

**Summary Minutes of the Multimedia Multipathway Multireceptor Risk Assessment  
(3MRA) Modeling System Panel Meeting  
October 28-30, 2003, JW Marriott Hotel, Washington D.C.**

Panel Members: See Panel Roster – Attachment A.

Date and Time: Tuesday, October 28, 9:00 A.M. – 5:30 P.M.; Wednesday, October 29, 9:00 A.M. – 5:30 P.M.; and Thursday, October 30, 8:30 A.M. – 4:00 P.M.

Location: JW Marriott DC Hotel, 1331 Pennsylvania Ave., N.W.,  
Washington, DC.

Purpose: The purpose of this meeting was for the Panel to be briefed by the Agency, hear public comments, and continue its discussion of the Multimedia, Multipathway, and Multireceptor Risk Assessment (3MRA) Modeling System in relation to the charge questions, as well as continue working on the panel's report to the Agency.

Attendees: Chair: Dr. Thomas Theis

Panel Members: Ms. Andrea Boissevain  
Dr. Linfield Brown  
Dr. John Carbone  
Dr. James Carlisle  
Dr. Peter deFur  
Dr. Joseph DePinto  
Dr. Alan Eschenroeder  
Dr. Jeffery Foran  
Dr. Randy Maddalena  
Mr. David Merrill  
Dr. Ishwar Murarka  
Dr. Doug Smith  
Dr. William Stubblefield  
Dr. Louis J. Thibodeaux  
Dr. Curtis Travis

EPA SAB Staff: Dr. Vanessa Vu, SAB Staff Office Director  
Ms. Kathleen White, DFO

Others attending:

Robert Ambrose, U.S. EPA / ORD  
Justin Babendreier, U.S. EPA / ORD  
Tom Barnwell, U.S. EPA / ORD  
David Cozzie, U.S. EPA / OSW  
Jace S. Cuje, U.S. EPA/ RRB  
Rick Haeuber, U.S. EPA / OAR

Barnes Johnson, U.S. EPA / OAR / ORIA (formerly OSW)  
Lori Kowalski, U.S. EPA  
Stephen Kroner, U.S. EPA / OSW  
I. Annett Nold, U.S.EPA / OEI / OIAA  
Rosemarie Russo, U.S. EPA / ORD  
Zubair Saleem, U.S. EPA / OSW  
Donna Schwede, U.S. EPA / ORD  
Candida West, U.S. EPA / ORD  
Kurt Wolfe, U.S. EPA / ORD

Steve Beaulieu, RTI  
David Case, Environmental Technology Council (ETC)  
Karl Castleton, PNNL/DoE  
Margaret Emory, IFC Consulting  
Mario Gamboa, ACC  
William Gillespie, NCASI  
Baxter Jones, ICF  
Nadine Weinberg, ARCADIS

Contractors supporting the meeting

**TUESDAY, OCTOBER 28, 2003**

Meeting Summary

The Discussion generally followed the issues and general timing as presented in the meeting Agenda (Attachment B) except that the meeting began at 8:30 A.M. on Thursday, October 30.

Welcome and Opening Remarks

Ms. Kathleen White, Designated Federal Officer (DFO) for the Panel, opened the meeting and welcomed participants. She advised participants of an addition to the day's agenda: Dr. Barnes Johnson (U.S. EPA) would address the Panel first, as he would not be available later in the day.

Dr. Johnson thanked the Panel for the work it has conducted, adding that its advice so far has been very useful and valuable to the 3MRA development group. He commented that it has been helpful to have external reviewers discuss and write about the model, and that he would look forward to the continued discussion over the next three days.

Dr. Vanessa Vu, SAB Staff Office Director, also thanked the Panel on behalf of the Agency, especially the leadership of Dr. Theis (Panel Chair) and the work and commitment of all Panel members during this review. She also thanked Ms. Kathleen White (DFO), the Agency representatives and writing team, and members of the public who have participated in the conference calls and meetings.

Ms. White added her welcome to all attendees, and informed those present that the 3MRA Modeling System Panel is a Federal Advisory Committee, whose meetings are public as required by the Federal Advisory Committee Act (FACA). The FACA also empowers this Panel to provide advice to the Administrator. Public notice is given of all meetings, and discussions are conducted in sessions where the DFO is present, to assure that FACA requirements are met. Public comments are invited during public meetings. No requests for comments were received prior to the meeting; members of the public who wish to provide comments were asked to inform the DFO during breaks. One written comment was submitted by ETC and is available as a handout (Attachment N).

Records are maintained of all public meetings of the Panel and are made available to the public. Minutes of this meeting will be taken and will be available about one month following the meeting. A transcript will also be recorded; however, the SAB cannot certify the accuracy of transcripts.

Biosketches of all Panel members are available in hard copy, as well as on the SAB website. Ms. White added that two Panel members were not yet present but would be arriving later: Dr. Alan Eschenroeder and Dr. Curtis Travis. Panel selection took place in accordance with the SAB's Panel Formation Process, a copy of which is available on the SAB website. SAB Staff documents the rationale underlying the selection of each panel in a "Panel Selection" document, a copy of which was provided at the meeting for review. Panels are selected after SAB Staff

completes its review of information regarding conflicts of interest, appearance of lack of impartiality, and appropriate balance and breadth of expertise, knowledge and experience needed to address the charge. The SAB Staff Office Director, who is the deputy ethics official for the SAB, has determined that there are no conflicts of interest or appearance of a lack of impartiality for this review. Therefore, no waivers were needed or considered for any of the panelists.

If any panelist discovers a potential for conflict of interest, or appearance of lack of impartiality, it is the duty of that panelist to inform the DFO. It is the DFO's responsibility to then work with EPA officials to document the issue. It is also the responsibility of each panelist to identify during the meeting any topics that arise which may draw on that panelist's research.

Ms. White concluded her opening remarks by expressing her appreciation for working with this Panel, and thanked the members for their work and the Agency representatives for their responsiveness.

#### Purpose of the Meeting and Brief Introductions

Dr. Thomas Theis, Panel Chair, also welcomed the Panel and Agency participants. He stated that the Panel has held ten conference calls since its last meeting on August 26-27 – some were for review purposes and others were fact-finding calls. The current document is Draft 1.2, the Panel's current working draft (see Attachment J), which includes changes made since the last meeting. Also available is the Agency's response to peer review comments (see Attachment R).

Dr. Theis then asked the Panel members, EPA representatives, and members of the public present to briefly introduce themselves.

Following the introductions, Dr. Theis summarized the plan for the meeting. Scheduled first were four Agency presentations, which would address issues that arose during Panel discussions: mass conservation, data comparisons with the TRIM Phase model, and uncertainty and sensitivity analysis.

Beginning on Wednesday, October 29, the meeting would consist of mostly Panel business, to include writing and editing the report, and discussing the summary points drawn from the Panel's discussions to-date. Though the Panel will continue to work on the report through conference calls, this is most likely its last face-to-face meeting.

Dr. Theis added that, though the goal for completing the report was the end of November, he did not think it appropriate to rush the Panel to premature words or judgment. The Panel may therefore take a longer time to finish the report if necessary.

Dr. deFur wanted to know if there was a plan to hold an additional meeting, in the event that the Panel does not reach consensus today on all the major points.

Dr. Theis explained that the Panel could discuss this if necessary, but added that an additional meeting was not likely.

Dr. Carlisle asked whether the Panel would disband following its review, and whether a new panel would be formed if work on this model continues. He commented that some of the recommendations proposed may take the Agency years to implement, and wanted to know if the Panel would have a chance to come back and review this work.

Ms. White explained that the SAB frequently reviews changing products. The Agency, however, does not have the resources needed to review each of these products several times. The process is for the Panel to review and provide its recommendations to the Agency; the Agency then responds to each of these recommendations, though it may not follow all of them. Panels do not go back to make sure the Agency has acted on all the advice provided. If new needs were to arise in the future, a new Panel would be formed to review a different product.

### Agency Presentations

Presentations by Agency staff involved in the development of 3MRA are summarized below. Slides from each presentation were distributed at the meeting and are included as attachments.

### **3MRA Mass Balance Concepts and Directions**

*Gerry Laniak (ORD/NERL) and Karl Castleton (PNNL)*

Dr. Laniak presented information on the balance and conservation of mass in the 3MRA model (see Attachment E). Before beginning his presentation he informed the Panel that he would not be presenting finished products – instead he would describe the Agency’s understanding of the Panel’s concerns, and present the 3MRA working group’s view of mass balance in this system. Following the presentation Dr. Castleton would present a demonstration of the software designed to deal with the mass balance issue in 3MRA.

Dr. Laniak began by stating the objectives for his presentation – primarily to address the SAB’s concerns about elements of mass balance in 3MRA, and describe the 3MRA approach and assumptions related to mass balance. Software for graphically displaying chemical fluxes will also be demonstrated to the Panel. Dr. Laniak noted that the Panel had requested specific mass balance exercises, but the 3MRA team did not have the chance to conduct them.

Several concerns expressed by the Panel were listed (slide 3), but the bottom line was that the Panel wanted to know where all the mass is at all times, or, short of that, to be assured that mass balance errors do not occur during the simulations.

Elements of mass balance in 3MRA include concentration fields in environmental media; secondary sources; inter-media fluxes; media to biota transfer; disappearance (e.g., biodegradation); and physical removal from the modeling domain.

Source unit mass balanced is fully quantified in 3MRA, as are losses and emissions to all media. All individual modules balance mass internally. Inter-media fluxes are written and read using a

core applications program interface (API) that verifies data characteristics. Secondary sources are considered insignificant contributors to the overall risk estimate, and chemical mass transferred to biota is assumed small relative to mass in the ambient medium. Dr. Laniak explained that the model developers made sure there is no double-counting for mass in 3MRA.

Dr. Murarka wanted to know whether the mass for each chemical from one medium to the next is tracked and summed over time. Dr. Laniak explained that it was, and that this would be demonstrated in the simulation of the software by Dr. Kastleton.

Dr. deFur commented that the burden would fall on the Agency to demonstrate that the last two assumptions listed (slide 5) are accurate. Dr. Laniak agreed, but stated that there are no data yet to demonstrate this. However, if information is obtained that indicates these assumptions are incorrect, they will be re-considered.

Dr. Laniak continued, and presented a series of diagrams showing all 3MRA modules and the connections between them, as they relate to the transfer of mass (slides 6-11). He indicated those modules where concentration fields are generated; where secondary sources are generated; those that report fluxes to other media; where biochemical disappearance and biotransfer occur; and where physical removal from the system occurs.

Dr. Foran commented on the last two assumptions on slide 5, stating that the only reason these assumptions were included seemed to be that the information could not be incorporated into the model. Dr. Laniak confirmed that was the case. In addition, secondary sources and mass transferred to biota were considered not significant with respect to the particular modeling problem statement 3MRA is designed to answer.

Dr. Laniak added that the system is designed to express itself with more than a single number in the output; the entire information package is available as a database in a standardized form, so that software can be written to access those files as needed.

Dr. Murarka commented that NPDES permitted discharge from surface impoundment could go directly to surface water, however that was not indicated on the diagrams presented. An EPA representative explained that, though the model depletes mass, it does not track movement from surface impoundment to surface water.

Dr. Theis suggested at this time that the discussion should move along. He stated that the Panel had two suggestions for the Agency: demonstrate mass conservation; and do so in a highly partitioned substance. He asked whether Dr. Laniak could frame his responses in light of those "extreme cases."

Dr. Laniak explained that he could not demonstrate that today, as he did not yet have the required data.

Dr. Murarka asked how the model deals with mass flux. Dr. Laniak used the example of mass flux from the atmosphere due to deposition, and explained that concentrations of particular points are reported. This may or may not be information that can be used to construct a plume.

Dr. DePinto asked how mass is balanced within a module. Dr. Laniak said that, using the same example as above (atmospheric deposition), a number of deposition points would be used. In general, a module will characterize a portion of the concentration field. He added that the TRIM comparisons would be used to make sure the assumptions were correct.

Dr. Stubblefield wanted to know whether the surface water module takes sediment deposition into account, and if so, the assumption used to remove that material from the sediment. Dr. Ambrose replied that it is assumed no mass is lost in stream systems. He explained further that sedimentation is not a removal process, although mass can be sequestered in the lower sediment layers. In response to further questions he confirmed that the food web is considered in the module, and mass is partitioned to the biota as well as to sediment.

Dr. DePinto commented that this is a reasonable assumption, adding that even zebra mussels do not hold a lot of mass – though they do cycle it. He said he was not concerned about this provided the algae component is considered (which has already been done). He asked whether algae concentrations are fed in the next module. Dr. Ambrose explained that the modules use the same partition coefficient – this is a partition coefficient-based methodology.

Dr. DePinto then stated that there is not a partitioning between surface water and the aquatic food web; mass does not transfer, instead it is computed taking into account potential losses from the balancing of mass. Dr. Ambrose confirmed that the food web module does not have biomass associated with it, only mass partitioning. Both modules, however, are consistent in using the same partitioning coefficient. He added that mass higher in the food web is assumed to be insignificant when compared to mass at the base of the food web. Dr. DePinto argued that this does not constitute mass balancing of the entire system.

Dr. Laniak then continued with his presentation, and outlined the long-term and short-term strategies for addressing mass balance issues in 3MRA. Short-term goals include developing software to read the 3MRA Global Output Files (GRFs) and graphically display the mass associated with inter-media fluxes; and assessing the biotransfer issue in context of the model comparison with TRIM. Long-term strategies will be investigating modification of the modules to report more mass balance information, as well as numerical routines to estimate mass in media plumes.

Dr. Castleton then presented a demonstration of the initial mass balance software – an extension of the site visualization tool which finds the mass balance information and displays it graphically. Graphs were presented as examples showing the release of mass from each source (e.g., air, watershed) for two chemicals, arsenic and benzene (slides 15-18). Dr. Laniak added that the information plotted was from one of the sites contained in the CD set, for a 2 km radius.

Dr. Murarka commented that arsenic should not be moving through the air as much as was indicated in the graphs. Dr. Castleton explained that this example was from a waste pile with a lot of [PM30?] emissions.

Dr. Castleton continued, and explained that in the cumulative source release graph (slide 17), it was evident that benzene volatile emissions are driving the release. He confirmed, in response to a question, that adding all the individual releases should result in the cumulative release.

Dr. Laniak concluded with a summary of the main points presented, emphasizing that 3MRA is moving toward a complete system mass balance / mass accounting approach (slide 19).

### **3MRA / TRIM Model Comparison Study**

*Gerry Laniak, ORD/NERL*

Dr. Laniak presented a status report for the Panel on the study comparing 3MRA to the TRIM fate model (see Attachment F). The main objectives of the study are to test the integrated model in a quality assurance context; to initiate work leading to increased knowledge on how 3MRA functions under specific environmental conditions; and to initiate efforts to compare 3MRA results with observed data and other multi-media approaches in the context of model validation. Although this presentation is an opportunity to gain feedback from the Panel on the model comparison process, it is not intended to elicit detailed review of the quantitative comparisons, as these comparisons are not yet final.

A chlor-alkali facility with mercury fugitive emissions was selected as the site, and endpoints were selected for model comparison. After modeling inputs are formulated, the initial comparison results were interpreted as a set. Modeling results will also be compared with available monitoring data.

Several caveats or “things to note” were then listed, particularly differences between the 3MRA and TRIM models that could affect their results, and assumptions used in the study (slides 6-7). A diagram was presented of all 3MRA model components, highlighting those which were used in the comparison (slide 8). Another figure indicated the specific modules used in the comparison (slide 9). Several images of the site and nearby areas were also shown (slides 10-18), including maps of land use, surface water / watershed, and ecological habitat delineations.

The results of comparisons in multiple endpoints were presented and discussed throughout the remainder of the presentation. Comparison data were presented for air, watershed soils, surface water (sediments and water column), and terrestrial biota (worms, roots, leaves, omnivores, small birds and small mammals) (slides 20-59), as well as a summary table listing all comparison results (slide 60). Fish tissue comparisons are also being conducted, though data were not available for this presentation.

Dr. DePinto asked what time periods the comparisons represent, referring specifically the comparison data for air. Dr. Laniak replied that these were thirty-year averages. He also confirmed that TRIM is a deterministic model, and added that national distributions were used for the partitioning of mercury.

Dr. Ambrose commented that the 3MRA prediction of elemental mercury in the water column seems to be too high. This is due to the mercury cycling model used in 3MRA, but not in TRIM.

Dr. DePinto wanted to know whether 3MRA includes volatilization of mercury from water to air. Dr. Ambrose replied that it does, but that amount is not added to the air, as it is not needed for a site-specific model like 3MRA. He added that loss from the model is accounted for, and the key was to estimate the total and methyl mercury correctly.

Dr. Maddalena asked whether this was a blind comparison, i.e., whether the inputs used were derived independently from each other. Dr. Laniak confirmed that they were, but only with respect to partitioning coefficients; transformation rates were not modified. In response to another question, he explained that the total concentrations were not the same because the loading rates used were not the same.

Dr. Laniak commented on the data comparison for mercury concentration in earthworms, pointing out a difference of two orders of magnitude between TRIM and 3MRA. This difference is highest near the sources, and may be due to the fact that TRIM compartmentalizes the soil surface and root zone (beyond 55cm), whereas 3MRA does not. Dr. Thibodeaux asked whether this meant the depth of mixing for TRIM was deeper than for 3MRA. Dr. Laniak confirmed that it was, and this results in a difference in what the worms have access to. He added that he would follow up on this, and have more information on it in the initial study report (scheduled for completion by December 2003).

Dr. Laniak then pointed out the difference between the two models in predictions for mercury in omnivores, and explained that the model results were within one order of magnitude. Dr. Carbone wanted to know whether a difference of one or two orders of magnitude was significant between two very low concentrations. Dr. Laniak agreed that it would be more significant in the higher concentrations. Dr. Carbone recommended that the Panel consider the importance of such differences, i.e., whether they are likely to have enough impact to affect a decision.

Dr. Laniak reminded the Panel that the purpose of this comparison was to gain insight, and not to predict measured concentrations. He acknowledged that if the model predicted concentrations much higher than observed, it would indicate a problem. However, validity cannot be determined in this case by looking at comparisons with monitoring data, as 3MRA is not modeling to these endpoints. Dr. Murarka suggested it might still be useful to get an appreciation for what “reality” is, and how it is different from the model’s results. Dr. Maddalena added that it is especially important to compare the relative values in different media (monitored versus modeled) rather than absolute values. Dr. Laniak agreed.

Dr. Theis asked whether the 3MRA team had any plans to conduct further comparisons using other chemicals, as mercury can be difficult to work with. Dr. Laniak replied that there is no research currently planned, but that the team would like to do this in the longer term. He added that any such recommendations on possible next steps would be useful to the team. Dr. Carbone suggested using sensitivity analysis – a Monte Carlo approach – to generate distributions of estimated concentrations, which would then be compared to monitoring data. Dr. Laniak said this was a good “next steps” idea, and that it should be easy to add distributions in for the partitioning at a later time.

Dr. DePinto asked how both models could be computing numbers that are significantly different from monitored concentrations, unless there was a problem with the source entered. Dr. Maddalena explained that only the facility itself was taken into account as a source; if there were an incinerator next door, for example, it would not have been considered.

Dr. Murarka and Ms. Boissevain discussed whether this could be considered a validation exercise. Dr. Murarka stated that the purpose of the comparison was to determine if there are fundamental differences between the two models, but agreed with Ms. Boissevain that the ultimate step would be to assess model validity.

Dr. DePinto commented that the only thing the model is designed to do with an original source is dilute and decay it. Even a very conservative model could not approach observed concentrations, therefore there must be differences in the sources, not in the processes. Dr. Murarka added that there are differences in the model constructs that could also contribute to the different outputs. These model runs, as conducted, are not yet ready to be compared with monitoring data.

Dr. Foran asked whether relationships between the two models could be compared. Dr. DePinto replied that this could be done with linear models. It is the same as comparing the ratios among media.

Dr. Thibodeaux asked whether the mercury at this site was originating strictly from air sources. Dr. Laniak explained that there were additional sources – including some air sources – that were not modeled. He added that he could look for an estimate of the total source, and compare it to what was used in the model.

Dr. Laniak informed the Panel that the goal of this study was a final quality assurance to test the integrated model. Part of the long term effort is to improve this model and make it more appropriate to different applications. Some questions for the Panel include whether the 3MRA team is following the right process in improving this model, and what incremental steps can be taken as the team moves towards model validation.

The Panel adjourned for lunch and reconvened at 1:30 P.M. Dr. Curtis Travis joined the meeting after lunch.

### **Investigation of Averaging Periods and Pollutant Concentration Distributions (EECs)**

*Robert B. Ambrose, ORD/NERL*

Dr. Ambrose presented the results of an investigation of averaging periods and pollutant concentration distributions (see Attachment G). A set of thirty-year simulations were performed using the pesticide exposure assessment software EXPRESS, which links the field scale PRZM model with the water body EXAMS model. Four idealized chemicals were simulated in a standardized ten-hectare field draining into a one-hectare pond for eight locations around the country. Uniform chemical applications were specified every two weeks throughout the simulations, and the differences compared between the predicted upper 10<sup>th</sup> percentile four-day

average concentrations and the upper 10<sup>th</sup> percentile annual average concentrations. For low decay chemicals with medium or low partition coefficients there was little difference between the two. For low partitioning, high decay chemicals, the 10<sup>th</sup> percentile, four-day average concentration was six times higher than the corresponding annual average concentration. For medium partitioning, high decay chemicals, they differed by a factor of thirty. From this it was concluded that comparisons of annual average concentrations with water quality criteria should be relatively unbiased for low decay chemicals, but that significant bias could result for high decay chemicals.<sup>1</sup>

Dr. Murarka asked about the risk implications of the case where the ratios differ by a factor of thirty, specifically whether that meant calculated risk is thirty times less than actual risk. Dr. Ambrose confirmed that was probably the case, and would indicate that, for this class of chemicals, it would not be appropriate to apply 96-hour criteria.

Dr. Carbone asked how this related to 3MRA in terms of source type. Dr. Ambrose said it was not meant to re-create the same source types.

In response to questions Dr. Ambrose also said that the concentrations were dynamic (not steady-state), and that the probability distributions were not cumulative, but rather a “rolling average”.

Dr. Brown asked how the concentration distributions were calculated. Dr. Ambrose replied that he believed percentiles were calculated using the entire thirty-year period. Dr. Brown noted that this would be different from a year-by-year rollup needed for a strict comparison with 3MRA. Dr. Ambrose agreed, but thought that these results would still be qualitatively comparable, saying that this was a quick analysis started last week. 3MRA could be altered to support these more dynamic analyses, but this would take a significant effort.<sup>2</sup>

*After the meeting, Dr. Ambrose sent the following additional comments to add to his response:*

*Dr. Ambrose discussed the statistical rollup procedures with Larry Burns after the meeting, and offers a correction to his explanation of the rollup procedure. EXPRESS takes the maximum four-day concentration predicted for each of the simulated thirty years, then ranks them and produces a Weibull plot, marking the upper 10<sup>th</sup> percentile for reference. This procedure actually makes the results from EXPRESS more relevant to the 3MRA application.*

Dr. DePinto commented that it seemed to be important to look at how often the chemical is applied; he suggested comparing application every two weeks versus every other month, or versus daily application. Dr. Ambrose agreed, but explained that this model only allows for twenty-six applications per year. However, application could be changed to less frequently, e.g., every month. He speculated that doing this will not make a difference for low decay chemicals, but may affect high decay chemicals.

---

<sup>1</sup> Adapted from a summary sent by Dr. Ambrose.

<sup>2</sup> Adapted from text sent by Dr. Ambrose.

Dr. Murarka commented that, in surface water and water column, there is not much mass to decay whether low-Kd or high Kd chemicals are applied, due to the interaction between the two parameters. Dr. Ambrose replied that EXAMS allows the use of two different decay rates: for dissolved versus sorbed phases.

Dr. Stubblefield referred to data from one of the sites (TX, 1<sup>st</sup> bar on graph, slide 13) and noted that there is a difference of one order of magnitude between annual and four-day concentrations, indicating that 3MRA may be estimating an order of magnitude lower than the actual exposure risk; this would make 3MRA less conservative than anticipated. Dr. Ambrose agreed, but explained that 3MRA is intended to produce a national estimate. Dr. Stubblefield remarked that this spoke to the importance of including site specificity in the process.

Dr. Theis recommended revisiting this topic, and suggested moving to the next presentation.

### **Sensitivity and Uncertainty Analyses**

*Justin Babendreier, ORD/NERL*

Dr. Babendreier presented responses to questions previously submitted by the Panel on the topics of uncertainty and sensitivity analysis (see Attachment H). He began by presenting the National Problem Statement for Human Risk, which is the modeling problem statement for 3MRA:

At what waste stream concentration ( $C_w$ ) will wastes, when placed in a non-hazardous waste management unit over the unit's life, will result in:

1. **(Human)** Greater than A% of the people living within B distance of the facility with a risk/hazard of C or less, and
2. **(National)** At G% of facilities nationwide,
3. **(Uncertainty)** With confidence H% accounting for subjective input uncertainty, and confidence I% accounting four output sampling error.

%H → Accuracy in %G; %I → Precision in %G, %H

The goals of the sensitivity analysis were to identify key input parameters that affect the systems-level model response; to develop prioritization for focusing future data collection efforts on key input parameters; and to facilitate the prioritization of review comments to focus Agency resources. The sensitivity analysis looks at the national assessment endpoint, %G.

The goal of the variability and uncertainty analysis was to estimate the confidence bounds on the national distribution of risk results, %G, given currently available data in 3MRA databases.

Although distributions for parameters included both variability and uncertainty, the uncertainty analysis assumed all distributions to be dominated by variability. A 2-D analysis could not be performed because the input sampling error (ISE) and standard measurement error (SME) data were not available, and because of limited computational capacity. The sensitivity analysis plan was designed to test the validity of these basic assumptions in interpreting the national outcome.

Dr. Babendreier then presented a series of issues and concerns the Panel had brought up regarding the uncertainty and sensitivity analyses, along with the Agency's response to each. These responses were discussed by the Panel.

Dr. Maddalena commented that  $K_{ow}$  is applied to every site across the country, yet it may be more important at some sites than others. Dr. Babendreier replied that 3MRA formulates a risk assessment endpoint that goes across all sites.

In discussing the problem of data storage, Dr. Babendreier explained that the disaggregated ELP1 tool allows the user to distinguish what is happening at a site. However, it produces a large amount of information, so a user would need to be judicious about choosing which of the several million outputs are important.

Dr. Maddalena asked whether the sensitivity analysis is conducted every time the model is run. Dr. Babendreier confirmed that it is, and added that Volume 3 examines some of the issues related to data storage.

Dr. Maddalena asked how many model runs would be needed to include more of the model inputs in the sensitivity analysis. Dr. Babendreier replied that it depends on the number of variants in the system, but guessed it would be ten or twenty million runs. He added that SuperMuse is able to do 3-4 runs in one month. Dr. Carlisle suggested setting at a constant value – the minimum value. Dr. Babendreier explained that, although this could be done, it is the simplest form of sensitivity analysis: it would rank the importance of the inputs, but not provide any information on how they may affect model outputs. He confirmed that “global analysis” meant that the analysis examines all parameters.

Dr. Maddalena then commented on the use of uniform distributions to replace a constant distribution, saying that specifying a uniform distribution for an uncertain parameter means one is less certain about this distribution. Dr. Babendreier agreed, but explained that no information is yet available to specify the uncertainty of this type of parameters.

Dr. Maddalena asked what product would be given to decision makers, so they can understand which inputs are important and why. Dr. Murarka commented that the results of the simulations are concentrations that correspond to specified conditions. He also wanted to know whether this is an adequate tool for making informed decisions. Dr. Babendreier stated that the analysis will provide probability distributions with respect to %G – though he agreed this would include a lot of built-in assumptions. The most appropriate thing to do would be to gather a single dataset and evaluate which of the model inputs are the most important ones. In response to Mr. Merrill, he confirmed that the end result will be something that tells decision makers which parameters are key, and that these key parameters will change depending on chemical, pathway, and other factors.

Dr. Brown asked whether the documentation includes a sample sensitivity analysis – either graphically, or in text – so that the Panel could see what the results might look like. Dr. Babendreier replied that such a sample has not yet been included, but that it would be a curve

showing how regression applies to each parameter. Dr. Brown asked for a more detailed explanation on how the “most sensitive parameters” concept would be transmitted. Dr. Babendreier stated that important parameters would be ranked quantitatively, using r-squared values to provide a measure of the importance for each. He added that the Agency is also looking into effective ways of communicating this information to regulators. Dr. Babendreier then confirmed that the results of several sensitivity analyses would be combined, yielding an elaborate matrix for each WMU. Mr. Merrill commented that it would be difficult to come up with a single endpoint – e.g., the five most important chemicals. Dr. Travis thought it difficult to believe that regulators would use the sensitivity analyses; rather, they would be more likely to accept the five “most important” parameters they are given. Ms. Boissevain added that it may also be difficult for regulators to understand information presented in a complicated matrix.

The Panel then discussed the assumptions made as part of the variability and uncertainty analysis. Dr. Murarka commented that the main issue was whether the probability function for a parameter is estimating the central tendency and standard deviation. Dr. Babendreier replied that there are no parameters in 3MRA for which there is currently a probability distribution. Therefore, it was assumed that the means are described by a uniform distribution.

Mr. Merrill disagreed with the assumption that all parameters are dominated by variability, given the information that none has a probability distribution. Dr. Babendreier explained that all parameters must be treated the same way, adding that the decision to treat them all as variable – rather than uncertain – was made based on the knowledge of these parameters. The analysis would be biased unless all parameters are treated the same way (i.e., either all are variable, or all are uncertain). Only a true 2-D analysis would allow different parameters to have different properties, and that cannot be conducted with the computational capacity currently available.

Dr. Babendreier then discussed a comment by the Panel on whether the difference between the true (for a local site) probability density functions (PDFs) and the PDFs from national databases was considered a source of input uncertainty in 3MRA. He confirmed that this was correct, and commented that this topic goes to the heart of the concept of a pseudo 2-D analysis. He gave the example of breathing rate, which is assigned as the value for a given cohort of the human population. Each site is assigned a single breathing rate, but its value differs among the 56 sites – thus introducing variability. There is also uncertainty by assigning a value to individuals, as each individual’s breathing rate cannot be known (unless it has been measured). When this is done across multiple subjects, variability is imparted. Referring to this as a pseudo 2-D analysis means that it generates many estimates of %G, building a distribution of %G which represents the uncertainty of accounting for the actual %G. Uncertainty (H) is a distribution of %G realizations, and exists because there is a finite set of sites, but an infinite set of input vectors.

Ms. Boissevain commented that regulators are not likely to wait the time it takes to run all the realizations needed. Dr. Babendreier replied that a range of %G can be computed in two months. Every time the model runs through a national realization, it computes one observation of %G. Confidence in this value will depend on the number of realizations run – i.e., the number of observations of %G obtained.

Dr. Murarka asked about modeling uncertainty. Mr. Merrill added that the uncertainty characterized in this analysis is different than what many people traditionally think of as uncertainty (modeling uncertainty). In this case, the term is being used in a different context.

Dr. DePinto noted that this approach will also not yield information on how well a sensitive parameter has been characterized. Dr. Babendreier agreed, but added that he had acknowledged this during his presentation.

Dr. Murarka commented that sensitivity, in his view, refers to the extent to which an input parameter affects the end result: a small change in a sensitive parameter will have a significant effect on the output. Dr. Babendreier explained that these were two different issues. He added that not every nuance of the system could be addressed; this analysis can only use available data under the assumptions that were made.

Dr. Stubblefield remarked that most of the analysis discussed so far has been on the fate or exposure side of the model, and asked whether there has been an effort to evaluate the uncertainty associated with the effects side. Dr. Babendreier replied that only parameters with stochastic distributions were addressed in the analysis. He added that the effects side may also be an issue of policy. Dr. Stubblefield commented that the assessment could only be as strong as the weakest part of the analysis. Dr. Babendreier agreed, and stated that the effects side analysis is another item that is planned, but has not yet been conducted.

Dr. Maddalena noted the fact that the Agency acknowledged that national risk is underestimated by 3MRA. Dr. Babendreier explained that this happens because ISE and SME, which are both big contributors to model uncertainty, are not taken into account in the analysis. Regulators will need to be informed of such uncertainties, which will allow them to take appropriate steps, such as adding safety factors.

Dr. Brown said that he understood the model underestimates at 95% confidence, but wanted to know if this is also the case at 50%. Dr. Babendreier replied that the 50% estimate should be closer (underestimate less). Dr. Murarka asked why the 95% confidence is lower, commenting that it could be higher. Dr. Babendreier explained that he referred to the confidence in whether a given %G is correct. Mr. Merrill added that the estimate of %G stays the same, but the confidence in it decreases.

At the conclusion of the presentation Dr. Babendreier presented a 3MRA Monte Carlo Schematic, using a single WMU / Chemical /  $C_w$  combination example (Figure Q2C-3, last page of Attachment H). This was modified from Figure Q3C-2 which the Panel provided.

Dr. Travis commented that there are two issues to consider in evaluating a model: whether it predicts the right answer, and whether it predicts the answer it was designed to predict. This analysis has focused on the latter. However, the problem statement is worded in a way that a regulator may think what the model provides is a “real” answer, rather than what the model was designed to predict. Dr. Babendreier replied that this could be avoided by explaining that the model may be incorrect; one way of doing this is by giving the sources of uncertainty. He added that Dr. Laniak’s comparison study should give more information on the first issue – whether the

model predicts “reality.” Dr. Travis recommended that there should be more discussion on the difference between these two issues to avoid confusion. He also noted that model error, which is not being addressed in this analysis, is one of the most important aspects of uncertainty.

Dr. Travis then noted that model validation should also be discussed, and suggestions offered on how it should be accomplished. Dr. Babendreier agreed, and added that the 3MRA team has discussed forward thinking concepts of how to deal with model validation and whether a model is fit for the task it was designed to perform. He commented that one of the main problems in this respect is the lack of data; collecting data to validate the model can be expensive.

Dr. Carlisle commented that, for each iteration, the output is a percentage of the population protected, and asked whether this percentage is then compared to a standard. He noted that this may be a policy question. Dr. Babendreier explained that several iterations result in the number of receptors protected; then, a decision is made on what percentage of the possible receptors was protected. Dr. Carlisle commented that generating that percentage, and then converting it into a “yes or no” result (whether it meets a standard) is throwing away a lot of information. Dr. Babendreier agreed that a lot of information is discounted, because so much of it is generated. He confirmed, in response to Dr. Brown, that the model does yield a percentage, but that the percentage is not communicated as part of the results.

Dr. Thibodeaux commented on the time the Panel had spent discussing this issue, adding that part of the problem may have been understanding the terminology. This may make it particularly difficult for regulators to understand. Dr. Babendreier said he had given a lot of thought to finding ways of making this topic more easily understandable, and added he would welcome any suggestions by the Panel. Dr. Thibodeaux thought Dr. Babendreier may know too much about the topic, and recommended it be written by someone who understands it, but is not on the same level of expertise.

Dr. Murarka noted an earlier comment on the need for data and empirical information. He stated that this was critical, as lack of knowledge cannot be replaced with mathematical equations. Dr. Babendreier agreed, and said there are efforts to involve scientists and collect data, but added that he did not think this problem would ever be unequivocally solved.

Dr. Theis suggested that the Panel move on to the next topic.

#### Panel Discussion / Agency Response to Peer Reviews

Dr. Theis informed the Panel that the Agency had provided responses to all the individual peer reviews of the modules in the form of a lengthy table which lists each comment and states how the Agency addressed it (see Attachment R). He noted that the Panel would need to spend some time reviewing this during the meeting.

Ms. Boissevain commented that the table is alphabetized and divided into groups such as human, ecology, fate, and others. She added that it may be best if Panel members review the sections in their areas of expertise.

Dr. Theis agreed, and asked Panel members to review sections in their fields and bring their comments back to the Panel before the end of the meeting. He added that it is not the Panel's role to re-review, but to improve its comfort level with 3MRA.

Dr. DePinto asked if it would be appropriate to identify items from the Agency's response as topics to add into the Panel's report – e.g., if something that came up in the review is still an issue with the model. Dr. Theis agreed, saying that Panel members should certainly not disregard what they feel may be important problems. He cautioned, however, that this is outside of the Panel's charge; if a serious error were found, it is outside of the charge of the Panel to bring it to the Agency's attention. Dr. Foran commented that there were probably no serious errors, but there may be significant shortcomings that have bearing on the modules.

#### Chair's Summary and Wrap-up

Dr. Theis informed the Panel that he had excerpted about twenty main points from the draft report, and included some topics discussed today. He explained that he intended those to become topical paragraphs in the final report, which would fit under one of the charge questions. It would be up to the individual authors of the sections on each question to support these points in as much detail as they deem appropriate.

Dr. Theis stated that the Panel would be discussing these points and prioritizing them over the next two meeting days. He also repeated that the members should review the table of the Agency's responses to peer review comments before the end of the meeting.

Dr. Travis agreed with the concept of including general statements in the body of the report, and adding any detailed comments in an appendix. Dr. Theis explained that major points could also be highlighted in the executive summary.

Dr. Travis suggested also that the Panel clearly express its main impression of the model, adding that it is easy to forget to say it was a good effort overall. He commented that he thought the Panel had not gone far enough in expressing this.

Ms. White informed the Panel that she would be providing copies of the Agency presentations the next day, and could also distribute them via email.

Dr. Theis adjourned the meeting for the day at 5:25 P.M.

**WEDNESDAY, OCTOBER 29, 2003**

Opening Remarks and Plans for the Day

Ms. White opened the meeting and informed the Panel that Dr. Eschenroeder had joined the meeting. She announced that photocopies of the previous day's presentations would be available later in the day, but noted that Dr. Laniak's slides could only be distributed as hard copies.

Dr. Theis stated that the plan for the next two days was for the Panel to work on its draft report to the Agency. This would include making additions or deletions to the summary points; an exercise in analyzing the modules that make up 3MRA; discussion of the Agency's response to previous peer reviews of the modules; and some writing and editing during the meeting. He set a goal for the Panel to have reached agreement and have the summary points completed by the end of the meeting. Further writing and editing would be conducted during conference calls. Although the initial timeline had called for the Panel to complete its report by the holidays, this is not a firm deadline; it is more important for the Panel to take as long as needed to produce a good final document.

Review of Report Outline

Dr. Theis presented the current report outline (see Attachment I). He suggested that the narrative addressing the charge questions should be as long as needed, while remaining parsimonious.

Dr. Eschenroeder asked whether the current draft report would be substantially reduced. Dr. Theis explained that the length would be up to the individual authors of the sections on each of the questions. He thought it was important for the report to be clear and concise.

Dr. Carbone noted that some topics could fit under more than one question, and asked if it would be appropriate to have some redundancy in these cases. Dr. Theis agreed that, if a given response pertains to two questions, it can be included in both, with cross references. Dr. DePinto gave the example of mass balance, a topic which, in his view, could fit under question 2 as well as question 3B.

Dr. Theis then read through the charge questions (see Draft Report, Attachment J). He noted that, at a minimum, the Panel must answer each of the questions in its report.

Dr. Murarka commented that the Panel had discussed variability and uncertainty, even though the questions only refer specifically to sensitivity. He asked whether comments on these topics would be outside of the charge. Dr. Theis thought that comments on variability and uncertainty would be appropriately included under question 2C.

## Panel Discussion of Current Consensus Points

Dr. Theis referred the Panel to a list of consensus points distributed, noting that these were taken out of the draft report. He explained that he added additional points based on the previous days discussion, specifically on the topics of mass balance, the Monte Carlo analysis, sensitivity analysis, and the validation protocol. He stated that these seemed to be points of consensus among the Panel, but acknowledged that this might not be the case for all of them. He invited the Panel to further discuss these points and finalize them.

### *Note:*

***Editing of the text of the consensus points/paragraphs occurred throughout the discussion by the Panel. The most recent version of this document, including edits as of the end of the meeting, is included as Attachment K.***

Ms. Boissevain asked whether the summary points would provide the basis for the report's executive summary. Dr. Theis explained that they would help in organizing the narrative portion of the report itself. He noted that there may be more than one topic listed under each question, and that the Panel could reassign paragraphs to different questions, or add new consensus points. He added that the Panel should also have copies of Draft 1.2 of the report; tables created by Dr. Smith and Ms. Boissevain to aid the Panel in analyzing the 3MRA modules; and the table provided by the Agency listing their response to the individual module reviews. He reminded the Panel that it had agreed to review all these documents as time permits.

Dr. Theis then asked the Panel members with which document they preferred to begin. The Panel decided to begin with the discussion of the consensus points.

The Panel began its discussion with the first paragraph listed under question 1. Dr. deFur thought that this model's treatment of human health risk assessment at the population level represented a departure from past practice, and a possible policy shift for the Agency. He stated that a single application (i.e., the 3MRA model) is not an appropriate venue for introducing new policy. He acknowledged that this may instead represent the development of a concept, for which a policy shift may be considered in the future; this is a subtle difference, however, as use of this model will be implemented.

Several Panel members disagreed with this. Dr. Carlisle argued that the Agency has always taken this approach, though this may be the first time it was made explicit, as well as quantitative. Ms. Boissevain noted that, in communicating risk to the public, it is customary to explain that risk is not computed for individuals, but rather a population. Dr. Theis added that environmental policy has been risk-based for a long time, and has always addressed populations at risk.

Dr. deFur agreed, and stated that the net effect of this might be the same, though the practical effect would be different. Dr. Smith thought it may be a difference in how the calculations are set up: this is a more stochastic approach, which tries to make more quantitative statements.

Dr. Carbone commented that a stochastic analysis includes an attempt to quantify the chance that true risk is not more than the risk estimated by the model. Dr. deFur stated that only partial distributions were used. Mr. Merrill argued that, though samples of distributions may have been used, this is not unreasonable, as there are physical limits to all these distributions. Dr. deFur replied that this depended on the choice of limits: physical versus numerical limits.

Ms. Boissevain noted that, when a distribution was used for a variable, it was the entire distribution; for variables where a single value was chosen, that value was intended to represent the central tendency of the distribution. Dr. Smith commented that reliable distributions were not available for the variables where a fixed value was chosen. He added that an advantage of this approach was that it set up the architecture for finding or improving the missing distributions. Dr. Babendreier informed the Panel that Volume 2 of the documentation explains how the distributions were developed.

Dr. Murarka requested clarification of Dr. deFur's initial comment, specifically whether the calculation of population level risk translates differently to individuals in that population.

Dr. Foran commented that although this model expresses exposure by distribution, it does not seem to express risk by distribution. It does not develop a distribution of risk, but only gives a risk number for a given distribution. In response to Mr. Merrill, Dr. Foran defined risk as "a probabilistic estimate of an adverse effect." He reiterated that this includes no distribution information, aside from the dose-response curve. Dr. DePinto said that he thought of risk as a combination of exposure and effects. Dr. Foran confirmed Dr. DePinto's comment that there is no probability distribution for effects.

Dr. Stubblefield remarked that a model can predict a probabilistic distribution of exposure, or the risk of exceeding a criterion or specific effects level. It cannot, however, make a statement about potential effects on a population, because there is no distribution of effects in that population. Dr. deFur agreed that there was no distribution of effects, but maintained that EPA is still departing from its standard practice.

Dr. Theis commented that he did not understand the issue of the policy shift. Dr. Foran thought that the use of %G, or selecting a percentage of a population based on a risk level, may come closer to a policy shift, as it has not previously been used. Dr. Carlisle disagreed, and noted that EPA has published guidance for stochastic risk assessment which requires choosing a percentage of the population as a "bright line." He added, however, that 3MRA is the first time where the two-fold statement of risk is used: "X% of people at Y% of sites."

Dr. Foran explained that the model does itself does not choose a particular protection level; it is risk management who makes that decision. Dr. deFur replied that this management decision has now been incorporated into the model. Several Panel members disagreed, noting that the model allows the user to choose the protection level; the model output itself includes different protection percentages for risk managers to consider.

Dr. Theis commented that the Panel can word this summary point accordingly, depending on how strongly the Panel feels about this issue. He noted that, in his view, this was not a policy

shift, but part of the risk assessment paradigm that has governed environmental policy for a long time. Dr. deFur replied that the Agency has made a point of repeating that this approach is different, because the model output is at the population level. Dr. Theis replied that, if the Panel concurs that the 3MRA methodology represents a shift in policy, it would need to back that up carefully in the report and present a clear rationale. Dr. deFur stated he would draft language to make it clear how 3MRA departs from policy, or if it does, for the Panel to review. Mr. Merrill recommended that Dr. deFur look into a human exposure model relative to air emissions used by EPA, which may have used a population level risk approach.

Dr. Theis noted that the Panel was also asked to assess the state of the science incorporated into 3MRA. He commented that science has progressed to the extent that this approach is now possible, and it may be science that is pushing this shift rather than policy. Dr. Travis and Dr. Eschenroeder both agreed, but Dr. deFur was not convinced this was a science-driven change.

Dr. deFur commented that when a distribution is used to protect, e.g., 95% of the population at 95% of the sites, clustered population groups can be omitted. He cited fish consumption by native Americans as an example. He also noted that there is often an unequal distribution of population around waste management units. Dr. Carlisle agreed that this was an important point, though different from the topic of policy change. Dr. Theis agreed, and reiterated his request for Dr. deFur to further explain the issue of possible policy change in writing. Dr. deFur agreed, adding that he may word his comments as an ‘if-then’ statement.

The Panel continued with some editing of the text to come up with the final paragraph. Dr. Theis mentioned that this topic could come under question 2B or 3B, though it was originally assigned to question 1.

Following a break, Dr. Theis reminded the Panel of the importance of this discussion, as the summary points which the Panel agrees upon must be included in the report and will become the topical paragraphs. He added that there is no limit to the number of these points; the paragraphs, as finalized during this meeting, will appear in the report followed by supporting information prepared by the primary author assigned to each question.

Dr. DePinto suggested that, as time during this meeting is limited, the Panel should focus less on editing and “word-smithing” and more on whether the Panel agrees on a particular point. Dr. Theis said he understood this, but added that changes in the wording could make the difference on whether a particular paragraph works for the Panel.

Dr. deFur suggested that the Panel should not say that the model predicts distributions of hazards (in the first paragraph), in light of the Panel’s earlier discussion. Dr. Theis thought the Panel had agreed there was a distribution of risk. Dr. Foran disagreed, saying that there is only a distribution of exposure. Dr. Stubblefield explained further that this was a distribution of the probability of exceeding a criterion, adding that this does not mean there will be an adverse effect. Panel members could not agree on whether the model calculates a distribution of risk or of exposure. Dr. Theis reminded the Panel that these paragraphs would not stand on their own in the report, but would be interpreted and further explained in the text that follows them. Panel

members continued to discuss whether the model predicted distribution of risk, exposure, or of the probability of adverse effects.

Dr. Travis commented that the 3MRA team claims the model computes a probability distribution, which the Panel in general agrees with; what it does not agree on is what this distribution represents. Though EPA claims that it represents a true distribution of risk, Panel members do not agree. Dr. Maddalena asked whether this makes the model more or less conservative. Dr. Stubblefield replied that, on the ecological side, it makes it more conservative, because it computes a protective value (not an effects value). Dr. deFur disagreed, because there are insufficient data to back up some of the assumptions made, such as third generation effects on aquatic organisms. Dr. Carlisle agreed, but added that the likelihood of being over-protective increases closer to the center of the curve (distribution).

Dr. Stubblefield commented that the documentation made no mention of how new compounds would be added to the model. He thought the documentation should acknowledge that this is a “living model” still in the process of development, and that the Agency should make certain that it maintains flexibility for adapting the model over time. Mr. Merrill noted that the Panel has already addressed this issue in its response to question 4.

Dr. DePinto remarked that EPA has published data quality guidelines which state that data used in models must pass certain criteria; he recommended that the Panel at least refer the Agency to its own guidelines. Dr. Carbone added that stakeholders should also be able to provide data to the Agency. Dr. Theis noted that both these topics had already been addressed.

Dr. Stubblefield suggested that the Panel should stress that the model should be overprotective, given that its intended regulatory use will be the delisting of wastes. He explained that, once a delisting decision is made, it cannot be revisited, so an overprotective model would ensure no wastes are delisted unless the Agency is confident there is little risk from them. The system should also maintain flexibility to allow for multiple tiers of assessment, and allow affected parties to contribute data when applicable.

The Panel then moved to making specific changes in the wording of the second summary point under question 1. Dr. Theis noted that this topic could fit also under question 2A.

The Panel then discussed the third consensus point under question 1. Dr. Smith disagreed that SuperMuse was required for all but the simplest modeling problems, as stated, noting that there are versions of the model that can be run using a PC. Dr. Travis added that some of the Panel’s comments seem to criticize the Agency for making this model usable on a PC, which others criticize the need for SuperMuse. Dr. Theis explained that it was the Monte Carlo analysis that may not be practical to run on a PC, but Dr. Smith stated he had run a 1-D analysis successfully.

Dr. Babendreier explained that version 1.0 of the model was the PC-based version; version 1.X has more tools, but is also feasible to run on a PC, as well as on SuperMuse. Version 2.0 will be a similar construct to 1.X. He added that clustering computers is only necessary for situations where a large number of model simulations is desired.

Dr. Theis asked whether users outside of the Agency were likely to use 3MRA. Dr. Babendreier said that ORD's position has been to make the model accessible to every stakeholder. He added that many industries might be interested in using it even if this involved building a cluster of computers in order to obtain additional information.

Dr. Brown commented that the Panel should note the model can be used in both clustered and stand-alone modes, depending on the user's needs. Dr. Babendreier added that, especially for problems limited to a site perspective, it was very feasible to run the model on a PC.

Dr. Theis stated that when the question of intended users for the model first came up, OSW had presented a different perspective than ORD. Dr. Babendreier confirmed this, and explained that ORD improves its science by allowing all stakeholders to use the technology in different ways. He confirmed, in response to Dr. Theis, that he did not think the need for SuperMuse or a similar system was an impediment to using the model, unless the user is interested in a full national study. Even in that case, a cluster can easily be built out of twenty, or even more PCs.

Ms. Weinberg (ARCADIS) thought that industry may not consider building a cluster of PCs a simple process. The complexity of the model itself may also present a problem in understanding what the exit level means, even if the model itself can be run on a PC. Dr. Babendreier argued that industries that may be severely impacted by an exit level may find it worthwhile to build a system like SuperMuse.

Dr. DePinto added that there are existing supercomputer facilities that industry could contract with if needed. He gave an example of a model (WASP) developed by EPA almost 50 years ago, which was thought too complicated at the time but is now widely used. He thought that 3MRA has the potential to become as commonly used, though it may take many years.

Mr. Case (ETC) commented that this model allows stakeholders to participate in and comment on proposed rulemaking. However, the public has a limited time to provide such comment – time which may not allow constructing a supercomputer and obtaining modeling results to comment on the proposed rule.

Ms. Boissevain stated that the Panel was asked to review this model with the knowledge that there were more updated versions planned (1.X and 2.0). Version 1.0 can run on a PC for limited runs, though it may take stakeholders some time to understand the model.

Dr. Theis explained that the Panel was considering two issues in this discussion: the transparency of documentation, and the implementation of the program. SuperMuse may be a burden to some stakeholders, but is still feasible to construct. Interpreting the model results, however, seems to be a question of better examples or more transparent documentation. He recommended that this summary point be included under question 4, rather than question 1, and that the reference to SuperMuse be removed from the paragraph.

Panel members agreed that the computer platform was less important than transparent documentation.

Dr. DePinto commented that 3MRA represents a new paradigm in multi-media risk modeling, and by its nature increases the need for computational capacity. Dr. Travis suggested the Panel could still recommend that EPA investigate methods for reducing the computer time required. Dr. DePinto agreed, and stated that Agency has already made some decisions to that effect, but the Panel has tended to criticize them.

Dr. Carbone noted that another alternative may be to use the results of the sensitivity analysis. These results may well identify a small number of sensitive parameters that could be used, and require less computer time than using the full complement of input parameters.

The Panel continued with editing the specific text of the paragraph until agreement was reached, then adjourned for lunch to resume at 1:15 P.M.

Once the Panel reconvened, Ms. White announced that copies of the remainder of Agency presentations were now available, as was a handout of comments from Steve Kronen of OSW in response to earlier comments by the Panel.

Dr. Theis continued the discussion of the summary points, moving to the paragraph under question 2A.

Ms. Boissevain noted that the report prepared by AMEC (see Attachment N) refutes the Panel's statement that 3MRA produces consistent and reproducible results. The report states that when dioxin was run on two different computers, five runs yielded five different results. Dr. Theis thought there was likely a good explanation for why this happened, but acknowledged that, if true, this could be a significant problem.

An EPA representative noted that the AMEC report did not provide sufficient information for the Agency team to be able to reproduce these results. Dr. Babenreier offered to provide the Panel with results from his own experiments, which have shown complete reproducibility for several thousand runs conducted on different computers, with different operating systems, and by different users. He also offered to attempt to simulate the experiment run by AMEC and provide his results to the Panel. He agreed to conduct these runs on Ms. Boissevain's computer. Dr. Smith also volunteered to run the model on his computer at the same time. Dr. Theis agreed, as this was a public process and input from the public – such as the AMEC – report should be considered.

Dr. Carbone asked whether the Panel had agreed to recommend a round robin testing procedure for 3MRA. Dr. Theis confirmed that there was such a recommendation under question 2, but he did not include it as part of the summary points because he was not sure that there was Panel consensus. He noted that the recommendation can be found on p.8, line 44 of the draft report. He asked whether there was consensus among the Panel to include this recommendation. Dr. Eschenroeder seconded this, and several members agreed.

Dr. Theis then informed the Panel that third party round robin testing could be included as a recommendation or, if the Panel feels it is critical, as a precondition to using the model. He cautioned, however, that the Panel can only set a limited number of preconditions. Dr. deFur

thought that the Agency could still ignore a precondition. Dr. Theis disagreed, but Ms. White was not certain this was correct.

Dr. Theis revised his statement to say that there is legal language which prevents the Agency from using 3MRA before it has undergone review. Dr. Eschnroeder noted that this does not prevent the Agency from using the model after the review, and Dr. Carlisle added that the language does not specifically mention the content or results of the review. Dr. deFur agreed it was possible for the model to be used even after an unfavorable review, but did not think this was likely to happen in practice.

Dr. Theis requested that the Panel return to its discussion of round robin testing. Dr. deFur thought it was a good recommendation. Dr. Eschenroeder recommended that the Panel be specific in defining the initial conditions and a protocol for any such testing, to avoid having different results due to variation in initial conditions. Dr. Carbone suggested another alternative: the Panel could request from EPA the results of its own repetitive simulations.

Dr. DePinto asked if the experiments would test the ability of two computers to run two exact test simulations, adding that if the initial conditions are the same, both computers should have the same results. Dr. Maddalena agreed, but stated that this does not always happen. Dr. Eschenroeder added that the experiment would also test the ability of different people to run the model. Dr. Carbone noted that it would be more feasible to conduct simple runs using one or two WMUs. Dr. Eschenroeder thought that the specifics could be left to the discretion of the Agency.

Dr. Babendreier commented that one reason the AMEC experiments yielded different results could be that clean-up was not run prior to each run. If that was the case, information from previous runs could have allowed the calculation of different exit levels.

Dr. Theis asked the Panel again whether it would be of value to conduct a series of tests under a specific suite of conditions, in round robin fashion, and interpret the results. Dr. Smith agreed this type of experiment would test the transparency and usability aspects of the model. Dr. Eschenroeder thought that it would also increase the credibility of the model results. Dr. Carbone also agreed, saying it could do no harm to keep the recommendation in the report.

Dr. Travis cautioned that such an exercise could turn into a lengthy and costly effort on the part of the Agency. Dr. deFur replied that it was not the Panel's role to specify the extent of effort the Agency should expend.

Dr. Theis noted that the Panel should decide whether this should be a test of reproducibility or of the model's use and transparency, stating that these were two very different topics. Dr. Travis thought that the study would find the model not to be very transparent – something that the Panel already knew. Dr. Theis cautioned that there was a difference between being transparent and being complicated.

Dr. Carbone commented that the basis of this discussion was the results obtained by AMEC, which indicated the model may not be consistent. He noted that data from the Agency's 4000

runs seemed more credible, but cautioned that it was not appropriate for the Panel to accept that at face value. Ms. Boissevain agreed, adding that, even if there were errors made by AMEC, it is pertinent to stakeholders for the Panel to make an objective decision.

Mr. Merrill suggested a middle-ground solution: if the Agency can include some examples in the documentation, including explicit input conditions, and state what the results should be, stakeholders could run the model and find out if their results match. If not, there is an opportunity during the comments period for them to state that the results could not be reproduced. This would alert the Agency that either the documentation is not adequate, or that there is a problem with the model structure itself.

Dr. Thibodeaux noted that this suggested transparency was the bigger issue. Dr. Theis agreed, saying transparency was more of an issue than reproducibility. Dr. Murarka stated that this would not answer question 2A, which asks whether the model is reproducible. Dr. Carlisle replied that taking this recommendation out of the answer for 2A implies the Panel's belief that 3MRA is reproducible.

Dr. Brown and Dr. Carlisle said they agreed with Mr. Merrill's suggestion. Dr. Eschenroeder also agreed, but noted that the documentation should be written to replicate real-world use, rather than using a pre-packaged, easy way to input parameters into the model.

The Panel agreed, and Dr. Theis edited the paragraph to state the Panel's recommendation that "...a series of benchmark examples be generated and placed in the 3MRA documentation."

The Panel also agreed with keeping the recommendation for carrying out third-party round robin testing, with the Agency to decide how extensive this testing would be and who would conduct it.

Dr. Theis moved the discussion to the next paragraph, listed under question 2B. He explained that the topic of whether 3MRA can be called a "screening" model came up during one of the Panel conference calls. This topic relates to terminology, as well as the concept of higher order models, and the Panel thought it was important to draw a distinction between the science on which the model is based, and the way in which it will be used. As a result of previous discussions, Ms. Boissevain and Dr. Smith compiled a list of attributes of the submodels comprising 3MRA to allow the Panel to examine the components of 3MRA individually (see Attachment L).

Dr. Thibodeaux commented that the use of a model is what classifies it as a screening model, regardless of the model's level of sophistication. Dr. Travis disagreed that 3MRA could be called a screening model. Dr. Carbone noted that Dr. Johnson (EPA) had used the term "screening", but later backed away from that concept. Dr. Murarka and Dr. Eschenroeder both agreed with Dr. Travis, and suggested the word "screening" be removed from the paragraph.

Dr. Smith explained that there were significant differences among the modules making up 3MRA, and the Panel had thought it would be useful to address the relative level of sophistication in the modules in terms of the science in each.

Dr. Theis suggested moving the paragraph to question 4, as this was a problem with definitions and documentation. The Panel agreed.

Dr. Thibodeaux reiterated his comment that the word screening refers to the way a model is used, and not its level of sophistication. Dr. DePinto countered that screening models do not usually undergo extensive validation. Ms. Boissevain noted that the Panel's thinking had been to separate the sophistication level of each of the modules.

Dr. Smith recommended at least listing the attributes that separate the most sophisticated models from the less scientifically rigorous, including in this some validation history. A third category would be models that represent the best description of the process that present knowledge can come up with; and a fourth, research models, that include even more detail but are not practical to include in 3MRA. Each model would have certain characteristics and would fit into one of the four categories. He then presented the categories listed in the table (Attachment N):

- Tier 1: Simple Screening
- Tier 2: Advanced Screening
- Tier 3: Advanced Risk Analysis
- Tier 4: "Models of the Future"

Dr. Smith then asked Panel members to assign each of the 3MRA modules to one of the four categories. That information would then be assembled in an attempt to derive the entire Panel's opinions. He added that it may be useful to present the Agency with an outside view of the quality of the tools included in 3MRA.

Dr. Thibodeaux asked what question the Panel would be answering by filling in this table (i.e., assigning modules to categories). Dr. Theis replied that the Agency did not define the term "screening", so it was left up to the Panel. The table was created as a thinking tool for the Panel, which could also be an explanatory tool in the report – perhaps as an appendix. Dr. Smith added that it should help answer the question on whether the best science had been used for 3MRA.

Dr. Carbone commented that, if 3MRA contained some screening level modules, then more advanced modules may represent an unnecessary level of sophistication. Dr. Thibodeaux agreed, but did not think this presented a problem with respect to the model's outcome. He suggested that each Panel member review the table and rate just those modules in his or her area of expertise. Dr. Theis agreed this was a good idea, and asked the Panel to do this after the meeting and bring back the tables the next day. Dr. Smith agreed to compile the results. Dr. Theis kept the summary paragraph until the Panel could review the module rating results, changing the text to a small font size so it can be identified.

Dr. Theis then moved to the next summary point, still under question 2B, noting that this was a statement of support for the work the Agency conducted, and a paragraph which summarized the answer to the question. Dr. Carlisle agreed that the model does provide flexibility, and added that this increases its utility.

Mr. Merrill commented that the model does not provide access to the underlying parameters that led to the model outcomes, but noted that this topic is already addressed in question 4. Dr. Carbone agreed that the report already includes a suggestion for storing critical outputs in a file.

Dr. Theis moved to the next summary point listed under question 2B, and stated that this was a summary of the previous day's discussion on mass balance in 3MRA. Dr. DePinto thought this point should be included under question 3B, with the discussion on validation. Dr. Theis agreed, as long as a distinction is made between this point and the Agency's proposed validation protocol.

Dr. DePinto also spoke to the topic of whether the Panel understands the processes in the intermediate transfer parts of the model well enough to make statements as to whether 3MRA is capable of balancing mass. He noted the example of flux from air to water or air to land, which is computed only by wet or dry deposition; however, for some chemicals such as PCBs, the mechanism of deposition is vapor transfer, which is not included.

Dr. Theis noted that he had stopped short of saying that the Agency actually demonstrated mass conservation, saying instead that significant efforts were taken to demonstrate it. Dr. DePinto and Dr. Thibodeaux both agreed with this, as neither thought mass could be conserved.

Dr. DePinto disagreed with the assumption that secondary sources are not significant.

Dr. Thibodeaux noted that this was described as a "feed-forward" system, which he interpreted to mean there was no *feed-back*. Without feedback, there cannot be mass conservation beyond the waste unit itself. Dr. DePinto thought the Panel should state that this will pose a problem for at least some chemicals. He agreed with Dr. Carlisle's comment, however, that it is possible to obtain this information by conducting additional, off-line calculations.

Dr. Theis asked the Panel to return to the topic of the summary point. Dr. Eschenroeder commented on the Panel's recommendation (already included in the summary paragraph) that the Agency conduct some research projects to test how mass is conserved with highly partitioned chemicals. He noted that the Agency is already conducting a study of seven such chemicals, but thought the Panel is not likely to see the results before completing its report.

Dr. Carlisle agreed with the opinion that this model is not conserving mass, but he pointed out the Agency's opinion that the mass that is lost is small. Dr. DePinto agreed that this was what the assumptions say, but he thought the report should identify the chemicals for which these assumptions are not correct.

Dr. Thibodeaux added that he did not think mass conservation was a problem for modules that were connected by flux – only for those connected by partition coefficient. He suggested that a check be placed in the software for this situation.

Dr. Maddalena suggested expanding the discussion on this point by including a figure which would list the chemicals for which the assumptions do not apply, and their solubilities.

Dr. Theis asked if there was agreement among the Panel on the paragraph stating the problem with mass conservation. Panel members agreed.

Mr. Merrill noted that one of the concerns brought up in the 1995 review was the lack of mass balance at the source. He thought the report should make clear that 3MRA now does conserve at the source, and that the Panel's concerns are with conservation downstream from the source. This would indicate clearly that the Agency did address the concern brought up in 1995.

Dr. Thibodeaux added that mass is also conserved within each individual module. Dr. Theis agreed, but thought the Agency would not be able to demonstrate mass conservation throughout 3MRA; it can only demonstrate that masses balance with acceptable scientific accuracy. The Panel agreed, and references in the paragraph to "mass conservation" were edited to say "mass balance."

Dr. DePinto noted that mass is lost also to volatilization, adding that it would not be lost if a boundary condition were placed on the concentrations. These losses are small but can add up to a significant amount over fifty years of simulation, and that mass could represent exposure. Dr. Theis agreed, and said the burden should be placed on the Agency to demonstrate mass balance, not only for the Panel, but also for the scientific and the regulated community. Failure to do this could result in mass balance becoming a point of contention among those who are regulated.

Dr. DePinto pointed out also the issue of the 2km radius, saying that mass could be lost from a site outside of this 2km radius. This could represent a large source, especially as there are thousands of sites nationwide, yet the model only considers 56 sites. He acknowledged, however, that this may be outside the scope of the review, given that the 2km radius is already defined. Dr. Theis agreed that the radius had been defined, but added that the model should still conserve mass; if there is a secondary source, it should be closed off.

Dr. Theis then moved to the next summary point, discussing the adoption of a Monte Carlo analysis (under question 2C).

Dr. Travis thought this paragraph may be addressing two issues: the approach used in conducting the pseudo 2-D analysis, and whether the uncertainty is the "right" kind of uncertainty to measure. He suggested separating this paragraph into two sections: examine whether sampling error was adequately characterized; and discuss the importance of understanding model error. Mr. Merrill agreed, but noted that the analysis does not include sampling error or model error – the two errors the Panel considers the most important.

Dr. DePinto added that model error encompasses two components: uncertainty associated with the coefficients of the model, and whether important processes were included in the model framework. Dr. Smith agreed, but said neither of those are included in the current analysis. Dr. Thibodeaux thought the mathematics in the model could be another source of error.

Dr. Theis noted that the Monte Carlo analysis conducted does not characterize mathematical errors in the model, or even mass balance errors, but the uncertainty associated with values for parameters that are difficult to know or measure. He said the Panel's contention was that this is

a minor source of uncertainty compared to other sources – e.g., model error or sampling error – that were not considered.

Dr. Travis said there was a problem with the way the Agency described the analysis it conducted, and should be more precise about what is meant by having X confidence in the model results. Mr. Merrill noted that he would go as far as suggesting removing mention of confidence, since it is addressed to an unimportant source of uncertainty.

Dr. Babendreier explained that the uncertainty characterized arose from variability in the number of inputs. He stated that the Agency had already acknowledged its omission of other sources, such as model error.

Mr. Merrill stated he was not convinced that the uncertainty presented by the analysis had any meaning other than being a factor of how many times the simulation was run. Dr. Babendreier replied that there would be some uncertainty for any number of model runs. Mr. Merrill noted that this still does not address uncertainty in the input distributions, and therefore no statement can be made regarding the confidence in the resulting risk distribution. He added that the two values of %G obtained from two model runs do not represent uncertainty in the %G, but rather a realization of all the input variables that went into computing them. Dr. Babendreier argued that if the model is run long enough, confidence in the calculated distribution will increase.

Dr. Travis noted that the consensus seemed to be that the Panel has trouble understanding how EPA conducted this analysis, and does not agree with the Agency's view of what the calculated uncertainty represents. He suggested writing a statement to that effect, rather than continuing the discussion on this point. Dr. Theis disagreed, stating that this was an important topic.

Dr. Theis then summarized the discussion up to that point. He said that the Agency's point of view is that there really is uncertainty, and the analysis conducted is a way to quantify it. The Panel may or may not agree with that, and most Panel members think the analysis results can all be explained by variability. Mr. Merrill agreed with Dr. Theis. He brought up Dr. Babendreier's explanation from the previous day, which stated that all parameter distributions were assumed to be variable. He thought that since all input values are considered variable but certain, then the output cannot be called a measure of uncertainty. Dr. Babendreier cited the breathing rate example cited previously, saying it perfectly described variability. Dr. Thibodeaux stated that variability in the input would yield uncertainty in the output. Mr. Merrill disagreed, however, saying it would yield variability in the output. Dr. Babendreier said there would always be uncertainty when there is a finite number of sites to describe, with an infinite number of ways to describe them.

Dr. Carlisle commented that, even if the Panel were to accept that the analysis computes uncertainty, it still does not include much more important sources of uncertainty.

Dr. Babendreier explained that, with the information available, and given the assumptions made, there would always be an uncertainty (%H) to modify the %G. He added that he was concerned about the Panel's position that %H represented an artifact of the analysis.

Dr. Thibodeaux agreed with Dr. Carlisle, saying he could accept this explanation, but the analysis still does not account for sampling error and model error. Dr. Theis stated that this was not an issue for discussion, since it was already acknowledged. He explained that the issue was that the way the 3MRA uncertainty analysis is designed, it does not really tease out uncertainty. He thought the Panel's question was whether this is the appropriate way to obtain uncertainty. Mr. Merrill agreed that there is uncertainty, adding that what was not obvious was the way in which it was quantified.

Dr. Carlisle noted that uncertainty and variability could not be separated in this analysis, therefore it could not be called a two-stage Monte Carlo analysis. Dr. Theis agreed with this, adding that this analysis samples from the same dataset, so it cannot be called 2-D.

Dr. Smith cited the example of fish ingestion, and explained that, in a modeling environment, fish ingestion is predicted from a set of parameters – not measured in a sample of the population. This leads to uncertainty of whether the model accurately predicts what the real ingestion rate is. That uncertainty is not captured in this analysis.

Dr. Babendreier said he had acknowledged model error was not addressed. He suggested five types of uncertainty: 1, model error; 2, input sampling error; 3, sample measurement error; 4, %H, arising from an infinite number of combinations to describe a finite number of sites; and 5, the precision issue related to using a model to conduct Monte Carlo analysis. Although the 3MRA team would like to address all these sources of uncertainty, there were limits in its access to information and computational capacity.

Dr. Carlisle said that he understood Dr. Babendreier to say his analysis characterizes two of these sources, but the Panel thought it only characterized one source. Dr. Babendreier agreed with this assessment.

### Chair's Summary and Wrap-up

Dr. Theis suggested that the Panel think about these issues carefully and continue this discussion on the next day. He proposed beginning the meeting earlier the following day, at 8:30 A.M. The Panel and other attendees agreed.

Dr. Theis then asked about the progress of the model runs begun earlier in the day to test reproducibility. Ms. Boissevain and Dr. Smith stated that they had obtained the same results in their runs. Dr. Smith added that he obtained the same result as Ms. Boissevain despite the fact that he conducted his model runs in two stages. Ms. Boissevain thought that the problem with the AMEC experiment seemed to be that old files were not cleaned prior to running the model, and suggested this be made clear in the documentation.

Dr. Theis said he would email Panel members the updated version of the summary points, and reminded the Panel to review the tables for classifying the 3MRA modules, along with the accompanying proposal. He adjourned the meeting for the day at 5:00 P.M.

**THURSDAY, OCTOBER 30, 2003**

Opening Remarks and Plans for the Day

Ms. White opened the meeting with advice to the Panel to note, during the ensuing discussion, any positive comments about the model. Though most of what has been discussed was specific criticisms about 3MRA, this was the last time the Panel would meet with the Agency, and was a good opportunity to voice the aspects of this effort that were done correctly or even well.

She also asked the Panel to put its criticisms in context, such as separating items that are “show-stoppers” from those that could be considered minor work. The Agency would particularly want to know about anything that could prevent this model from being implemented and used. In addition, she encouraged the Panel to provide a path forward and suggestions for correcting aspects of the model the Panel criticized.

Dr. Theis reviewed the day’s plan, saying he would like the Panel to complete its discussion on the summary points and come to consensus on the paragraphs to be included, as well as prioritize these and choose the four or five most important points.

Dr. Vu also addressed the Panel briefly, and asked members to take the purpose of 3MRA in the context of its intended use as an additional tool in practicing risk assessment.

Time-Table for 3MRA Report

Dr. Theis then presented the timetable for completing the Panel’s report on 3MRA, emphasizing the November 14 deadline for submitting comments and new material to the question organizers. He also called the Panel’s attention to the conference call scheduled for November 24, during which Draft 2 of the report would be discussed.

The complete 3MRA timetable was presented as follows:

- |               |   |
|---------------|---|
| July 21:      | Initial conference call: establishment of meeting and call times, initial discussion of charge questions  |
| August 15:    | Conference call: finalization of charge questions   |
| August 26-27: | Face to face meeting: EPA presentations, Panel member assignments, discussion in terms of charge questions, initial development of consensus points, organization of report |
| September 16: | Conference call: structured discussions   |
| September XX: | Additional conference call?   |
| September 25: | Individual input to/from question leaders   |
| September 30: | Question leaders synthesize input in terms of charge questions (due to Chair)   |
| October 6:    | Assembly and distribution of Draft 1  |
| October 9:    | Conference call: discussion/revision/re-writing of Draft 1  |

- October 20: Revised input from Panel members, synthesis by question leaders (due to Chair)
- October 24: Assembly and distribution of Draft 1.2
- October 28: Face to face meeting: discussion/revisions/re-writing of Draft 1.2
- November 14: Revised, edited material for Draft 2 due to question organizers
- November 20: Integrated Draft 2 charge question narrative to DFO
- November 24: Conference call: discussion of Draft 2

Dr. Theis noted that, at the conclusion of this meeting, the Panel will have agreed upon the summary points (topical paragraphs) that will guide the report writing. A lot of the material already submitted will be significantly edited and used in support of these summary points. It will be up to the question organizers/integrators to draft language that further supports the summary points. Material submitted that cannot fit under a summary point can be included in an appendix. Dr. Theis also reiterated the request to keep the narrative no longer than it needs to be to convey and adequately support the summary points.

Dr. DePinto, the organizer for question 3, requested that members submit their comments in two groups: those that can be used in support or explanation of the summary points, and, separately, those that are unrelated and would better fit in the appendix. Dr. Theis agreed with this suggestion, adding that it would be a good idea to do this for all comments submitted.

Dr. Theis also agreed with Dr. Carlisle's suggestion to number the summary points so they can be more easily referred to.

Dr. Murarka noted that the current approach does not clearly indicate the Panel's recommendations under each question. Dr. Theis replied that many of the summary points include recommendations. Dr. deFur reiterated Ms. White's earlier comment to clearly indicate the Panel's overall opinion on the entire 3MRA effort.

#### Panel Discussion of Current Consensus Points (continued)

***Note:***

***Editing of the text of the consensus points/paragraphs occurred throughout the discussion by the Panel. The most recent version of this document, including edits as of the end of the meeting, is included as Attachment K.***

Dr. Theis reminded the Panel that it had planned to continue yesterday's discussion of the Monte Carlo analysis, and noted that Mr. Merrill had suggested alternate wording for those two paragraphs for the Panel to review and discuss.

Mr. Merrill began by pointing out the first sentence in this text, which endorses the adoption of a Monte Carlo approach as a sound and advisable strategy for 3MRA. Dr. DePinto added his opinion that the Agency should be commended for using its access to additional computational power for an attempt to quantify uncertainty, rather than for adding complexity to the model.

Dr. Foran stated that his understanding of the new paragraphs was that the analysis does not characterize uncertainty. Mr. Merrill confirmed that, adding that in his view, uncertainty is not quantified by this analysis, though he endorses the approach. Dr. Foran said his question was related to whether the model was ready to use, adding that there are a number of things about the model that could cause it not to provide an adequate level of protection.

Ms. White asked how 3MRA compared to existing models used for environmental analysis. Dr. Foran replied that 3MRA is a lot more complex, but not necessarily more accurate. Dr. DePinto countered that decisions have been made in the past on less information. He added that if this model is explained adequately to decision makers, they will be aware that there is a margin of safety built into the calculations. The exit level produced by the model is intended to be used as a guideline in making decisions. Dr. Travis agreed, saying 3MRA has no more faults than models currently used to make similar decisions, and may even be more conservative. In his opinion, the model is ready to be used.

Dr. Stubblefield commented that the fact that 3MRA provides a framework for addressing multimedia interactions is one of the good things about the model, and a major step forward.

Dr. Carlisle was concerned about three parameters that he thought may have been captured incorrectly: fish ingestion, exposure duration, and fraction of waste ( $F_w$ ). He added, however, that the uncertainty in the toxicity parameters is so overwhelming in the opposite direction that, even though he agreed uncertainty is not quantified, intuitively he believed the model is being protective. Dr. Theis noted that this type of information would fit well in a supporting role under one of the topical paragraphs; he encouraged Dr. Carlisle to submit his comment.

Dr. Foran commented on whether the model is ready to use, and was specifically concerned that EPA will use the model after the Panel disbands without having implemented some of the recommendations (e.g., conducting studies on mass balance). He did not think the Panel should endorse this model prior to receiving some of the information it has already requested. Dr. Theis replied that he planned some discussion on prioritization of the Panel's recommendations and their bearing on whether the model is ready to use, but would like to complete the discussion of the summary points first.

Dr. deFur agreed with Dr. Foran in thinking the model is not ready to use. He asked whether a true 2-D Monte Carlo analysis could be conducted. Dr. Murarka stated that it could only be done after collecting a lot of new data. Mr. Merrill agreed that it would take a lot of resources to characterize the second dimension. He added that the sensitivity analysis planned by the Agency may illuminate some of the related variables, and could be used at a later time to add a true second dimension to the Monte Carlo analysis.

Dr. deFur commented that this was important, as he did not know before now that a true 2-D analysis was even planned. Dr. Travis, however, thought it would not be possible to do a true uncertainty analysis of 3MRA, given that uncertainty analysis had not been conducted on any of the modules.

Dr. Theis urged the Panel to move on. The Panel agreed to use Mr. Merrill's text as the new summary paragraph relating to the Monte Carlo analysis.

Dr. Theis then moved to the next summary point, related to including benchmarks in the documentation for 3MRA; he noted that the Panel may have already covered this.

Dr. Foran thought this was a relatively minor issue, thought it was contained within a broader, more important set of issues. Dr. Theis asked if it could be used as supporting information for one of the other summary statements. Dr. Foran remarked that this may not be an easy fit to any of the questions. These comments were directed to the accuracy of risk modeling, but they were included in previous peer reviews, and the Agency has seen them and responded to them.

Ms. Boissevain suggested including this point under question 1, which asks about items that were not included in the model. Dr. Carlisle suggested including a list of issues that should be addressed under question one, perhaps as an appendix. Ms. Boissevain replied that if these were action points for the Agency they should not be in an appendix. Dr. Smith agreed with Ms. Boissevain, adding that the appendix could be used for additional information or examples.

Mr. Merrill thought the Panel should clearly state whether it believes the Agency should take certain steps, or whether it agrees this is the best effort for this model.

Dr. Stubblefield commented that there was a high level of complexity on the effects side of the model, but not the same amount of research or attention characterized the exposure side. He added that additional work could have been done on the exposure side (such as population based studies) but was not, therefore the model may not reflect the state of the science. Mr. Merrill asked if this comment could be phrased as a recommendation, e.g., if a module could be replaced with a better one. Dr. Stubblefield said there was not such a module currently, though new models were expected to be available in the near future. He clarified that, though computing code does not exist to conduct this type of analysis, there are other processes that can be used instead.

Dr. Foran stated that he was not confident the model results on the exposure side were as fine-tuned as they could be, though he could not tell how accurate they are. Dr. Smith commented that a recent paper reported that using a combination of similar models resulted in over-prediction of ambient concentrations. Dr. Foran cautioned that ambient concentrations are not necessarily equivalent to exposures.

Dr. Travis noted that, though the summary paragraph said the model is under protective, Dr. Smith had just stated it was over-protective. Many Panel members answered "yes", implying that there were different opinions, and that this was a difficult matter to ascertain.

Dr. Theis suggested either question 2B, 2C, or question 1 would be appropriate areas for this and related issues. Dr. Foran thought this discussion was related to dose-response; he recommended deleting the entire paragraph. Dr. Theis agreed, adding that Ms. Boissevain would work on a re-wording of this topic for the Panel to review later in the day. He suggested moving to the next summary topic.

The next paragraph discussed was a comment that some of the databases of Subtitle D facilities used for the model contained information from 1985.

Dr. Maddalena asked which way using these data would bias the model. Dr. deFur replied that it was not possible to know how current data are different from the 1985 data.

Dr. Theis asked whether there was Panel consensus that 3MRA should be updated at regular intervals with more recent modules and databases. Dr. DePinto agreed that the Panel should emphasize that this is a “living model”, adding that the Agency should commit the resources to updating this tool as needed. Mr. Merrill added that the Panel could go a step further, asking the Agency to include a plan for future modifications and updates. Dr. Murarka thought the recommendation should include developing new data, as well as using data to update the model/modules. Dr. Theis noted that this last point was also addressed in a subsequent statement.

Dr. Stubblefield commented that the Agency relies on water quality criteria for 3MRA, but the program to develop these criteria has essentially stopped. He suggested recommending the Agency revitalize that program to some extent. He acknowledged this may be a policy issue, but added that it may be important if the model relies on these criteria. Dr. deFur agreed, saying that the model would soon become of limited use if new information is not added to it. Dr. Maddalena agreed with this comment for 3MRA when used as a research mode. For regulatory use, however, it is necessary to choose a number and decide that decisions will be based on that number. Dr. deFur noted that, by keeping the model updated, it can be used to aid regulatory decision making for many years to come.

Dr. Maddalena thought the Panel could specify updating the model on an incremental basis, and he cited the example of the U.S. Census. Dr. Travis agreed the Panel should recommend updating the data used in the model, but did not think it appropriate to comment on the criteria program. He said that, in general, the Panel should avoid comments such as “the policy is wrong”, though it can recommend a specific policy be re-examined. He reminded the Panel that the model developers must work within certain policy constraints.

Dr. Theis then moved to the next summary paragraph, regarding the FRAMES architecture and adaptability of the model, which the Panel accepted without comments or modification.

The next summary point concerned the difficulty of validating 3MRA by data-matching, due to its complexity.

Ms. Boissevain noted that an epidemiology study could be conducted after a long period of time, to possibly look at incremental cancer risk. She agreed with Dr. Murarka, however, who commented that such a study would not be able to attribute risk to each waste or chemical. Dr. Foran noted that some studies have attempted to match cancer risk with potency, to specific chemicals; he also agreed, however, that the risk predicted by an exit level cannot be confirmed by data from an epidemiology study.

Dr. Theis moved on to the next point, discussing peer review of the modules, and reminded the Panel of the Agency's responses to these previous reviews. He noted that this topic was important, and had been discussed repeatedly on Panel conference calls.

Ms. Boissevain said she understood that some review comments were implemented, while others were not. She noted, however, that some comments were not acknowledged at all, and cited the comment regarding the volatilization pathway as an example.

Dr. Foran stated that the charge question specifically asks whether the peer review comments were "adequately implemented." He noted that, though there was a response to all the comments, this did not mean it was always an adequate response, nor that all comments were implemented.

Dr. Theis asked whether these comments could be framed in the context of the constraints under which the model was developed – such as limited funds and computational run time. He also noted that the question may be asking whether, given those limitations, the Agency addressed and adequately implemented those comments that were most important.

Dr. Maddalena agreed this was likely a matter of resource constraints, adding that this may be part of the learning curve of how to conduct peer review on a model. He did not think the Agency anticipated the extent of resources needed to address all those comments.

Dr. Theis then noted that the validation of the legacy modules was part of the validation protocol, and a separate topic from the validation of 3MRA as a whole, which was addressed in the next summary paragraph. He suggested the Panel frame its recommendations in terms of the known constraint factors. If any major issues that came up in the original peer review process were missed, the Panel can certainly identify those – by choosing no more than three such issues.

Dr. Murarka noted that one such problem was modeling uncertainty, which could be a substantial source of overall uncertainty. Not being able to implement all the suggestions that arose from the peer review process only supports the Panel's opinion that overall uncertainty could be significant.

Dr. Thibodeaux expressed concern about the concept of generic soil, stating that the generic soil column in the model has some aspects that are not giving the correct answers. He added that he thought this topic was a priority, as the generic soil column serves as the originating source for all of the contaminants.

Dr. Maddalena commented that the peer review was impressive and resulted in a lot of constructive criticism. He agreed that the Panel could look through the comments and identify those issues that were not addressed or implemented. Dr. Theis replied that there were a few such issues; he gave the example of secondary sources, in particular the issue of volatilization brought up earlier by Ms. Boissevain.

Mr. Merrill asked if it would help to explain which specific sub-models the Panel had concerns with. Dr. Theis replied that the Panel should attempt to phrase a specific recommendation or

concern. If members thought there were numerous problems remaining, the Panel could even recommend more review, or go as far as saying the validation protocol failed.

Dr. Thibodeaux suggested prioritizing any specific concerns. Dr. Maddalena thought a positive way of addressing this could be to recommend the Agency use the comments as a valuable resource it can mine in making improvements to 3MRA. Dr. Theis agreed with this suggestion.

Several members also offered specific comments. Dr. Murarka reiterated the concern about the volatilization pathway, and in more general terms, the fact that secondary sources were not included. Dr. DePinto thought that the overt coding errors were already addressed when the Panel discussed the model's verification.

Dr. Theis reminded the Panel that it cannot suggest actions that the model developers cannot take – actions that may go against Agency policy, such as those relating to exposure.

Dr. Foran commented that when the Agency responds that something is a policy issue, it can be interpreted in one of two ways: either policy refers to the way the Agency has acted for a long time; or a policy decision was made to simply not incorporate a suggestion. He thought the summary paragraph served no real purpose, given that the Agency had already provided its responses to the peer review comments.

Dr. Theis replied that the Agency would also be responding to the report of the 3MRA Panel. Dr. Foran suggested making concrete recommendations, even if in some occasions they reflect issues already brought up by the previous reviews. Ms. Boissevain suggested explaining that some important issues first identified in the peer reviews re-surfaced during discussions by the Panel.

Dr. Stubblefield commented that criticisms related to policy decisions should not be directed to the model development team. Dr. Theis explained that the report would be read by Agency level personnel as well as by the 3MRA team.

Ms. Boissevain commented that if the Panel states the need for more data or more work, this may be used as a leveraging point by the team to request funds for improving the model. She acknowledged, however, that it may be outside the Panel's role to justify funds allotted to Agency projects.

Dr. Theis suggested keeping specific recommendations out of the summary paragraph, but including more detail in the supporting text or in an appendix. The Panel agreed.

Dr. Theis then moved to the summary paragraph discussing the validation protocol followed by the Agency, noting that this was one of the topics discussed over the last two days.

Dr. Brown thought the Panel should take into consideration the type of data that are likely to be available, noting that it was not realistic to expect to find data in all the relevant areas. Dr. DePinto replied that there are numerous datasets of contaminant levels in various media. Dr.

Brown noted these may not be matching datasets. He added that databases appropriate for testing the weakest components of the model system are more difficult to find.

Dr. Carbone agreed with Dr. Brown, but commented that validation of each module or component did not necessarily mean the entire model system had been validated. Dr. Thibodeaux agreed. Dr. Brown added that datasets are needed that go across more than one module.

Dr. DePinto thought that the main problem is that the source terms are not known, and asked whether data could be obtained from monitored landfills. Dr. Stubblefield replied that this type of datasets do exist, and gave the example of a holding pit in Alaska on which monitoring data were taken for about fifteen years.

- **Dr. Stubblefield will email Ms. White more information on this dataset.**

Dr. DePinto commented that this paragraph should address more than just the comparison of model results with monitoring data, in terms of evaluating model performance.

Dr. Brown proposed recommending a field study and monitoring program as a long-term effort. Dr. Carbone thought such a recommendation had already been made, suggesting a number of smaller prospective studies which might lead to weight of evidence that would increase confidence that the model reflects what is measured in the environment.

Dr. Theis cautioned that the Agency would be unlikely to undertake an extensive monitoring study, even if it were recommended by the Panel. Dr. DePinto suggested conducting “post-auditing” of the model, i.e., using the model to make regulatory decisions and following these up by taking measurements at some of the sites. Dr. Theis thought this to be an appropriate recommendation.

Dr. Thibodeaux commented that Superfund sites could also be used in this approach. Dr. Eschenroeder confirmed that data are often collected at Superfund sites for many years before remediation.

Dr. Travis noted that a lot of computational effort had gone into examining uncertainty, but similar steps were not taken to examine how well the model is predicting exposures. Dr. Babendreier replied that this question would partially be addressed by the performance-based sensitivity analysis, which would examine whether the model predicts what it was designed to predict.

Dr. Theis moved to the next summary paragraph, which represented another approach to the validation question – whether the model leads to “correct” decisions. He added that this point was intended to express that there are ways to validate a model apart from point-by-point data matching.

Dr. Carbone said that one such example was the LAF test, but Dr. Theis did not think it was needed as an addition to the summary point. The Panel had no further comments.

Dr. Theis presented the next summary point, discussing the sensitivity analysis in 3MRA applications.

Ms. Boissevain thought the statement in the paragraph addressing how the model outcome might be presented to decision makers was especially important. Dr. Maddalena agreed, adding that the Panel had also been asked to judge whether the presentation of the results was helpful.

Dr. DePinto noted that the outcome of the sensitivity analysis would depend on both the WMU and the chemical. The paragraph text was edited to reflect this comment.

Dr. Theis moved to the summary paragraph under question 4, relating to documentation. He noted that the subset of the Panel which responded to this question provided a lot of detail, including a suggested outline for organizing this documentation.

Mr. Merrill commented that detailed comments on specific issues raised might be more appropriately included in an appendix. He also reiterated an earlier discussion on allowing the user to delve into the combination of 3MRA parameters that led to a specific risk outcome, adding that this type of information is important for really understanding the model outcome.

Dr. Babendreier explained that such tools would be available as part of version 1.x of 3MRA, and referred to a list of these tools, beginning in Chapter 6, line 4. He also noted that version 1.X as well as these tools can be used when running the model on a single PC.

Dr. Stubblefield commented that there are portions of the model that are hard-wired into the code, and encouraged the Agency to write software to make these portions more easily accessible. This would allow users to see the specific numbers used, or modify them.

Dr. Travis seconded Mr. Merrill's earlier suggestion, saying it also relates to the model's transparency to stakeholders: though users may not understand the model code, they would most likely understand information identifying the dominant pathways.

Dr. Carlisle thought that coding issues and additions or improvements in the software should not be discussed as part of question 4, since these are not issues that can be addressed in the documentation. The Panel agreed and the above comments were addressed in a new paragraph, suggested for inclusion under either question 4 or question 3B (see Attachment K, p. 6, 2<sup>nd</sup> paragraph).

Dr. Theis announced the meeting would break for lunch; in the afternoon the Panel would prioritize the summary points, discuss some additional items, and hear the Agency's response.

Upon reconvening, Dr. Theis presented an additional summary point drafted by Dr. deFur, who left the meeting earlier in the day (see Attachment S). Dr. Theis stated that Dr. deFur presented two issues: 1, whether 3MRA represents a policy shift on the part of the Agency; and 2, the fact that 3MRA does not always use the most current scientific information. The Panel agreed that the second issue had already been addressed during previous discussions. Dr. Theis said that he

thought the majority of the Panel was not comfortable with the first issue, but requested comments on this topic from the members.

Dr. Foran said he was not aware of a policy of including a conscious decision to protect a certain percentage of the population. He cited water quality criteria, which are set to a specific level of risk, but do not include a probability component. Dr. Escheroeder agreed, adding that the Agency does not claim these criteria protect anyone; they are absolute values. Dr. Thibodeaux explained that previously population protection was implied, whereas in the case of 3MRA it is explicitly stated.

Dr. Murarka countered that the model itself is neither making a decision nor setting a policy of what the exit level should be. Instead, it provides information that can be used by a decision maker. Dr. Foran agreed, but noted that decision makers did not have the option of selecting a protection level prior to the development of 3MRA. He agreed with Dr. Eschenroeder's comment that there is no guarantee decision makers will, in fact, choose a protection level.

Dr. Theis stated that there did not seem to be consensus among the Panel, and proposed further discussion of this topic during subsequent conference calls. He also noted that this may be construed as commenting on policy, and may be beyond the Panel's role.

Ms. Boissevain presented a revised version of one of the summary points which was deferred for later discussion (see p. 35). She noted that this was originally a talking point under question 1, and relates to the exclusion of secondary sources from exposure pathways.

Dr. Maddalena thought that the Panel had already discussed this topic in terms of using new science to continue to improve the model. Dr. Carbone replied that this paragraph addresses the difference between the level of probabilistic approach used for the ecological side versus that used for human health.

Dr. Foran proposed a recommendation to include the dermal exposure pathway. Ms. Boissevain and Dr. Carlisle added that the vapor intrusion pathway should also be included.

The Panel agreed, and the paragraph was edited to include the above recommendations and added under question 2B (see Attachment K, p. 2, last paragraph).

#### Discussion of *Priorities* among Consensus Points

Dr. Theis asked the Panel to discuss the prioritization of the consensus points, adding that this was a required step in the process. He informed members that he had attempted to identify the topics that seemed important to the Panel, which were indicated in bold in the document. He asked the Panel to discuss these and decide on the final priority points. Some of the chosen paragraphs could be omitted from the priority list and others added, but the total number of priorities should not exceed five or six points.

Dr. Murarka remarked that one of the most significant points the Panel could make was a strong recommendation to devote Agency resources to the continued development and improvement of this model. Dr. Theis asked which paragraph should be taken out, and Dr. Murarka suggested the one discussing documentation, as it was a message directed more to the users than to Agency administration.

Dr. Travis agreed with Dr. Murarka, and noted that the first point the Panel makes should be that this model is a valuable and important approach which EPA should continue to use, fund, and improve. Dr. Theis noted that this did not fit under any of the charge questions. Dr. Travis explained that, as the Panel's main point, it did not need to refer to a charge question. He added that the major points and conclusion should be stand-alone, irrespective of the questions.

Ms. Boissevain and Dr. DePinto thought the executive summary was a good venue for listing those major conclusions. Dr. Maddalena added that the letter to the Administrator was another logical place to list overarching comments.

Dr. Travis, along with many Panel members, thought that the Panel should list five or six main conclusions that could be read and understood even without having seen the charge questions.

Dr. Theis agreed that the executive summary could be written in such a way, but asked the Panel to continue with the prioritization of the summary points.

Dr. DePinto suggested emphasizing the recommendation to complete the model to model comparison study, as it is the Agency's effort to validate the model. Mr. Merrill pointed out, however, that the TRIM comparison had already been chosen as one of the priority points.

Dr. Theis reviewed the highlighted paragraphs again and the Panel agreed on six topics, which were indicated in bold type in the list of summary points (see Attachment K). Panel members decided to emphasize the need for continued work and improvement on 3MRA, in favor of the paragraph discussing documentation.

Dr. Theis commented that the Panel should keep in mind the alternatives currently in use, and decide whether 3MRA represents an improvement. He acknowledged that there are still imperfections associated with 3MRA, but the Panel's statement that the model is ready to be used implies that it is an improvement on the alternatives.

Dr. Stubblefield agreed that the model is a valuable tool from a regulatory perspective, yet it is still built on conservative assumptions and limited data. He noted that he would include more detail on this topic in material he submits for integration into the report.

Dr. Carlisle noted that the Panel had focused on about twenty main points, and asked how other comments would be addressed. Dr. DePinto replied that other material could still be sent to the question integrators to be incorporated in the report in a different way (not connected to the topical paragraphs). Dr. Theis said he understood Dr. Carlisle's point about additional comments, but added that there is a need for the Panel to limit itself in order to complete the report.

Dr. Murarka proposed recommending that the Agency run workshops for potential users of this model; such workshops would be easier to follow and understand than the written documentation. Dr. Travis replied that some such workshops had already been conducted, and more were likely being planned.

### Preliminary Agency Response

Dr. Theis informed the Panel that the Agency response would be presented by three Agency representatives: Dr. Justin Babendreier, Dr. Gerry Laniak, and Dr. Barnes Johnson.

### **Babendreier's Response**

Dr. Babendreier began by referring to the discrepancies in model output values suggested by the AMEC report, and explained that the reason for those discrepancies was a failure to run the clean-up function prior to the model runs. He also addressed the topic of uncertainty and acknowledged that it cannot be quantified, therefore it is not possible to characterize and rank the sources of uncertainty. In order for model error and sampling error to be addressed in the future, the 3MRA team would need to pursue the development of version 2.0, which will include additional modules and data. He concluded by saying that technology and tool development is crucial to improving 3MRA.

Mr. Case (ETC) suggested that the documentation state explicitly that file clean-up is required prior to new model runs; currently, this is only given as a recommendation.

### **Laniak's Response**

Dr. Laniak thanked the Panel for the opportunity to respond to some of its review comments, and outlined ORD's perspective of the three most important elements of the 3MRA effort.

The partnership between ORD and OSW was a voluntary partnership that both sides consider an unqualified success. It led to increased knowledge on ORD's part on how to target science for the real mission of EPA – an issue that had been a source of difficulty in ORD's relationship with the program offices. As a result of this partnership OSW can bring more science to bear on regulatory problems and decisions.

The issue of Agency policy is one that is not dictated by the 3MRA engineers and scientists, whose role is to provide tools and technology for the program offices. Policy shifts can be anticipated, however, and tools can be created accordingly. 3MRA is an adaptable platform, or a "living model", which can be adjusted to accommodate policy changes.

Numerous comments were received on 3MRA, due in part to the technical details associated with integrating seventeen modules. Though these comments are considered and addressed, they cannot all be implemented. Even if this were possible, new comments would likely be received even as the original comments were being addressed.

On the issue of whether the model is ready to be used, Dr. Laniak reiterated an earlier comment by a Panel member who stated that a model does not make decisions. Large uncertainties associated with the current version of the model system do not preclude its value in the decision making process. He asked that the Panel consider whether the model has captured enough of the science to be useful as a regulatory tool. He noted that this is the first time in integrated model of this type was presented. A model can be considered ready for use if it could add value to the decision making process and 3MRA, in ORD's view, does add value.

Dr. Laniak concluded by thanking the 3MRA team, including OSW, ORD and contractor support. He also thanked the Panel members for their valuable and efficient work, and the SAB and DFO for their work in scheduling and coordinating this peer review process.

Dr. DePinto said that he agreed with Dr. Laniak's statement that this is a continually evolving model and noted that the Panel would be making comments to that effect. He asked whether the Agency agrees with this position, and whether it is likely that this effort will continue to be supported. Dr. Laniak replied that he could not be certain that resources would be available to continue improving the model. He added that the Panel's comments may be instrumental in determining whether funding of this project continues beyond a few years.

Dr. Murarka wanted to know the deadline for using 3MRA to determine exit levels. Dr. Laniak replied that it was in a "holding pattern."

### **Johnson's Response**

Dr. Johnson addressed several issues beginning with the deadline for using 3MRA. Since the Agency is currently prohibited from using this model, it has been difficult to establish a deadline. The rule that this was originally intended for was finalized in a different way.

The Panel has commented on broadening the applicability of the model to include advanced waste technologies. One example given was combustors, but there are difficulties in modeling all the products of incomplete combustion. The program has considered such new technologies, including combustors and recycling, and kept abreast of 21<sup>st</sup> century waste management issues, though it is still difficult to reflect this in 3MRA.

Dr. Johnson then emphasized the fact that 3MRA provides a common dataset, thus a common set of inputs for all modules, adding that this is an important benefit of this framework.

Multiple contaminants were also mentioned by the Panel, but present a problem in the context of modeling, as there is no way to know the multiple combinations of chemicals in different types of waste.

The complexity of this model has been brought up as a disadvantage. On the other hand, comments were also received that requested more processes included. The Panel specifically discussed the dermal and vapor intrusion pathways, which were both debated at length by the

3MRA team. Decisions were made to exclude these because, though important, they are both relatively minor when compared to other pathways.

The Panel also discussed whether the population weighted metric in the model is a new way of making decisions. Agency science in this type of waste metrics has been evolving for about ten years. These risk metrics have been used before, beginning with all hazardous waste listings in the 1990s. ORD has become increasingly familiar with these metrics and has been exploring ways in which they can be included in the decision making process.

Dr. Barnes then referred to the Panel's concerns about whether comments from previous reviews had been adequately addressed. The Agency has used considerable resources in developing this model, and a decision was taken to stop its development and conduct a review. In this sense, this is not a completed product, but rather a "living model." The team is hopeful that 3MRA will continue to evolve, as well as be used by others who will decide whether it is a useful tool to adopt, develop and enhance. The model is available to any stakeholder, and has the potential to be enhanced and adapted to multiple uses. For this reason, this review is important and has implications outside of the Agency.

Dr. Barnes urged the Panel to remember the current standard, which is using screening models for both ecological effects and human health, and think about what the use of 3MRA can achieve in comparison. He concluded by thanking the Panel for its insight and valuable work.

Ms. White asked whether the Panel's review provided answers to the charge questions, and whether those answers were clear. Dr. Barnes agreed that the review provided answers to the charge questions. He stated that it would be helpful to the model development team if the Panel were to provide detailed information with its recommendations, and particularly provide alternatives for those aspects of the model which were considered lacking or incorrect.

Dr. Murarka asked whether there were incentives to continue enhancing the model once the court ordered needs had been met. Dr. Barnes noted that OSW recently completed a report on the future of waste management, which included information on better characterizing contaminants and emphasized risk-based waste management programs. There is a need for the Agency to make multimedia risk management decisions. There is also an interest in creating risk-based thresholds for allowing contaminants to exit the waste management system. Modifications to this model can also increase its use among a number of other applications, though this is a longer-term potential use.

Dr. Maddalena commented that another strength of 3MRA is its ability to be adapted or improved quickly – something which is not always the case with other models. Dr. Kastleton noted that such modifications should also be less costly for 3MRA than other models.

Chair's Summary and Wrap-up

Dr. Theis reminded the Panel of the timetable presented earlier. He set a deadline of **November 14<sup>th</sup>** for sending revised material to the question organizers, and asked the Panel to keep in mind the agreed upon summary points when drafting comments.

The organizer of each charge question will be responsible for compiling materials (new or revised) from the Panel members and submitting these to the DFO by **November 20<sup>th</sup>**.

The Panel will then discuss these compiled materials at a conference call scheduled for **November 24<sup>th</sup>**. This call was extended by one hour, and will be held from **1:00 to 5:00 P.M.** Eastern Time.

The Panel then scheduled a second date and time for a conference call, if one is needed: Monday, **December 15<sup>th</sup>, 1:00 – 5:00 P.M.** Eastern Time.

Dr. Theis thanked the Panel members for their attendance and efforts, as well as the EPA representatives for compiling and presenting material requested by the Panel. He also thanked the participating members of the public, and noted that 3MRA is an important tool developed to help regulate an important environmental product. He concluded by thanking the DFO and SAB office for their work in organizing this Panel and the review process.

Ms. Boissevain thanked the Chair for his leadership and ability to keep the group to task. Other Panel members agreed, and many noted that they have enjoyed the process.

Dr. Theis adjourned the meeting at 3:55 P.M.

Respectfully Submitted:

Certified as True:

                  /s/                    
Ms. Kathleen White  
Designated Federal Official  
Environmental Engineering Committee

                  /s/                    
Dr. Thomas Theis, Chair  
3MRA Panel

## **ACTION ITEMS**

1. Dr. Stubblefield will email Ms. White with more information on the dataset from a holding pit he previously worked on (see p. 39).
2. Panel members will submit new or revised text to the question organizers by November 14, 2003. Members were asked to distinguish between their comments in support of the topical paragraphs and other, more general statements.
3. Question integrators will compile materials received and submit to the DFO by November 20, 2003.
4. The DFO will distribute the materials as a single file on November 21, 2003.
5. The Panel will discuss these materials at a conference call on November 24, 2003, from 1:00 to 5:00 P.M. Eastern Time.
6. A tentative conference call (if needed) is scheduled for December 15, 2003, from 1:00 to 5:00 P.M. Eastern Time.

## ATTACHMENTS

Attachment A:	Roster and Biosketches of the 3MRA Model System Panel
Attachment B:	Meeting Agenda
Attachment C:	Federal Register Notice
Attachment D:	Participant Sign-In Sheet
Attachment E:	PowerPoint Slides: 3MRA Mass Balance
Attachment F:	PowerPoint Slides: 3MRA/TRIM Model Comparison Study
Attachment G:	PowerPoint Slides: Investigation of Averaging Periods and Pollutant Concentration Distributions
Attachment H:	PowerPoint Slides: Sensitivity and Uncertainty Analyses
Attachment I:	Report Outline as of August 26-27 3MRA Panel Meeting
Attachment J:	Draft 1.2 of 3MRA Panel Report
Attachment K:	Consensus Points as of the end of the meeting (10/30/2003)
Attachment L:	Preliminary Proposal for Method to Classify Models / Modules of 3MRA
Attachment M:	Questions for Agency regarding 3MRA Sensitivity, Variability and Uncertainty Analyses
Attachment N:	Second Evaluation of 3MRA (Prepared by AMEC for ETC)
Attachment O:	Ecological Risk Assessment Framework (ERAF) for 3MRA
Attachment P:	Beck, M.B., <i>et.al.</i> "On The Problem of Model Validation for Predictive Exposure Assessments." <i>Stochastic Hydrology and Hydraulics</i> 11:229-254.
Attachment Q:	Beck, B. "Model Evaluation and Performance." Encyclopedia of Environmetrics. By Abdel El-Shaarawi and Walter Piegorsch, Eds. Chichester: John Wiley & Sons Ltd., 2002. Vol. 3 1275-1279.
Attachment R:	Agency Response to Peer Review Comments (table)
Attachment S:	Comments by Peter deFur

These materials will be found in the FACA file for this meeting