximate concentration range is identified, the range of Cw's within this narrowed range could be selected such that the interval between each successive Cw is less than an order of magnitude.”

The chair finds the last two confusing. They are,

”4. Sensitivity analyses planned for 3MRA model/exposure parameters will no doubt reveal those that have very large impacts on model output. Prior to implementing the 3MRA and developing exit levels, the Panel recommends that the Agency conduct a 2nd order MCA analysis using a manageable number of such key parameters (*e.g.*, say less than 20 input parameters for example), for a subset of chemicals, one or two WMU types, and a reasonable subset of sites. Such an analysis would provide a more quantitative assessment of the degree to which uncertainty in key input distributions in turn impacts the exit levels.”

and

”5. The Panel recommends including a 2nd order analyses that include the uncertainty/variability of chemical toxicity factors to the MCA. In the Monte Carlo analysis, toxicity parameters are treated as fixed when, in fact, they are both variable (not everyone’s threshold is the same) and uncertain (most criteria are based on laboratory animal data). On the one hand, this has the effect of artificially narrowing the distribution of risk and percent population protection. However, because the fixed values are upper-end estimates, the distribution of risk versus probability is artificially shifted to the right (meaning that a given scenario appears more risky than it really is). Ideally, toxicity parameters should be entered as distributions, like other variable and/or uncertain parameters. It should be a long-term goal of EPA to develop distributions for toxicity parameters. While the Agency has indicated it does not intend to adopt such an approach, at the very least, the documentation should make it clear that the risk and hazard estimates corresponding to the exit levels are exaggerated on the basis of the selection of high-end toxicity factors. However, even if the Agency will not incorporate toxicity variability/uncertainty in the derivation of the exit levels, such an analysis could and should be conducted on a subset of the chemicals that are being modeled as part of the uncertainty/sensitivity (UA/SA) analysis. Published studies describing possible approaches that could be considered for this analysis are listed in Appendix Q2c.3.”

#4 looks like a pre-condition for national exit levels

The Panel has already admitted a full second-order MCA cannot be done, so why are they asking for something that can’t be done. Carbone suggested a limited sensitivity analysis followed by a full second level uncertainty analysis on those. Maddalena thinks the Panel agreed a manageable second order analysis could be done and would be a good thing, but it has to be a very constrained and limited analysis.

Boissevain suggested something like a demonstration exercise. Maddalena questions whether reducing the number of parameters from 700 to 20, does it reduce the time to run the second order MCA? Carlisle thinks the issue is parameterization, not run-time. He confirmed uncertainty and variability are separately characterized and run as separate loops so that we then have (DFO did not catch last few words.) He does not know to what extent this is intended for toxicity parameters, but for those, this would be a severe challenge. He fully supports incorporating PDFs for toxicity, but this other

would be a huge task. Merrill wasn't thinking of this application. Eschenroeder thinks "second order" should be dropped from number five, but not number 4.

Smith says that if you are working on a demonstration exercise you can say the demonstration is limited but gives insight about other factors you could include, which are the most important, and what you might guess from looking at field validation studies of models. Theis can understand this as a demonstration exercise. Merrill will take a stab at clarifying this language and make it clear the Panel is not asking EPA to develop exit levels on this basis.

Eschenroeder suggested a new first sentence for recommendation #5 along these lines, "The Panel recommends extending the MCA to include uncertainty and variability of toxicity factors." Carlisle asked if this is a pre-condition. Eschenroeder thinks it makes the analysis more real. Brown says 3MRA has the capacity and this isn't the way to tackle a policy question. There seemed to be agreement this was not a pre-condition. Perhaps it will be a suggestion.

It sounds to Theis like the Panel wants this to be done before 3MRA is used to develop national exit levels. Carbone doesn't see why this should be a precondition for use. He doesn't think it is any heavier than the other issues the Panel brought up. Theis thinks there are very few that have been brought up for national level exit levels, there have been some on site-specific use. Theis thinks this is the first recommendation of the Panel that adds value to the national level analysis.

There were no other suggestions for improving the response to Question 2.

At 4:00, the Panel moved to question 3A. DePinto had expanded it to include Boissevain's concerns on data aggregation, which she wishes to reconsider in light of the Agency's comments on the third draft. Her point was that there is loss of resolution; EPA says there isn't. She wants to check. In terms of verification, a panelist thinks EPA did a stellar job. It was quite impressive and ought to come out as a complement to the effort they put into it, but it doesn't seem to jump out as a kudo here. Perhaps what is in the first para is enough.

Theis may move the third paragraph, on bias and error propagation.

On 3b, under Panel commentary, the first part replicates part of the response to question 1 and the redundancy will be eliminated one place or the other. There were no comments on page 2, but a question was raised about the strength of a recommendation under *Model-Data and Model-Model Comparison*, beginning, "The panel applauds the effort that has been initiated for mercury at a former chlor-alkali site, but urges that additional, albeit partial, site-specific datasets involving other contaminants be located, with emphasis on . . ." A panelist said they wanted EPA to do more field testing of the model. Thibodeaux thinks the key words are "do more" Brown said he thought the Panel was asking the Agency to be vigilant to obtain new data sets for validation of modules that have not been extensively validated. The easiest place to do validation in the data matching sense is the individual modules. Travis thinks the Panel recognizes the data sets don't exist. It is a very difficult thing to get the data sets. Thibodeaux said if we

can't validate 3MRA and you can't validate the modules, where are you? Looks like think ice to him. Travis seems less optimistic. Theis thinks Brown captured the thought. DePinto spoke of increasing confidence.

Carlisle had a small point about the first sentence, "The panel is concerned that the validation procedures include careful comparison with actual datasets, " and suggests something like, "The panel encourages . . . "

Theis brought the Panel to the discussion of GSCM on pages 6 and 7

With regard to the General Soil Column Model (GSCM module is embedded within several of the transport modules of 3MRA), the panel is concerned that this module, which is not a legacy model with a long history of peer review and field-testing, has not received the same degree of scientific scrutiny as other modules. Of particular concern with this model are its method of mass transfer from wastes to environmental media and the assumption of local equilibrium among phases. A more detailed discussion and review of this module is presented in Appendix Q3-1.

Given that the GSCM is relatively untested and has some potential theoretical inadequacies, it is incumbent upon the agency to convincingly demonstrate that the GSCM provides the needed accuracy, using data matching under a wider range of conditions and chemicals, comparison of results with more robust models, and theoretical or error analysis. The LAU Module, which contains GSCM, has been compared to experimental data obtained on organic chemicals during application of municipal wastewater onto soil (Schmelling, et al. 2003). Four elements of evaluation were tested: volatilization, first order chemical decay, appropriateness of the quasi-analytical solution an LAU thickness and temperature play significant role in volatilization. The volatilization rate was reported to be in the "right order of magnitude" for all categories of compounds. However, for the highly volatile chemicals the model was consistently lower than observed. In another validation exercise for the LAU module, measured half-lives of dioxin in sewage sludge were compared. Remaining concentrations at equivalent human health risks were calculated for the LAU in order to estimate the half-lives. Results suggested that: "The range of half-lives over the selected percentiles was 20 to 48 years, which is in reasonable agreement with the observed half-lives at several monitored sites." However, the numerical range was not reported; and the number of monitoring sites not agreeing was not reported. The panel also recognizes the model comparison effort between GSCM and MODFLOW-SURFACT that has recently been made by EPA. Several insights were gained through this exercise, including an explanation for why GSCM gives higher volatilization fluxes in

the first several years of a simulation – it solves for fluxes sequentially with volatilization computed prior to leaching. These validation exercises are the type of activities that the panel strongly recommends; however, the panel recommends continued and more rigorous testing of this crucial 3MRA module with a more complete documentation of the results.

Thibodeaux still owes DePinto the Appendix.

This wants a consistency check between this language and what is in the response to question #1. Boissevain said the Agency wants to know whether the GSCM can be used, or not. This asked for the sense of the panel and read what he had from the response to Q1 ending “it will be incumbent on the Agency to convincingly demonstrate . . . “ This does not say it has to be fixed up before the model can be used. Carlisle said the Agency’s comment says, to make it clear whether the model can be used. Smith thinks he understands Maddalena’s concern, but he sees the Agency as putting forth in a gentle way that they would like things clarified. It is not that subtlety is lost on them, but ambiguity is not useful.

This came up with some language that got general agreement and then “yeas” Brown remained on the fence because lots of models aren’t mechanistic. BOD, for example, is modeled as first order, although in fact, it isn’t. The question is whether or not the approximation is adequate to the task at hand. Thibodeaux said he would agree if it weren’t a source term. Travis says cut off volatilization, see what you get in groundwater; then to the opposite. That would allow you to bound the conditions. Brown doesn’t think this limitation is very limiting in this situation.

They went to page 8 of the response to question 3b, “In that regard, the panel recommends use of 3MRA for its stated purpose pending completion of the planned performance validity tests. However, the panel strongly recommends to validate and upgrade the 3MRA model and to clearly communicate the results of this work to the stakeholder community along with commensurate statements regarding model limitations and caveats for its use. “ The chair thinks the stated purpose is national level exit concentrations. DePinto says he was referring to EPA completing things they said were under way. The chair would like the text to be specific.

At 4:45 the Panel moved to discussion of the response to question 4. The only comment the chair had was being clear when the text applied to national level calculations and when to site-specific applications, for example and the bottom of the first page.

Carlisle had a question about general recommendation #2 relating to population protection at individual sites, but it was resolved without changes.

A panelist suggested item 7 be changed to “complete and document” a users guide. This wonders if “prior to” is needed for national exit levels. He thinks the users guide would be useful for people on the outside doing site-specific analyses. Panelist thought “prior to” could be eliminated, and “users manual” added.

Brown had a comment on the last line of item 8 on page 3. He suggested “clear definition and consistent use” of screening.

Murarka brought up the issue of style and tone and hoped that the chair would edit the report so it sounds like it was written by one person. The chair promised to make it suitably bland.

At 4:50, the chair summarized where we are. He hopes to re-edit the text before February 27. There are few changes for the responses to questions 3 and 4, more for question 2. Murarka will do what he can today or tomorrow and send to Theis. Theis will do the editing for Q1. He would like all materials by Thursday February 12. Murarka and Theis will draft a cover letter February 12. Then he will edit for consistency. He will turn it around by February 20 so people will have a week to think about it. Besides the chapter coordinators, material is expected from Carlisle, Thibodeaux, and Stubblefield. Stubblefield will send his stuff to Murarka this afternoon.

Theis has not had a chance to read the Agency’s comments on draft #3, but he had a set on draft #2 which he used in today’s discussion. We should read them and take them seriously, just as we do public comments. Carlisle wants to respond to a couple, possibly by making some of his text more clear.

At 5:05 Nadine Weinberg had comments on behalf of the HWIR Consortium.

On charge question 1, the Panel’s discussion about whether the 3MRA can be used today. They would like “today” struck because elsewhere, the Panel appears to be identifying things that need to be done before the model can be used. She thinks it would strengthen the discussion to list what needs to be done before the model must be used and other recommendations as well. It would be easier for the Agency and the public. Also, the discussion of evaluation of ecological impact she thinks the big issue is the lack of data and the assumptions the Agency has used to fill the data gaps. The criteria are at least based on some data.

Question 2b, asks about the flexibility of the model, there is a statement to the effect that even though the model is flexible it isn’t necessarily correct. She thinks the response to 2a should include a parallel sentence to the effect that even though there are many good things, the answers could still be wrong. Regarding native American populations, the distribution in the exposure factor handbook is clearly protective of subsistence populations.

She had no other comments.

At 5:10 EPA’s Gerry Laniak thanked the Panel for their efforts and the DFO for the logistics. They appreciated the invitation to comment on the three questions in the Reader’s Note. This conference call has responded to their questions on clarity, technical error and misunderstandings. He wants to address the adequacy of the Panel’s response to the charge. They feel the Panel did respond to the charge and did even more than that. The Panel took on the task and was thorough. Because the Panel did, they have good input on how to prioritize the hundreds of comments they had

received earlier. When you couple that with the sensitivity analysis they have planned and are implementing, this gives them some direction they much appreciate.

He then touched on a couple of other issues. When the Panel discusses the 2-D analysis, he would like the Panel to be very, very clear and acknowledge they have about 2 minutes per scenario and just think about the implications of what they recommend. The second is the GSCM, which is really tough. Given the clear statement that no other model exists that does what this model should do, it seems inconsistent to them to ask them to prove what no one else has. They recognize that they need to move this forward, but think it should not be a pre-condition.

They appreciate the Panel's sensitivity to distinguish between:

National and site-specific

National policy v what the 3MRA technology can and can't do, especially with regard to informing

Pre-condition v necessary future development

They are very pleased that this is coming to conclusion. They are pleased that the Panel gave so much time to it. It tells them the work is important, regardless of what the individual recommendations may be.

Theis thanked the Agency for the time they gave and said they deserve recognition for embarking on this pathway.

Babendreier said he had tried to provide specific information on the computational burden of the 2D analysis, which is not technically feasible at the national level. He asked with the benefits are of such an analysis on a site-specific level.

Dr. Theis adjourned the meeting at 5:20 p.m..

Respectfully Submitted:

Certified as True:

_____/s/_____

Ms. Kathleen White
Designated Federal Official
Environmental Engineering Committee

_____/s/_____

Dr. Thomas Theis, Chair
3MRA Panel

Attachments (hardcopy)

1. Agenda for the meeting
2. List of attendees
3. Committee roster
4. Federal Register Notice
5. DFO's notes from the January 9 Fact-Finding Call on the 2 km radius
6. DFO's notes from the January 12 Fact-Finding Call on uncertainty