FIFRA SCIENTIFIC ADVISORY PANEL (SAP)

OPEN MEETING

SELECTED ISSUES ASSOCIATED WITH THE RISK ASSESSMENT PROCESS FOR PESTICIDES WITH PERSISTENT, BIOACCUMULATIVE AND TOXIC CHARACTERISTICS

U.S. ENVIRONMENTAL PROTECTION AGENCY

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2777 South Crystal Drive

Arlington, Virginia 22202

OCTOBER 31, 2008

8:32 A.M.

FIFRA SCIENTIFIC ADVISORY PANEL

MEETING

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MS. CHRISTIAN: Good Morning, again. By now, you all know who I am, but just for the record, my name is Myrta Christian, Designated Federal Official for this FIFRA Scientific Advisory Panel. And without any delay, I would like to introduce Dr. Heeringa, chair for the FIFRA Scientific Advisory Panel.

DR. HEERINGA: Thank you very much, Myrta, and welcome back everybody for the final morning session of our four day meeting on the topic of selected issues associated with risk assessment process for pesticides with persistent, bioaccumulative, and toxic characteristics.

We have made steady progress through the presentations and charge questions this week. I think we all agree, there's been a lot of exchange of information, and we elected to save the final two charge questions, which have some overarching aspects to them, for this morning, so we'd all be fresh and ready to go.

I appreciate the panel and the EPA staff willingness to go to this fourth day. I think it's going to be valuable to have done that in the end. At

this point, I'd like to turn to, either, to Steve Bradbury, or to Don Brady, of the EPA for any opening remarks or follow up on yesterday's session.

DR. BRADY: No, Dr. Heeringa, I think we're ready to proceed to number nine.

DR. HEERINGA: Okay, then, again, since, we've had introductions at the beginning of the week, I won't have the panel introduce themselves. I think we're all quite familiar with one another at this point in the process. Why don't we launch right into question number nine, and Dr. Brady, if you would please read that into the record, please.

DR. BRADY: Okay, question number nine, example pesticide assessments. In this White Paper, the Agency provides examples of how it has assessed the environmental persistence, bioaccumulation, toxicity, and long-range transport of several, unidentified pesticides, using refinements to its ecological risk assessment methods.

Given the data available, as illustrated in the pesticide examples provided in the White Paper, please comment on whether the Agency has used these data appropriately, to the fullest extent possible, in assessing ecological risks of pesticides with PBT characteristics; methods it has used to characterize

environmental persistence, bioaccumulation, toxicity, and long-range transport potential of the example pesticides.

DR. HEERINGA: Thank you very much, Dr. Brady. And Peter Delorme is our lead discussant for question nine.

DR. DELORME: Could I get that slide put up of Table 8.1, please. I just want to thank, start by acknowledging and thanking Steve for the extra time. This question is, as it says in the document, a cross-cutting question. It's, actually, a question that is trying to integrate the responses from most of the previous questions.

Again, I just want to emphasize that, and I want to recognize that the proposed approaches and methods used for the example pesticides do represent a significant change from the current approach to ecological risk assessment of pesticides. Personally, I think that they, generally, appear to be on the right path towards being able to better assess pesticides with PBT characteristics.

I just want to point out that there needs to be a dialogue between risk assessors and risk managers to ensure the results of any risk assessment are fulfilling the needs of the risk managers; and

interpretable and understandable by the risk managers, so that they can understand things like the degree of variability uncertainty associated with them.

And I just want to make sure, I'm sure that Steve Bradbury is aware of the importance of doing that, but that dialogue is important, and it usually goes along, on behind the scenes.

With respect to the first charge question, or the first part of this question, there are a couple of panel members who, we did have some deliberations. These are mostly my thoughts. We did meet, uh, I did meet with the associate discussants through the week, and discussed the new things, but these, my, what I'm going to say here are, mostly, my view on things.

There were a couple of panel members that thought that the question was a little bit loaded, 'cause it was really given what the EPA had to work, which we interpreted as, or more appropriate, what they chose to share. We did not have access to the full data, or the study, which sometimes make difficult interpreting the context of how they developed the numbers that they used in their risk assessment. They did provide a good outline of the process in the results of the analyses.

When you're looking at this question, two aspects need to be considered. The first is how they used the registrant submitted data. And second, how they used other data, or information, which is available, and which can be used to help characterize the risk. For example, non-chemical specific model input, six values, assumptions, and whatnot.

With respect to the registrant submitted data, for the most part, it appears that the Agency used the data provided. Without understanding or having access to the context of the data used, it's difficult to judge if it's been used to its full potential. So, we get one value from the study, so, we're not quite sure, you know, were there other stuff, was it a range of things, but, you know, generally speaking, we, it's difficult to comment on that.

There are a few cases when faced with a range of values, rather choose a single conservative input, they performed their analysis with values bracketing the range to understand the impact on the output, and I think, that's a good thing to do. It provides additional information, with respect to whatever your modeling.

However, I thought that there were more cases with only one value was chosen, when multiple

values or ranges were available. So, for example, for KOW pesticide four, you had a range of 7 to 8.1. He used, for 7 to 9, he used 8.1. You know, maybe, it would have been nice, I don't know if it makes a difference, but, you know, it's nice to, sort of, give that idea of what difference it makes in the value for a model. You get that with sensitivity of the model.

Going back, in a tiered approach, the use of conservative value is appropriate for initial tiers, though. I will say that. But, again, understanding the variability of response, the methods of the model should be part of the risk characterization.

Oh, you know what, I have the long version here, just a second. Oh, I can't find the right on. Anyways, with respect to the other types of data that were used to characterize approach, sort of, the input for the model, where there is data, there are some cases where you provided supporting data, but there wasn't in the analysis.

For example, in the suspended sediments, you provided data on ranges of suspended sediments. I didn't see where there was a real strong case for how you picked the one you did, at least, not in the white paper. It may be in another, other background papers.

So, there are areas where, you know, we need to explore whether or not how you're using the additionally available data from the literature can be used more fully. Okay, and that's a hard thing to do. I understand that. And I recognize that when you're doing these things, the science tell you the information. The policy may drive how you pick a value, or how you use particular data, and it's working at that science policy with it, okay. But, unfortunately, I'll have to look back. I may be able to find it later, and we'll address that later.

Now, with respect to the method that you've used to characterize the various issues here, what we discussed, and how I've approached it is, we've taken Table 8.1 here, and it also appears other where, looked at the issue, examines what you've presented, okay, and the methods that you've been proposed.

And what I did is, when you were talking about all these various issues, I was listening to see, was anybody jumping up and down and saying what we've done is really inappropriate. Or, are there serious concerns, are there minor concerns about things, okay, 'cause the question is asking, you know, what do we think about the methods, are they sound. That's, basically, the way that I've interpreted it.

I just want to start off by saying that, when you step and examine this whole package, there are several common themes that seemed to emerge over the week when we were discussing things across all the issues, or the majority of the issues. And it may effect to the varying degree how things are interpreted, or they're the ultimate acceptability of the proposed approaches from a scientific perspective. Again, it's from a science perspective. And these include things like, characterizing the uncertainty in the variability of the model and the model results. There's very little on that directly done.

Identification of assumptions was brought up several times. You know, we need to be clear about what the assumptions are, and, you know, it's, in a general sense, probably a good idea that, at some point, you have an idea of what the impact of those assumptions might be on the output.

Assessment of model performance, okay, always an issue that gets brought up. You have to understand how well your model represents what's going on out there, how, you know. And one of the ways, I think, that you can achieve this, in this case, for PBT pesticides is, there is data, both empirical, well, mostly empirical, on older historically used pesticides

with these kinds of properties.

So, I strongly urge you to take those and use them to a full extent by running them through your processes, your models, your methods to see what the results are. I mean, a lot of these things are already gone. And if we can't learn from the mistakes we've made in the past, we're on a treadmill to I don't know where.

Maybe to where that guy that was handing out candy was in the front this morning. And I think it was brought up yesterday by Dr. Oris, you know. We accrue the benefits now, and then pay the price later. We're probably not doing our jobs properly.

Understanding model sensitivity to keep parameters, you've done a little bit of that, okay, but it needs to, you need to do that to better help you use your model.

Feasibility of existing studies or protocols for use in the assessment of PBT. This came up, you know, a few times where study protocols that exist now are more aimed at those things that are soluble, or you know, help lower KOWs, lower Kocs, and whatnot. And that hampers the interpretation of the data.

We need to make sure that, if those

things need to be tweaked, if you need to put a criteria in there that says, when you're KOW, KOA or whatever parameter it is exceeds, or is less than a certain value, you need to do this. That's a good idea. That's also going to help the registrant to make sure that they come in with data that's usable right out of the get-go, which is, then, going to make it easier for you guys to get stuff done, efficiently, and us.

Suitability of the data requirements themselves. You know, our, I like to say that our data requirements read like a history book. They reflect the problems that we've seen in the past. Unfortunately, in the past, we weren't seeing environments or risk assessments of some of the chemicals that we've gotten rid of. So, they don't, necessarily, reflect well, you know, these kinds of chemicals.

So, there may be a need to, actually, have new or different kinds of data produced for these kinds of chemicals. And that was going to have to be put, then, in your data requirements, and in ours in Canada, and, possibly, in Europe.

Incorporation of scenarios or models that go beyond field scale assessments, okay. Current

paradigm is, field scale, things don't move, you've got to move beyond that, consideration of appropriate temporal scales. So, maybe we don't need to model just for a year. Maybe we need to do it five, six, seven. Maybe we need to do that model, project it out into the future.

And another emerging, another theme is definition of tiered approaches where applicable. Obviously, the general approach is to start conservative, you know. If you pass something, or if there's no problems identified, then there's no use, no need to waste time and resources in, you know, building a Cadillac if a Fiat will do.

There are logical links between the models and methods proposed for consideration. For example, you know, ATMOS-EAC feeds into PRZM feeds into EXAM feeds into QWASI feeds or into AGRO. You need to be cautious about building a house of cards through changing a component in variability and uncertainty.

At some point, the uncertainty may render the results less than ideal for making the decision, okay. You don't want to do a QSAR that, you know, you're not really sure of, and have that as the basis of a number of different steps or a number of

different models, only to find out in the end, that it's not right, and your whole assessment falls apart. So, you need to be aware of that.

I'm not quite sure how to address that, but. And I know, in other areas, they do use these kinds of things. I think we have the advantage with pesticides in that, we can go back and ask for data, and we can modify our data requirements. If we're putting them out in the open environment, we need to be careful. We need to have good data in order to do our assessments.

So, now, what I'm going to do is, I'm just going to go through the topic areas, and basically, touch on the issues. Again, as I said before, the approach that I take is, I listen to the discussions. I tried to see whether or not people in the panel were, sort of, saying, yeah, generally, we're okay with what you're doing. You need to tweak it here or there and other places.

Or, the general, my general comment to the comment to the panel is, this is my perception of what I've heard. If you don't agree with it, we'll be discussing it. And if I've missed something, I apologize, and let me know, and we can make sure we get it in the record and reflect it.

So, for combined exposure, we used a progressively more refined approach, depending on data availability is logical, you know, whether you use Total Residue, Residue Summation, or FD. Obviously, FD was, generally, agreed to be the best way to do it. There didn't seem to be much consternation or concern that there is anything wrong with the approach that you had proposed.

The only point that was made is, again, understanding, in those cases, where you're using Total Residue is to understand what the difference might be from an FD situation. So, using the existing data, again, to go back and characterize that a little bit.

Aqueous solubility, there were proposed changes to incorporate precipitate compartment. You know, their people seem to, generally, be okay with that. Another method, a hockey stick method, I believe, Louie suggested yesterday. You might want to consider looking at that. I think, I don't know if that will be in question three, the response. And again, you should be able to go back to the specific questions and get an idea.

All these things should appear there. The issue needs additional work to better understand differences between lab and field solubility to assess

the potential impact on the interpretation of tox data and the results of modeling. Again, you can maybe do some data mining. There are information out there which, probably, compare those two things. See how your models react.

I did have a question about the assumption of freely dissolve, only the freely dissolve being bioavailable. But I am a little uncomfortable with that assumption, although, I know in scientific circles, it's, generally, held as true.

With respect to degradation half-life, generally, agreed that the whole system half-life is good for characterization of the overall persistence in aquatic ecosystems. It gives us a good understanding of, you know, how pesticides are going to react out in the environment. The problem it presents is just the modeling when you're trying to do that.

Generally, I think, we just said that it was, probably, an artifact of the study design. From a risk assessment perspective, it could be, generally, regarded as a conservative approach when distribution of a chemical would be dominated by absorption to descended matter or the sediment.

For example, high Koc, KOW is greater than five. It might be useful, it might be appropriate

for an initial tier assessment just to see. And, again, tier one assessments go back to the, if your tier one assessment tells you that there's not a lot of problem there, then, fine. Don't spend the effort to do anything else. Consideration should be given to, we talked about modifying data requirements to include a water only biotransformation study in a spike sediment to maybe help get some initial data that could be useful for the modeling.

With respect to persistence in soil and sediment, use of PRZM exam to examine your carryover in field soil is a, you know, good, science-based, logical first step. You can do that right now. It's just a matter of implementing it. You might want to think about how you might further refine this in other tiers, you know, in terms of how, I understand how you input your data, and stuff like that, but mimicking the actual application pattern a little bit better, if it's not every year, if it's every second year, and stuff like that.

You can also look at field dissipation studies there. You know, if you get a field, we get field dissipation studies that cut across different areas. So, if, at the end of the year, you're still seeing thirty, forty percent, there's a flag right

there. And your model should be, you know, in line, at least, if they're working properly. So, you know, that gives you an idea right there.

For sediment, this issue needs to be integrated with the sediment dynamics issue of burial bioavailability, bioturbation. I think the key issue is burial. You know, you need to better define, and then adjust the model in the receiving waters scenarios appropriately. You may need to develop additional receiving waters scenarios to adequately characterize the impact on different sediments dynamics in different types of receiving water volumes. I think that both myself and Dr. Thibodeaux indicated that.

Now, we weren't, specifically, asked to address sediment dynamics in the question, but I'm going to do it anyways, 'cause I think it's important. I think that there was a lot of discussion. It was, you know, I, actually, had trouble, at times, following all the details of the science and whatnot, not being from the area.

But, I think, it was, generally, agreed that incorporating sediment dynamics into modeling is necessary for assessment of PBT pesticides. It was noted that this is scientifically a complex issue. I have to get together with the people from question

three to get an understanding of how they're going to answer that question. In the end, there was, I was unclear on certain parts of it. So, I apologize for that.

Based on, you know, the discussions and what you guys presented, I think there is general agreement that burial, at least, is an important process to consider. But there were questions about the appropriateness of the rate of permanent burial that you used in your modeling. You guys picked a high erosion scenario, and there were questions, at least, in my mind, whether or not that's appropriate.

There's concern that what is buried is not disappeared. It's only temporarily out of circulation. Again, going back to historical knowledge, experience with PBT chemicals shows it can, and will, come back. And as elegantly noted by one of our panel members, shit moves downhill.

For PBT chemicals, redistribution among and between environmental compartments is the key factor that needs to be considered in problem formulation of risk assessment. And it should inform both the temporal and aerial scale used in the assessment. And that's not only for sediment. That's for everything.

There were a couple of us, as I said, that said that for PBT chemicals, you need to give serious consideration to developing additional receiving water scenarios, including those for flowing water, so we can adequately characterize what's going on out there.

Under bioaccumulation, your use of multiple lines of evidence, I think, does have merit. You know, it's in, sort of, a weight of evidence to the approach. So, if you have field data, you have mesocosm data, if you have the modeling all together, you know you're going to get a pretty good idea of the importance of this.

Use of food web bioaccumulation models is consistent with what's been done elsewhere within the EPA, such as the Office of Water, and you know, they appear to be scientifically reasonable. Again, there was a lot of discussion about specific points within the models, and whatnot, that are going to have to be sorted out.

But, you know, I think, there's general agreement that, you know, food web modeling of bioaccumulation is a reasonable thing to do. Dynamic models are, probably, appropriate for field scale. But, you know, for field assessment in a longer term,

you may want to consider studies, and that could be a simplifying assumption for doing, say, an arctic or a mountain peak scenario.

For chemicals which are PB, you know, again, back to the data and modification or additional data that might be needed of existing protocols. Things like, given that you might not reach equilibrium or steady state in the BCS study, you need to have rates. You might have to refine the sampling protocol for those studies to make sure that you can calculate those rates with confidence. And for larger animals, you might want to look at, necessary to measure residues in compartments, specific compartments, again, tiered approach.

For the terrestrial bioaccumulation, at this point, there's some proposed screening methods. There's some potential models for risk assessment, so they don't really bear on the cases that you talked about. You need to look and see what their suitability is, and stronger link in the future between aquatic and threshold models.

Toxicity, most of this discussion focused on critical body residues or TRVs, and, again, this is consistent with approaches that are being taken elsewhere within EPA. The science is understood and

well characterized in the supporting documentation that was provided. So, again, that's one of those, probably, a no-brainer type thing.

There was some challenge identified with work on chronic issues and the use of PRA. And that's especially important to know. If you have your assessment endpoint at a population level, and you're feeding into things like growth, repro, survival, you know, how that was used in that, you know, it's going to be a little bit trickier.

Let me see here. You did have some mention of the TU and TEF approach, but in the White Paper, it wasn't really discussed in the question. You talked about the assumption of additivity. There needs to be some support when considering this approach. It's especially important if there's co-applications of different pesticides, or you're getting into those kinds of situations in, sort of, some cri-, and you provided a little bit of information on when it might be appropriate to use additivity and when not, but needs some guidance, I think, on that to better understand that, probably, more for the evaluators than for people, other people who may not understand all the issues.

Again, going back to one of the

cross-cutting themes is, you know, looking at protocols, and the data requirements as to whether or not they need to be changed, you know, specifically, requiring or asking for tissue residues in some of the studies, rather than just the media.

For the long-range transport, several models were identified and available for quantification screening. All appear to be well rooted in science. You have the OECD models, global POPs, that's the information Dr. Bidleman presented to them, Money, et al, 2006. And it appears that a lot of these are used in other jurisdictions already. So, there's some confidence there, you know, that they are reasonable approaches.

You know, there's general consensus that these models are suitable, and a tiered approach has, actually, proposed by the panel, so, they've done a little work for you there. And it was suggested that, if you read the OECD models, look at, potentially, using the Monte Carlo, or doing specific values on any of the ranges to see whether or not that impacts the conclusions about long-range transport.

Also, suggested that you develop a comparison set of pesticides based on the start to use pesticides in the past, the PBT stuff, but I would,

also, add to that. It's also useful sometimes to add in other pesticides that aren't subject to LRT, so you know both ends of the spectrum. Okay, so pick a few that are appropriate. Here's ones that we know don't, aren't subject to long-range transport.

How do they come into it. My only caution here is, scale of use may be important in this one. We know that we see in Canada pesticides in air, in rain, absorbed the particles that, when you look at their properties with confidence, they would say, no, they're not LRT, but because millions of tons a year are being put on, or hundreds of thousands of tons are being put on, just the scale of use was enough that, even if it's a fraction of a percent, that's volatile. It's getting up and it's moving around.

Those aren't, maybe, as much of a problem, because they're not persistent, and they may not be as bioaccumulative, but it's something to consider. Especially, I think, the issue of, sort of, medium range transport was brought up. I'm not quite clear on what long range is any more. I thought I knew before I came here. Terry changed my mind.

Consideration should be given, you didn't discuss it explicitly under question number eight. I did have a discussion with Keith on this one,

whether or not KOA and KAW should be added as data requirements. You know, I had that in my notes and forgot to mention it, but I think you might consider adding them as data requirements as they, they are key components getting into the OCD model.

Mind you, if you have lab data or, actual, empirical data both, better to have that than something from a QSAR. And that's going to trigger, if you do that, then you're going to have to look at whether or not there's existing protocols out there for developing those data, if there's ASTM protocol. I'm not sure.

With respect to far afield concentrations, there were suggestions made on how to develop models and links to the near fields. There are datasets out there that could be mined, and empirical models developed to help you in that assessment. There is going to be considerable uncertainty in those. It's going to take a little bit of work, but I think there's probably enough information out there, that it can be done, to give you, at least, a screening level assessment of what might go on, again, far afield, and, also, temporally displaced from the time of application.

There were a number of points that were

given to me by various panel members that I included under additional considerations. Things like, what Dr. Abbott had brought up yesterday about scenarios, making sure scenarios are representative of, sort of, the, not necessarily the AGRO ecosystems that we deal with all the time, whether it's a wetland or a stream or an estuary, stuff like that.

As well, one point that was brought up, that's, sort of, general is, and this is where I think dialogue with the risk manager is important is, understanding the implication of dealing with some of these international conventions and laws. There are conventions on trans-boundary pollutants. There are things with respect to POPs, like UNECE in Stockholm, and how is that going to impact what you need to do for your risk assessment and how you must do it.

So, that's about what I have to say, now. Again, I think, in general, there was, nobody stood up and down and said, yeah, you shouldn't be doing what you've done. Definitely, there were tweakings. Two areas, the one area that seemed to be the most contentious, I would say, was, sort of, the sediment dynamics, and how to incorporate that in. And, that one, I think, there is a bit of angst there, with respect to the burial.

DR. HEERINGA: Thank you very much, Peter. Our next discussant is Dr. Maddalena.

DR. MADDALENA: Yeah, I think Dr. Delorme covered it quite well. I mean, I would simplify things, somewhat, to a degree of, I'm not sure how much, t he OECD tool, for example, in long range transport, when you see results like you see in the table in the White Paper for some of these case studies, it's hard to understand why you would go on.

And so, I'm not sure, what other information you would need. I don't think, there's some ways to improve the long range transport model, and get a little better feel for it, but I think, some of those numbers are like, okay, this is not good, so let's look at some of these other properties. If it's as inert as water.

And it has a long range transport like that, then, well, okay, we'll go on with it, but. So, then, you can be done with the long range transport, and focus your attention on, maybe, bioaccumulation and toxicity. And then, if you have something that has a, clearly, the KOW KOA range that's going to lead to bioaccumulation, or has a pretty good potential, you could focus there, too.

So, certainly, I don't understand all of

the dynamics that go into the regulatory process and the data generation, but it seems like you could focus your attention. And I don't see a need, really, to develop very sophisticated models for these particular class of chemicals. So, I'll participate in the discussion, but that's, really, other than what Dr. Delorme said, that's pretty much where I would go. Thanks.

DR. HEERINGA: Thank you very much. Dr. Abbott.

DR. ABBOTT: I have very little to add to Delorme's excellent comprehensive presentation. In fact, I, really, have nothing to add to it, but I do want to re-emphasize that I think it's very important for the Agency to use some of the data that you've already collected, possibly, on older chemicals that may not even be on the market anymore to perform case studies, and see whether or not the modeling techniques that you're using, or propose to use, are going to point out the problematic nature of some of those chemistries. And, I, also, strongly recommend that you expand the aquatic scenarios that you are considering. Thank you.

DR. HEERINGA: Thank you, Dr. Abbott. Dr. Oris.

DR. ORIS: I have nothing to add.

DR. HEERINGA: Well, Peter, you must have nailed it, I guess. I want to open it up, at this point in time, to, is there another discussant? In any case, if I've missed you, please speak up at this point, but any member of the panel who would like to contribute on this particular question, yes, Dr. Bidleman.

DR. BIDLEMAN: Let me get the mike over here. I have a couple of points to bring up that Peter touched on. Early on, Peter, you said something about physical chemical properties, and the variation in them. This is a subject, a topic that cuts across every single issue with PBT compounds, the toxicity, bioaccumulation, LRT.

We need good physical chemical properties. As anyone who has looked into this subject knows, by just scanning through the Mackay, et al, handbooks on p-chem properties, there's a bewildering number of these. For the same chemical, you can find orders of magnitude variation in different measurements of them.

One way to assess the differences, as Peter suggested, is to plug the ranges into the models, and see what the outputs are. The other way is to try

to bring some order into all the various measurements of these chemicals. And this has done quite successfully for PCBs and the organochlorine pesticides, by recognizing that these p-chem properties are thermodynamically related.

So, if you have vapor pressure water solubility and the three partition coefficients KOW, KOA, and KAW, you can take the various laboratory measurements of these properties and combine them, and then, do an adjustment procedure, such that you minimize the errors in the predicted property, based upon the other properties. I didn't explain that very well, but it's an iterative method. And, as I say, it's been used quite successfully to derive what Frank Byner's group would call final adjusted values, which take into account all the thermodynamic data.

So, if you're after KOW, for example, you would not just look at the measurements of KOW. You would look at all the other measurements of things that could be combined to give KOW, and you'd do adjustments to minimize the errors in the predicted KOW. And that allows you to arrive at a consistent set of physical chemical properties, which are statistically better than the simple average of the properties just obtained from the tables of the Mackay,

et al, handbook.

And I'm suggesting that this approach be looked into more thoroughly for currently used pesticides, for which a number of data also exists, to see if we can get a better set of p-chem properties for these rather diverse chemicals.

The second point involves the long range transport. The models that we discussed were really long range transport models. They were designed to predict the transport across wide ranges of latitude.

So, for example, from the middle United States up to the Arctic, or across continental scale regions of Europe. They weren't designed to take a pesticide from Southern Illinois to Lake Michigan. For that, you need a set of models that operates on a final scale, and these were not really discussed here.

But, I can see that there's a need for this. And so, I think we need to consider modeling approaches, not only that takes things a long distance, but to take things medium, and even short distances, also.

DR. HEERINGA: Thank you very much, Dr. Bidleman. Yes, Dr. Norstrom.

DR. NORSTROM: Sticking to the topic, and as a person who has tried to use some of those

published values for things like KOW, my question is, what is the reason for the variation in these values? Is it because of older methods that just weren't very good? Or the laboratories that were doing them that weren't very good, or what?

Because, it's perhaps moot for new chemicals if the methods have been sorted out, and we know, now, that we can, actually, get a really good KOW or KOA, then we shouldn't be importing the problems of the past into the present. What's your view on that, anybody?

DR. DELORME: Yeah, I would have to agree with you, Ross, there, that, you know, for the newer chemicals where you've got. I think that's one of the reasons why other regulatory agencies, PMRA and EPA like the protocol for these studies, because, you know, they're controlled, and you know, there should be consistency in results. And that's, actually, a big part of our job, is reviewing those studies and ensuring that the studies are scientifically sound when they were conducted. So, and, or you probably see more variability in some of the older information, definitely 'cause of changes methodologies and whatnot.

DR. HEERINGA: Dr. Bidleman.

DR. BIDLEMAN: Well, Ross, I have a

rather cynical reply to your comment. And that was, when was the last time you tried to get funding to measure p-chem properties? You know, I've talked to other people who have been in this business, and it's, virtually, impossible to, actually, get stable funding to do this type of work over the long term.

You, usually, end up measuring a Henry's law constant, because you need it for a particular study on the Great Lakes. So, you do a quick job of it. You don't investigate all the nuances which may be necessary. And for some of these things, there are definitely technique differences which cause real differences in the measured properties.

For example, the Henry's law constant is a biased by the most common method used, and that's the bubble stripping method. And it's biased for hydrophobic chemicals because of adsorption of the bubble water interface, which was suspected, but never really tested, until a couple years ago, and there some nice experimental papers that show that this is a real effect.

So, when you go back and you look at the Henry's law constants for PCBs, you might be tempted to say, well, they're okay for the lower molecular PCBs, but when you get to the heavy ones, there's likely to

be a bias in that particular experimental method. But to investigate these biases and differences requires some stable funding to do it. And it's very difficult to get that support.

DR. NORSTROM: It seems to me, Norstrom, considering the importance of these things in so many models, that we really need to, somehow or another, have a better feel for the real variation in these things. Perhaps, relative consistency is more important than absolutes, and so we can always make some kind of correction for bias across correlations with properties and that kind of things, but at least, the numbers should be internally self consistent.

DR. HEERINGA: Dr. Meador.

DR. MEADOR: It was my understanding that the slow stir method was about the best for estimating KOW. The people that run the spark model have found extremely high correlations between what slow stir and the spark model puts out. And they are, actually, quite pleased with the results.

Once I did a review of KOWs for polycyclic aeromatic hydrocarbons, and I had about a dozen values for, oh, I think I did thirty, thirty or so PHs, and course, they're all over the map, because of the different methods. But the mean value for those

in the spark model was just about right on. So, that's a fairly good estimate, of course, there's always variants that you have to deal with, I mean, their log values, and you have to consider that. It's never going to be a precise number, so, you have to live with it.

DR. HEERINGA: Okay, Dr. Lick and then Dr. Gan. If you can turn on your mike, Dr. Lick.

DR. LICK: I would like to comment on this whole system half-life. I did that before, but I'll do it again. The present procedure, I think, is very misleading, because, somehow, it gives you some sort of average between what happens in the overlying water, and what happens in the sediments. And we talk about very hydrophobic chemicals.

The half-life in the sediments is extremely long. And I've never measured them, but the reason I say that is that, when you look at buried sediments, you'll find highly chlorinated PCBs and dioxin, and things like that, that have been there for fifty years, or as long as they've been produced. And at intervals, they don't seem to have changed their concentration that much.

So, the half-lives are extremely long. What really determines the life of these chemicals is

whether the sediments are buried, or whether they're exposed. And if they're exposed, then the half-life in the overlying is much more relevant than what's in the sediments. But if they're in the sediments, they're extremely long.

DR. HEERINGA: Thank you for thinking that issue out again. Dr. Gan.

DR. GAN: What, while there's a few chemists here, I just want to see something, maybe, that's very obvious to some of you, most of you. I spent about two days to go over the White Paper, and I think it's very informational.

But reading the case studies, one impression I did not get is the emphasis that's on sediment toxicity. Because, for these chemicals, we know maybe eighty or ninety percent of it will be in the sediment phase. To me, I think the sediment toxicity would be the number one issue here.

Maybe, you guys will address this in a different protocol, I guess, but I, you know, that's the impression I did not get after reading this 200 page document. It's mentioned here and there, even sediment cold water is mentioned here and there, but I would think sediment toxicity probably is the key. And looks like, my impression from reading this is, we're

looking from the water into the sediment, not in the sediment. That's my impression.

DR. HEERINGA: Thank you, Dr. Gan. Dr. Simonich.

DR. SIMONICH: Staci Simonich, yes, I would totally agree with that. In fact, I should have called it out sooner. I had sidebar discussions with my colleagues, but I definitely agree with that assessment.

DR. HEERINGA: Okay, Dr. Hickie.

DR. HICKIE: I would just like to comment on Dr. Delorme's commenting in his talk about using steady safe models for bioaccumulation, in regards to long range transport.

And if you think about a system of long range transport, it's kind of like a chromatography column, in that your pulses will gradually get dampened the farther you move along. You'll also get dilution of the concentrations. And at some point, you do approach the point where a steady safe bioaccumulation model is fine. I don't, can't quite comment on how far depends on the chemical.

But the other thing is, if you're using a generic pond system and food web, you're going to get the same bioaccumulation factors, no matter where you

are along that track. And if you want to go beyond that, then you need some idea of the loadings to get actual concentrations, so you can do a toxicity evaluation.

DR. HEERINGA: Okay, Keith Sappington.

MR. SAPPINGTON: Thank you, I just want to address the comment, a couple of comments on the panel regarding sediment toxicity, and I agree with that. We chose, in the case of pesticide four, we chose to focus on the higher level organisms, in the White Paper, the actual risk assessment that was conducted for that included sediment organisms and sediment toxicity.

And in fact, those were the drivers in that particular risk assessment. Likewise, for pesticide one, we had quite a bit of sediment tox information for the parent and the degraded compounds, and we chose not to include that in the White Paper. But those, in fact, were part of the risk assessment. So, we probably should have made that more clear. Thank you.

DR. HEERINGA: Thank you for that clarification. At this point, I guess, unless there are additional comments on nine, we have a chance for closing comments and general comments later on, why

don't we move on to question number ten. Dr. Brady, if you would read that question into the record for us.

DR. BRADY: Question number ten: Future PBT-related refinements. The Agency is considering refinements to its problem formulation process to improve the ecological risk assessment of pesticides with PBT characteristics, as outlined in Chapter 8 of the White Paper.

In particular, please comment on the Agency's proposed process for identifying pesticides for potential PBT risk assessment issues that need to be addressed; and the priority for developing new models, methods, and information for addressing PBT issues.

DR. HEERINGA: Our lead discussant on this question is Dr. Donnelly.

DR. DONNELLY: Thank you, Dr. Heeringa. I'm going to try to give a quick overview of what our discussion was, and hope that the co-discussants will fill in any details that I left out.

We worked on this several nights, and I think, put together quite a bit of information. This is almost the, what I would describe as the kitchen sink question. Anything that was left out in questions one through nine, kind of, fell into question number

ten. So, we did the best, I think, that we could to address things, and as soon as we get our slides up, we'll get going.

The first issue that they asked us to comment on was the process for identifying or screening pesticides for PBT risk assessment issues. Go ahead and go to the next slide.

The comments that we had was that really the criteria that are listed, which come from the national and international screening criteria for classifying chemicals for PBT and LRT characteristics. These appear to be reasonable.

I don't think anybody had any questions about that. And we, also, felt that meeting the criteria for a particular attribute will help the Agency identify which pesticides and which parameters it needs to focus its efforts on. The only concern that we had was that a number of the criteria that were in Table 8.2 are pretty broad ranges.

And especially looking at the lower end of those ranges, we thought it would be important to analyze the sensitivity of models, and whether or not some of the criteria might need to be modified or adjusted a little bit. Next slide.

One of the panel members suggested that,

as an alternate screening criteria, the Agency might want to try to identify level three fugacity model. It could provide an overview of distribution of various media.

This alternative model would provide a more informed means of investigating persistence. It would, also, allow the Agency to determine which compartments should be the focus of additional investigations of modeling efforts. And we've had some of those discussions previously, with regards to whether it would be sediment or surface water, et cetera.

The Agency should probably considering adding KOA or use multiple models. In the relevance of using a Q toxicity for bioaccumulation persistence was not clear as a criteria for this particular flat chemical.

The second issue that we were asked to comment on was priority for developing new models and methods and information for addressing PBT issues. The best method that we came up with to answer this or comment on this was to use Table 8.1.

Table 8.1 in the White Paper is a list of current challenges associated with ecological risk assessment of pesticides with PBT characteristics. So,

what we did was come up with a new table, and in this new table, we have added two new columns. One is a column for comments, so that the comment on the various risk assessment issues. And then we, also, gave, what we thought was a first cut at trying to prioritize those issues.

So, to begin with, on environmental persistence, the issue was quantifying exposure to parent and degradation compound. The comment that we had was that we felt it would be good to look across larger groups of chemicals, specifically, to see how the results differ from the TR or RS method to the FD. Which, again, is kind of the gold standard. This, we felt, was a medium priority.

Second issue, interpreting predicted or measured exposure concentrations that exceed solubility. This we listed as a high priority issue, something that we felt needed to be addressed fairly quickly. The comments were, it needs additional research to understand the differences between laboratory's solubility and a parent solubility in the water. And then, second comment was, there's a need to develop a better understanding of the need to incorporate transfer kinetics for precipitate compartment model in the modeling effort. And this we

ranked as a medium priority.

Third issue was interpreting degradation half-lives when dissipation processes dominate. The comments that we had was, this is an experimental artifact. Definitely needs to be resolved. And it's possible that this could be resolved through modified data requirements. This was ranked as a medium priority.

And the fourth issue, quantifying long-term exposure multi-year carryover in soils. We did feel that this was largely covered with the existing models, but there is a need to assess model performance in estimation of sediment concentration. And this was ranked as a medium priority.

Moving on to sediment dynamics, the first issue was addressing, understanding the importance of sedimentation processes on bioavailability in the context of model agricultural pond systems. This, we felt, was a relatively low priority, and largely depended on the modeling approach that was being used.

Second issue, identifying and quantifying the principle processes related to sediment dynamics. The comments were that there is a need for a better understanding of sedimentation burial rates.

This, we felt, was a very high priority, as was the second comment, which was the need to develop additional receiving water scenarios. And this has been discussed quite a bit in some of the previous questions, as well.

The third issue on sediment dynamics, was to identify appropriate methods for modeling these processes for aquatic exposure assessment. The comment that we had was assess existing models beyond the PRZM, EXAMS, and AGRO models, but we did feel that this was a relatively low priority.

Bioaccumulation, the first issue is quantifying exposure by aquatic food web. The comment was that, relative to most of the other pathways, this was is, probably, pretty well characterized. And so, we felt that there was a need to modify that, but that's kind of where we left it.

Second one, interpreting and integrating results from labs, fields, and model-based bioaccumulation methods. This needs to be done to assess the model's performance. We felt that this could, probably, be done fairly quickly, and so, we gave it a high priority.

And then, the third issue was assessing bioaccumulation potential in terrestrial based food

web. This is a high priority. The comments were, we need to identify all existing models for assessing bioaccumulation. Second comment was to explore and assess existing models to better understand the implications of, and magnitude of, terrestrial bioaccumulation, which we gave a medium priority.

We added a fourth issue to bioaccumulation, which was to explore the links between terrestrial and aquatic bioaccumulation. Comments on this was, that it's needed to assess the model performance, and there is a need to consider additional terrestrial links to the model. Both of these were ranked at medium priority.

And the last two, long-range transport and toxicity. The issue with long-range transport, number one, establish relationships between near-field pesticide loadings and far-field concentrations. The comments that we have, this may be resolved by following current literature. There's an opportunity, we think, there to mine a lot of the existing information that's in the literature on some of the persistent organic pollutants, such as chlordane, DDT, DDE, to establish this relationship. We ranked this as a medium priority.

The second comment was, there needs to

be a dialogue within the Agency with regard to how to translate long-range transport into risk estimates, and again, this was ranked as a medium priority.

Second, on the long-range transport list, was understanding the applicability and reliability of available models for screening transport potential. We did feel that as a screening tool, there's a need to develop a tiered approach. And I think this is something that will be emphasized at the end of this with some of Dr. Portier's comments. This was ranked as a medium priority. And, again, the second comment was the need to integrate some of the existing models into long-range transport.

Finally, on toxicity, the first issue, estimating combined toxicity of parent and degradation products. The first comment was to use existing information. The existing information that's available seems to address this issue largely. There may be a need to consider including the carrier influence on toxic insolubility. This was ranked as a low priority. And as a medium priority, the second comment was to examine the possibility of using or modifying test protocols to obtain residue levels in tissue.

The second issue on toxicity was to assess toxicity due to multiple exposure routes and

steady state conditions, both of which may not be adequately evaluated in a standardized test. The comments that we had on this were to assess the performance of different models, and, or field methods to evaluate multiple exposure routes and steady state conditions. This was ranked as a medium priority.

Finally, we've listed what we think are some of the information needs, both to clarify some of the issues in the White Paper, but also, to kind of move this to the next step for the future refinement. One of the issues is, there's a need to more clearly define the input and output needs.

Some of this is in the White Paper, but it wasn't always clear what inputs are required, and then, what the anticipated outputs would be. One of the things that I think has been emphasized several times on this panel is a need to identify sources of uncertainty.

We know these are there. We know, in some cases, they're quite large. And I think, this will, also, affect the next bullet, which is sensitivity analysis. There's a consensus of the discussant groups, seem to be that there are some parameters for which you could almost use the default factor, because they really don't influence the outcome

of the model. And I think, doing a sensitivity analysis of input parameters would help this.

And, then, finally, this is an issue that Dr. Portier will discuss in a little bit more detail. I think there was, really, a consensus amongst our group that there's a need to look at opportunities to integrate some of these models. And with that, I will allow Dr. Portier to finish the discussion on the model.

DR. HEERINGA: Thank you, Dr. Donnelly. Ken, I guess we'll go to the other associate discussants after-

DR. PORTIER: I appreciate the opportunity to speak at this point. I wanted to address kind of the second bullet point, which is kind of moving forward, and develop priorities or developing new models, methods and information for addressing these issues. I was of 2 minds as to whether I wanted to say anything on this, but when Mr. Sappington put up this graph, and I looked at it, I thought to myself, okay, is this what I think is going on, and is this a process that can handle 70 chemicals a year?

When I look at this draft, it basically says that the information is being processed by one or more risk assessors who stands in that blue box in the

middle, and grabs that material and is being asked to integrate all this information and make some very key decisions, on not only what we want to do with PPB related chemicals, but pretty much all your risk assessment kind of works this way.

What I want to do, if you could click the...I want to talk about, is moving the conceptual model from a peripheral location in the process to a little bit more central location in the process. And this is may be a conceptual approach that how EPA might want to think about using these models to speed up the process and to make the process a little bit more steady. Next Slide.

When I think about models, I think about what is the utility of those models. So you use a model to integrate what we know. In the previous graph, the risk assessor is the integrator. The risk assessor is the person who integrates all the knowledge, and then makes kind of a decision. I'd like to put a model in there that allows, that helps the risk assessor to do that integration.

Not only as a leveler for comparisons, we're talking about a particular scenario here of a 10 hectare field, and a 2 hectare pond, and you've created a conceptual model that helps you to run chemicals

through a scenario so that you can compere them. So that model helps you compare things when the data coming in may not be that comparable.

The kind of actual field measurements and utilities, utilization, doesn't always lend itself to direct comparisons of the raw data or the data that comes out, so you pass it through a model to kind of levelize things. The model is a means of gaining insight into the expected effects, so you are able to predict things out to address things like Dr Delorme keeps saying, we need to look 5 to 20 years out into the future.

That's kind of hard to do with existing data, unless you pass it through a model. A model is a focus for data analysis, and collection, so the model really the whole process is using and integrating the model forces you to look at the holes in your data, and where do I not have information, where do I have information? Since I guess that shifts in framing the problem was at the top, so it's an interesting...when I move my slides to Dr. Donnelly's slides things move around.

In my way of thinking, data collection and experimentation should support filling in the model deficiencies, rather than the model accommodating the

available data. And I worry, not just in this panel, but in a number of eco-risk panels, I worry some time that EPA is using models that can accommodate the data, rather than the model that's really a picture of the situation you are dealing with.

And I think that you have to put the horse in front of the cart, and I think that the model that depicts the situation appropriately is the Harst. And then there is always this discussion between the empirical data and the association you wee in the theoretical data and the theoretical relationships that you know you know exist, and how do these 2 kind of tie to each other, next slide.

So, it's kind of my picture of, my modification of the previous graph looks a little bit more some thing like this, where the information of the circles that are around.

You have information on physical/chemical properties that we just talked a lot about that, on toxicity, on metabolism, bio-accumulation, long range transport. And that information goes through a process that says, do I have any new information for this particular scenario? Which yes, I am going to estimate the parameters I need to put into or model, or no, I'm going to use some kind

of default parameters.

And at that stage, which is really to my way of thinking, the first part of a problem formulation. What do I know, and what parameters do I have good estimates, what parameters I can change for this scenario. And it's also where I identify all the uncertainties in those parameters.

The default parameters, we have the uncertainties defined. It's always the new parameters that you have to worry about. And then the second part is kind of forming the model, and you have, I have the major components of the model that we've been talking about here. And I kind of have to extend my box off to the right for PPB chemicals, because I need to put that long range transport model in.

The Panel hasn't seen that before in the eco risk that we've looked at before. We've had the pesticide application model. How is the pesticide applied to the field, used in practice?

We've had a lot of discussion on the fate and transport models, EXAMS and the PRZM models, and we've had a lot of discussion here and in previous SAPs on food web effects and utility. Now we've got long range models. If you put long range models in you have to worry about these source emissions and

geographic variability.

But when you are forming that model, you are really, that model has to address the assessment end point, which is the second big part of the problem formulation. What are we really interested in measuring our output against. Is it human health effects? Is it ecological population impacts, or what? And then there's this other big issue which we haven't talked about here, is whether the model is formulated to look at what happens to the individual versus what happens to the population?

And once you've got that model formulated, then you can ask the general risk questions against the model, or the PPT specific risk questions, and I just kind of listed those out. You can also look at national and international risk kinds of issues. Next Slide. So there was a quote in some of the material from Einstein that says, "Make things as simple as possible, but not any simpler." I think that's a good philosophy.

The big question is tough, how do you get to what is the appropriate sized model? In this presentation, and in past presentations, I think the Agency has used kind of a forward approach. Which basically says, you have some kind of core model that

everybody agrees on, and then you add components to the model as they are needed.

So the risk assessor looking at the data says I have to have a terrestrial exposure component, so I go find a terrestrial model and I add it. And I'd like to see the Agency kind of take/think about what I would call a backward approach. And the backward approach says we start from the most complex model that everyone can agree on. That has all of the ecosystem components there, and then when we look at a new chemical we subtract components that we don't think are going to be important in that model.

Now this has a real benefit, because 1, you only have 1 full model that everybody can agree on. And as you start thinking things out in the model, you know there is a finite point at which you are going to stop, because you can always go down to 0, right? In the forward approach, it can be an endless process, because someone can always think of something else to add, right?

Some additional detail to go down. In the forward approach, it's very subjective, and it's very open-ended. In the backwards approach, it's more defined and the process you know it has an endpoint. And in problem formulation, subtracting from the full

model becomes 1 of the main tasks, it becomes like the third part in the problem formulation, is what's the level of resolution and what are the components that I need in that particular model? So that's kind of looking to the future, in thinking of a strategy that you can develop. Next slide.

As we have been talking the last few days, I've taken this model which is one of the graphs in the presentation, and it's in the white paper, and I've added some of the other things that we've talked about and added it to it, and there is a strategy to my coloring of this graph, because the things in red are primarily processes, and the things that are in the orange boxes are sources of fates really.

The source is up there at the top, the application of the pesticide. And I've added a lot of transport out, you see the little blue things that indicate transport. In some of these things we have talked about, but only briefly. For example, terrestrial animals don't always stay in the field in which they were exposed, so they're a net of...they transport pesticide out of the area.

I'm always reminded of years ago there was some presentation I saw on tortoises, utilizing nuclear fuel rod storage ponds in the Savanna Research

Center, where they would go in the ponds, swim, they'd pick up the radiation and go walking into the woods and then die a kilometer away, and you had a nice little exposure of radiation and they were able to track these things. A net transport from the source.

So when I look at a model like this, and I will be very brief, I think the Agency owes it to itself to take some of the excellent modelers that they have, and kind of turn them loose to see if they can develop for their risk assessment purposes their own modeling framework.

What I call a full and complex modeling framework that can be very structured, very much into components that interlock, that have processes that can be placed in and moved out again. The computational technology to build these kinds of models that can be easily scaled up or down is available.

I just don't think the Agency has tried to make a decision to move forward into this kind of model, and your still looking around and trying to, - what was the word?- linking together existing models. At a certain point there is a lot of effort that goes into linking that could actually go into creating your own model that works for your purposes, that can be documented to the level of resolution that you need for

your clients and you are not constantly depending on someone else to add functionality that you need or don't need.

I think a model like this, or a structure like this would facilitate rapidly screening and assessing those 70 chemicals per year, which I can't even contemplate how you do that without this kind of a structure.

Last slide. And the last slide just says that within that structure we've had a lot of discussion about, well sometimes we are going to need a whole animal model, sometimes we are going to need a part of the animal model, and these kinds of models can now be structured so that that level of complexity can be built in, but only utilized when you nee it.

So you've got a generic animal, the generic animal has inputs and outputs and internal constructs, and it's a little bit getting closer to the PBBK type modeling concept too. We need a component when we need a component.

So you can create generic animals, and then you say well certain changes this becomes a rabbit, and certain change it becomes a quail, right? But it's not necessary that you have to build a rabbit model and a quail model for the kinds of things you are

doing. I think at that point I am going to stop, and I had no idea how I'm going to write this up. It might just be nice pretty pictures...but.

DR. HEERINGA: Thank you very much Dr. Portier. What I'd like to do, is I like to turn to the associate discussants. Give them a chance to weigh in. We have had sort of 2 excellent overviews, but Peter Delorme.

DR. DELORME: Just a couple of points. I don't think by any means that when we were discussing this we were able to capture some of the finer details with respect to what might need to be done. So I would encourage the other leads on the other questions to identify things in their responses that we might be able to add to the table, as well as some idea of what they think the importance or priority is.

With respect to the priority, I can't remember if Dr. Donnelly mentioned, but again we looked at it from the point of view of if there is something that is easily done, readily done, that you could knock off quickly, then it might be a high priority.

The other consideration is, you know, we're aware from comments provided by Dr. Bradbury and Dr. Brady over the week that, you know, decisions are coming up on chemicals that are PBT, and so things that

might impact your risk assessment probably need to be dealt with sooner rather than later, in some way, shape or form. So that was some of our thinking. We also are trying to limit the number of things that were identified as high priority.

Obviously if you look at it from a disciplinary point of view, you know, everybody at this point is going to think that their issue is the most important to deal with. But the reality is that you have to look at how they feed into the risk assessment, and how they do that. So that was some of our thinking in doing these things. We haven't ascribed time frames for them. I didn't want to go there, recognizing the resources that are available withing EPA to deal with these things is another consideration.

DR. HEERINGA: Thank you Peter, I want to mention too in our final report the presentation, the table that KC presented I think, as other questions, responses are assembled. Clearly if there are additions there, or priority changes, they can be reflected in this overview section too. Dr Maddalena.

DR. MADDALENA: Yeah, it may just be late in the week, but I am running out of things to say, so yeah, I can't add much right now.

DR. HEERINGA: Maybe it's a sign of

success, or... Dr. Meador.

DR. MEADOR: I have a few questions, I guess some points about the Table 8.2, specifically the top part, persistence bio-cumulation toxicity, the attributes. I may have missed this, it doesn't seem clear to me but they probably should be, well they actually are independent attributes.

So I wondering, like on persistence, why not have a half life for tissue? Since we are going towards a tissue residue approach for toxicity, especially bio-cumulation as an independent attribute. You know, why not make that like 3 or 4? I guess I'm not clear on your process. If you find one that's persistent, it triggers it in with a category that you would consider PBT, or 2 or 3 of the attributes or how you actually approach that.

I'm just thinking of a refinement for these different ones. So persistence, half life for tissue; I don't know what that would be, 2 weeks, 3 weeks, 4 weeks maybe. Bio-cumulation; some compounds may bio-cumulate and be very toxic and persistent at a lower KOW. And as far as toxicity, I assume these are environmental ambient concentrations, water, sediment, whatever. So I would imagine eventually it would go to a tissue number. And also I would recommend you change

that to a lower concentration, because that's a much better indication of toxic potency. I think that's all I have on that.

DR. HEERINGA: Thank you Dr. Meador. Dr. Oris.

DR. ORIS: I'm kind of with Randy at this point. I don't have a whole lot to say, but I do have one question about problem formulation, and where you are headed. I know from ORD and ecology there has been discussions of using eco system services and valuation as part of the problem formulation stage. Is that going to be the case as we move forward with Pesticide Risk Assessment?

DR. BRADBURY: The Pesticide Risk Assessment is sort of independent of what...in the case of what is different in the pesticides. The risk assessment is an estimate of the risk, independent of what the benefits may be.

The risk management decision is taking into account what the risks of the pesticide are in the context of the benefits that the pesticide provides to agricultural production, fruit and fiber. Now in that context, OPP is involved in a lot of Agency discussions of ecosystem values, services, goods and services that ecosystems provide and how that factors into the

benefits analysis of the overall risk management decision.

Obviously there's feedback groups as one starts to have a better understanding of ecosystem goods and services and that may influence the assessment end points that are used in the risk assessment. So there is obviously feedback in the dialogue.

DR. ORIS: I guess the concern I have is with chemicals that may move very far from the source of input. Those kinds of discussions may become more important than in our typical pesticide assessment.

And if the trend is to use the idea that ecosystem service systems are more valuable the closer they are to human habitation, as has been discussed in the past, then the value of worrying about chemicals getting into the arctic in that scenario is sort of tenuous to me.

So for example the only vale that the arctic has, as an ecosystem service, in that situation is the ability to derive oil, if value is based on where we are as human. So, I think that discussion needs to be made in this context, because of the ability of these things to move so far, that's my only comment.

DR. HEERINGA: Thank you very much Dr. Oris, Dr. Norstrom.

DR. NORSTROM: I'd also like to comment on Table 8.2. We know for example that there are a number of chemicals out there that have a low KOW's, actually less than 4 that are still found in remote environments.

So I think it's really an interactive thing. I'm not sure that these things can be taken in total isolation from each other. The comment that Dr. Delorme made earlier about volume of production, and that kind of thing. It's possible that something that is produced in enormous quantities has a fairly low, long KOW might still be of interest in long range transport.

Whereas the same chemical produced in small quantities wouldn't be. Simply because the amount in the environment would be so small that would be transported. So I think that has to be taken into consideration. You can't really take them in total isolation from each other, and I would certainly add long KOA's, since we know now that that's also a factor, in terms of persistence. Thanks.

DR. HEERINGA: Thank you, Doctor Norstrom, Dr. Thibodeaux.

DR. THIBODEAUX: Louis Thibodeaux. You are making a very radical proposal about the backwards approach. It's almost philosophic. But I agree with you, where you are trying to go, because we seem to be in many aspects of modeling to add on.

Add on parts and start with one and add on a module that does this, that...for example, the EXAMs, which I cut my teeth on in the early days, adding PRZM on it, onto it, as a driver for it, and then now going on to AGRO. But that's the way science works.

There's this big black unknown out there that we all are striving to understand, and by a process of hypothesis and experiment and mistakes, we tend to push that back...the time..The world is a very complex place, and the environment takes so many people to try to understand it, it's very interdisciplinary, as the make up of this room shows.

But we get to a certain point where people need answers. These people have means and tools to get answers, so we scientists sit around and say, "okay, do we know enough about this to really stop the clock at this time and build a model that they can use as a tool?", and that's the way we do it.

Two points you made. One about the

model, that we could sort of use it, but I don't think that the model will ever be complete. I mean I can sit here and think of at least 100 reasons why what we are doing now used to be vexed.

So it's a forward moving boundary. And the other thing is I'm not sure you would get any more than 2 scientists in one room who will ever agree on what the model is anyway. So I see where you are coming from, and it's an ideal that would be nice if we had one and we start chunking things out, so that we need the constraints of the problem we have and can apply it. So it's really a refreshing approach, but I guess I could say, well keep working on it.

DR. HEERINGA: We know he will. Dr. Schlenk, and then Dr. Mehta.

DR. SCHLENK: One of the benefits you have of sort of being on a permanent panel is you actually get to see an assortment of different methods, in terms of how different parts of the Agency address different issues.

In our last panel I think I was the only, sort of aquatic tox person in the whole room that was present, and I got to see how human health risk assessment was performed, and the problems associated with that human risk assessment. And then before this

meeting took place, we were provided an insight into turns and how the Agency is progressing. And the National Academy of Sciences paradigm was put forth.

I had some discussions with Dr. Bradbury yesterday, and was very encouraged in the fact that that isn't just being relegated to the human health realm. That those components will be implemented into the eco-rest paradigm at some point.

So I just wanted to go on record to say I would encourage the Agency to do that, there are a lot of really -although this won't help you today, but if we're assessing this second part of this particular question 10, in terms of how to move forward, particularly on the toxicity side of things, - I've provided in my written comments some examples that I won't go through here.

But I think there is some real benefit, not only for PPT compounds but for all compounds, in terms of the approaches that are being proposed in terms of using a little bit more elaborate focused approach, in terms of bio assay, the targeted Bio assay testing. So I just want to go on record to say that.

DR. HEERINGA: Dr. Mehta.

DR. MEHTA: Yeah, I to liked Ken's presentation, but I interpreted it a little

differently. I found what you meant was that there had to be a conceptual framework, and then we may or may not have any numerical or whatever model for, but it allows you to look at the whole picture and say, well we have this and have this, or we don't have this.

I like that idea, because it, as you said, it allows you to encompass all the processes in your mind, even though you may not be able to simulate all of this. So I think that's the interpretation of what you were saying. I could be wrong too.

DR. HEERINGA: Jim.

DR. ORIS: Yeah, I guess you're right in terms of sediment. The model, I should have said, A model framework. My concern is that when you...the whole idea, EXAMs and PRZM and AGRO is that it's nice when these things plug in, but a lot of the feedback mechanisms that go between models aren't there, because 1 model feeds the next model.

And as long as EPA is just putting models together, they can't incorporate this feedback. That we already know that we agree as ecologists, that we understand it there. We may not be able to measure everything, but we understand there should be a link. We may not know what that link is, and so my encouragement is to think...okay, so that's part one.

Part 2 is that the framework can be built at a number of levels of complexity. So you can build a framework at a very high simplistic level, and then each component can be made more complex, and more complex as our knowledge grows or as we agree, that needs to be in there.

It came to mind with the sediment issue. We looked at least 3 different approaches to modeling settlement in this room 3 days ago. One approach is to look at it as a whole component that has mixing. Another 1 was to look at layers and compartmentaling. That kind of detailed model, those kinds of detailed models, those kinds of models could be slotted in for a sediment box and a simple model, the simple model is there.

My third point is the model to me, acts as a checklist for the risk assessment to make sure that they are looking at all of the pieces. When things are allowed, when a project is assigned to an individual, you know that individual is going to incorporated their own subjective knowledge in that process. The only way to make things comparable was to make sure everybody is working from the same checklist. Have you looked at long range transport? Yes. Have you looked at this?

Have you looked at terrestrial effects? Yes. So to meet a consensual model works as a big checklist to make sure that in these very complex kinds of interactions and effects that we are talking about here, that everything that we already know is at least looked at, at some point in the process.

And I'm not always sure when I talk to risk assessors that everyone of them has the same mental image that they are working from. It may be very subjective, and so they are coming at it and they may get to the same place, I'm not sure. I'd rather they all have the same checklist, so I can be a little more sure they are going to get to the same place.

DR. HEERINGA: Dr. Steenhuis.

DR. STEENHUIS: I do agree it needs to be more complex, the system has to be more complex. But the big problem with making models more complex, and I can talk about hydrology models, which can be very complex. But they take years to validate.

The more complexity, the more input data you need too. And I really think we should restrain the complexity of models by the types of input data we have. There is HDSF model for example for hydrology out there. It takes 2 years to calibrate, get all the parameters, and at the end you really don't know

whether you have the right parameters. The SHE model in Europe, exactly the same, it takes too long.

While the precision you get in these models are really not that much better in the overall things than this exam model.

So I do agree partly with you. I mean the complexity of the system, I mean you need to have these linkages, but the models themselves within the system should be restrained by the input data we have.

DR. HEERINGA: Dr. Lick, we'll come back to you.

DR. LICK: I want to contribute or may subtract from this discussion, I don't know. But I'd like to comment on Einstein's statement about models being as simple as possible, but not more so.

This is a very confusing and misleading statement, and it's always been used by modelers to justify what they've been doing. Incidently, I have never, nor has anybody else, ever found a reference where or even if Einstein ever said this thing. So I don't know if I can blame Einstein for this.

But the question is, when you develop a model or if EPA asks for a model, I think the first thing you should say is, "What's the question? What are you trying to do with this model?" The second

question is, "How accurate do you expect this model to be?". I mean I would like to see a factor of 2, but nothing we've talked about in the last few days has a factor of 2 in there.

It's more like a factor of 10, but you know, you have to first of all try to say, "How accurate do you expect the model to be?". Then you look at this overall conceptual model with every damned process that you can possibly think of, and ask yourself, "Could it possibly contribute a factor of 2? Or is it greater than 2, or is it 10 percent?". If it's less than 10 percent, ignore it.

If you are asking for an accuracy with a factor of 2, and this thing can contribute a factor of 2, you've got to include it. You don't have to include it extremely accurately. I mean I think, hydrodynamicists as we pointed out sometimes go overboard, because they can make these hydrodynamic models extremely complex, and with a lot of calibration extremely accurate.

But so what? I man it you are throwing other processes in there, which you don't know the order of magnitude it's a waste of time. So I think the first thing you have to ask is, "What's the question, how accurate do you want the model to be?",

and then include processes which can effect a solution to that accuracy. If you can find Einstein's reference, I'd appreciate it.

DR. HEERINGA: Dr. Mehta, Dr. Thibodeaux, and then Dr. Delorme.

DR. MEHTA: I think many of these meeting end up on the issue of models. This in the nth time that we have had a discussion on the subject, but a couple of things. One is that I think that Tammo made a comment about constructing more, and I think this; the only point that Ken is making is that we should be aware of the processes and the feedback.

It's not to build the most complex model should be the ultimate goal of an agency. If you just want to work on one end of it, that would be fine. But I think these things have to hold up in court, and if you are not even aware of some of the processes.

I'll give you one example. If you take mud from the coast of Louisiana, and you put it on a board and you take a spatula, you could actually make a block out of it.

What it is, it's a gel, and if you shake it, it liquefies and it can roll down a slope. Which is how 95 % of sediment actually rolls into the Gulf of Mexico from the river. So in that kind of a situation

you don't even have this pick up and deposition function important at all.

Now here there was a value judgement made in one of your presentations that to do anything beyond AGRO is a low priority. Well how do you know it's a low priority unless you put the whole process together?

So I think that the decisions we come to, as far as what processes we should consider and not consider, as per Dr. Lick there, depends on our ability to look at the whole picture. I think that's the only point that is being made, as far as I know by Ken.

DR. HEERINGA: Thank you Dr. Mehta. Dr. Thibodeaux, you had a...

DR. THIBODEAUX: I can remember the time, - see the color of my hair? - that model was a no no in meetings like this. That you didn't talk about models. Models were something that, - you guys don't remember that - you sat looking at me, you know. I can remember talking to an algae person, and he thought I was absolutely crazy that I could try to model the algae production process in the lake.

Times have changed. Now we feed the models, scientists are feeding the models. The models are growing in number, and I think your point is very

good. You almost want to say, let's stop with the models, let's stop adding them on. It seems like we have, we grow large models by just adding modules of others.

Sometimes we should, and I think this is a more far reaching issue than just this committee. I think it's something that maybe should go up to the upper level of the SAP and EPA, because I think it's time to try to arrive at your goal of at some point saying, okay, let's put all these together at this space and time and be the best model, and get rid of all these sub parts. So I like that idea, that maybe that sort of over-reaching idea that there is a time of maybe of model consolidation.

DR. HEERINGA: Thank you very much Dr. Thibodeaux. My experience even with this process, with the SAP, which is probably limited now to about 10 years. I haven't seen that full transition, but I know in the early days there was a lot of challenge, and a lot of work to build and justify and evaluate these models.

And the SAB I know, even the whole discussion of comp tox and all that, suggests that there is a mind set change to essentially say we've got to rely on these, we can not afford, or in other words

have the time or resources to essentially use old methods to evaluate everything that needs to be evaluated. Actually let me stay in order, Dr. Delorme, and then Dr. Maddalena.

DR. DELORME: Of course I have to bring my risk assessor view into this. I guess you're used to it by now. Essentially the models we're talking about are mathematical representations of reality, okay, that's all a model is.

Put a bunch of equations together, explore relationships between variables, you know, pull the trigger and let it go and see what comes out. They're a tool, okay, their one part of risk assessment.

They're a tool that helps let us characterize whether it's toxicity, whether it's concentrations in the environment, it allowed, they allowed us to explore relationships that you know, maybe we can't get at easily otherwise. They're also a tool that allow us to do our job simply and efficiently.

But they're not the only thing that's done. There are other types of models. There are models up there which we would call like a mesocosm. You can go out, put a chemical in a defined eco system,

and watch what happens to it, and measure it.

Maybe rather than spending money on developing mathematical models, we should go back and look at what we can get from some of the field data that's out there. Arguably, the models that we use are ultimately validated or benchmarked, whatever you want to call it, against reality.

So I think what we are struggling with is finding a balance between the two worlds in the risk assessment community. You know reality is we don't want to be making the wrong decisions, if there is a right and a wrong decision. But when we are asked to put a pesticide out in the open environment that's a serious thing that we have to do.

We have to look for ways of understanding where it's going to go, how long is it going to stay there, who it might be toxic to, what might be the ultimate effect. So we're trying to balance off that in an efficient way, so they are a tool.

I can appreciate where Ken is coming from, and I think it's part of what I was trying to get at, with the idea that you chain all these models together...In the end, Steve is sitting there trying to make a decision, and he's got uncertainty like this,

how is he going to make the decision? So we balance off. The models are considered, the outputs are considered, but we could also get empirical data sometimes on these things to help us understand what's actually going on.

DR. HEERINGA: Randy.

DR. MADDALENA: I appreciate Dr. Licks comments on the complexity here. If you don't understand the uncertainty that you are dealing with, and you add something that's not going to reduce, it's of concern. But I think what concerns me more with the idea of consolidated models is that we might be invited back to review them when they are actually built. And that just scares the heck out of me.

DR. HEERINGA: I can guarantee you.

DR. MADDALENA: I think we should be careful what we recommend here. But actually there is a case study in this exercise, if you want to put, if you want to look at the ultimate I think linked model, side by side with the ultimate coupled or fully integrated model, you could look at TRIM.FaTE and this 3MRA model.

Within the Agency, one of them was a whole series of legacy models all stacked on top of each other. And the other one was kind of the ground

up approach. You build a polygon, and it's going to tell you how to stack the different media, and then each of the polygons are fully coupled with this fugacity concept.

And both of those monstrous, potentially monstrous models, potentially take how many computers did 3MRA take to run? It was a fascinating exercise in modeling, because the modeling experience turned into a engineering problem of linking hundreds of computers together in an office just to run a simple sensitivity, a relatively simple sensitivity analysis.

So caution in the growth of models, they could be over-fertilized very quickly, and you end up with something you can't really interpret. But definitely look into those 2 models if you are trying to decide which way to go.

And I think I would recommend a fully coupled, compartmental model, that Dr. Oris has come up with quite often. It's going to be necessary to step back from...I believe that these chemicals step back from the pond.

It's worked for years and it works really good for a lot of pesticides I think, but for some of these chemicals I think you're going to have to step back and do a fully coupled system where if you

apply it to the soil it's going to go in a lot of places. The lengths and the feedbacks are going to be important to track.

DR. HEERINGA: Dr. Abbott, and Dr. Norstrom and then I'm going to take a break and after the break we'll come back and wrap up. Dr. Abbott.

DR. ABBOTT: Doesn't one model contain all of what we need right now? It would be an interesting theoretical exercise, but I wonder if we could even do that if over time we wouldn't need to add to that model as new issues arise.

As a risk assessor, and knowing how EPA is schedule is going to demand them to keep pumping out risk assessments and analyzing chemicals...although that's a very interesting idea, I don't see where it's particularly practical for them at this point. But what I do see, that was very interesting from Dr. Portier's discussion was using what you put up there, maybe not as one large mathematical model, but as a conceptual model.

When I think of performing a risk assessment, I think not just of the modeling but organizing all of the data that I have, not just the data from the models, the data from experiments. Maybe data that can't be easily combined quantitatively.

Qualitative data, and taking that whole record to make my risk assessment.

What I liked about what your approach did, it linked everything together in a conceptual model. The only thing I would add to it would be perhaps how the chemical was applied. So that you would have more insight into what kind of agricultural practices you would expect to see effected, so that maybe you could predict what environments this chemical might be accumulating in, and develop more scenarios to address that.

DR. HEERINGA: Dr. Norstrom.

DR. NORSTROM: As having dabbled a bit in modeling myself, and being a bit of a reductionist determinist kind of person, I know that models take on a life of their own. And modelers... sometimes because the people that are using them don't entirely understand how the whole thing works can drive the whole thing. And I think that we need to kind of look more at what we want for answers.

A model should only be useful, or the best use of the model would be if it only answered the questions that we want it to, and it does it with a minimum data requirement.

So we can start with rather complex

models that are based on our concept of what we think reality ought to be, but the aim should always be to dropping as many of those things as possible. Other than models, it doesn't really actually matter, the answer we want to get out of it.

And that we can do that, you can eventually get to the point where you have something that will model most of the realities that you know, and give you the answer you want with relatively minimal data requirements that satisfy everybody, including industry.

And I don't think that it's too possible to do that with the way things are being done, as the criticism has been linking existing models together, unless you have some kind of almost like in house control over what you do with those things. You need some, I think, internal modeling expertise at the development and not just simply buying package models from outside, which are someone else's idea of what reality is.

DR. HEERINGA: Thank you, Dr. Norstrom. Dr. Meador, and then what I'd like to do is take a break and come back and wrap up and get general comments from the panel. Dr. Meador.

DR. MEADOR: Just a quick comment. As an

experimentalist, frankly models make me really uncomfortable. Some models I think do a great job. Minacules are a good one, chemical speciation model, the SPARK model for KOW actually do a good job. The ones based on physical chemical properties.

When you get to some of the fate models based on fugacity, I think they do a decent job. But when it comes to modeling what organisms do, I don't even think we're close. They're really not just bags of liquid, you can't model based on cumulative fugacity or whatever. I mean they have kinetic rates.

We find animals that are very closely related that have extremely different update elimination kinetics. You just can't model that.

DR. HEERINGA: Thank you very much, Dr. Meador. At this point in time, I'd like to call for a let's make it a relatively short break of about 10 minutes, and plan to get back here at, well let's say 25 minutes of 11. And my intent would be to do any final wrap up including a chance for Dr. Brady and Keith Sappington to ask the panel questions on number 10. And then final general comments that anyone on the panel might have, that they would like to make before we conclude. Try to wrap up by 11:15...so it that works for everybody.

(WHEREUPON , a break was taken)

DR. HEERINGA: Okay, with Dr. Thibodeaux back I think we can turn to the, some of the questions that...everyone will have an opportunity for wrap up comments fro each of the panel members, but what I would like to do right now is turn to Dr. Brady, to see if there are any specific questions that they would like us to again, sort of revisit or focus on.

DR. BRADY: Okay, I think we have 1 or 2, we'll start with Dr. Bradbury.

DR. BRADBURY: We need to get ken back here, but I'll start the questioning and we'll catch him off guard and see what the answer is.

But I guess some of the discussion we have had over the last few days and came up here and this morning maybe we'll start with a full and complex model, and one of the things that gets, and just imagine that as a conceptual model sort of in the problem formulation stage and one of the concepts that we worked through with the risk assessor/risk manager is trying to define the eco system potentially at risk.

So one thing that would I think would be helpful as you put words around the picture is one sense, or the sense of spacial scale. So how do we define what the spacial scale slash ecosystem

potentially at risk is, when we look at that picture, and does that picture change, how does that picture change in terms of P, or B or long range transport characteristics of the chemicals being thought about. The pesticides P is sort of a given, because by design, it's designed to control certain animals or pests.

And then I think one thing related to that, - and that's important for the risk manager and the risk assessor, - just to figure out what the heck we are trying to protect, and how do we get our heads around what that is. Is it near field, or is it soil on the way to the Great Lakes, or is it from the Mississippi to the Gulf of Mexico?

Where is the scale that we doing? And I think related to that were the blue arrows in the diagram that showed transport and the idea that it's leaving the system. When do we need to wonder about where the stuff is going, and the blue arrow.

Is it moving in that blue arrow to another screen shot, which is the next ecosystem potentially at risk, and when do you need to worry about what's going in the blue arrow or not have to worry about what's going in the blue arrow. I think that gets back again to sort of the aspect of long range transport, of different ways that blue arrow can

be important.

And I think there is another dimension to this figure, which maybe is implicit in there, but as you guys right this up it could be helpful, would be the time dimension on that conceptual model. This gets back again, ecosystems potentially at risk, and how long should we thin about that ecosystem, and maybe potentially at risk.

If the half life of the chemical is 2 or 3 days, and it's only used once a field system, or the time frame of the ecosystem potentially at risk, not ignoring the community level effect even the short acting chemicals can have on community ecosystem structure.

Just thinking about direct effect, our time horizon for the ecosystem potentially at risk is a lot different than if the half life is 200 years in sediments, and those sediments can move from a second order stream and eventually make their way to the Gulf of Mexico. Not only are the ecosystems potentially at risk a lot bigger than the second order streams in Arkansas, it may be all the way down to the Gulf of Mexico, but it may be in a time frame that's 10 or 20 or 30 years, again, depending upon the characteristics of the chemical.

So it would be helpful in that concept, which even as a conceptual model I think is very valuable, some attributes to that description that I think would help us.

Which sort of gets back to the one question I asked yesterday before lunch and then through events I couldn't control, - I apologize we couldn't get back after lunch, - at the end of the day, then you can tell me to shut up, and I'll read the report when it comes out.

But when I left at lunch I had the feeling that at the terrestrial ecosystem scale, in the context of problem formulation question 10, it seems to be, the discussion seemed to be at a temporal and spacial scale. It was bigger, for a lack of a better word.

And at the aquatic ecosystem potentially at risk, when we were moving from a pond there is still the feeling that we are looking at a stream leach or we are looking at an estuary, which is bigger, but it didn't seem to be at the same spacial scale. Maybe it's correlated the same temporal scale, and I just, I mean I reached back into Ken's graph there and that would be a way to sort of capture what seems to be a time/space discontinuity, but maybe I'm wrong. Maybe

you guys all figured it out yesterday?

DR. HEERINGA: Would one of the panel members like to try to volunteer to...I think there was a considerable about of...particularly with Dr. Bidleman's presentation. I don't know, I think probably brought the aquatic up to the sort of at least time and spacial scale of terrestrial. Peter Delorme.

DR. DELORME: For a questioning, in fact I just happened to be working on my answer here and specifically on that one. And what I had is that the first part of the question dealt with whether or not the issues had all been identified, and the issues that had been identified were generally okay, but what I had said was that the aerial scale of use and the aerial scale of assessment, i.e. moving away from a field TL assessment, are both important considerations that need to be factored in.

These are not implicitly included in the assessment issues discussed, although they can have a profound effect on WRIT Characterization. So that will be in the response. The 8th, I didn't separate it between terrestrial and aquatic. I don't know that it was specifically said about you need to like a Great Lakes scenario or something like that, but I thin it's there. I think there would need to be further

discussion on, you know, what the appropriate scale might be.

DR. HEERINGA: Dr. Hickie, if you could.

DR. HICKIE: I don't know if you were here for it, but I think it was Terry Bidleman that mentioned Trent Vonya's paper on arctic contamination potential. And there they just chose the arctic because that's what they were interested in, but there's probably no reason that you couldn't take that concept and pick another receptor and do the same sort of analysis. Whether it's 500 kilometers from area of use, or 1,000. I think the idea applies.

DR. HEERINGA: Dr. Maddalena?

DR. MADDALENA: So you ask one question you get three different answers. I don't know how helpful that is, but specifically your question is how big to build the boxes in these models and we, when we, the little bit what I participated in TRIM.FaTE at the development in that process. I helped with some of the plant update stuff and some of the initial mass balance models. But once we got this thing built, then we just stepped back and said, now what do we do.

How do you put this thing together? And one of the questions was how big do you make the boxes and this goes back a decade and a half to how deep do

you make the soil. It was the other question that came up a long time ago. You know, plow depth was nice and convenient in these mass balance models, so 15 centimeters, we go with that. But, it's really chemical dependent.

And that's the take home message. The tools are becoming available, how to deal with these, as far as the depth of the soil, there's a -- number, I don't know what, it's basically how far the chemical will penetrate into the soil before it decays. A combination of advection and reactivity.

We kind of use the same thing for building the sides of the polygon using the characteristic travel distance. How far is this chemical likely to travel in the environment before half of it is gone or some other bright line number is gone. And so then you can begin to build your boxes chemical specific in that sense.

DR. HEERINGA: Dr. Mehta and Dr. Bidleman, then I think I'd like to move to the second question. Dr. Mehta?

DR. MEHTA: The spatial and the temporal states are related to each other, so you have a series of boxes there. And just as an anecdote Ferum Falcon worked out the time that some of the particles stayed

in air. Because I think he lived in Los Angeles. But the longest time, if you look at some of the books, is 80 years, so obviously the temporal and spatial scales would also be very different.

But also, I think the, one of the things we look at in coastal engineering is to look at time scales in some sort. Evolution of shorelines and so on and so forth. And to know the equations for the models also change, maybe because of the fact that you don't want the details in some of the larger models. So, my main point was that there is a cascading system that conceptually could be developed. You may or may never ever be able to actually develop a model or maybe even there will be a model, but...

DR. HEERINGA: Thank you Dr. Mehta. Dr. Bidleman?

DR. BIDLEMAN: I'd like to make a few comments about arctic contaminants, partly in response to Brendan's comments. The emphasis on arctic contaminants is to a large part, due to the exposure of indigenous people. Both in the Canadian Arctic, Greenland, Alaska, Russia, the circumpolar arctic in general. And because of this issue, the transport of chemicals to the arctic has been viewed as a canary in the coal mine.

We were very protective about getting new chemicals up into the arctic. And when evaluating transport to the arctic, or any of the long range transport models, it's important to keep in mind that mobility is key. Because when you use the OECD screening tool, you put in generic factors and you put in persistence values. They're at 25 degrees.

Well that may be good and well for evaluating the chemical with respect to initial mobility. But if it ever manages to get up to the arctic, then the persistence of 25 degrees doesn't mean squat. Because it's cold up there and the persistence of chemicals is far, far greater in a cold environment.

One good example is the pesticide lindane. The concentrations of lindane in arctic ocean water are the highest of any oceans in the world. Part of the reason for that is because the arctic is a cold ocean and also because of a very heavy use of HCH's in the Northern Hemisphere. The half life due to hydrolysis of lindane in temperate waters, 25 degrees, is half a year.

The half life in arctic ocean waters is 30 years, simply due to the temperature effect on chemical hydrolysis. So it's very important to keep in mind, if a chemical is mobile, if you assess the CTD or

any other measure of long range transport, to carry this chemical a long way, you better be prepared to evaluate it's persistent characteristics at the receptor site. And this is certainly true for the arctic, but it even holds true for a cold lake like Lake Superior.

DR. HEERINGA: Thank you, Dr. Bidleman. Dr. Simonich, and then we'll move on.

DR. SIMONICH: I concur with Terry's comments, but I'd also point out that I think from a long range transport potential standpoint, I think the new canary in a coal mine is the mountains. And we see both historic use pesticides and current use pesticides being deposited annually in our high elevation ecosystems and our U.S. National Parks.

And it even transfers to effects and so, for example, we see both in Rocky Mountain National Park and in Glacier National Park enhanced phatelligenin and even intersect fish in some of these remote high mountain lakes.

So effects that you might expect to see at the outfall of a wastewater treatment plant, you in fact can even see enhanced characteristics over time in our high mountain lakes. So I think those are our new canaries in the coal mine and I think they're important

and they're very close to agricultural areas in the U.S.

DR. HEERINGA: I'd like to turn now, I know there's a second question Dr. Brady wanted to introduce.

DR. BRADY: I think we're okay.

DR. HETRICK: I just want a little clarification. Dr. Parker in his presentation, and I'm going to bring back this sediment dynamics question again on burial. There's been a lot of discussion here on the importance of burial when considering modeling and in our little assessment we did in the white paper, we see that really, the burial effect is more prominent on those chronic concentrations.

It has a bigger impact on that. And that's probably, from what I've heard with the discussion, is the area that we need to be more concerned about, is the chronic issues with these particular type of chemicals.

And the other thing that Dr. Parker said, and I think I'd like to get some clarification on and get some recommendations on is that today after this meeting, we break up and you guys go home, but on Monday we come back to a situation where we have four chemicals staring at us where we have risk assessments,

where we have to go in and we possibly have to do some modifications and do some refinements to those risk assessments.

Do you have any recommendations on how to do that under the current process and knowing that we use PRZM EXAMS and how do we do that to adequately account for burial. Is the approach that's used in the white paper, is that an adequate first approximation burial to provide.

And then the other question is, and I guess this goes back to what Dr. Mackay said. You know, really, probably if we're going to look at burials, we recommend that we look at non-burial and burial and have those as a side by side comparison in the assessment.

DR. HEERINGA: In the interest of time-management, I'd like to give about ten minutes to this question, but I'd like to begin with Dr. Mehta.

DR. MEHTA: Yeah, I had a talk with Ron and a you know, I'll be able to send the 1-B model that I talked about. But also, in methods that I think I can see to determine the erosion and deposition function or rates. So I can't do that. But I wanted to say, Monday they'll be 40 students looking at me too. So I also have a limited amount of time.

DR. HETRICK: I can appreciate that. But I guess what I'm driving at is it's nice to have another model that we're really working with in the paradigm of the PRZM EXAMS in our current approach.

DR. MEHTA: Yeah, I know. I think that under the current approach, this protocol that I was sending should give a better idea about what the velocity should be and what the erosion rate should be. Now that is more for aggro, because in the present model, you don't have any. You just have an omega or something like that.

DR. HETRICK: Well, this is the dilemma we're in and to be quite frank with you, to adopt a new model is not something that happens overnight. Not only does it require getting up to speed on the model, but it requires integrating those models into assessments and looking at those compared to older assessments.

So I guess the question is, do you have any recommendations on how we can use the PRZM EXAMS model and incorporate burial into that and do it in a defensive way. And be realistic.

DR. HEERINGA: Dr. Steenhuis and then Dr. Lick.

DR. STEENHUIS: Concerning the present

model, the EXAMS, I mean if you look at it, the PRZM EXAM is more conservative than the AGRO model. I think if you have one model, you need to look to the situation which is most, that gets the highest risk. And the highest risk is really the situation where there's no sedimentation and you can't think about situations in the environment where there's no sedimentation.

For example, if the pesticide is applied to a grassland, that would be variable sedimentation in the pond. You can also think about situations where there's no pond, where the sediment goes in and goes out. So, if you work with existing models, I really think you need to take the most conservative estimate and an estimate without sedimentation.

With the AGRO model, we can choose these parameters in such a way that persistent chemicals disappear. That is not difficult. I looked at the aGRO model and I could get any answer I wanted simply by choosing these parameters in a certain way.

DR. HEERINGA: Dr. Lick?

DR. LICK: As the main problem as of now with the EXAMS is the fact that you deposit pesticides, but you do not deposit runoff from the surrounding area. So the correction is fairly obvious.

You not only deposit pesticides but the runoff that goes with that pesticide. And if you keep a constant depth of benthic region then when you deposit at the surface, some will go out the bottom, but the fact is that your concentration of the chemical coming in on the soil will keep the concentration in that benthic layer constant.

What your problem now is it goes up, which is totally unrealistic. But if you deposit pesticide and soil at the rate that it comes in, you'll solve that problem. That's trivial to put in your model. The other thing would be a simple correction to this Priven parameter. Which I think is fairly easy to do, based on that dimensionless parameter that I gave.

DR. HETRICK: I want a clarification on that as well, since you brought that up. My understanding that your dimensionless parameter is estimated, now am I to say that it's using a desorption coefficient or a desorption rate coefficient?

DR. LICK: Desorption time.

DR. HETRICK: Okay, so we don't put that, we just....

DR. LICK: Well, no. If you have a desorption rate coefficient, that's more or less an exponential decay and you can deduce the time from

that. But it is a -1 of it's original value.

DR. HETRICK: But we're just getting desorption coefficients, that's it. We're not getting it as a function of time.

DR. LICK: Well it is a minus Kd kind of thing? What do you mean by....

DR. HETRICK: We're just doing it, we're just getting a simple equilibrium desorption coefficient. At a set time, at 24 hours of appropriation.

DR. LICK: Oh. Well if you've seen the exponential, then you can get a time from that.

DR. HETRICK: Oh, I see. Let me run this by you because I talked to Dr. Thibodeaux about this yesterday. That we were discussing within our, the science group upstairs, about the possibility of having a PR Ben that is dependent, you could make it dependent on two things actually.

Dependent on the total suspended solids that come into the pond as a function of what's runoff coming off the PRZM field, as well as the function of the KOC of the compound. And that could vary then as a function of those runoff events. And so therefore, those compounds that have low KOC are going to be more predominantly found in the water column versus those

compounds with high KOC's that are going to be wanting to go preferentially into the sediment. You find that as a reasonable first approximation of a possible fix in the short term until we get some more sophistication in our modeling.

DR. LICK: If you calculate carbon reasonably well, then the fraction that stays with the particles in the overlying water will equilibrate and that's what I think Dr. Thibodeaux was talking about. So that automatically will do that.

DR. HEERINGA: Dr. Mehta?

DR. MEHTA: Most of the transport in the continental U.S. takes place under episodic conditions. So if you look at the time series of storms, there are substantial peaks and there are calm periods. So one ratio could be the current period of a storm of a certain intensity and the half life of the material in suspension.

But I agree with Tammo in the sense that, I get the feeling that you guys want to come up with a lower number, but I think that the best way to do is to do the most conservative calculation and that would include no burial at all. Because how would you know that there is not going to be a hurricane which is going to pick up....for example, if you did that in

Florida, it would be quite different than doing it somewhere else.

So since you are not considering more things, you're only looking at these points, I just don't see how you could come up with burial as a sure thing that would reduce the concentration.

DR. HETRICK: And that's the million dollar question, to be quite frank with you. Because we're sitting in a seat where we have to make an assessment and we don't want to miss a problem. And by burying it, we might miss a problem.

DR. HEERINGA: Keith Sappington?

MR. SAPPINGTON: I think I'm conceptually in between Steve and Jim here in that I try to boil it down. Could we get a farm pond right but everything else wrong? And that's the question of scale and whether we're operating at the correct scale for a problem and I just would like that, I know there's been quite a bit of discussion on scale, but I think that is kind of the core of what's in the back of my mind. Thank you.

DR. HEERINGA: We're going to go to Dr. Maddalena and then Dr. Delorme and then I want to move on because we do have more.

DR. MADDALENA: I haven't had the luxury

of reviewing PRZM and exam, I haven't been in these conferences before. So I just did in the last, during this conversation, reviewed PRZM. It's not the right model. It's a route zone model.

I'm sure it's got good runoff stuff, it's got premium chemistry and mixing and stuff, it's got great farm stuff. But the range of sources is starting in the wrong place. Again, this is a five minute review of what, a 200 and some page document and a model that's been around for 20 years.

I said that in that way just to highlight the fact that there are some very simple options. Look up Tom McKone as a model, CalTOX. Don Mackay, who I'm really glad to see here, he's got a model, CHEMcan. Dick Vandemant's got a model, that gone into USIS. These are all models designed and have cut their teeth on these types of chemicals.

This particular type of chemical, persistent chemicals that move in multi-media, stay in the environment long enough for us to scratch our heads and say what's going on. These are interesting chemicals, challenging chemicals and these models are out there, just to give you very coarse looks at whether varial is important.

And yet I agree, they do a great job on

burials, but if you don't have good reaction rates on the planet surface, I don't know if PRZM includes degradation or any kind of reaction rate in the cuticle. I mean there's a lot of details there that I couldn't pick up.

DR. HETRICK: No, there is the ability to put in plant wash-off and plant degradation kinetics into that model.

DR. MADDALENA: So I guess the simple answer from just one of the panel members is pick up one of these off the shelf models and put your KOW, your MS log and your solubility in, put a generic application rate and see what gets into houses and plants. Again, it's a cartoon world, and I can't go past that. It's really easy to do those and the information that gets up to that level is more general.

DR. HEERINGA: Peter Delorme? And then I'd like to move on.

DR. DELORME: We're sitting here looking at figure 4.8 in the white paper, which shows the mean daily sediment deposition for a number of different scenarios. And you guys picked the one that has the absolute most in it and I mention that you're picking one that's depositing 200 grams per meter squared per day in what you presented.

Yet, the range is between .2 and 200. You've got three orders of magnitude there, so a couple of approaches. You could just take some of those other things and see what happens with burial on them as well.

DR. HETRICK: The concept here is what we're thinking about doing is have this scenario dependent so that each scenario, the runoff we could calculate that as a function of scenario, the loading, the average loading....we're just using a Mississippi cotton just as an illustration, that's all that is.

DR. DELORME: So you've actually done it for all of these?

DR. HETRICK: No, we have not done it for all of them, but we're considering that depending on what the recommendation of the panel is.

DR. DELORME: That might, I mean there's a lot of scenarios to run there. I recognize how much work that is to do, because I've done it. But you may pick, sort of high, medium and lows, just to give you a sense of what it does to your risk characterization. Then somebody like Steve can take a look at it and say, okay, it's not a problem if you have high levels of varial, but it is if you do. And then you've got to get into the interpretation of what kind of situation

you predominately have out there in the areas where this is used.

DR. HEERINGA: Dr Hickie?

DR. HICKIE: Just a very brief comment on that exact figure that Peter brought up. I took the numbers of that and I calculated the arithmetic mean and the geometric mean of those values and I can't find the page right now. But it was something like 55 for the arithmetic mean and 13 for the geometric mean of those values, so, and I think you used 80 as your illustrative, sort of selected high range. So it's how you look at the numbers.

MR. SAPPINGTON: From one of the chemicals, we actually ran all those scenarios. And what we do see however, is a competition in terms of the ultimate results between the delivery of the mass to the pond and the varial potential.

So while a California tomato only gets two tenths of a gram per meter squared per day and that's just a daily average value, that's not actually how it comes in, it comes in pulses, but just for comparative purposes.

So the varial potential is much lower, but if for these compounds, since the main vector to the pond tends to be the absorbed sediment erosion, you

also have a lot lower loading to the pond. So there is this kind of see saw if you will between those two. Yeah, we ran all of those.

DR. HEERINGA: Okay, at this point, what I would like to do is move on and give the panel an opportunity and go systematically around and we'll begin I believe, with Dr. Norstrom. Just to see if there are any final comments or inputs that you'd like to have based on the last three days or your knowledge of the subject matter.

DR. NORSTROM: Certainly nothing overarching. I think I made my point quite clearly. Just thinking outside the box and it really comes to bio-accumulation and aquatic and terrestrial ecosystems. I think it's really important for this class of chemicals.

DR. HEERINGA: Thank you Dr. Norstrom. Dr. Meador?

DR. MEADOR: I second that and that's it for me.

DR. HEERINGA: Dr. Mehta?

DR. MEHTA: No comments.

DR. HEERINGA: Dr. Steenhuis?

DR. STEENHUIS: I would much urge that we talk about the sediment model in choosing

parameters. The problem with the model is not, the model is arbitrary. The parameters in the model are arbitrary. So I would urge, for the part that I know, to improve the model in such a way that it becomes, it can be done, becomes more scientifically updated as soon as possible. Because you cannot justify the parameters in this model in any way.

DR. HEERINGA: And that was the sedimentation models. Dr. Simonich?

DR. SIMONICH: I have a few things to say. I think I come to this from a fairly unique perspective because I spent six years of my career, in the first stages of my career after receiving my PHD in chemistry, working in the consumer products industry. So I have a unique perspective among the panel members based on my consumer product industry experience and also being a professor at Oregon State University.

So in my job working in the consumer products industry, I was in part responsible for the registration of new chemicals under TOSCA. So I have direct experience under that. Not under FIFRA, but under TOSCA.

So the point I'd like to make is when we're looking at pesticides with PBT characteristics, I think one point I'd like to make is that if approved,

they should have significant global and societal benefits.

Because these are global chemicals with global transport properties. So a significant global and societal benefit. I think both the agency and the registrant should be prepared to see unprecedented scientific scrutiny.

Likely, along those lines, also unprecedented data generation is required in that consideration. And if approved, there will be unprecedented acceptance of risk on the part of the registrant and the EPA.

DR. HEERINGA: Thank you Dr. Simonich. Dr. Oris?

DR. ORIS: I've got three general comments I'd like to make and some of this will maybe come from naivety or ignorance. But I'm going to say them anyway. So the first one that I need to make is that in general, overall, for the FIFRA risk assessment process that risk quotients are not a measure of risk and I really bristle at the use of the terms risk and risk quotients.

They're really hazard quotients and they don't give an indication of risk. And I always say that, and I've been saying that for a long time and it

doesn't seem to have much of an effect. But I'll say it again. The second comment is a general one but also applies specifically to this case. And that's in traditional pesticide risk assessments, my impression is that the toxicity values are driven primarily by acute toxicity for non-targets.

In PBT assessments, and again that may be my naivety and inexperience here, but what I'm driving at is a PBT assessment that's going to be almost exclusively driven by chronic toxicity assessments.

In chronic toxicity assessments, we use the no observable effects concentration as an endpoint. Statistically that has some disadvantages and I would encourage you as you move forward and improve the process, to use regression based approaches and dew point estimation instead of using the NOEC.

The NOEC is an endpoint based on the failure to reject an old hypothesis and I can go on and on about the disadvantages of an NOEC, but using the failure to reject an old hypothesis as an endpoint in a toxicity test is invalid. It also, unfortunately when you have the stake holders conducting the test, encourages making type two errors. And again, we can go into detail later on that.

But it certainly does. So that's my second comment. My third one is basically why are we doing this. If compound five turned out to be DDT, would you approve it using your current process? And I think that's a question I would like you to assess on Monday when you have to do these things.

Do you want to see compound four, in twenty years, causing problems? I don't think you do and I just don't understand why we're going towards more persistent chemicals that are going to get up and move around the world.

Peter and I discussed this, if the glove doesn't fit, you must acquit. I think the glove fits pretty well here for the chemicals you're looking at and so to put it in the risk assessment or risk management context if I were the risk manager here, if the uncertainties, and in my case the certainties, are too high, you must deny. And in this case, that's where I'm falling. Thank you.

DR. HEERINGA: Thank you Dr. Oris. Dr. Donnelly?

DR. DONNELLY: I'm just going to echo an earlier comment from Meador, that whenever possible, you want to validate or confirm the results from these models with laboratory and field data.

DR. HEERINGA: Dr. Portier?

DR. PORTIER: After this morning's discussion, you know why I prefaced my comments as to why I wasn't sure I wanted to bring the topic up.

DR. HEERINGA: Dr. Schlenk?

DR. SCHLENK: Nothing to add. Thanks.

DR. HEERINGA: Dr. Abbott?

DR. ABBOTT: I have nothing to add either.

DR. HEERINGA: Dr. Bidleman?

DR. BIDLEMAN: I'm fine.

DR. HEERINGA: Dr. Delorme?

DR. DELORME: I'm looking forward to seeing the risk assessments on some of these chemicals.

DR. HEERINGA: Dr. Doucette?

DR. DOUCETTE: Just a minor point I guess regarding scales of models. I thought it was interesting that we talked about input like KOW and KOA for example and KOC as being key for parameters to models when they themselves are models.

I don't typically worry about spilling octanal in the environment and worrying about a partition coefficient. In an octanal phase, octanal air represents cuticle interactions and KOC is only part of the soil. So sometimes I think in looking at

these grandiose models, we have to remember all the assumptions that go into those and key parameters that are taken for granted now are really in themselves, a model.

DR. HEERINGA: Dr. Gan?

DR. GAN: I have a comment pertaining to the refinement of tools for the future. I'm sure what I'm going to say is not similar for tackling the four chemicals you have on your mind. But as Bill said, we assume KOW or KOC or KDOC as a constant and then we go from there. But we know KOC can vary easily by ten times and then we use models to estimate from KOW and KOW estimates again from the structure of the chemical.

And very soon, I think the errors can propagate through the models and you have some results but you really don't know what the results mean and how close they are. And the reason for these types of chemicals, since I work on proliferates on a daily basis, they are very similar I think. The reason why we are trying to use this KOW, KOC, or KDOC is to try to get to the free concentration. I think that's the most essential parameter here, not just go with the bio-availability, but that's really important.

But now, there's a, I know, you know, for a fact that chemistry has advanced so much that

there are very good techniques that we use to measure the free concentration. A lot of good work has been done in Europe. Also by people here in the U.S. and I hope EPA can look at this map instead of going around and around that we indirectly estimate something we do not know. You know, just to ask people to measure the free concentration and just one thing I will say, that you as EPA, if you ask, you get it, people will do it for you. Thank you.

DR. HEERINGA: I think he just bequeathed you powers that you may or may not actually have. Thank you Dr. Gan. Dr. Hickie?

DR. HICKIE: I'm just thinking, poor Randy he's the last one in the line. So I was trying to think of something that hasn't been said and temperature, it effects phys-chem properties, long range transport, persistence, biology of organisms, and bio-accumulation.

DR. HEERINGA: Dr. Lick?

DR. LICK: Yeah, while this is all happening, go around, I was thinking about this re-suspension deposition question and I asked myself, why does it matter. To a first approximation, the amount of chemical and the amount of sediment coming into the pond is important because there is varial.

But re-suspension and deposition doesn't change. It goes up, it comes down, it goes up, it comes down. It doesn't modify varial to a first approximation. It really doesn't modify chemical concentration in the overlying water. So, I hate to say this because I a sediment re-suspension guy, but for a shallow pond and two first approximations I would.

DR. HEERINGA: Dr. Maddalena?

DR. MADDALENA: Sorry if I came on too strong about PRZM, I know it's a really good model. To show how easy it is, I just ran chemical four in one of these models and it's pretty much like DDT in it's behavior in the environment. If you use all the assumptions that we use in to build these models. I don't know what you can do with that information, but....

DR. HEERINGA: Okay, at this point we're approaching the end of our scheduled session and I think with travel plans and everything, I'd like to bring it to a close. We've had three and a half productive days and before I wrap up, I'd like to turn to Dr. Brady and Dr. Bradbury to see if you have any closing comments.

DR. BRADY: Not really, I'd just like to

repeat our appreciation for the work of the panel. Thank you for all the feedback and discussion, we've got a lot of useful feedback right now. So, we look forward to the written report. And also, once again I'd like to repeat my appreciation for the work the E-FED scientists did to prepare for the discussions.

DR. HEERINGA: Dr. Bradbury?

DR. BRADBURY: I just wanted to echo Don's thanks to the EPA team in putting it together and also, once again thank all of you for the time and effort in this meeting. I've been at several SAP's over the years and this certainly is in the top tier or 95th percentile.

I thought there was some excellent discussion of the challenging issues we're dealing with. There's a little bit of looking back in time and dealing with the present and looking into the future and I thought from both the philosophy and the hard core issues that we dealt with, it was very instructive, both from a risk management and a risk assessment perspective. So I thank you all for the excellent discussion and input.

DR. HEERINGA: Keith?

MR. SAPPINGTON: I would just echo what Don and Steve said. I think the feedback has been very

good. I know I had some angst about the depth and thickness of the white paper and how that was going to be a problem with the example chemical. And I appreciate you all taking on this mission and the charge and the level of detail that you provided. So thank you very much.

DR. HEERINGA: On behalf of the SAP, I want to express a note of appreciation to the Environmental Fate and Effects division for bringing these issues to us. We recognize that they're probably more critical and urgent for you than even the discussion here has let on. But it has enough of a horizon, we think that makes these discussions very relevant and something you can operate on.

Also, to the scientific staff in the Environmental Fate and Effects division, I don't have enough expertise to judge all of the components of the white paper, but my reading of it and in comparison to many of the things that we are able to see over the years the white paper, along with the supporting documents, I thought not only was well-written but generally well-organized and integrated to the point where I think it can generate and support the sort of effective discussion we've had.

So I really wanted to commend everybody

for that work. You know what it takes to put that together, various reports and papers and something with that sort of comprehensive scope. An excellent job, I felt. The other thing I'd like to do, I'd like to thank all of the panel members.

I'm always pleased and the EPA FIFRA staff who assemble these panels, that we can bring together such expertise on so many dimensions on this particular issue and bring you all to give your week to this process. I certainly appreciate it. I thank the EPA and ultimately we hope it is a contribution to society and protection. I want to make a special note to thank all the participants who came down from Canada.

Clearly well-represented here not only on the panel, but also among the formal presenters and I think in the audience as well. A lot of shared interests and I know a lot of collaboration between PMRA and the EPA and I greatly appreciate your participation in these meetings. I think I'll turn to the designated federal official, Myrta Christian, for some closing comments.

MRS. CHRISTIAN: I also want to thank the panel for their participation and for the advice to the agency. To the presenters, I also want to thank

for a job very well done. And as a last note, the report for this meeting will be available in approximately ninety days.

DR. HEERINGA: A final administrative note. Panel members, if we could meet immediately in the breakout room, we'll discuss briefly our schedule for assemblage of written components and the process of finalizing our written report. So with that, I would like to again thank everybody for their participation over the last three and a half days and bring this meeting to a close. Thank you very much.

(WHEREUPON, the **MEETING** was concluded.)

CAPTION

The foregoing matter was taken on the date, and at the time and place set out on the Title page hereof.

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Further, as relates to depositions, it was agreed by and between counsel and the parties that the reading and signing of the transcript, be and the same is hereby waived.

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I further certify that the inspection, reading and signing of said deposition were waived by counsel for the respective parties and by the witness.

I certify that I am not a relative or employee of either counsel, and that I am in no way interested financially, directly or indirectly, in this action.

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SUBMITTED ON OCTOBER 31, 2008

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