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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  
CONFERENCE CENTER- LOBBY LEVEL  
ONE POTOMAC YARD (SOUTH BUILDING)

2777 South Crystal Drive  
Arlington, Virginia 22202

OCTOBER 29, 2008

8:34 A.M.

## FIFRA SCIENTIFIC ADVISORY PANEL

## MEETING

OCTOBER 29, 2008

**MS. CHRISTIAN:** Good morning. My name is Myrta Christian; I am the designated Federal Official for this meeting; and I would like to welcome everyone today to this meeting to review Selected Issues Associated with the Risk Assessment Process for Pesticides with Persistent Bioaccumulative and Toxic Characteristics.

Again, I would like to thank the panel, presenters and the public for participating in this meeting. Also, I would like to remind everyone that all the documents related to this SAP meeting are available at the EPA docket, in addition to our EPA website.

For presenters, panel members and the public, please identify yourself and speak into the microphone provided, since this meeting has been recorded. I look forward to another day filled with lively discussion and great panel participation.

At this point, I would like to introduce Dr. Steve Heeringa, Chair of the FIFRA Scientific Advisory Panel.

**DR. HEERINGA:** Good morning, everyone;



1 and hello again. As Myrta indicated, I'm Steve  
2 Heeringa; I'm with the University of Michigan. I am a  
3 biostatistician, applied statistician, with a specific  
4 expertise in research design for population-based  
5 studies.

6 I would like this morning, again -- I  
7 don't know if we'll do it each morning this week, but  
8 certainly on the second morning, to have each of the  
9 members of the panel introduce themselves and provide a  
10 little bit of background for the EPA participants and  
11 the public.

12 **DR. SCHLENK:** Good morning. My name is  
13 Daniel Schlenk; I am a professor of aquatic  
14 ecotoxicology at the University of California  
15 Riverside. My area of expertise is mode of action of  
16 pesticides in aquatic organisms, and I'm a member of  
17 the permanent panel.

18 **DR. POPE:** Hi, my name is Carey Pope;  
19 I'm a professor of toxicology at Oklahoma State  
20 University Center for Veterinary Health Sciences. My  
21 area of interest is mammalian toxicity and  
22 organophosphorus neurotoxicity.

23 **DR. PORTIER:** Good morning. I'm Ken  
24 Portier, director of statistics at the American Cancer  
25 Society national home office in Atlanta. I'm a



1 biostatistician and a member of the permanent panel.

2 **DR. CHAMBERS:** I'm Jan Chambers; I'm a  
3 professor in the College of Veterinary Medicine at  
4 Mississippi State University. My area is pesticide  
5 toxicology, and I am a member of the permanent panel.

6 **DR. BUCHER:** I'm John Bucher; I'm a  
7 toxicologist at NIEHS. I'm the Associate Director of  
8 the National Toxicology Program, and I am a member of  
9 the permanent panel.

10 **DR. DONNELLY:** Good morning. I'm Casey  
11 Donnelly; I am a professor in toxicology at Texas A&M  
12 University School of Public Health, and my expertise is  
13 exposure assessment in complex chemical mixtures.

14 **DR. ORIS:** I'm Jim Oris; I am a  
15 professor of zoology at Miami University in Ohio, and  
16 my expertise is in aquatic toxicology.

17 **DR. SIMONICH:** My name is Staci  
18 Simonich; I'm an associate professor at Oregon State  
19 University in the Departments of Chemistry and  
20 Departments of Toxicology. I'm an environmental  
21 chemist, and my specialty is in long-range and regional  
22 transport.

23 **DR. STEENHUIS:** I'm Tammo Steenhuis; I'm  
24 a hydrologist and I come from Cornell University.

25 **DR. THIBODEAUX:** I'm Louis Thibodeaux,



1 Professor of Chemical Engineering at Louisiana State  
2 University. My field of expertise is chemical  
3 transport across natural environmental interfaces.

4 **DR. MEHTA:** Ashish Mehta; University of  
5 Florida; coastal hydraulics and sediment transport.

6 **DR. MEADOR:** James Meador, environmental  
7 toxicologist at the National Oceanic and Atmospheric  
8 Administration in Seattle, Washington.

9 **DR. NORSTROM:** Ross Norstrom. I am an  
10 adjunct research professor at Carlton University in  
11 Ottawa, Canada, and a private contractor, formerly a  
12 research scientist with the Canadian Wildlife Service.  
13 My expertise is, I'm an environmental chemist with a  
14 focus on food led biomagnification to wildlife.

15 **DR. MADDALENA:** Hi, I'm Randy Maddalena;  
16 I'm at Lawrence Berkeley National Lab; environmental  
17 chemist, analytical chemist, and do a little bit of  
18 fate and transport modeling.

19 **DR. LICK:** Willy Lick; University of  
20 California at Santa Barbara; sediment contaminant  
21 transport in surface waters.

22 **DR. HICKIE:** Brendan Hickie; I'm a  
23 professor in Environmental Science at Trent University  
24 in Ontario, Canada. My specialty is bioaccumulation in  
25 the aquatic food web.



1                   **DR. GAN:**       My name is Jay Gan; I'm from  
2 the University of California Riverside; a professor in  
3 Environmental Chemistry. My specialty is fate and  
4 transport of para -- of pesticides.

5                   **DR. DOUCETTE:**     Bill Doucette; Utah State  
6 University; environmental chemistry.

7                   **DR. DELORME:**     Peter Delorme; I'm with  
8 Health Canada, Pest Management Regulatory Agency, with  
9 expertise in the area of environmental risk assessment  
10 of pesticides.

11                  **DR. BIDLEMAN:**     Terry Bidleman with  
12 Environment Canada; an adjunct at University of  
13 Toronto; environmental chemist.

14                  **DR. ABBOTT:**     Linda Abbott; USDA's Office  
15 of Risk Assessment and Cost-Benefit Analysis; I'm a  
16 regulatory risk analyst; and my area of expertise is  
17 ecological modeling.

18                  **DR. HEERINGA:**     Thank you very much,  
19 again, members of the panel. Before we begin today's  
20 session, just a note of appreciation to John Bucher for  
21 filling in for me yesterday afternoon while I had a  
22 teaching obligation. John, I understand that you kept  
23 everything very well on track, so we are starting out  
24 exactly on our agenda this morning.

25                               At this point in the process, we have





1 heard the first set in the sequence of presentations in  
2 which we expand on the topics covered in the White  
3 Paper, the presentations from the scientific staff of  
4 the EPA.

5 Before we open and turn to our first  
6 presentation of the morning, I'd like to turn to Steve  
7 Bradbury and Don Brady to see if they had any opening  
8 comments, any follow-up from yesterday. Don.

9 **DR. BRADY:** Thanks, Dr. Heeringa. I  
10 think we're ready to proceed --

11 **DR. HEERINGA:** Okay.

12 **DR. BRADY:** -- unless there's anything  
13 from--

14 **DR. HEERINGA:** No. Very good. Thank  
15 you, Dr. Brady.

16 At this point in time, then, I'd like to  
17 introduce Kristina Garber, who is with the  
18 Environmental Fate and Effects Division, and she's  
19 going to cover the topic of the Assessment of  
20 Terrestrial Bioaccumulation.

21 Good morning, Kristina.

22 **MS. GARBER:** Good morning. Thank you.  
23 Good morning, members of the panel.

24 This presentation will start out with a  
25 brief review of relevant definitions for this topic.





1 I'll go into a conceptual model depicting  
2 bioaccumulation in the terrestrial habitat, and then go  
3 into the current OPP approaches for assessing exposures  
4 to terrestrial organisms.

5 I'll discuss some future directions that  
6 OPP could potentially pursue for assessing terrestrial  
7 bioaccumulation, and then discuss some of the models  
8 that are available in the literature that can be used  
9 to assess bioaccumulation in terrestrial habitats.

10 As we've already discussed yesterday,  
11 bioaccumulation is defined as the net uptake of the  
12 chemicals on all the exposure routes that would be  
13 relevant to that organism.

14 Biomagnification is an increase in the  
15 chemical concentration in the tissues of the  
16 higher-trophic-level organisms as compared to the  
17 lower-trophic-level organisms that that higher-trophic  
18 level would be feeding upon.

19 This is a conceptual model depicting  
20 bioaccumulation in a terrestrial system. Spatially  
21 speaking, this habitat could be the treatment site  
22 where a pesticide would be applied; it could be an area  
23 adjacent to a treatment site. And thus, this area  
24 would be receiving pesticide from direct deposition  
25 from an application or from spray drift from an



1 application.

2                   Alternatively, this terrestrial habitat  
3 could represent an area that is far away from a  
4 treatment site; and thus, it would be receiving  
5 pesticide mass from long-range transport and subsequent  
6 deposition.

7                   And in this figure, the arrows represent  
8 movement of pesticide mass from different -- between  
9 different compartments. The compartments are  
10 represented by air, soil, plants and animals.

11                   Pesticide mass can move into organisms  
12 from the air through gas exchange or from deposition,  
13 whether that be wet or dry deposition. Pesticide mass  
14 can move into organisms from the soil, through uptake,  
15 either by direct ingestion or through dermal contact,  
16 or through -- no. Sorry.

17                   Once into them, pesticide mass can move  
18 from one organism -- one trophic level to another  
19 through trophic transfer.

20                   So plants could be exposed to a  
21 pesticide through uptake from the soil, from air  
22 exchange, and then, through wet or dry deposition.

23                   Animals could be exposed through dietary  
24 uptake, whether that be ingestion of soil or ingestion  
25 of organisms that have accumulated a chemical in their



1 tissue. They could also be exposed through inhalation,  
2 through dermal contact or through ingestion of  
3 contaminated drinking water.

4 Organisms can eliminate a chemical  
5 through several different routes, including  
6 respiration, through incretion -- excretion of  
7 different fluids, including urine, feces or milk. They  
8 could also eliminate a pesticide or chemical through  
9 biotransformation into a less-toxic form.

10 As with the aquatic exposure assessment,  
11 OPP used a tiered approach for assessing exposures to  
12 terrestrial organisms. The first tier is intended to  
13 be conservative, and it's assumed that the non-target  
14 organisms are located either directly on a treatment  
15 site or adjacent to the treatment site.

16 And with this, it's assumed that a  
17 pesticide concentration will be highest at the treat --  
18 at the treatment site, with decreasing concentrations  
19 as the distance from the field increases.

20 The Tier I approaches for assessing  
21 exposures to plants and animals do not explicitly  
22 account for bioaccumulation.

23 There are some refinements available to  
24 OPP risk assessors to account for the routes of  
25 exposure that aren't accounted for in the Tier I



1 approach; and some of those approaches can be used to  
2 account for bioaccumulation to some degree. And those  
3 refinements include models as well as empirical data.

4 The Tier I approach for assessing  
5 exposures to terrestrial plants involves use of the  
6 Terra Plant Model.

7 In this model, it's assumed that  
8 non-target plants are located directly adjacent to a  
9 field. They are receiving spray drift and runoff that  
10 would contain a pesticide directly from the treatment  
11 site.

12 And in this model, it's -- exposures are  
13 assessed from single pesticide applications only,  
14 multiple applications that may be made over a season or  
15 a year, are not assessed.

16 This pesti -- this model does not assess  
17 bioaccumulation in plants, and so it cannot be used to  
18 estimate concentrations of a pesticide in plant tissue.

19 This is the conceptional model that  
20 Keith Sappington introduced yesterday. The  
21 blue-highlighted portions of the model depict the parts  
22 of the model that are represented in the Terra Plant  
23 Model. In this conceptional model, you can see that  
24 pesticides are applied to a field, and then they're  
25 moved offsite through spray drift and runoff to



1 terrestrial plants.

2 For terrestrial animals, the Tier I  
3 approach involved use of the T-REX Model. This model  
4 was used to assess the site exposure to herbivore and  
5 insectivore, and the animals in them, and birds.

6 Exposures assessed using T-REX involve  
7 dietary uptake only for pesticide residues that are on  
8 plants and insects. The T-REX model does not involve  
9 pesticide uptake through dermal contact, inhalation or  
10 drinking water. It also does not account for  
11 bioaccumulation in a terrestrial habitat.

12 Each bioaccumulation would be something  
13 that -- of interest to PBC chemicals; there is concern  
14 that the comparability of the EECs that are generated  
15 using the T-REX Model to excessive exposures to  
16 terrestrial animals that would be expected from  
17 bioaccumulation is an unknown.

18 This is the conceptional model again,  
19 depicting the portions of the model that are accounted  
20 for in the T-REX exposure portion of the model. This  
21 -- T-REX basically assumes that pesticide mass is  
22 directly deposited onto terrestrial food residues that  
23 would be ingested by terrestrial animals.

24 As you can see by the model, there are  
25 several other potential exposure routes that are



1 depicted as dotted lines. It could be -- that could  
2 represent pesticide exposure routes for terrestrial  
3 animals. These are dotted because they're not part of  
4 the Tier I approach. In cases where a particular route  
5 of exposure may be of concern for a pesticide, a risk  
6 assessor may utilize other tools that are available to  
7 assess exposures through those routes.

8                   For assessing potential  
9 bioaccumulations, there are some models available to  
10 OPP risk assessors. One of these models is the  
11 Earthworm Fugacity Model. This basically can be used  
12 to estimate pesticide concentrations in earthworm  
13 tissues, and then assess an exposure through dietary  
14 uptake through -- of those earthworms. Exposures can  
15 be assessed to mammals or birds that would consume the  
16 earthworms.

17                   This model is typically used for  
18 pesticides that have a granular formulation that would  
19 be incorporated into the soil, but it could potentially  
20 be used with pesticide concentrations that are  
21 generated using the PRZM Model. And that was something  
22 that -- that was an approach that was discussed  
23 yesterday in the discrete sections.

24                   KODAM is a bioaccumulation model that  
25 incorporates the Arnot and Gobas bio, aquatic



1 bioaccumulation models. It's an -- that model is used  
2 to estimate pesticide concentrations in aquatic  
3 organisms; and then, dietary in some species of birds,  
4 mammals and birds that would consume those aquatic  
5 organisms. This model is currently undergoing QA/QC  
6 within EFED.

7                   The Tin Model is a probabilistic model  
8 used to assess acute exposures to birds. This model  
9 includes multiple exposure routes that are relevant to  
10 birds, including dietary uptake, as well as inhalation,  
11 dermal and drinking water.

12                   It has the ability to assess  
13 bioaccumulation in the bird that's being assessed;  
14 however, in order to do that, it would be necessary for  
15 the model user to input elimination rate constants that  
16 are derived externally.

17                   So, getting back to that conceptual  
18 model one more time, highlighted in dark blue is the  
19 portion of the model that's incorporated into the T-REX  
20 of Tier I approach. The blue portions of the model  
21 that are -- that are dotted represent exposure pathways  
22 that EFED risk assessors have the -- have some tools  
23 available to characterize.

24                   As you can see from these -- as you can  
25 see on the bottom in red, there is a -- right there --





1 trophic transfer is an exposure pathway for terrestrial  
2 animals that OPP risk assessors have a limited ability  
3 to assess. That can be done using, assessing trophic  
4 transfer from earthworms to birds or mammals, as well  
5 as trophic transfer from aquatic animals to birds and  
6 mammals.

7                   However, there are no tools available  
8 for assessing trophic transfer from plants to animals,  
9 as well as from some smaller, lower-trophic-level  
10 animals to higher-trophic-level animals, such as from  
11 herbivores and insectivores to carnivores.

12                   In addition to models, OPP risk  
13 assessors utilize empirical data that may be available  
14 to characterize the bioaccumulation potential of a  
15 chemical. Risk assessors can utilize available  
16 metabolism data for plants and for livestock, and  
17 perhaps for, for that.

18                   If available, risk assessors will also  
19 use monitoring data from within field studies or from  
20 the scientific literature. Generally, studies that are  
21 available in the scientific literature are of limited  
22 utility for risk-assessment purposes, because the  
23 studies are generally not targeted to -- and the  
24 bioaccumulation that's observed in the study could  
25 potentially be from multiple sources. In addition,

1 these studies cannot be used to link a specific  
2 application of a pesticide to a field through the  
3 bioaccumulation of the earth.

4                   Because trophic transfer potentially  
5 represents the exposure pathway of an animal, of a  
6 terrestrial animal, due to a pesticide, there is a need  
7 to have proof of this though for risk assessors to  
8 assess test site exposures resulting from trophic  
9 transfer. Now, in order to do this, this would involve  
10 modeling bioaccumulation and this would also require  
11 the ability to determine which pesticide would be  
12 expected to accumulate in tissues of organisms and thus  
13 move through trophic transfer into higher-level  
14 organisms. So that would involve having the ability to  
15 identify which characteristics of a pesticide would be  
16 expected to accumulate.

17                   If OPP were to develop a tool to assess  
18 terrestrial bioaccumulation, this would involve  
19 representing the -- that conceptual model that I  
20 initially introduced in this presentation; and that  
21 would include representing the routes of exposure to  
22 terrestrial plants and animals, as well as accounting  
23 for the routes of elimination.

24                   It would be necessary for  
25 risk-assessment purposes to have the ability to connect



1 a specific pesticide application to the observed  
2 bioaccumulation and the resulting trophic transfer. It  
3 would also be necessary for risk-assessment purposes to  
4 have the ability to represent high-end concentrations  
5 in the environment. So basically, for this model to be  
6 conservative.

7 Tool development would involve defining  
8 the non-target terrestrial habitat of concern, whether  
9 that be a habitat that's overlapping the treatment site  
10 or an area that's far from the treatment site. And  
11 this may involve consideration of specific sensitive  
12 species, such as endangered species. And finally, tool  
13 development would involve identification of specific  
14 mathematical models to represent bioaccumulation.

15 There are several bioaccumulation models  
16 present in the literature. This table represents some  
17 of the models that are in the literature. It's not  
18 meant to be comprehensive, but just to give an idea of  
19 the different processes that can be represented.

20 Generally speaking, for plants, there  
21 are models available to represent movement of a  
22 pesticide from air into plant tissues, as well as from  
23 soil into plant tissues. And all of the models  
24 depicted can be used in some manner to estimate  
25 concentrations of the chemical in plants.



1 If you look at the chemical-specific  
2 parameter in this table, in one way or another, all of  
3 these models rely upon the KOW of a chemical to predict  
4 the transport of the chemical from the media, and the  
5 model by Cho et al uses Koc as a determinant.

6 These models -- the models that would  
7 account for movement of a pesticide from air into plant  
8 tissues rely upon the vapor pressure of the, of the  
9 constant of a chemical.

10 Two of these models that are depicted  
11 rely upon partitioning coefficients that are specific  
12 to the plant being modeled. The model by Reader  
13 requires a partitioning coefficient between the cuticle  
14 of a plant and water, and the model by Cho relies upon  
15 a partitioning coefficient between the plant organic  
16 matter of a chemical and water. I mean, the plant  
17 organic matter and water.

18 And so, this brings up an interesting  
19 point when considering plant bioaccumulation models, in  
20 that the model itself may rely or be dependent upon the  
21 characteristics of the model plant that's being  
22 depicted.

23 There are some terrestrial  
24 bioaccumulation models in the literature that account  
25 for bioaccumulation in plants and animals. The model



1 published by Kelly and Gobas in 2003 tracked the  
2 transport of a chemical between air and lichen, lichen  
3 to caribou, caribou to wolf, as well as between the air  
4 and caribou and the air and wolf. This model uses the  
5 KOW and the KOA, the alcohol/air partition coefficient  
6 of a chemical to estimate chemical concentrations in  
7 the tissues of lichen, caribou and wolves.

8                   The model published by Armistead and  
9 Gobas in 2007 tracked the bio -- the accumulation of a  
10 pesticide from soil into earthworm tissue, and then  
11 from earthworm into shrew, and then also from soil into  
12 the shrew tissue. This model also uses KOW and KOA to  
13 estimate chemical concentrations in earthworm tissues  
14 and shrew, as well as bio to soil-accumulation factor.

15                   Both Kelly and Gobas and Armistead and  
16 Gobas concluded in their publications that  
17 biomagnification in terrestrial food webs may be  
18 predicted using the KOA and the KOW of a chemical.  
19 Specifically, they concluded that a chemical with a KOA  
20 greater than 10-to-the-5th, and a KOW greater than  
21 10-to-the-2 has the potential to biomagnify in a  
22 terrestrial food web. Now, this is assuming that there  
23 is no metabolism of the chemical in the organisms.

24                   This is of relevance to OPP because this  
25 indicates that a chemical that may not be expected to

1 bioaccumulate in an aquatic system may have the  
2 potential to bioaccumulate in a terrestrial system.

3           These conclusions have relevance to the  
4 example pesticides that are discussed in the White  
5 Paper and at this -- at the meeting yesterday. If you  
6 look at this table, the estimated log KOA values of all  
7 four example pesticides exceeds 5; and the log KOW  
8 values of all four example pesticides exceeds 2.

9           And so, based on the conclusions of  
10 Kelly and Gobas and Armistead and Gobas, all four of  
11 these example pesticides may bioaccumulate or bio --  
12 I'm sorry, may biomagnify in terrestrial habitats.

13           To summarize, organisms can receive  
14 pesticides through several different outputs -- or,  
15 several different sources in the terrestrial habitat,  
16 and they can also eliminate a pesticide through several  
17 different mechanisms.

18           OPP's Tier I approaches for estimating  
19 exposure to terrestrial organisms do not exclusively  
20 account for bioaccumulation; and this is of concern for  
21 PBC chemicals because the comparability of the EEC as  
22 generated using the Tier I approach to exposures due to  
23 bioaccumulation is unknown.

24           OPP has some refined approaches  
25 available for characterizing exposures due to trophic

1 transfer, but these approaches are limited in that  
2 they're incomplete. There is a need for OPP to have  
3 some tools available to assess exposures of terrestrial  
4 organisms to pesticides resulting from bioaccumulation.

5 In order to effectively implement such a  
6 tool, it would be necessary for OPP to have an  
7 understanding of the chemical's characteristics that  
8 would indicate the potential of a chemical to move  
9 through trophic transfer in the terrestrial food web.

10 With that, if anyone has any questions?

11 **DR. HEERINGA:** Thank you very much,  
12 Kristina, for that presentation.

13 Are there any questions as to  
14 clarification? Yes, Dr. Norstrom.

15 **DR. NORSTROM:** Thanks for your  
16 presentation. I have two questions here, if I can find  
17 them.

18 The first one is: In your T-REX Model,  
19 it wasn't clear to me whether your insects are eating  
20 plants, or they're just kind of being exposed by direct  
21 contact.

22 **MS. GARBER:** Both plants and animals are  
23 -- it is assumed in the T-REX Model that they're  
24 exposed to the chemical through direct deposition. So  
25 those EECs that are generated using T-REX are a result





1 of -- they're a reflection of deposition just to the  
2 surface of --

3 **DR. NORSTROM:** Okay.

4 **MS. GARBER:** -- the organisms.

5 **DR. NORSTROM:** So there's no food-chain  
6 kind of thing at all in there.

7 **MS. GARBER:** That's right.

8 **DR. NORSTROM:** The other one was: I'm  
9 not clear what types of terrestrial habitats are  
10 assumed in your model. In slide 8, you had the plants  
11 -- it was about plants adjacent to the treatment site.  
12 And if that's the case, what kind of plants? And is it  
13 characterized? And it would seem necessary that you  
14 would have to do that in order to make any sense out of  
15 it.

16 In slide 18, you addressed some of this  
17 concern that seemed more focused on ten to the species,  
18 if I recollect, than it was, sort of, characterizing  
19 the actual type of vegetations in that area. It's just  
20 unclear to me how you would apply this model in real  
21 life, somehow.

22 **MS. GARBER:** Okay. So. . .

23 Okay. The first question related to  
24 slide 8; is that right?

25 **DR. NORSTROM:** It just -- well, I mean,

1 basically, my question is: How -- how do you apply  
2 this model actually? As an -- in an example ecosystem,  
3 do you define the kind of vegetation and that kind of  
4 thing? And then, what do you do with it?

5 **MS. GARBER:** In reference to the Terra  
6 Plant model, which is our Tier I approach that we're  
7 using now, we actually differentiate the plants between  
8 -- we defined them as either terrestrial or as  
9 semi-aquatic.

10 And the terrestrial plants don't have --  
11 really, it's more related to where they're located, and  
12 that is -- it's assumed that they're located directly  
13 adjacent to the -- to the field where a pesticide would  
14 be applied. So they're not differentiated as  
15 broadleafs or monocots or anything, in terms of how we  
16 assess exposure.

17 **DR. NORSTROM:** But surely you must have  
18 to say something like total leaf surface or whatever  
19 per hector or something like that; right?

20 **MS. GARBER:** No, we don't do that in our  
21 Tier I approach.

22 Currently, our effects data for  
23 terrestrial plants are received in terms of an  
24 application rate. So the report -- the results are  
25 reported as of pounds a.i. per acre application rate.



1 And so, essentially, what happens in  
2 these effects tests is: There are two tests that we  
3 are concerned with. And I know it's a little backwards  
4 that I'm talking about effects first, but that's  
5 important to understand in how we do the exposures.

6 So, we have two terrestrial plant tests  
7 that are received as data to understand the toxicity of  
8 the chemical to the plant. One is the seedling  
9 emergence test, where pesticides -- I'm sorry, where  
10 seedlings of a plant would be present in the soil of --  
11 of the pods, basically. And then the pesticide is  
12 applied to the surface of the plant -- or, of the soil.  
13 And then we look at the effects that would be observed  
14 in the treatment plants as compared to the controls.  
15 That's the seedling emergence test.

16 The second test is vegetative vigor, and  
17 where you would have a plant that's grown up to a  
18 certain height or a certain -- based on a certain time.  
19 And then the pesticide would be applied directly to the  
20 foliage.

21 And so, the way that those tests are  
22 reported is in terms of the application rate to those  
23 plants. And so our exposure is assessed in terms of an  
24 application rate that would be representative, that  
25 would be comparable to those effects data. So we'd



1 come up with a pounds a.i. per acre that would be  
2 either -- well, that would be deposited onto a  
3 non-target site as a result of spray drift and runoff.

4 I hope that answers your question. Does  
5 that--

6 **DR. NORSTROM:** That answered it.

7 **MS. GARBER:** Okay.

8 **DR. NORSTROM:** Thank you.

9 **DR. HEERINGA:** Dr. Maddalena.

10 **DR. MADDALENA:** I'm curious, why hasn't  
11 the OPP looked at this TRIM FaTE model that could be  
12 adopted very easy?

13 **MS. GARBER:** I can't answer that.

14 **DR. MADDALENA:** Has -- are you aware of  
15 the model?

16 **MR. SAPPINGTON:** Yes, it's a  
17 multimedia-type model that evaluates exposure coming  
18 down from air. And -- but that's one of the models, I  
19 suppose, that we would look into and consider. I think  
20 we just provided just the representations of several of  
21 them here.

22 **DR. MADDALENA:** Actually, it -- full  
23 disclosure. I helped on that model, as -- in part, for  
24 a number of years. And it has -- it's a fugacity-based  
25 fate and transport model, not just air; it's



1 multimedia.

2                   It's -- the conceptual model, I mean,  
3 you almost can't tell the difference between your  
4 conceptual model and the one they started with. And  
5 so, obviously, it's a very complex model, but it  
6 incorporates a lot of these pathways. So it should be,  
7 I don't know, just considered before you reinvent one;  
8 they put a lot of effort into that one.

9                   **DR. HEERINGA:** Randy, they should  
10 definitely get that into comments in our report too  
11 obviously.

12                   **DR. MADDALENA:** Mm-hmm.

13                   **DR. HEERINGA:** Other questions. Dr.  
14 Delorme?

15                   **DR. DELORME:** Just a clarification: You  
16 indicated that you had some tools available for looking  
17 at the dotted blue lines and limited tools for the red.  
18 I'm assuming that's for quantitative risk assessment,  
19 not for qualitative risk assessment? So if we're  
20 actually generating EECs, that you can then compare  
21 with the test data?

22                   **MS. GARBER:** Yes.

23                   **DR. HEERINGA:** Well, that took a long  
24 time.

25   Dr. Hickie.



1                   **DR. HICKIE:**     Couple of quick questions:  
2 In the models you have used, are the plants treated as  
3 a single compartment, or is there any consideration  
4 that these different parts of plants, seeds, fruits,  
5 leaves, things of that sort?

6                   **MS. GARBER:**     As far as the T-REX model  
7 is concerned, that model does compartmentalize plants  
8 out into -- it generates different EECs for different  
9 parts of the plant. One of them is seeds; one of them  
10 is leaves; and I think another part is fruit. And  
11 then, it also differentiates fru -- the leaves between  
12 grasses and broadleaves.

13                  **DR. HEERINGA:**     Dr. Gan.

14                  **DR. GAN:**     On your slide 21, the  
15 accumulation that's happening is that, do you mean  
16 plants or animals?

17                  **MS. GARBER:**     That would mean in the  
18 entire food web. So the chemical is not biotransformed  
19 in any part of that food chain. So that would be in  
20 the lichen, the caribou, the wolves, the shrews and the  
21 earthworms. In those two models.

22                  **DR. GAN:**     Okay. You know, from what I  
23 have seen, like in plants, clearly 90 percent or more  
24 of the residue is just, like, in the concentrated form;  
25 and I think bioavailability would be a very important



1 factor here.

2 **MS. GARBER:** Mm-hmm.

3 **DR. GAN:** Is that considered somehow?

4 **MS. GARBER:** In those two models, let's  
5 see, they -- they both have factors that would account  
6 for efficiency of uptake. The -- both of the models  
7 break out the tissues of the organisms into three  
8 phases, basically, into lipid, non-lipid or organic  
9 matter, which would encompass carbohydrates and  
10 proteins, essentially, and then water.

11 And so, there are different efficiencies  
12 of digestibility of those different tissues, which  
13 would be related to the uptake of the chemicals. So  
14 that would indirectly account for that.

15 **DR. GAN:** Thank you.

16 **DR. HEERINGA:** Dr. Abbot.

17 **DR. ABBOTT:** Hi. Perhaps I missed this,  
18 but the T-REX Model doesn't take into account any kind  
19 of dietary exposure. Is this true?

20 **MS. GARBER:** T-REX is a dietary-based  
21 model, so it's --

22 **DR. ABBOTT:** Oh. Go ahead.

23 **MS. GARBER:** Oh. So, T-REX assesses  
24 exposures through dietary dose base exposures,  
25 actually. And so, it accounts for -- the EECs





1 represent pesticide residues that are on either insects  
2 or on the surfaces of the plants.

3 But it doesn't account for  
4 bioaccumulation that would be expected in those  
5 organisms, or those food items.

6 **DR. ABBOTT:** I knew I had missed that.

7 **MS. GARBER:** Okay.

8 **DR. ABBOTT:** Thank you.

9 **DR. HEERINGA:** Dr. Maddalena and the  
10 rest of the panel.

11 **DR. MADDALENA:** Is the ultimate goal to  
12 consider the whole universe of chemicals, or are you  
13 really trying to focus on boxes?

14 **MS. GARBER:** This would be relevant to  
15 the chemicals with PBT characteristics. And, you know,  
16 one of the issues is that -- actually, as I pointed out  
17 at this slide, is that we need to be able to define  
18 which -- which chemicals would be expected to  
19 bioaccumulate in terrestrial food webs, and that, you  
20 know, using the KOW as we do for aquatic systems may  
21 not capture the chemicals that would be expected to  
22 bioaccumulate in terrestrial food webs.

23 **DR. MADDALENA:** Okay, because two of --  
24 some of the models or most of the models you showed had  
25 KOA as the driver, and that indicates that it's a --



1 it's an air pathway to get into the system.

2 **MS. GARBER:** Mm-hmm.

3 **DR. MADDALENA:** And PRZM doesn't provide  
4 that air pathway; all you have is spray drift. And for  
5 persistent chemicals, the idea is you're going to have  
6 this cycle going over and over, and you don't seem to  
7 capture that in the current draft.

8 **MS. GARBER:** In the Kelly and Gobas  
9 model and Armistead and Gobas model, the KOA actually  
10 factors in, in terms of the elimination-rate constant.  
11 And so, basically, as your KOA increases, you have less  
12 elimination through that route. And so that could be  
13 one of the parts that would be affecting your  
14 accumulation in those -- or, your biomagnification in  
15 that food web.

16 And so -- although, that's not generated  
17 using PRZM, but this would be another -- a separate  
18 issue from that.

19 I think it -- it might be relevant to  
20 point out here that, you know, we're -- we're not as  
21 far along in this -- in terrestrial bioaccumulation as  
22 we are -- in terms of our method, of characterizing and  
23 of quantifying the -- we're not as far along in  
24 terrestrial bioaccumulation as we are in -- in aquatic  
25 bioaccumulation. This is more -- we're a lot more



1 conceptual here, and just trying to -- trying to get  
2 some feedback at the beginning of the process.

3 **DR. HEERINGA:** That's why we're here, I  
4 think --

5 **MS. GARBER:** Yes.

6 **DR. HEERINGA:** -- Kristina, so you get  
7 that.

8 **MS. GARBER:** And that's appreciated.

9 **DR. HEERINGA:** Dr. Doucette.

10 **DR. DOUCETTE:** This is a follow-up to  
11 Randy's question, although, instead of looking at the  
12 PBT chemicals that are going to be primarily taken up  
13 into plants from an aerial route, the other end is also  
14 interesting. I've looked at the -- your two models  
15 that you've highlighted here for the plant  
16 bioaccumulation from root uptake, and I think there's  
17 several others that are -- that should be considered;  
18 they're a little bit more up-to-date.

19 Don Kiseman has published a model,  
20 Seppen Trapp is I think on his fourth generation --

21 **MS. GARBER:** Yep.

22 **DR. DOUCETTE:** -- was that one. And  
23 just make sure that the models that you do choose look  
24 like, I guess, the state-of-the-art.

25 **MS. GARBER:** Thank you.



1                   **DR. HEERINGA:**     Thank you.   And again,  
2 we'll make sure we get this worked into the minutes of  
3 our report, too, so references are there.

4                   Other questions or clarifications?   I'm  
5 not seeing any at this time.   I'd like to thank you  
6 very much for your presentation, and I think if any  
7 other questions occur to the panel, we'll hopefully be  
8 able to call you back to help us out.   Thanks again.

9                   At this point in time, we'll move on to  
10 the second of this morning's presentations, which is  
11 going to be a presentation by Faruque Khan, Dr. Faruque  
12 Khan, who is the -- going to introduce the topic of the  
13 assessment of long-range transport.

14                  Dr. Khan.

15                  **DR. KHAN:**     Thank you, Dr. Heeringa, and  
16 the panel members.

17                  I'd just like to introduce the topic of  
18 the long-range transport.   It has been issue throughout  
19 the -- yesterday, so let me start with:   That the  
20 persistent bioaccumulative and the toxic, which is the  
21 PBT, chemicals are of particular concern up in North  
22 America, because they're found in one or more sensitive  
23 areas, such as arctic, Great Lakes, and national parks  
24 of the western states.

25                  And transport of PBT chemicals to the



1 polar of the U.S region are well-documented. In this  
2 presentation, I would like to introduce to you the  
3 issues that are likely important consideration in the  
4 characterizing of long-range transport.

5 My presentation outlines the  
6 reproductions, and then the factors affecting  
7 long-range transport, and some of the global efforts  
8 such as treaties designed to impact and how do we  
9 address this long-range transport and the limits and  
10 challenges we are facing, and the references I use for  
11 this presentation.

12 This is a conceptual diagram describing  
13 the movement of applied pesticides. As you can see in  
14 the diagram, that the applied pesticides can be  
15 potentially partitioned into various media, such as  
16 air, water or soil. The intermedia mass exchange and  
17 the transformation process that fuels the long-range  
18 transport processes.

19 Once airborne, there's the  
20 volatilization or spray drift or wind duration from the  
21 application site, but, but move into upper atmospheres  
22 for a widespread regional and global distribution to  
23 the redistribution. And persistence in air will play  
24 an important role in the redistribution.

25 Although the atmosphere pathways lead to



1 the dominant pathway for the long-range transport of  
2 volatile, and the semi-volatile chemicals. Non-volatile  
3 pesticides transferred by ocean current is a governing  
4 transport mode for long-range transport.

5 In addition, certain migrating species  
6 and drifting ions can also play a role in the  
7 long-range transport of chemicals. However, that  
8 contribution from migratory species and drifting ions  
9 are relatively small, as compared to the media such as  
10 air and water.

11 And as the -- several speakers yesterday  
12 and today, we talked about our risk-assessment process  
13 is actually a very narrow field, but we are -- the  
14 scale is very limited scale. We don't go from the  
15 regional or remote for our risk-assessment purposes.  
16 We have a limited tool, as you can see, to this  
17 presentation.

18 Let's recap the previous slide. Define  
19 the long-range transport again, when a chemical enters  
20 into the transport medium, such as air, water, it can  
21 potentially travel long distances, from the point of  
22 release to the limit region. And then the following  
23 factors influence long-range transport of chemicals,  
24 the properties related to the parts to and transport,  
25 properties related to persistence, and the



1 environmental factor. And in a few slides, I will  
2 address each of the factors affecting long-range  
3 transport.

4                   Okay. Getting to know your chemical and  
5 how it likely behave at various given organisms. This  
6 interest intrinsic peak in properties such as water  
7 solubility, vapor pressure, partition coefficient, as  
8 well as absorption and desorption of the soil and  
9 sediment will dictate the mobility of a chemical.

10                   For example, a chemical with a very high  
11 vapor pressure and Henry's Law Constant will have a  
12 tendency to emit from the first to an aquatic  
13 environment to the atmosphere. Also, a chemical with a  
14 very high Koc and low velocity can transport as a  
15 particulate in the air or suspended material by the  
16 ocean current.

17                   In general, there is very strong  
18 surviving product chemistry data to the Agency except  
19 octanal air coefficient, which can be estimated from  
20 octanal water and Henry's Law Constant.

21                   Any number of things can happen when the  
22 pesticides get applied to the field. A biodegradation  
23 process such as hydrolysis in soils and water, as well  
24 as biodegradation in the soil, water and sediment can  
25 provide persistent behavior of a chemical in various





1 media.

2                   This then provides us internal fate data  
3 of the substance along the entire length it perform.  
4 However, agents that rarely get studied, we have the  
5 colloids in air. Which, the critical information for  
6 volatile and semi-volatile chemicals to evaluate  
7 long-range transport.

8                   Any number of things can happen to  
9 pesticides into these environmental factors. And one  
10 factor, such as climate, geology, hydrology,  
11 vegetation, many other factors, can influence the fate  
12 of the transport behavior.

13                   For example, high temperature in the  
14 tropics will increase the volatilization and transport  
15 by -- via air currents, than deposits to the cool --  
16 cooler regions such as the polar region. As the cooler  
17 temperatures slow down the degradation rate in the  
18 polar regions, that transport chemical become more  
19 persistent.

20                   Another example is the general ecology,  
21 you can shape our landscape and consequently the  
22 distribution of the polar. The map, lower and  
23 right-hand corner is the global distribution of the  
24 polar region, shows the distribution of various toxic  
25 particles. And each particle has unique



1 characteristics, such as texture, organic matter  
2 content, moisture, that can influence the fate  
3 properties of the chemicals, and will contribute to the  
4 transport properties.

5                   Understanding how a chemical migrates  
6 through the global environment is very important to  
7 address in the long-range transport. And when Nehr and  
8 Mackay presented a conceptual model, how chemicals move  
9 around the globe.

10                   I'm sure those who are familiar or have  
11 worked with long-range transport get this concept of  
12 our guidance documents or guidance picture of all of  
13 this -- looking into it and try to you know, evaluate  
14 how things are actually conceptualized.

15                   On a global, various hypotheses have  
16 been conceptualized, to both the net transport of  
17 chemicals from lower latitudes to the higher latitudes.  
18 Many transfer processes are depicted in this figure.  
19 In this figure you can see that in the lower latitudes  
20 is a more of an upper breaking than the deposition. As  
21 you move to the mid-latitude is encountered very  
22 similar deposition to what I am saying. But when we go  
23 to the higher latitude, the more deposition compared to  
24 the air transport, evaporation of the chemical.

25                   High volatile compounds tend to remain



1 airborne and move, migrate faster. Semi-volatile  
2 compounds have a tendency to pursue into soil, water,  
3 ice, or using this type of chemical to fractionate and  
4 migrate at different velocity and that's on the right  
5 hand side of the picture as you see, that, that better  
6 mobility of the chemical, which is pictured here.

7           Also the semi-volatile chemicals also  
8 migrate at a higher latitude when it's feasible to do a  
9 short jump, known as the grasshopper effect, which is  
10 here. And this is the, how a simple temperature  
11 variation, you know, greatly affect under the  
12 grasshopper of the cannonball.

13           And deposition rates will vary within  
14 latitude and potentially deposition in the temperate  
15 regions, deposition will differ in the temperate  
16 regions and polar regions because of the condensation.

17           Since this is a global problem,  
18 international efforts were taken to address long range  
19 transfer. Since long range transfer is a global  
20 problem, the formal treaties like LRTAP or long range  
21 transboundary air pollution were signed by many  
22 countries to reduce or eliminate the use of persistent  
23 pesticides.

24           Although LRTAP convention was initially  
25 to respond to the acid rain, a total of 8 protocols now



1 negotiated. And how do you find specific measures to be  
2 taken by the parties for the range of air pollutants?

3               This regimen include the European  
4 countries, the United States, and Canada. And in 1998,  
5 they negotiated a protocol for persistent air  
6 pollutants with a permission to consider other  
7 substances for the future. Since then nations  
8 throughout the world began negotiations under the  
9 United Nations and MR program on a global regimen to  
10 prohibit or arrest or reduce or eliminate the use of  
11 persistent chemicals. And in 2001 the Stockholm  
12 protocol negotiated a similar protocol to the 1998  
13 LRTAP protocol.

14               The Stockholm protocol is much broader  
15 if you look at the list of limitations than the LRTAP  
16 protocol. It particularly is the protocol to address  
17 PBT and long range transport potential of chemical, and  
18 there were lots of nomination criteria for the PBT and  
19 long range transport potential. I guess this is the,  
20 because you've heard about the PBT, I'm more interested  
21 in the long range transport and this is the criteria  
22 that the Stockholm had been proposed and I just  
23 summarized a little part of it.

24               Now the measured level of the active  
25 substance and the location distance from the source



1 offers release and are of potential concern. And one  
2 figure is showing that the longest transport of an  
3 active substance is the potential for the transport of  
4 the receiving environment, may offer via air, water or  
5 migratory species.

6 Or in long fate property and the model  
7 result illustrating that active substance has potential  
8 for long range transport and environmental transport  
9 through the air, water, and migratory species. For the  
10 active chemical that migrates significantly through  
11 air, its half-life in air should be greater than two  
12 days.

13 This criteria is useful in identifying  
14 the environmental hazard for the chemical, but it has  
15 limited utility for the risk assessment process. As  
16 Dr. Steve Bradbury mentioned yesterday and the FIFRA  
17 also report addressed risks and benefits given the risk  
18 assessment process.

19 Now I move to the methods how we can  
20 actually address this long range transport. And the  
21 next few slides I would like to introduce that  
22 important method to characterize long range transport  
23 of this chemical. At top we see, understanding that  
24 transport and persistence property and monitoring and  
25 the modeling.



1 As I mentioned earlier, that how  
2 physical, chemical and environmental fate properties  
3 provide a lineup and formation that can be used to  
4 characterize whether a compound is persistent and had a  
5 long range transport potential.

6 Moving from that, let's move to the next  
7 topic, which is the monitoring. Monitoring data in the  
8 model efficient distance from the use side can be  
9 unambiguously satisfy the long range criterion. And  
10 the detection of example pesticides 1 and 2 in the  
11 regions such as Arctic are well documented. Many  
12 nations and international programs are reflecting  
13 monitoring information on a toxic substance in the  
14 various media.

15 For example, USEPA and Environmental  
16 Canada operate an integrated atmospheric deposition  
17 network that measures level of toxic substance in the  
18 air of the Great Lakes region. Council of Air and the  
19 substance have been selected since 1998 and the  
20 substance monitored of the network including the PCB,  
21 organo-chlorine pesticide and many other substances,  
22 like a metal.

23 In addition, the Great Lakes National  
24 Program Office also funded selected monitoring program  
25 that samples water, aquatic life, sediment, in order to



1 assess the health of the Great Lakes ecosystem.

2 And there are so many others, like there  
3 is a program for monitoring the Arctic. Also there is  
4 a recent publication about the Park Service working on  
5 monitoring in our, in our western states. So this  
6 actually should be able to provide us some sort of a  
7 indication of the pesticide distributions and the long  
8 range transport.

9 And I'll also explain that the  
10 monitoring data has limitations. The monitoring data  
11 can show presence and in what location but not the  
12 route of transport.

13 It's a non-targeted area linked to the  
14 specific pesticide application site. Also monitoring  
15 takes time to validate the data. So that's reactive,  
16 not proactive.

17 The monitoring data is only available  
18 for probably residual pesticides. Monitoring data is  
19 not likely to exist for the newer chemistry which is,  
20 we are facing, you know, when you're trying to  
21 characterize some of these chemicals in the modeling.

22 The model, the behavior of chemicals in  
23 the environment is very complex, and we have seen it  
24 from time to time that nothing in the models can  
25 characterize



1 this partitioning behavior in the various media.

2 Multimedia models are based on the application of the  
3 fugacity input versus environmental problems.

4           This model serves appropriate in  
5 treating transfer and transformation of the chemical  
6 that's coming out from the non-point sources over  
7 literally a long time, and the model can also sustain  
8 new chemicals. Multimedia models are valuable tools  
9 for providing screening assessments for a long term,  
10 suspended long range transport. And in recent years  
11 researchers have developed several multimedia models  
12 that compute numerous indicators for overall  
13 persistence and the long range transport potential.

14           And as I mentioned in my previous slide,  
15 these two indicators overall persistence and  
16 characteristic distance are important components of the  
17 multimedia models dealing with the long range  
18 transport.

19           These are the two terms I will use,  
20 I'll be using during rest of my presentation and tend  
21 to define as the overall persistence is derived from  
22 the degradation rate constant in soil, water and air,  
23 weighted by the chemical mass fraction present in two  
24 media. The overall persistence is different from the  
25 single media half life or the soil half life, and the



1 characteristic travel distance is the distance at which  
2 the chemical concentration at the point of release has  
3 decreased to 37 percent, assuring that the chemical is  
4 transported by the constant flow of air or water.

5           There are many mod -- multimedia models  
6 that are available in a plotted model assessment. The  
7 most widely used multimedia model are mass conservative  
8 mechanic type of compartmental model. And the full  
9 levels of the complexity presents it in the bioassay  
10 and summarized in the table. And the key is on the  
11 second column, and based on that assumption, what you'd  
12 like to get from that model. And I'm not going to go  
13 very far with this one because you already have this  
14 from Mackay, he can answer all your questions for  
15 everything you wanted to know about the model, the new  
16 model.

17           As one progress from the level one to  
18 the level four estimation, the reliability of the  
19 estimation to the actual environment increases, but  
20 requires additional data and effort.

21           This slide has a few examples of the  
22 multimedia model, and most of these models are level  
23 three except the CEMC level 2, which is a level 2 and  
24 global pop which is a level four and dynamic model.

25           In 2001 the Organization of Economic



1 Cooperation and Development and the United Nations  
2 Environmental Program organized a workshop to define  
3 the role of multimedia models in chemical exchange and  
4 assessment for the persistence and long range  
5 transport. This literature is publicly available about  
6 models and transport calculating over persistence and  
7 long range transport.

8                   Several comparative, comparative studies  
9 by Theron 2005 and Bismarck in 2006 evaluated these  
10 models and concluded that the most models predict  
11 similar rankings of overall persistence and long range  
12 transport potential values for a set of chemicals  
13 encompassing a wide range of physicochemical and in all  
14 fate properties.

15                   Based on this model evaluation that OECD  
16 experts then developed a screening tool to estimate,  
17 you know, overall persistence and long range transport.  
18 EFED used this screening, OECD screening tool to  
19 evaluate the overall persistence and long range  
20 transport of this whole example chemical or pesticide.

21                   In the next few slides I will describe  
22 the OECD model features and the results obtained by the  
23 tool. With the tool the consensus multimedia model  
24 developed by the OECD work group, it calculates the  
25 multimedia indicators for overall persistence and the



1 potential for long range transport from the chemical  
2 properties. It uses a benchmark approach to provide  
3 the context of the model results, which can allow a  
4 comparison PBT parameters against acknowledged PBT or  
5 pops.

6 Also has the capability to perform Monte  
7 Carlo uncertainty analysis and analyze this. This  
8 model based on actual worksheet that includes embedded  
9 visual basic and application approach. The model is  
10 also publicly available and easy to use.

11 This is a model features the level three  
12 and steady state fugacity model, and the unit is the  
13 whole mode. Has a compartment like the air, the height  
14 is about 600 meters, the land is 21 percent, and water  
15 is 79 percent. And it should have a constant velocity  
16 in air is a full meter per second in air and two  
17 centimeters per second in water. And this is a screen  
18 shot of the first of the fugacity 2 model.

19 The environmental attributes, percent of  
20 air to particles, water content to suspended particles,  
21 includes the actual long range transport to the  
22 stratosphere in a deep ocean, includes small burial,  
23 leaching to the deep soil and soil changes in deep  
24 ocean water.

25 Chemical properties such as molecular



1 weight, log KOW and log KOA and the degradation  
2 half-life in air, water, and soil are needed to enter  
3 in the chemical column, which is on the right hand side  
4 of the screen.

5                   As I mentioned earlier, the registrants  
6 provide most of the required values for the two, except  
7 the half-life and the air, which can be obtained from  
8 epi-3, another model. OECD too had built in the  
9 warning system, there's two types of warnings that are  
10 available, if values entered are suspect or invalid, a  
11 color code next to the input parameters and input  
12 status indicate whether this entry is possible. It's  
13 just like your street light, if it's a red, it's a no  
14 go.

15                   Here is the results from the tool and  
16 the stimulus has a persistent, overall persistent and  
17 characteristic travel distance as well as the transfer  
18 efficiency for this example. As well as some reference  
19 chemicals. In column two, the left, over here, has  
20 over-persistence ranging from 81 days to over 599 days,  
21 for example. And this third column has a  
22 characteristic KOW range from 153 miles to about  
23 221,000 miles. And also the transfer efficiency as  
24 seen in the last column, as a percentage of transfer  
25 efficiency.



1                   And transfer efficiency is a ratio  
2 between the deposition flag in the network region and  
3 the emission flag from the source area. Key examples  
4 that transfer efficiency for the pesticides exceeded  
5 100%. And it is possible to obtain more than 100%  
6 transfer efficiency. In this case, there is multiple  
7 cycles of air and surface media and that is through  
8 several cycles of deposition and re-fertilization and  
9 again deposition in that case.

10                   So let's summarize the OECD tool  
11 results. There's chemicals under consideration except  
12 pesticide one and isomer one, have a comparable higher  
13 overall persistence than the odd ring, but lower than  
14 the PBT and end ring.

15                   Pesticides one and three have comparable  
16 or higher number for estimate than the end ring. Two  
17 and four are comparable, are higher for long distance  
18 estimates for all three reference chemicals. All  
19 pesticides under consideration for PBT have a higher  
20 transfer efficiency estimate than those of the odd ring  
21 or end ring.

22                   The models also have a capability to  
23 differentiate the contributions from the vapors or  
24 aerosols for the long range transport. But some are  
25 going to hunt pesticides, 99% vapor from the pesticides



1 one and two. And for the high Q.O.C. pesticides, which  
2 is slide four, 99% is aerosol for pesticide four.

3 So the estimated maximum travel distance  
4 has been estimated from air transport for the vapor  
5 phase of pesticides one and two. And for air transport  
6 of aerosols for pesticide four and the transport of  
7 pesticide three. The OECD model results of the  
8 overload persistence and the characteristic travel  
9 distance suggests that the example chemicals have a  
10 potential for long range transport.

11 Also, we have limitations and  
12 challenges. Again, to characterize the long range  
13 transport- monitoring data can provide definitive  
14 evidence of long range transport of pesticides, but  
15 this data has limitations for providing quantitative  
16 estimates of chemical loading from the various  
17 environmental media from specific use sites.

18 Multi-media models have limitations in  
19 estimating quantitative loading in the various  
20 compartments of the environment. And lastly, a number  
21 of multi-media models have emerged to provide screening  
22 attachments for environmental persistence and long  
23 range transport.

24 Application of screening models is  
25 critical in determining the long range transport of



1 pesticides, specifically for the new chemicals. This  
2 is the references I used for this presentation. Also,  
3 before I conclude my presentation, I would like to take  
4 this opportunity to thank Professor Don Mackay for his  
5 contribution in the development and evolution of these  
6 multi-media models. We are honored to have him here as  
7 our guest and thanks for your attention. If you have  
8 any questions, comments....

9 **DR. HEERINGA:** Thank you very much, Dr.  
10 Khan. Dr. Simonich has the first question.

11 **DR. SIMONICH:** Thank you for a very  
12 excellent presentation. I appreciate it. So one thing  
13 we're struggling a bit with is the definition of long  
14 range transport. How would you define long range  
15 transport?

16 **DR. KHAN:** In my sense, in my work,  
17 anything from the application side is a long range  
18 transport. But you know, sometimes you have to go with  
19 the flow, you know. And we do, especially when we did  
20 the field, we looked beyond our field application of  
21 the field side. Beyond that. Even in some other  
22 cases, we did our assessment beyond our, like on the  
23 regional level, not the regional level, but a few miles  
24 from the application site.

25 **DR. SIMONICH:** So, in your mind,



1 transport to the great lakes, transport to the arctic,  
2 maybe transport to remote mountain ranges all fall  
3 under that?

4 **DR. KHAN:** Right, they fall under that.

5 **DR. SIMONICH:** Okay, another question.

6 In kind of the more routine assessment of pesticides  
7 for registration, how do you currently assess the  
8 potential for long range transport?

9 **DR. KHAN:** We don't. Case by case, we  
10 do. For example, Lindane, we have looked at because we  
11 know it is problematic. Our main source was this  
12 monitoring data.

13 **DR. SIMONICH:** But for new-to-the-world  
14 pesticides?

15 **DR. KHAN:** Yes, new-to-the-world, that's  
16 where, we are struggling with that one. Because in  
17 some of the characteristics of the chemicals suggest to  
18 you, in a way, like it has the potential. Just to  
19 characterize the hazard side of that, at this point.

20 **DR. HEERINGA:** Dr. Bidleman?

21 **DR. BIDLEMAN:** I also want to say thank  
22 you. I really enjoyed that overview of long range  
23 transport and I was going to ask similar questions to  
24 what Stacy asked and that's what EPA is using now and I  
25 guess....you're not using anything right now, you're



1 sort of keeping an open mind.

2 **DR. KHAN:** Right. Absolutely. That's  
3 why you are here.

4 **DR. BIDLEMAN:** The OECD screening tool,  
5 well, we'll talk more about this in our panel tomorrow.  
6 But I think the prediction that pesticide #4 has a  
7 characteristic travel distance of about 2500 kilometers  
8 really needs to be viewed with caution. Because one of  
9 the features of most of these models, including the  
10 screening tool, is that you have a constant  
11 precipitation. It must be a very, very dreary world,  
12 because it's always drizzling. And of course, this  
13 removes particles quite efficiently.

14 If you run the models with intermittent  
15 precipitation, you get very different results than if  
16 you run them with continuous precipitation and that  
17 increases the transport capability if you have  
18 intermittent precipitation. But then you also have to  
19 take into account the forest filter effect, the fact  
20 that when the air passes over vegetative forests, you  
21 remove a lot of things, including particles, quite  
22 efficiently. And this decreases the characteristic  
23 transport distance.

24 So I would say when you get into  
25 compounds of partition, appreciably to particles, which



1 could be a lot of currently used pesticides, then you  
2 may want to look a bit beyond the OECD screening tool.

3 **DR. KHAN:** No, I agree with you. Even  
4 when we do a prism exam or our tool we use, we go into  
5 deep actuaries where we see this uncertainty and we  
6 describe in our risk characterization that they may be  
7 showing us these results but it may have some effect  
8 for this region.

9 **DR. BIDLEMAN:** But for an initial tool,  
10 it's pretty good. It's a whole lot better than just  
11 two days.

12 **DR. HEERINGA:** Dr. Thibodeaux?

13 **DR. THIBODEAUX:** Yes, I agree, very nice  
14 presentation. You answered Dr. Simonich's question by  
15 saying that your definition of long range transport is  
16 everything from the field to the north pole.

17 **DR. KHAN:** You can't stretch it however  
18 you want to.

19 **DR. THIBODEAUX:** But my question is I  
20 think maybe your priorities are sort of reversed. It  
21 seems to me your slide #2, if you could bring it up,  
22 for your purposes, particularly with pesticide and  
23 their impact, it seems to me the local, that endpoint,  
24 particularly with the previous speaker having to do  
25 with uptake of terrestrial, is of much more concern and



1 should be higher on your radar than what happens to the  
2 polar bears.

3 **DR. KHAN:** Okay. This one you're  
4 talking about?

5 **DR. THIBODEAUX:** Yes. And looking back,  
6 both air and water, you've got local, regional and  
7 remote. And that's a lot on your plate. So, I guess  
8 my question is, shouldn't you be focusing more on the  
9 local?

10 **DR. KHAN:** Well, local would do, like  
11 the near field do local. But there are some chemicals  
12 we just talked about like in the eliminated data. It  
13 moves around. And that's where we, we're concerned  
14 about that.

15 **DR. THIBODEAUX:** Do you have any, you  
16 might say, legislative mandate that you're following on  
17 long range transport? Is there a law?

18 **DR. HEERINGA:** Dr. Bradbury, think  
19 that's in your court.

20 **DR. BRADBURY:** Before I answer that  
21 question, let me go back to the earlier question about  
22 near field and near the site of application. One of  
23 the tools we've only alluded to but haven't gone into  
24 great detail includes modeling approaches, includes a  
25 spray-drift model that allows us to make estimates of



1 what the flux can do, what the concentrations of the  
2 pesticide could be at the ground application or the air  
3 application to get a sense of pesticide movement  
4 through spray-drift.

5 Then Faruque also discussed some models  
6 that we've used with a fumigant registration decision  
7 we completed a few weeks ago in which we used different  
8 models to get a sense of flux, of fumigants off field.  
9 Not to say there isn't room for improvement on those  
10 near fields, we've got an SAP coming up later next  
11 calendar year, we were looking at volatilization in  
12 both human health and ecological risk, near field, if  
13 you will.

14 And I realize we were switching  
15 definitions, but, so while we can always improve on  
16 that, what we're sort of struggling with right now is  
17 beyond sort of what a spray-drift model could do a few  
18 thousand feet off the overhead fumigant, the flux model  
19 is giving us, in terms of a mile or so off.

20 We're serious about perhaps use of  
21 pesticide A and the potential it could end up at 13,000  
22 feet in Boulder or further, sort of gap that we're  
23 trying to get some insights on how to approach that.  
24 I'm going to turn to some of the treaties that Faruque  
25 mentioned and I think I'm about 90% right.



1           The country more or less has ratified,  
2 or since ratified the treaty at the Stockholm  
3 convention. But TOSK and FIFRA haven't been amended to  
4 fully implement the protocols from Stockholm.

5           So the U.S. goes to the meetings and  
6 dialogues at the meetings where we sort of sit at the  
7 table, in terms of the parties making the actual  
8 decisions. But having said that, our perspective here  
9 is that we should take a look at the properties of the  
10 chemicals, look at exposure properties, look at effects  
11 properties and try to do the best ecological or human  
12 health risk assessment we can with the information we  
13 have and take that into account with the risk  
14 management decision.

15           And what we're trying to work through  
16 here is, in this specific talk, is if there are  
17 attributes of a compound that suggest it may move  
18 beyond what our spray-drift models would suggest or our  
19 fumigant flux models would suggest, how do we deal with  
20 that. What's the best available science that can then  
21 inform us in terms of FIFRA as to what the proper risk  
22 management decision would be. So that's a challenge  
23 for risk analysis.

24           **DR. HEERINGA:**     Dr. Simonich? And then  
25 Dr. Delorme.





1                   **DR. SIMONICH:**     I just wanted to mention  
2 that the U.S. EPA, NOAA, and NASA has asked the  
3 National Academy of Sciences National Research Council  
4 to assess the transport of persistent organic  
5 pollutants into and out of the U.S. and that should be  
6 done by next year.

7                   **DR. DELORME:**     One of the things that I  
8 noticed you didn't factor is the scope of use or the  
9 scale of use of the chemicals. I think that's also an  
10 important variable you have to consider. If you have a  
11 chemical that's in use in the millions of tons, it  
12 doesn't necessarily have to be persistent in order to  
13 find in areas where it's not applied. There are  
14 examples I think you see in Canadian data air  
15 monitoring where, during the spring we see stuff that  
16 is not applied in Canada up there, but only for the  
17 fact that tons and tons of the stuff are being applied.  
18 It doesn't matter that it's not particularly volatile.

19                  **DR. KHAN:**       That's what Dr. Bradbury was  
20 alluding to because that's what will qualify a decision  
21 as a component of that and that's what we'll be looking  
22 into in the next SAP.

23                  **DR. HEERINGA:**     Dr. Maddalena?

24                  **DR. MADDALENA:**    I'm still a little  
25 unclear, when you use the OECD tools, all four



1 chemicals have been flagged as of concern. What else  
2 do you need to know? Where do you go from there?

3 **DR. KHAN:** Well that's what I said. You  
4 can go more deeper than that. You just take those data  
5 and then again, there's a lot of other components in  
6 the model. Like for example, I was showing that the  
7 chemical flow, as a transport of air particulates, and  
8 Dr. Bradbury was explaining that there are lots of  
9 things, because we're taking it at a constant flow  
10 rate, you know.

11 But that doesn't happen all the time.  
12 So those, and also like precipitation, like every day  
13 we don't have precipitation. So those are the things  
14 we need to think about it, before we start leveling  
15 something, like this is a persistent, this has a long  
16 range transport.

17 **DR. MADDALENA:** A number of these  
18 multi-media models do have intermittent rain now and  
19 the long term particles deposition, you're right it's  
20 very simplified. But I think what I'm getting at more  
21 was the last comment. Do you need to know what the  
22 mass use is? Can you put a cap on that? Is that even  
23 a policy decision that you could do? The chemical is  
24 clearly going to end up in the north pole if you start  
25 using it, even if it's a hypothetical scenario. You



1 might want to think about how much you can release.

2 **DR. KHAN:** That's the management  
3 decision Dr. Bradbury can answer.

4 **DR. BRADBURY:** And without dodging the  
5 question, I think your discussions tomorrow or the next  
6 day when we get to the charge questions will be very  
7 helpful. We're starting to talk about it now. So with  
8 the screening level models, I view the personally as  
9 part of the problem formulation. It's certainly  
10 probably useful to say, here's a pathway you may need  
11 to dig in deeper and get insights as to what that  
12 exposure potential is so we can do a better job of  
13 quantifying risk or estimating what the risk is.

14 Based on that outcome, potentially or  
15 theoretically providing scenarios to put out. But I  
16 think what will be helpful tomorrow is as you all talk  
17 about this with respect to describe what levels of  
18 certainty or uncertainty quality can you expect from  
19 current tools. What are some reasonable forecasts for  
20 the future, in terms of tool development, in terms of  
21 what kind of certainty can they be associated with.

22 With what's on the horizon, no pun  
23 intended. So you can start to get at some of the  
24 questions you're asking. So there's flexibility if you  
25 will in terms of risk management decisions, but it's



1 highly dependent on what's the state of the science and  
2 the quality of the science that helps inform that risk  
3 management decision.

4 And again, as I said before, some of  
5 these chemicals are in the decision making process now,  
6 so we are balancing that with what's today's best  
7 available science, what are the strengths and  
8 limitations of today's best available science, through  
9 an articulated decision. And that gets into how you  
10 define the uncertainties and certainties.

11 **DR. HEERINGA:** Dr. Bidleman?

12 **DR. BIDLEMAN:** If you look into these  
13 transport models, the results are hugely dependent on  
14 whether the chemical is released into the air or  
15 released into the soil or released into the water.  
16 That greatly affects the outcome.

17 In the case of pesticides, we know where  
18 they're applied. They're applied to soil for the most  
19 part. But even there, it depends greatly on whether  
20 it's applied on the surface, whether it's a foliar  
21 spray, whether it's granular, whether it's soil  
22 incorporated and this gets into the emissions scenario,  
23 which isn't really treated in these long range  
24 transport models. And it's not treated in the OECD  
25 screening tool.



1 But you have to put the whole package  
2 together, and to evaluate atmospheric transport, you  
3 need to start back at the source and also consider how  
4 these chemicals are getting out of the soil and into  
5 the atmosphere and at what rate.

6 **DR. HEERINGA:** Well at this point, it  
7 looks as though we have no additional questions. At  
8 this moment, Dr. Khan I'd like to thank you and also  
9 Kristina earlier for excellent presentations. My own  
10 opinion is the material has been extremely well  
11 organized, at least to set up the discussions and our  
12 review of the charge questions. I thank everyone for  
13 that. Panel members and public, I think we're at 10:03  
14 on my watch. The company clock has 9:57 but we'll take  
15 a 20 minute breack and we'll be back at 10:20 then.

16 **DR. HEERINGA:** Welcome back everyone.  
17 We're on our second day in the second half of our  
18 morning session, FIFRA science advisory panel on  
19 selected issues associated with risk assessment process  
20 for pesticides with persistent bio-accumulative and  
21 toxic characteristics. And at this point, we hear the  
22 last sequence of presentations, two more this morning.  
23 I'd like to welcome Brian Anderson on the topic of  
24 evaluation of aquatic toxicity of persistent  
25 bio-accumulative pesticides. Brian?



1                   **MR. ANDERSON:**       Thank you very much.  
2 I'll be talking about evaluating aquatic toxicity in  
3 persistent and bio-accumulative chemicals. I'd like to  
4 start by acknowledging a few people who aren't  
5 presenting but have made significant contributions to  
6 the white paper and to this presentation.

7                   Dr. Tom Steger and Michael Hoffman have  
8 both made significant contributions and I just wanted  
9 to acknowledge them. In addition to the rest of the  
10 team as well. We're going to talk about three basic  
11 things during this presentation. I'm going to give  
12 some background information on toxicity data that we  
13 typically get to evaluate aquatic toxicity.

14                  We're going to look at some types of  
15 studies that are particularly important for persistent  
16 bio-accumulative chemicals. And we're also going to  
17 look at some methods we use to evaluate aquatic  
18 toxicity where dietary exposure is the predominant  
19 exposure route. And we're going to look at total  
20 residues of concern.

21                  Both how we choose toxicity values to  
22 describe the total residues of concern and we're also  
23 going to look at some information that was presented  
24 yesterday. When three methods were presented to  
25 estimate total exposure residues. And we're going to



1 see how each of those methods relates to a potential  
2 changes in risk conclusions. We'll look example  
3 chemicals one and two for that.

4                   So data that we typically get for an  
5 aquatic toxicity assessment includes acute chronic  
6 studies, which are typically water only exposure  
7 studies. Acute studies are 2-4 days in duration. The  
8 endpoint we use for risk quotients is mortality or  
9 immobilization. The toxicity value that we use in our  
10 risk quotients is an LC-50 or an EC-50, that's a 50%  
11 effect level. For product studies or longer duration,  
12 from about 3 weeks to 6 months or more, depending on  
13 the organisms being tested and the type of study, the  
14 endpoints include growth, reproduction, and mortality.  
15 The toxicity value that we use in our risk quotient for  
16 chronic risk quotients is a no observed adverse effect  
17 concentration.

18                   So the highest concentration does not  
19 result in an adverse effect. A couple studies that are  
20 particularly relevant for bio-accumulative chemicals  
21 include sediment toxicity studies, which is the case  
22 because chemicals that tend to bio-accumulate tend to  
23 have high, long KOW's, high KOC's so they tend to  
24 partition in the sediment, so they can persist for an  
25 extended period of time. Therefore, obtaining sediment





1 toxicity studies, both acute and chronic duration, can  
2 be important. In addition, we have two types of  
3 studies we can get to evaluate the chronic toxicity in  
4 fish, the early life stage study and a life cycle  
5 study.

6 The life cycle study has the potential  
7 to account for maternal transfer, which is transfer of  
8 lipid rich compounds to developing eggs with the  
9 associated contaminants. And the early life stage  
10 study does not have that capability. So obtaining the  
11 life cycle study can be particularly useful for  
12 chemicals that bio-accumulate. In addition, there are  
13 some other studies that we get on a case by case basis.

14 For example, chemical one, you'll see  
15 we've updated on degradative concerns. For example,  
16 chemical four, a number of studies are available.  
17 They characterize both accumulation and toxicity for  
18 multiple exposure routes.

19 In addition, we can get microcosm,  
20 mesocosm studies although those are less commonly  
21 submitted, but those are less commonly submitted, but  
22 those are available on a case by case basis. There are  
23 some challenges with our typical data sets with respect  
24 to persistent and bio-accumulative chemicals.

25 One of these challenges is study

1 duration. Chemicals that have high KOW's take longer  
2 to reach steady state and steady state is not achieved  
3 during the duration of the study. That could result in  
4 an under-estimation of toxicity. For example, example  
5 chemical 4, during the duration of the acute studies,  
6 10% of studies say it was expected to be achieved. But  
7 even if you go to the longer duration studies, even 30  
8 or 60 days, steady state still isn't expected to be  
9 reached.

10 That's based on the kinetics that were  
11 observed in the bio-concentration studies. So in  
12 addition, the data that we think we have are water  
13 exposure toxicity studies and in cases where dietary  
14 exposure is particularly important, then the water  
15 exposure studies may not fully express or evaluate the  
16 toxicity of the chemical, as we'll see with example  
17 chemical 4. So looking at example chemical 4 as the  
18 example, it has a very high KOW, very high KOC, high  
19 bio-concentration factor and very low solubility.

20 I expect it to be persistent in both  
21 water and sediment. And what this means is when a  
22 chemical enters the water, it's not probably going to  
23 stay in the water phase, but it's going to tend to  
24 partition to the sediments and to the biota and  
25 therefore dietary exposure would be expected to be a



1 predominant exposure pathway.

2 And that means that doing a water based  
3 risk assessment, meaning comparing water-based EEC's to  
4 a water based toxicity value may not be particularly  
5 meaningful or not be expected to fully evaluate the  
6 risks of this chemical. And therefore an alternative  
7 method would be useful in evaluating this chemical.  
8 And we're going to look at the critical body residue  
9 approach to do that.

10 The critical body residues in this case,  
11 we're defining that to mean the level of pesticide in  
12 an organism that corresponds to a defined effect. So  
13 in other words, what we're doing is instead of  
14 expressing toxicity in terms of concentration exposure  
15 media, we're expressing toxicity with respect to the  
16 assessed organism.

17 Yesterday, during the bio-accumulation  
18 assessment, Keith Sappington presented methods that  
19 allow organisms that, hypertropic level organisms that  
20 consume aquatic organisms that bio-accumulate the  
21 chemical to be assessed, meaning how we assess risk to  
22 birds or mammals that consume aquatic wildlife.

23 This is a way to evaluate potential  
24 risks for the organisms that are actually accumulating  
25 the chemical. So the critical body residue is a



1 toxicity value that can be compared to results from the  
2 accumulation assessment to calculate a risk quotient  
3 using methodology that we would otherwise typically use  
4 except for the EC and toxicity value are now in terms  
5 of milligrams per kilogram organisms as opposed to, for  
6 example, milligrams per liter water or milligrams per  
7 kilogram sediment.

8                   And our standard acute and chronic LOC's  
9 would apply. The levels of concern range from .05 to  
10 .5 for acute effects and 1 for chronic effects. A  
11 major advantage to this approach is that it does allow  
12 for multiple exposure routes. It addresses the issue  
13 of lack of steady state and bio-availability, which is  
14 a key issue for chemical 4. It's also an established  
15 approach, it's not new, it's been around for some time.

16                   Some assumptions with this approach, one  
17 is that toxic effect is indeed related to body burden.  
18 There are some chemicals where that wouldn't be the  
19 case. Strong irritants are surface acting types of  
20 chemicals. But this is an assumption that can be  
21 tested with measured data and it's also an assumption  
22 that's reasonable for most interorganic chemicals. In  
23 addition, another assumption is the potency is  
24 equivalent across exposure routes.

25                   What that means is the CBR would be the



1 same, regardless of whether or not dietary exposure is  
2 occurring or water exposure. In addition, the critical  
3 body residue for a given endpoint like mortality is not  
4 time dependent. What that means is that the critical  
5 body residue would be the same, regardless of whether  
6 or not it's resulting from high intensity exposure for  
7 short duration of time or low intensity exposure for a  
8 longer duration of time.

9 That would be the constant critical body  
10 residue approach. So ideally, what we would want for a  
11 critical body residue would be a measured study,  
12 meaning a measured dose response where the exposure is  
13 expressed in terms of body burden and the other typical  
14 responses that we would measure in an acute and chronic  
15 toxicity study.

16 However, those data typically aren't  
17 available for our risk assessments. In the absence of  
18 such data, there might be a need to estimate a critical  
19 body residue and we'll see an example of how we have  
20 done that. Using example chemical #4, which did not  
21 have any measured and critical body residues available  
22 in fish, so we tried to make best use of the data that  
23 we had to estimate the critical body residue.

24 Using this simple first order equation  
25 that relates concentration in an aquatic organism to



1 the concentration in water, uptake and elimination,  
2 kinetic parameters from the bio-concentration study and  
3 time. So when the concentration in the water is  
4 equivalent to an LC-50 or a NOAC or whatever toxicity  
5 value that we're using, the concentration in the  
6 organism becomes an estimate of the critical body  
7 residue.

8                   Listed here are some of the parameters  
9 we used in the estimate. So plugging in the numbers to  
10 the equation, we end up with a range of critical body  
11 residues for this chemical. Around 160 to 970  
12 milligrams per kilogram. We give a range just due to  
13 some of the certainties with respect to the toxicity  
14 study and some of the bio-availability issues and that  
15 correlates to, on a molar basis, to around .3  
16 millimoles per kilogram to 2 millimoles per kilogram.

17                   When comparing to some of the range of  
18 values that have been reported for neutral organic  
19 narcosis range from around 2 millimoles to 8 millimoles  
20 per kilogram. This range is kind of on the lower side  
21 of that.

22                   So there are number of uncertainties in  
23 this estimates, particularly in the differences in  
24 bio-availability, species, life stages across the  
25 various studies. Meaning we often have a



1 bio-concentration study, one species, a remote  
2 sensitive species in toxicity studies might be a  
3 different species under different conditions and  
4 different life stages that are also tested.

5                   This results in considerable  
6 uncertainty, I think. Particularly, in this case when  
7 we have use of co-solvents throughout. And so one  
8 thing we can do to try to ground through this estimate  
9 is look at what other data we might have that's  
10 available to us that has measured residue.

11                   The only other study that's typically  
12 submitted to us that does measure body residues would  
13 be bio-concentration studies and although not designed  
14 to evaluate toxicity, when fish start dying, that's  
15 typically recorded in a spot report, toxic effects that  
16 are observed. So in this case, we have a  
17 bio-concentration study that did measured effects after  
18 about 2 milligrams per kilogram and no report of  
19 anything dropping dead. This at least gives us some  
20 idea that our 160 value isn't overly conservative.

21                   We would have an inconsistent estimation  
22 versus our measured data if our estimate was below this  
23 2 milligrams per kilogram value. That was for an acute  
24 estimation for chronic effects. It's a little more  
25 difficult I would say. An attempt to estimate a





1 chronic CBR based on a water concentration and the  
2 duration of the study resulted in a chronic critical  
3 body residue that's greater than the acute body  
4 residue.

5                   What that would mean is our estimate of  
6 mortality is lower than an estimate of body burden  
7 where no effects are occurring. That would be  
8 inconsistent. So we would want to see a measured data  
9 to help better characterize that critical body residue  
10 for chronic effects.

11                   So since we're bringing this into a risk  
12 picture here this really what we're concerned about.  
13 Our acute risk quotient then could be calculated based  
14 on results in bio-accumulation assessment and compare  
15 that to our critical body residue. So we just pulled  
16 in some examples from the accumulation assessment and  
17 the results and our cue is around .05 to .2. That  
18 would mean that our endangered species LOC would be  
19 exceeded.

20                   Given the uncertainties in the estimate,  
21 we would still want to see a measured value to confirm  
22 these conclusions here. We also note that the  
23 conclusions would be highly sensitive to the assessment  
24 methodology, both on the accumulation side and the  
25 toxicity side as well and our chronic risk would be



1 answered. So going through the fish, the same approach  
2 would be used for invertebrates as well.

3 We would look to see what measured data  
4 we have that characterize the critical body residues,  
5 estimate one if it's needed, and then we can calculate  
6 ours using the PRZM scale and compare those with the  
7 LOC's. And I think there's some utility in looking at  
8 some of the data for chemical 4 because we have a  
9 number of studies that are not typically available to  
10 us, but since these data are not usually available,  
11 then we might need to make best use of the data we have  
12 to try and estimate a critical body residue for  
13 invertebrates as well. So we're going to present  
14 methods we've used to estimate a CBR and compare that  
15 to our measured values and see where that leaves us.

16 So our most sensitive species for this  
17 chemical was acelas, which is a small isopod. We had a  
18 measured CBR of somewhere around .1 to .5 as a mesocosm  
19 study. So basically, what we did was took our fish  
20 kinetic data and applied that to the exposure levels  
21 that were in the study and the time durations when  
22 effects started to be observed to the estimated  
23 critical body residue.

24 Again, with acknowledging the  
25 considerable uncertainties going from one taxonomic

1 group to another, it results in an estimated value  
2 that's really within the range of the measured value  
3 here. I'm just going to look at 3 species, we'll look  
4 at choronomids as well. In this case, we actually have  
5 a preliminary study that's been submitted that measured  
6 body burden and toxicity. We also have the same  
7 mesocosm studies.

8                   And again, applying our fish kinetic  
9 information and duration and exposure values. We would  
10 estimate the range of somewhere between 20 and 300  
11 milligrams per kilogram and that's a much bigger range  
12 than what we saw for the last organism. And then for  
13 daphnids, again what we have is a bio-concentration  
14 study which is still in review that suggests that  
15 critical body residue would be somewhere between 6 and  
16 30 milligrams per kilogram. And again, taking our fish  
17 kinetics data, we can estimate the critical body  
18 residue around 4.5 milligrams per kilogram, which is  
19 within that range.

20                   Close to being in that range; it's  
21 slightly outside that range. So just to give an  
22 example of how an RQ would then be calculated based on  
23 these values, again these are just for example purposes  
24 only. We took the low end measured value, compared  
25 that to just a representative EEC from the



1 accumulations assessment to calculate risk quotients.

2                   And you see our RQ's range from around  
3 .7 to around 400 and then on the sensitivity of the  
4 organism and the accumulation potential as well. So to  
5 conclude then, the critical body residue approach is  
6 being considered for evaluation. Persistent  
7 bio-accumulative chemicals in cases where dietary  
8 exposure might be important and when steady state will  
9 not be achieved during the duration of toxicity  
10 studies.

11                   Ideally, this will be based on a  
12 measured critical body residues but there are ways to  
13 make best use of the data that we have to estimate a  
14 value needed. Changing gears here, we're going to look  
15 now at soil residues of concern. We're going to look  
16 at three basic things, provide a very rich summary of  
17 soil residues of concern, describe how toxicity values  
18 might be chosen to characterize soil residues of  
19 concern and then look at the sensitivity, the risk  
20 conclusions, both of the methods that are used to  
21 evaluate exposure, for example chemicals 1 and 2 and  
22 toxicity for those chemicals as well.

23                   So for some background information, our  
24 total residues are typically the parent pesticide plus  
25 degradates but it's not limited to that. Sometimes



1 there are contamination byproducts or other types of  
2 substances that might be included. But typically  
3 you're looking at the parent, plus its degradates. The  
4 potential total residues of concern are first  
5 identified in the environmental fate studies and the  
6 degradates then are evaluated to determine whether or  
7 not there are toxicological concerns.

8           It can be done either with submitted  
9 data. Some might have studies that have been submitted  
10 either. Rates are offered in the study, but it might be  
11 an open literature study. Or it will be based on  
12 professional judgement as typically done through  
13 structural analysis. So the toxicity value that we can  
14 use to describe the total residues depends on a number  
15 of factors that depend on the availability of fate and  
16 toxicity data. Let's go ahead and look at our examples  
17 to illustrate these.

18           For chemical 1 in this case, we have a  
19 parent and we have a degradate. Toxicity of the  
20 parents and the degradates are similar. LC-50's for  
21 fish are within a factor of 2 of each other.  
22 Invertebrates, about a factor of 6 within each other.  
23 Sabatodes, their toxicities are similar. The  
24 structures are also fairly similar, so we would expect  
25 to see a similar or same mode of action. EEC's were



1 calculated for this chemical using three methods.  
2 Total residues, residue summation, and formation  
3 defined kinetics and we'll look at how EEC generated  
4 formation methods and how the affect risk.

5                   And we're only going to go with the  
6 acute fish analysis, just for time constraints but the  
7 same time of analysis can be done for invertebrates or  
8 for chronic effects as well. So, what we figure then,  
9 these are the EEC's, the toxicity value and the risk  
10 quotient for the various three methods that were used  
11 to estimate exposures. We EEC's that range from about  
12 30 to 50 micrograms per liter and pairing those to our  
13 lowest LC-50, just for the parent compound, results in  
14 risk quotients around 40 to 60.

15                   That can be interpreted to mean that the  
16 EEC is about 40 or 60 times higher than the most  
17 sensitive LC-50. So then, some questions we can ask is  
18 what is the predominant component of the total residue.  
19 What are the differences in toxicities of the  
20 components. And then how would that affect risk. And  
21 we're going to look at one way to do that. So we took  
22 the formation decline kinetics, EEC's, and we broke  
23 that down into parent and degradate. And what becomes  
24 pretty clear is that the predominant component of the  
25 EEC is the degradate and not necessarily the parent.



1                   So we can look at the difference in  
2 toxicity and the difference in the exposure from the  
3 total residues and the parent to look at how  
4 consideration of these factors might affect the risk  
5 quotient. So you look individually at the parent and  
6 the degradate and you get RQ's of around 1120. And we  
7 can simply add those up, assuming adaptivity, to get an  
8 RQ of around 31. And this is essentially the same  
9 thing as a toxic equivalency factor where an EEC is  
10 going to be weighted based on the various potencies of  
11 the two chemicals.

12                   And that's a lot easier if you just add  
13 the two numbers together. I just wanted to conclude  
14 with a slide. So basically, what this means is our RQ,  
15 even considering the difference in toxicity and the EEC  
16 is still pretty close to the RQ's that were calculated  
17 originally using the three different methods. It's a  
18 little bit lower, but still the risk conclusions are  
19 the same. The risk conclusions are not sensitive  
20 either to the choice of toxicity value or to the choice  
21 of the exposure method.

22                   So now looking at chemical #2, the  
23 parent lists four residues of concern. We see similar  
24 toxicity in the fish values, the LC-50's were within a  
25 factor of around 2.5. Invertebrates, we see some





1 greater variability. EC-50's range from about 12 to  
2 300. The EEC's calculated for parent only and the  
3 total residues of concern using the total residue  
4 approach only. Sufficient data weren't available to  
5 calculate EEC's using the other two methods, the FD or  
6 the RS.

7                   Again we're only going to look at the  
8 acute fish assessment, but methodology for looking at  
9 other species or chronic effects would be equivalent.  
10 So when we start looking at the parent only for this  
11 chemical, EEC of 18 micrograms per liter for that to be  
12 an LC-50 of 100 micrograms per liter, you get an RQ of  
13 .18.

14                   So if you consider the degradate, then  
15 the EEC only goes up very modestly from 18 to 19  
16 micrograms per liter. Given the similar LC-50's of  
17 fish, that results in an RQ range, depending on  
18 whatever toxicity value we choose, somewhere between  
19 .14 and .18. So again, the conclusion would be that the  
20 risk conclusions would not be sensitive to the choice  
21 of an LC-50 or the method used to estimate exposure.

22                   Now given the similar or the low  
23 contributions of the degradate to the parent and the  
24 similar toxicity of the degradates and the parent, it's  
25 almost silly to further characterize it. Meaning what



1 is the contribution of the degradate to the EEC, what  
2 is the difference in the toxicity and how does that  
3 affect the RQ. But the idea here is that even if we  
4 don't have enough information to estimate our EEC's  
5 using the FD or RS approach, we can still further  
6 characterize our RQ's if necessary to account for  
7 differences in contributions of the parent versus  
8 degradate.

9                   Particularly if there are differences in  
10 toxicity observed. And we could do that using the same  
11 basic approach. In this case, we just make an  
12 inference that the degradate, EEC, is the total residue  
13 minus the parent only. So that would result in a  
14 degradate EEC around one microgram per liter. So you  
15 can use the toxicity value lowest across the  
16 degradates, which is 56 micrograms per liter, to  
17 calculate the individual RQ and you can add those up  
18 the same way that we did for the last chemical.

19                   And I'll acknowledge there's a mistake  
20 here too on the equation. The numerator and the  
21 denominator got mixed up, that should be 100 divided by  
22 56. I apologize for the mistake. So the conclusion  
23 here is that risk conclusions aren't sensitive to  
24 choice of TRV or of the EEC. The toxic value or the  
25 exposure value. Methodology- RQ's range from about .14



1 to .34. The peak EEC is predominantly parent in this  
2 case, but even if you look at the chronic EEC's as  
3 well, 21 day chronic EEC is what we use to evaluate  
4 invertebrates, about 90% parent. But the contribution  
5 of degradate versus the parent increases as duration  
6 increases.

7 That may be something that's important  
8 to consider in risk characterization. So, to conclude,  
9 for chemical #1, the predominant component of the TROC  
10 was the degradate. The acute risk conclusions weren't  
11 sensitive to the choice of toxicity value or the  
12 exposure value after. For chemical #2, the predominant  
13 component of the total residue of concern was the  
14 parent chemical in this case. Including toxicity, the  
15 degradate had little acute effects but it could have  
16 greater toxicity on the chronic effects. And use of  
17 the parent LC-50 to represent the TROC was reasonable.  
18 And that is all that I have for this presentation.

19 **DR. HEERINGA:** Thank you very much,  
20 Brian. At this point, Dr. Schlenk has a question.

21 **DR. SCHLENK:** Yes, actually I have  
22 several. The white paper is a little bit different  
23 from your presentation. Actually, I was a little  
24 confused a bit on some of the things you went over. In  
25 the white paper, there's a discussion of an ECOSAR and



1 that is supposed to generate estimates of toxicity  
2 according to the text. I'm curious how that does that.

3 **MR. ANDERSON:** ECOSAR, that's a  
4 program that estimates toxicity based on KOW and  
5 chemical class. It has a number of chemical classes in  
6 it. We typically use that as more of a screen to tell  
7 us whether or not we might have a concern or not. We  
8 typically don't use it to satisfy data requirements or  
9 anything like that. Basically what it is, it's just a  
10 QSAR that relates toxicity to KOW.

11 **DR. SCHLENK:** And how is toxicity  
12 defined?

13 **MR. ANDERSON:** Toxicity is defined as  
14 LC-50, EC-50 or...

15 **DR. SCHLENK:** So acute lethality...

16 **MR. ANDERSON:** Acute lethality. But it  
17 also has QSAR's in there for chronic effects as well,  
18 that's right.

19 **DR. SCHLENK:** I'm sorry, what did you  
20 say?

21 **MR. ANDERSON:** There are chronic QSAR's  
22 available as well now. There are acute and chronic  
23 QSAR's.

24 **DR. SCHLENK:** So that's included in that  
25 sort of initial analysis?



1                   **MR. ANDERSON:**       That can be one tool that  
2 we use to identify a concern, that's right.

3                   **DR. SCHLENK:**       And what's ECIWIN?

4                   **MR. ANDERSON:**       ECIWIN? Ecostar is  
5 called a sub-component of ECIWIN. ECIWIN, there are  
6 basically a suite of different programs that are used  
7 to estimate various things with respect to  
8 environmental fate, bio-concentration and toxicity.  
9 They're all QSAR's that are based on different types of  
10 things. But they're just a way to estimate fate and  
11 toxicity parameters based in chemical structure.

12                  **DR. SCHLENK:**       And those assessments, in  
13 terms of mode of action, are all primarily, I'm  
14 guessing narcosis based? Is that the idea?

15                  **MR. ANDERSON:**       There are a number of  
16 different chemical classes. I'm not exactly sure how  
17 many.

18                  **DR. SCHLENK:**       Well, for PBT's. Is the  
19 assumption acute narcosis?

20                  **MR. ANDERSON:**       I would say that would  
21 depend on what data you have.

22                  **DR. SCHLENK:**       For these pesticides that  
23 you used in this white paper, would that, it seems like  
24 you're using acute narcosis as your toxicity estimate.  
25 Is that accurate?



1                   **MR. ANDERSON:**     I would say, when you're  
2 looking at the critical body residue, for example, what  
3 we saw was critical body residue that was based on the  
4 estimate that was lower than what had been recorded for  
5 narcosis. And that could suggest excess toxicity.

6                   **DR. SCHLENK:**     The trouble I'm having  
7 here is in terms....there's several statements in there  
8 that, you know, the assumption of adaptivity is  
9 reasonable.

10                   And I'm, looking at the data provided,  
11 I'm having a hard time seeing how that conclusion was  
12 made and there's another thing basically you've got the  
13 LC-50's values in table 7.3 were relatively similar and  
14 the statement there is that there's similar toxicity.  
15 And I guess I'm really struggling kind of with how  
16 you're defining acute toxicity because I think it's  
17 pertinent to how you assess exposure. Which is what  
18 this critical body burden thing is really more of an  
19 exposure assessment. It's not necessarily a toxicity  
20 assessment.

21                   I mean, you're actually looking at an  
22 amount of a compound in an organism and I'm having a  
23 hard time relating that exposure assessment to an  
24 effects assessment. Does that make sense? And it  
25 really boils down to the assumption of adaptivity



1 because in order to assume adaptivity, you assume the  
2 same mode of action and if you backed up in order to  
3 assume mode of action, you're using QSAR to assume. So  
4 I see a tremendous amount of uncertainty for making  
5 that first assumption all the way down to an assumption  
6 of adaptivity.

7 **MR. ANDERSON:** I just want to make sure  
8 I understand what you're saying. So you're saying if  
9 we're looking at a CBR for multiple residues of  
10 concern, for multiple chemicals. Typically I would say  
11 we would look at the various structures of the  
12 chemicals of concern. How similar are they? What do  
13 we know about the toxicity of the chemicals? Is there  
14 a possibility it's kept intact? Or is it not? Is  
15 there something fundamentally different about the  
16 chemical that would affect it's toxicity?

17 **DR. SCHLENK:** And you mean toxicity,  
18 again, acute lethality, right? It seems like all the  
19 data that you're presenting is primarily acute  
20 lethality derived.

21 **MR. ANDERSON:** That's true.

22 **DR. SCHLENK:** And that you're using the  
23 degradate with the parent in terms of an additive  
24 approach based on acute lethality. Is that accurate?

25 **MR. ANDERSON:** When we presented the





1 TROC analysis we only presented the acute assessment.  
2 But we would typically do this, depending on what data  
3 we have, we would probably make the same assumption on  
4 chronic effects.

5 **MR. SAPPINGTON:** Just to go back. When  
6 we're looking at the degradates, we would carefully  
7 look at the structure of those and compare them.  
8 Obviously you have to exercise some judgement in terms  
9 of similarity and potential modes of action.  
10 Recognizing of course, that the acute mode of action  
11 may differ from the chronic mode of action. The  
12 preference here is to actually generate, actually have  
13 measured values to we can explicitly consider the  
14 toxicity differences between the parent and degradate.

15 When we do not have that information,  
16 sometimes we don't have the luxury of waiting until  
17 those tests are generated and we're coming here and  
18 suggesting what ways might we, what set of assumptions  
19 might be reasonable.

20 So we would be bounding this context of  
21 adaptivity with information the best that we could gain  
22 from mode of action of this compound. The other source  
23 of this information may come from our sister division,  
24 HED, where they have a standing committee called the  
25 residues concern committee which is designed to



1 evaluate the formation of degradates as well as their  
2 mode of action.

3 So that information will be brought to  
4 bear as well. Before it was just an automatic, default  
5 assumption.

6 **DR. SCHLENK:** Okay, that's what I needed  
7 to know because that's not spelled out in the white  
8 paper. The process that you go through to actually  
9 make the assumption of adaptivity and then the  
10 assumption....so that's primarily what I was after.

11 **DR. HEERINGA:** Dr. Chambers.

12 **DR. CHAMBERS:** I had a question about the  
13 third assumption that you had in the CBR approach, that  
14 for a given endpoint it is not time dependent. So are  
15 you ignoring that; any kind of physiological  
16 adaptation? Any kind of down regulation or up  
17 regulation of receptors or something like that? That  
18 can really make it time dependent, couldn't it?

19 **DR. ANDERSON:** There are some approaches,  
20 as in the literature that have looked at time  
21 dependence of the critical body residue--I'll defer to  
22 my colleague.

23 **MR. SAPPINGTON:** Yes, time dependence has  
24 been, of the CBR has been shown to be-- to occur for  
25 some compounds. And there are different models out



1 there to evaluate that such as damage repair mechanism,  
2 actually treat that as a kinetic process. I think I  
3 would add that with regards to the assumption of time  
4 dependence and the CBR, I would be uncomfortable  
5 stretching that assumption all the way from acute to  
6 chronic effect, but within the realm of exposure  
7 durations, it might be considered acute and within the  
8 realm of exposure durations it might be considered  
9 chronic or subchronic.

10 That that may be where that function,  
11 you know, would be placed. I would again put some  
12 bounds on that, because once you get into chronic  
13 toxicity your modes of actions can differ and the  
14 ability of the organism to evoke their repair  
15 mechanism; if they are not being as overwhelmed as they  
16 would be in acute exposure.

17 The other thing that comes into play  
18 there is different life stages of the organism,  
19 particularly if we are talking about a life cycle path.  
20 And we know that different life stages have different  
21 abilities to biotransform chemicals. So, I would  
22 again--I think what Brian is pointing out is that by  
23 using a CBR you are making that assumption. However,  
24 when we're applying it, I don't think we would use  
25 necessarily an acute CBR for a full life-cycle type



1 assessment.

2 **DR. HEERINGA:** Dr. Norstrom?

3 **DR. NORSTROM:** My question is on the  
4 same topic, actually. It just happened, I was reading  
5 a paper last night by Simon Harmons where they reviewed  
6 some acute, in this case, toxicity native to things  
7 like chlorobenzenes in fish and concluded there can be  
8 up to a factor of four difference, depending on time,  
9 of exposure. So even in acute exposure phenomenon, I  
10 think you might consider that there can be that kind of  
11 an error in it, simply because there seems to be  
12 different mechanisms operating depending on whether the  
13 fish dies within the time frame were talking about here  
14 is one day or two days versus three days, that kind of  
15 thing. It's not universally true that it will only be  
16 one value for acute.

17 **DR. HEERINGA:** Dr. Schlenk?

18 **DR. SCHLENK:** Yeah, just one other thing  
19 I forgot to ask the last time. So again, the  
20 assumption of the mode of action is equivalent between  
21 all species, or is that taken into account as well? In  
22 terms of acute lethality?

23 **MR. ANDERSON:** Yeah, I think that would  
24 really have to be considered, particularly if you have  
25 an insecticide or something like that.



1                   **DR. SCHLENK:**     Right, so that choice is  
2 made in the sort of problem formulation meeting or  
3 counsel that you have before you actually deciding to  
4 go to CVR? Is that accurate?

5                   **MR. ANDERSON:**     My understanding of that  
6 committee is mainly mammalian based. However, in some  
7 of the QSAR models that are available, they are  
8 stratified, if you will, by broad taxonomic grouping.  
9 For example, we'll have, I believe we have outputs  
10 predicted for algae, for daphnia type planktonic  
11 invertebrates, as well as for fish.

12                                 And the other output that comes from  
13 that is the assumption, based on the structure of the  
14 chemical, of the mode of action to use to generate that  
15 prediction. So all of this ultimately gets back to the  
16 structure of the compound, but also the data sets that  
17 are used to validate those predictions. So yes, we  
18 would look at differential modes of action depending on  
19 the receptor species.

20                   **DR. SCHLENK:**     I guess that, for example,  
21 if I had an insect specific receptor antagonist that  
22 was DVT in fish, but obviously because it could survive  
23 in fish, if you were trying to use an invertebrate, you  
24 couldn't because it would kill it so fast you'd never  
25 have a chance of getting a body residue. So you are



1 looking at that?

2 **MR. SAPPINGTON:** And that would be the  
3 difference in the target versus non-target, put that  
4 around, the same thing occurs with an herbicide and if  
5 you look at the algal SAR predictions, they're nowhere  
6 near close to what we've actually observed, because  
7 they're based on more baseline type toxicity and not a  
8 specific mode of action that has been developed for  
9 that particular herbicide.

10 **DR. SCHLENK:** So I would assume then  
11 that this program that's utilized then differentiates  
12 that or is that done just more on a committee basis?

13 **MR. SAPPINGTON:** The SAR Program that I  
14 mentioned does give you the output of highly broad  
15 taxonomic classes, yes.

16 But I will add that this is an area  
17 that, internally, we are working on and that is to link  
18 up with our eco-toxicity data information on mode of  
19 action that is specific to different species. Because  
20 you have the mode of action, you may have that  
21 information for the target species provided by the  
22 registrant.

23 But we're charged with protecting the  
24 whole gamut of species out there, so to the extent that  
25 there are information available for other species, we



1 actually are starting a project this January to try to  
2 collect that and incorporate it into our database for  
3 this exact purpose.

4 **DR. HEERINGA:** Dr. Bradbury?

5 **DR. BRADBURY:** This will be a little  
6 more background on the context of some of the dialogue  
7 that's been going on and Dr. Doucette may be able to  
8 help during the deliberations as well.

9 Some of the QSAR modeling systems that  
10 Keith and others have been referring to have been  
11 developed by the sister part of the agency that deals  
12 with the Toxic Substances Control Act. And they've  
13 developed a QSAR system that's actually a function of  
14 work with ORD and the toxics program that has  
15 algorithms that take a look at the potential mode of  
16 action, looking at chemical structure.

17 It's not a plug and chug sort of  
18 operation, we use expert judgment as well as going  
19 through SAP review and OECD, it gets part of the OECD  
20 toolbox, QSAR tools. So that's just an example of one  
21 of the tools, one of the approaches to be used to help  
22 provide some insights into how to interpret the  
23 toxicological potential of a structure and clearly mode  
24 of action is a big part of that deliberation.

25 So I just wanted to clarify that. In





1 OPP, we're accessing other parts of the agency, but I'm  
2 using tools that have gone through extensive peer  
3 review in terms of both how they're built and the  
4 proper application of those tools in the context, for  
5 example, of mode of action and related issues that  
6 you've been raising.

7 **DR. HEERINGA:** Dr. Hickie?

8 **DR. HICKIE:** I wonder if you could go to  
9 slide sixteen? My impression is CVR is essentially  
10 independent of time, correct? And yet, when I look at  
11 that equation, that suggests that CVR should be  
12 dependent on time.

13 **MR. ANDERSON:** That's going to be a  
14 function of the toxicity study, meaning that's the 48  
15 hour LC-50 study. That's estimating concentration in  
16 the organisms at the time where effects occurred. So  
17 that would the concentration in the organism associated  
18 like an LC-50.

19 **DR. HICKIE:** So that's a time-dependent  
20 LC-50 that's plugged in there?

21 **MR. ANDERSON:** Yes, that's right. It's  
22 the specific duration of the study.

23 **DR. HICKIE:** So, in this case, it would  
24 be a 72 hour study? It took three days?

25 **MR. ANDERSON:** Yeah, that's right. It's



1 a four day test and we took values from day three, but  
2 yes, that's right.

3 **DR. HICKIE:** It's not quite clear then.  
4 I was wondering what happens if you plug in two days or  
5 four days and particularly since the depuration half  
6 life is substantially longer than the testing period.

7 **MR. ANDERSON:** Yeah, that's right,  
8 that's right.

9 **MR. SAPPINGTON:** I think this is  
10 designed to estimate the concentration in the organism  
11 that's associated with the LC-50 that's observed in a  
12 particular test.

13 **DR. HICKIE:** So that should be, probably  
14 the location there should be, concentration in water  
15 should be a time dependent LC-50 as opposed to....

16 **MR. SAPPINGTON:** Yes, I mean that's one  
17 of the issues we brought up with these compounds.  
18 They're not at steady state during these tests. But  
19 the notion of time dependence, if that assumption is  
20 reasonably valid, would be that a CVR from a longer  
21 term exposure should be....the LC-50 associated with a  
22 longer-term exposure should be lower, but the CVR,  
23 because it's longer term exposure, would be close to  
24 the CVR you would get here. So that's the idea.

25 **DR. HICKIE:** It's just not entirely



1 clear in the white paper.

2 **MR. SAPPINGTON:** Okay, okay.

3 **DR. HEERINGA:** Dr. Delorme?

4 **DR. DELORME:** Just following along with  
5 Brendan's line of questioning here, there is a another  
6 uncertainty in that you're assuming that the death take  
7 place at ninety-six hours. In fact, for an LC-50,  
8 you're looking at the sum over that time period, so if  
9 the organisms all die significantly earlier then you're  
10 actually probably over-estimating your critical body  
11 residue. Because you're allowing longer time for  
12 updates.

13 **MR. SAPPINGTON:** I've also seen in the  
14 literature, issues about which organisms you measure,  
15 in terms of the residues, alive or dead and I think  
16 Peter Landern's group has published some information on  
17 that.

18 So yes, advice that you could give us on  
19 constraints, limitations, things to really pay  
20 attention to with this approach would be useful and  
21 recently there was a pellston workshop that Jim Meador  
22 chaired and I was involved with that workshop on the  
23 tissue residue base approach in general. And so  
24 information from that could also be brought in.

25 **DR. HEERINGA:** Thank you. Dr. Hickie?



1                   **DR. HICKIE:**       I should send you my PHD  
2 from years ago, which was focusing on pulse exposure  
3 toxicity and CVR's.

4                   **DR. HEERINGA:**     Dr. Hickie, we can  
5 certainly cite that and provide the references and if  
6 you want to provide it earlier, that would be fine.  
7 Include it in the docket for the meetings. Dr.  
8 Schlenk?

9                   **DR. SCHLENK:**     Just one other comment.  
10 You had mentioned earlier you are interacting with your  
11 sister agencies and I'm just curious, has there been  
12 interaction with, in terms of Duluth with John Nichols  
13 and PBK type aspects, particularly related to this in  
14 terms of critical body.

15                  **MR. SAPPINGTON:**    Yes, we work closely  
16 with the Duluth lab on a number of fronts. One of  
17 which would pertain to this effort is the Astor program  
18 which is another useful toxicity estimation procedure,  
19 that's with Chris Russell, indoor, that's being  
20 released out on the web, but also to update information  
21 in the Astor with some of the newer pesticide  
22 ingredients so we can bring the estimation procedures  
23 up to par with newer modes of action and newer  
24 compounds.

25                               With regards to John's work, his work



1 with trout PBTK modeling and he's also working on PBTK  
2 modeling and in birds, namely a kestrel model with  
3 methyl mercury, that's an obvious extension that could  
4 be pulled in here. In fact, I'm working to bring him  
5 down here in December to give us a seminar on some of  
6 that to see where that plays in.

7 **DR. SCHLENK:** I think in terms of  
8 determining target organ specifically within the animal  
9 is pretty critical in this. I mean, I think this is,  
10 you know a good approach in terms of a first step, but  
11 you really want to refine it, it's determining where  
12 the compound is actually going within the organism I  
13 think is a very important step in that regard. His  
14 methodology would allow you to do that. At least in  
15 fish, anyway.

16 **DR. HEERINGA:** Yes, Dr. Meador?

17 **DR. MEADOR:** I may have missed it did  
18 you speculate why bacillus is so much lower on the CVR  
19 than those other two invertebrates?

20 **MR. ANDERSON:** I don't know why. I  
21 don't know why. I don't know if anybody else has  
22 any....it seems to be more sensitive, I haven't....

23 **DR. MEADOR:** One possibility, I mean  
24 that was a ninety-eight day test versus two forty-eight  
25 hour tests, so based on that KOW, it could have been



1 really slow internal re-distribution kinetics.

2 **MR. ANDERSON:** The issue is though that  
3 we saw effects pretty quick in that study, about six  
4 days into the study we started seeing effects.

5 **DR. MEADOR:** Even though it went out  
6 ninety-eight days?

7 **MR. ANDERSON:** That's right, that's  
8 right. But it seemed to be a short, possibly an acute  
9 effect. It wasn't, didn't appear anyway to be a result  
10 of slow accumulation over a period of time.

11 **DR. MEADOR:** I mean internally, a  
12 re-distribution. That takes quite a while, a KOW like  
13 that.

14 **MR. ANDERSON:** That's right, but we did  
15 see effects occurring within the first week.

16 **DR. MEADOR:** Did you consider the fish  
17 residue approach for those other two pesticides, one  
18 and two?

19 **MR. SAPPINGTON:** We did not apply a  
20 tissue residue approach to those. We did look at  
21 bio-accumulation, but only some aspects of diet and  
22 terrestrial organisms.

23 So as a way to estimate exposure to the  
24 diet. But not directly to the organisms themselves.  
25 The example chemicals we provided in the white paper



1 really do reflect a number of assessments done over a  
2 several year time period and some of the models we've  
3 used in the earlier ones have changed slightly to the  
4 next, to the next.

5 So it does reflect a pretty significant  
6 range in terms of the time and year that the assessment  
7 was done.

8 **DR. MEADOR:** So would you consider those  
9 pesticides in another assessment? I mean, would you  
10 look at the tissue as a new approach?

11 **MR. SAPPINGTON:** Well, for pesticide  
12 one, the KOW range would probably suggest that the diet  
13 isn't a dominant exposure route. Three and four, the  
14 diet, which is located around five and obviously we did  
15 it for four.

16 Those could be considered. But again,  
17 one of the issues here is addressing uncertainties with  
18 regard to estimating the CVR, which we've been talking  
19 about some aspect of that here versus actually  
20 verifying that with measured data and I think one of  
21 the potential outcomes from this meeting may be well  
22 when we have a chemical that meets a certain profile  
23 and if we get an indication of that early on, then  
24 perhaps we can be more pro-active in trying to get the  
25 type of information at the onset that would help us to





1 reduce the uncertainty. Otherwise, we will be in a  
2 mode of basically having to estimate CVR using whatever  
3 information we have from water-only exposures.

4 **DR. MEADOR:** Yeah, I'd recommend it for  
5 any bio-accumulative compound, that really doesn't  
6 matter if it's diet or water. The dominance for the  
7 route exposure. So it has utility for lots of  
8 different compounds.

9 **MR. SAPPINGTON:** Oh yeah, the approach  
10 is, yes. It's just that right now, the tools we have  
11 for compounds that are in the low hydrophobicity range  
12 seem to be adequate in terms of addressing the route of  
13 exposure as well as addressing the issue of steady  
14 state. It's when we start rubbing up against the  
15 steady state issue and the dietary problem.

16 Now the other aspect of CVR that wasn't  
17 mentioned but is particularly useful is this whole  
18 issue of mixtures and dealing with mixtures with  
19 similar modes of action. So that's another potential  
20 application, regardless of the other two aspects.

21 **DR. HEERINGA:** Dr. Oris?

22 **DR. ORIS:** Jim Oris, Miami University.  
23 One of the things I think you need to be very clear on  
24 are all of the assumptions that you are making.

25 And some of the assumptions can make

1 this work or make it fall apart really fast and so I'd  
2 encourage you to be very clear on the details of some  
3 of your assumptions.

4                   For example, in the slide that's up  
5 there now, this is a concentration based  
6 pharmaco-kinetic model and as the mass of the organism  
7 changes or the concentration of the compound changes  
8 during the exposure, then the model is not valid. And  
9 so those aren't assumptions that are laid out in what  
10 I've read and need to be very explicit about those  
11 kinds of things.

12                   So for example in maybe the invertebrate  
13 studies, you may not be able to make this assumption of  
14 a constant or no growth assumption in the four day  
15 test, for example. And if it's a static test, then you  
16 may not be able to make the assumption of constant  
17 concentration in the exposure.

18                   So those are things that need to be I  
19 think explicitly laid out. And then in your list of  
20 assumptions for the CVR approach, if you back up to  
21 slide thirteen, I think there's some caveats you need  
22 to put on some of these to again, make them more clear.  
23 So potency is equivalent across exposure routes only if  
24 there's no first path metabolism.

25                   CBR is not time dependent if there's no



1 repair. And an assumption of no growth also has to be  
2 put in, so that starts making this more utility in  
3 terms of acute toxicity, but if you lay those  
4 assumptions out explicitly than the utility that's for  
5 more chronic effect, then you need to be very careful  
6 how you apply that. So I just encourage you to be very  
7 explicit about how you lay out the assumption.

8 **DR. HEERINGA:** Thank you Dr. Oris and  
9 we'll make sure too that we bring that forward to our  
10 response to the charge question. At this point in  
11 time, I think I would like to thank Brian Anderson for  
12 the presentation and move on to the final presentation  
13 and conclusion which is going to be offered by Keith  
14 Sappington. Keith?

15 **MR. SAPPINGTON:** Thank you. I'm going  
16 to be discussing conclusions and some of our early  
17 thoughts regarding a path forward with respect to the  
18 issues associated with PBT-like chemicals. When we  
19 were, certainly after we put the white paper together  
20 and we were considering different presentations and the  
21 wide scope of these presentations, we thought it would  
22 be useful to try to have a wrap up at the end because  
23 we're covering quite a lot of territory.

24 So that will be the first half of my  
25 talk and the second half will be focusing on where



1 might we go from here. Obviously, that's going to be  
2 pending a lot of discussions that are going to continue  
3 this week and your recommendations and your report.  
4 But we thought it would be good to put out a few ideas  
5 that we have and get some specific feedback on that.  
6 So in terms of broad points, as outlined in the white  
7 paper and as presented over the last two days, we've  
8 encountered a number of scientific challenges and  
9 ecological risk assessment of pesticides that have  
10 varying PBT-like characteristics and those are listed  
11 here and these follow the topics in the white paper as  
12 well as the presentation.

13                   And what we seek in this SAP is input on  
14 how we have addressed these issues in past assessments,  
15 so sort of backward looking. But also considering  
16 where we go from here in the future, because we'd like  
17 to have a systematic process, if you will, in the  
18 problem formulation phase where we can identify these  
19 issues and know when to address them with specific  
20 tools and understand the limitations of those tools and  
21 their strengths.

22                   We are particularly interested in your  
23 feedback because we need that to help focus our  
24 resources on the most problematic issues in terms of  
25 uncertainty in our assessments and those that are more



1 tractable in the near term, as well as those in the  
2 long term. And lastly, we're looking for  
3 recommendations of steps we can take, both in the near  
4 term as well as the long term.

5 We do work closely with the office of  
6 research and development and do have opportunities to  
7 develop tools but as Dr. Bradbury and Dr. Brady  
8 mentioned, we have quite a rigorous schedule we  
9 maintain for conducting our ecological risk  
10 assessments. The steps that we can take in the near  
11 term would be very helpful as you're formulating your  
12 recommendations.

13 Environmental persistence, just to recap  
14 here, regarding consideration of parent degradants,  
15 again, it's not a question of if but it's a question of  
16 how. We presented three methods with the formation of  
17 the Klein method being the preferred method, however  
18 the question here is when this method is not feasible  
19 because of limitations and available data. All of the  
20 other two methods, reasonable approximation or do we  
21 need to consider other approaches or modifications to  
22 these approaches. And the actual selection of these  
23 methods will ultimately depend on the available  
24 information we have, these or other methods, and the  
25 toxicity data and associated uncertainties.



1                   We talked a lot about the solubility  
2 issue and the fact that with these types of compounds,  
3 when you include them in our aquatic exposure  
4 assessment models, we can on occasion predict, estimate  
5 environmental concentrations that exceeds the  
6 solubility limit report in laboratory studies. We also  
7 discussed two different ways in which this issue has  
8 been addressed. One is to assume the laboratory based  
9 solubility, to actually cap concentrations at that  
10 limit.

11                   The other is to cap them but assume that  
12 the precipitate that is hypothetically formed is  
13 allowed to dissolve when concentrations go below  
14 solubility. I think one of the big issues here that  
15 would be particularly helpful is your input on the  
16 uncertainty of extrapolating our laboratory-derived  
17 solubility values to the field.

18                   It's not entirely clear to us what level  
19 of uncertainty that entails, we heard about some  
20 aspects of materials in the field that may enhance  
21 solubility and so with both of these approaches, they  
22 make this assumption and I think that's a pretty  
23 critical step that would be useful to receive your  
24 advice.

25                   Degradation rates, with specific regard



1 to aquatic metabolism studies, our understanding is  
2 that these studies are not designed currently to  
3 distinguish between degradation processes that would be  
4 occurring in water and sediment, through a two phase  
5 system.

6                   We do not interpret the partitioning  
7 from the water column to the sediment as a degradation  
8 process. And in these cases where our models do  
9 account for this partitioning process, for example with  
10 KOC, we have demonstrated the use of a total system  
11 half life as a way to represent the biotic degradation  
12 in the system and that this is used as a degradation  
13 component for the model and the partitioning process is  
14 handled separately.

15                   We talked also quite a bit about the  
16 issue of long term pesticide accumulation and we think  
17 this is an issue with these compounds for year to year  
18 carryover. The white paper does provide information  
19 based on the prism model with respect to predicting  
20 long term concentrations of pesticides in soil.

21                   This would be an obvious starting point  
22 for some of the terrestrial bio-accumulation issues we  
23 just talked about earlier this morning. This is not  
24 typically done in our assessments, but the capability  
25 is there. And so we are considering this as a logical





1 starting point for those types of assessments and would  
2 appreciate feedback on that. And then the combination  
3 of two models can also provide a long term estimates  
4 and sediments of pore water.

5           The issue of sediment dynamics, I think  
6 it's very clear from the presentations that how you  
7 treat the notion of sediment dynamics, that is  
8 resuspension, burial, and deposition and other related  
9 processes. How you treat those in your water quality  
10 model can have a substantial impact on the risk  
11 estimates by changing exposure concentration.

12           We recognize that the issue of varial,  
13 that is assuming a permanent loss, is not a  
14 conservative assumption and we sort of have kind of two  
15 extremes captured here, one in which varials are seen  
16 to be permanent and the other in which it's not  
17 addressed explicitly. And so your input on that would  
18 be especially useful.

19           Also, in the context of the spatial  
20 scale, because we are talking about a pond field scale,  
21 and to the extent that there is uncertainty when  
22 extrapolating to other types of water bodies, and  
23 keeping in mind that our program is at a national  
24 scale, I would offer those as considerations as well.  
25 Dr. Ambrose and Dr. Gobis and Dr. Mackay and also Dr.



1 Parker, provided a summary of a variety of models for  
2 addressing the issue of sediment dynamics and it's  
3 potential effect on pesticide bio-availability and it's  
4 very clear that these can vary from relatively simple  
5 processes to highly complex and the question here is  
6 how complex do we really need to go and so that's sort  
7 of the main question we have in front of us.

8 Bioaccumulation for these types of  
9 compounds we are concerned about other exposure routes  
10 and similar to other Agency programs we're considering  
11 using a suite of methods, not just one model or a  
12 particular type of field study. We believe that the  
13 various methods have strengths and they also have  
14 limitations and they complement one another in terms of  
15 an overall bio-accumulation process and we'd like  
16 feedback on that.

17 With regards to bio-accumulation and  
18 terrestrial food web this is not routinely evaluated  
19 but we recognize that this may be important for some  
20 pesticides and we suggest that we need some tools to  
21 evaluate when in the problem formulation process we  
22 need to be concerned about this and again, I can't  
23 emphasize enough the notion of in the problem  
24 formulation process focusing our resources on those  
25 pathways that are likely most important to a problem.



1 Given the volume of these it's tough, but we have to  
2 do.

3 Long range transport , we believe that  
4 this issue is relevant, not only for the historical use  
5 but also for the current use pesticides and we have  
6 summarized our current methods which largely rely on  
7 retrospective assessment, that is, looking at  
8 monitoring information at remote locations and I've  
9 summarized some of the limitations for this.

10 Dr. Khan also presented information on  
11 one tool that could be used to characterize long range  
12 transport potential, but we still in terms of  
13 ultimately getting to the risk question, we're  
14 struggling with linking our near term field loadings to  
15 far field concentrations and again this could be the  
16 issue of scale in that we're largely addressing what I  
17 would call the near field type risk and with a field  
18 scale model both in terrestrial and aquatic risk  
19 assessment, and so we are particularly interested in  
20 your recommendations of how we might put the rest of  
21 the spatial scale with relative temporal scale issues.

22 Regarding aquatic toxic toxicity of  
23 these compounds, we have highlighted limitations of our  
24 existing methods with respect to multiple exposure  
25 routes and toxicity in space eight.



1 We think the tissue residue approach has  
2 some utility in addressing some of these limitations  
3 and as we just discussed, as Brian Anderson presented,  
4 it is important to understand the function of this  
5 approach, but also in the context of the data that we  
6 traditionally get.

7 We think it's preferred to use measured  
8 residue effect in relationship and it would be nice to  
9 identify this up front where we might need this  
10 information and so we could gather that information  
11 early in the assessment process but we're also  
12 interested in your feedback on the use of estimated  
13 residue effect relationship.

14 We combined toxicity of parent and  
15 degradate mixtures. One approach there is to conduct a  
16 screen by using the most sensitive toxicity value for  
17 the individual components of the mixture but then  
18 refining this approach if need be depending on the  
19 results of the discussion.

20 As we just discussed the assumptions  
21 regarding mode of action, time dependent, fate and all  
22 are integral components to that assessment. Okay, I'm  
23 going to shift gears a little bit and talk about the  
24 thoughts, these are very early thoughts on path forward  
25 and again to reiterate this review represents just a



1 first installment on this process, at least from our  
2 perspective of integrating new methods into address PBT  
3 related issues and I've put new in quotations, because  
4 it may be new to pesticide programs but a number of  
5 these methods have been used in other programs and have  
6 been vetted quite rigorously in those programs.

7           Pending this review our thinking is that  
8 the established national and international criteria for  
9 classifying compounds according to their persistent  
10 bio-accumulative and toxic characteristics might be  
11 used as an initial screen in the problem formulation  
12 process for identifying when these risk assessment  
13 issues should be addressed.

14           We have listed these criteria here, and  
15 the ranges reflect different values used by different  
16 institutions and I would add that potentially with  
17 regards to bio-accumulation, we might need another  
18 bullet here addressing KOA.

19           These are the criteria summarized even  
20 further with regard to the long range transport and  
21 toxicity and then just to suggest visually how, the  
22 question is how would the problem formulation process  
23 differ for these compounds?

24           I think the overall framework is the  
25 same, but the type of information that you would be

1 really keying in on might be different and the types of  
2 questions that you're going to need to address may  
3 differ for these types of compounds and so this figure  
4 is basically suggesting a possible way of approaching  
5 this in problem formulation. The top part of the  
6 figure really represents the integrating available  
7 information box that I showed in the framework  
8 yesterday.

9                   That's where information on the chemical  
10 property, its potential for long range transport,  
11 persistence, bioaccumulation and toxicity are brought  
12 together in conjunction with available screening  
13 criteria to ask the question are these related risk  
14 assessment issues likely?

15                   This may not be all three of the  
16 combinations, there may be one for persistence, for  
17 example, or it may be two or it may be all three. If  
18 these aren't likely according to either these or a  
19 modified set of screening criteria then the problem  
20 formulation would likely proceed. It would typically  
21 for most of our compounds. However if the issues are  
22 flagged then there's a series of questions, appropriate  
23 questions, that we just provide some early examples and  
24 I'll walk through those.

25                   If we focus on the slides. It's part of



1 the problem formulation process and the answers to  
2 these questions, we think these and other questions as  
3 they are developed would help inform the selection of  
4 that conceptual endpoint, the conceptual model, and  
5 ultimately the blueprint of the risk assessment itself.

6           Some of the questions again, I put these  
7 up here as examples, they're not intended to be  
8 exhaustive. They all focus on the PBT issues, so there  
9 are I would suggest many other kinds of generic  
10 questions that would also be part of the problem  
11 formulation process, but with regards to the PBT type  
12 questions, obviously understanding which environmental  
13 compartment the pesticide is likely to persist and the  
14 formation of degradates and their fate and toxicity is  
15 also highly relevant.

16           For compounds that have low solubility  
17 we need to ask the question and be careful about our  
18 predicted concentrations that may exceed solubility and  
19 how, be very explicit in how the bioavailability of  
20 these compounds is addressed in the assessment.

21           It's also important to understand the  
22 relationship between dissipation processes, that is  
23 movement as well as the degradation of a compound and  
24 interpret these in conjunction with the way our  
25 environmental models are using them and right now those





1 processes are used separately, the partitioning and the  
2 degradation processes are represented separately.

3                   Understanding the potential for long  
4 term accumulation, that's important in basically  
5 interpreting the temporal scale of the assessment as  
6 well as the utility of both single season exposure  
7 estimates and toxicity estimates and then understanding  
8 how sensitive the results are to assumptions regarding  
9 sediment dynamics and the impact of that on pesticide  
10 bioavailability would be another potential question in  
11 this process.

12                   These are questions regarding...related  
13 to the bioaccumulation assessment and actually we went  
14 over these questions yesterday and just in a nutshell  
15 I think some of the key questions here are  
16 understanding the role of metabolism, particularly when  
17 we're using some of the food web models and having an  
18 understanding about steady state, how long does the  
19 pesticide take to reach steady state in different  
20 organisms.

21                   And then of course recognizing the  
22 limitations and how to integrate the results from the  
23 different types of approaches and with regard to  
24 threshold bioaccumulation, particularly as we move  
25 forward and potentially develop or evolve or apply



1 existing tools in this area, that would be an obvious  
2 part of the problem formulations process that is not  
3 currently rigorously addressed.

4                   Questions regarding long range  
5 transport, I think these are already part of our  
6 processes in terms of looking at monitoring data but it  
7 would be nice especially for new compounds to have some  
8 way to flag reliably long range transport potential and  
9 understanding aspects of the methods and models that  
10 might do this, understanding the norms for that so that  
11 we aren't getting too many false positives or false  
12 negatives.

13                   Regarding toxicity, a key question here  
14 is in understanding the importance of multiple routes  
15 of exposure for affecting the sensitivity of the  
16 organism, the exposure of the organism and ultimately  
17 toxicity to the receptors of concerns and also  
18 understanding the potential differential toxicity of  
19 the parent and degradate compound and how likely they  
20 are to have the same mode of action which is getting  
21 back to our earlier conversation.

22                   And we talked about various tools that  
23 we could use to try to pull them in in expert judgment,  
24 that we can use to try to assess this question and  
25 understanding that mode of action can vary across



1 issues.

2                   It's also important to recognize  
3 limitations of our existing standard protocols with  
4 regards to steady state and knowing when we need to  
5 request data for even longer term exposures if steady  
6 state isn't reached even in our, some of our current  
7 climate tests like the early life stage tests which  
8 would not get at the potential form of eternal  
9 transfer.

10                   And another important aspect is  
11 understanding the variability and toxicity information  
12 that we observe, how likely is that to be actual  
13 differences in species sensitivity versus differences  
14 in bioavailability perhaps, that's observed in these  
15 tests and this becomes I think more relevant when  
16 comparing results from a laboratory to the field, but  
17 when you're looking at compounds of KOW ranges, of log  
18 KOW ranges upwards to eight, bioavailability is  
19 extremely important.

20                   And that's what we have in terms of just  
21 some questions that we think would be good to have in  
22 front of a risk assessor if they're addressing these  
23 types of comments. Thank you very much.

24                   **DR. HEERINGA:**       Thank you very much, Mr.  
25 Sappington, for that overview.   Questions of



1 clarification from the panel? Dr. Simonich.

2 **DR. SIMONICH:** This is certainly more of  
3 a policy question but in the real evaluation of current  
4 use pesticide, do you consider the regulatory status of  
5 that pesticide in other parts of the world?

6 **MR. SAPPINGTON:** It's something in a new  
7 chemical program and in an existing chemical program,  
8 there is a big emphasis for global work sharing and  
9 global partnering and undertaking risk assessments, new  
10 chemicals and old chemicals.

11 We have a longstanding collaboration  
12 with PMRA in Canada and part under NAFTA which we try  
13 to work together to use common tools and common  
14 insights driving risk management because you can vary  
15 between countries based on the benefits of the  
16 compound. In addition notwithstanding we have  
17 partnerships with the European Union and Australia and  
18 through OECD they look again to try to develop and  
19 harmonize approaches.

20 **DR. HEERINGA:** Dr. Bucher.

21 **DR. BUCHER:** John Bucher. In the White  
22 paper there was something that the concept called  
23 levels of concern and I'm not sure if I may have missed  
24 the discussion of that but I was, as part of the risk  
25 characterization that I believe it is there's some,



1 what could be fairly broad levels of concern category  
2 that, categories that it looks like the Agency uses,  
3 and my question really is are these categories broad,  
4 so broad that a lot of the things that we've talked  
5 about today are really refinements that aren't going to  
6 affect the overall level of concern?

7 **MR. SAPPINGTON:** The, let me first  
8 explain the level of concern. They rec...they, when the  
9 risk estimate is derived it's basically taking its own  
10 estimated exposure and dividing it by an estimate of  
11 the toxicity of the compound and that produces a risk  
12 quotient.

13 Levels of concern for acute effects,  
14 that toxicity value is something like a LD 50, so there  
15 is a, basically an adjustment, if you will, to that  
16 risk quotient to reduce that down to more of a  
17 threshold level effect so for example, the acute LOC is  
18 a value of .5 so an RQ of .5 would raise, or higher,  
19 would raise concern regarding potential for acute  
20 effect because obviously if you're killing half the  
21 organism at an RQ of one that's a pretty severe effect  
22 level and there is a gradation of those LOCs depending  
23 on some aspects of where different label language might  
24 be included and even endangered species, so the LOC is  
25 just an adjustment on the magnitude of the RQ that the



1 Agency uses as a flag.

2 I think one aspect of this  
3 characterization is that may not be carried through or  
4 captured just by the magnitude of that RQ or something  
5 like the duration, and what we're talking about here  
6 are potentially long duration, even after management  
7 actions might be taken, so that's another aspect of  
8 this characterization to be evaluated. And it's really  
9 the ability of the ecosystem to recover after exposure  
10 may be adjusted in some way. I'm not sure if that  
11 clarifies your question or not, but that's how the LOCs  
12 are used and then they are not compound specific right  
13 now. They're part of all compounds.

14 **DR. HEERINGA:** Dr. Bradbury has some  
15 additional...

16 **DR. BRADBURY:** If I could just expand a  
17 little bit on what Keith said, the levels of concern  
18 aren't pass/fail value if you will. As the presenters  
19 discussed over the last few days, it goes through a  
20 series of tiers in the risk assessment process,  
21 iteration of the risk assessment process, and the LOCs  
22 can be very helpful if you don't exceed a LOC then our  
23 basic assumption is that the likelihood of adverse  
24 effects, that use is low enough that you can proceed  
25 forward with a regulatory decision and be reasonably



1 comfortable at a low likelihood of ecological risk.

2                   If the LOC is exceeded it may just be a  
3 reflection of the assumptions in that first tier of the  
4 risk assessment that has led to those exceedances, if  
5 you will, and so it's getting an LOC and many times  
6 the, you kind of roll up your sleeve and go to  
7 potentially greater levels of refinement of the risk  
8 assessment to try to better understand what the risk  
9 potential is and try to better quantify the risk  
10 potential.

11                   So, that as best we can we move toward a  
12 more refined assessment and then you've got to take a  
13 look at what that predicted risk is in the context of  
14 the benefits of the subject product between ecological  
15 applications. So it isn't a pass fail value, it's a  
16 value that helps decide, do we need to focus and in  
17 what context do we need to focus.

18                   **DR. HEERINGA:**       At this point in time it  
19 looks as though everybody is at least satisfied with  
20 questions of clarification. I would like to again  
21 thank EPA scientific staff, EFED staff for these  
22 presentations that we've heard over the past day and a  
23 half.

24                   I think it's, again, been highly  
25 organized in my experience and I'd let the panel





1 members comment for themselves but we very much  
2 appreciate the way it's been handled and organized all  
3 the way from the organization of the packet in  
4 sequence, instead of a pile of papers dropped here in  
5 various arrays and permutations, I very much like that  
6 and we move on.

7 I think we'll give the panelists a  
8 little extra time over lunch if they have any other  
9 questions of clarification for after the period of  
10 public comment. I mean just return briefly for a few  
11 questions of clarification before we launch into the  
12 charge question, but at this point in time I'd like to  
13 bring this segment of the meeting to a close with a few  
14 notes.

15 Again for panel members, I think there  
16 was a call again from Keith Sappington which I think we  
17 ought to pay attention to in terms of both near term  
18 and long term recommendations because of resource and  
19 the need to move ahead. I think it's valuable to be  
20 brought in at the planning process at this point.

21 I think maybe if we can work to sort of  
22 differentiate that and not to limit our recommendation  
23 but to sort of differentiate the practicality and  
24 potentially the other implications in near term and  
25 long term recommendations.



1 For public commenters, we'll enter the  
2 period of public comment after our lunch break. There  
3 are three scheduled public commenters and I want to  
4 make sure that all of the audience is aware that they  
5 do have the opportunity to make public comment, at this  
6 point it would be limited to a short comment of five  
7 minutes.

8 If you've not already contacted Myrta  
9 Christian and registered as a public commenter, you  
10 have the opportunity to do so over lunch and we'll add  
11 you. For the public commenters who have preregistered  
12 and have presentations that we'd like to ask that  
13 during the lunch break if you'll take a moment to have  
14 your presentations loaded on the lap top and Keith,  
15 would it be possible to use that lap top for the  
16 public, I guess, Myrta says it is, the DFO says it is,  
17 so if you have it on a memory stick or transfer, we  
18 would appreciate it if you would load your presentation  
19 over the lunch hour so that we'll be ready to go and  
20 move steadily through the public comments.

21 We are going to break for lunch now,  
22 we're at a few, about eight minutes short of twelve  
23 o'clock and I'd say that we take the time until 1:00  
24 p.m. and we reconvene for the afternoon session at 1:00  
25 p.m. Thank you.



1 (WHEREUPON , the proceedings were concluded at 11:52  
2 a.m.)

3 **DR. HEERINGA:** Good afternoon,  
4 everybody, and welcome back to the afternoon session of  
5 our second day of our FIFRA Science Advisory Panel  
6 meeting on the topic of Selected Issues Associated with  
7 Risk Assessment Process for Pesticides with Persistent  
8 Bioaccumulative and Toxic Characteristics.

9 At this point in the process we have  
10 completed the series of presentations by the EPA  
11 scientific staff, staff of the environmental fate and  
12 effects division and had a chance for questions of  
13 clarification and we're now entering the period of  
14 public comment and we have had three public commenters  
15 who have approached the SAP staff and DFO Myrta  
16 Christian for permission to make public comment. If  
17 there's anyone else that would like to offer a short  
18 public comment you can see either Joe Bailey or Myrta  
19 directly here and we can try to get you on the schedule  
20 but that should happen immediately.

21 For the scheduled presenters, the first  
22 that we have is Dr. Jay Obermeyer who is representing  
23 Crop Life America. Dr. Obermeyer. Please feel free to  
24 introduce yourself, you have the floor.

25 **DR. OBERMEYER:** Good afternoon, again,



1 I'm Jay Obermeyer, presenting on crop protection.  
2 Today I speak on behalf of Crop Life America and I just  
3 want to give a few comments on the risk assessment  
4 process for pesticides with PBT characteristics.

5 Just a general comment to start out  
6 with, we appreciate the inclusion of the following  
7 formulation steps in this area of evaluation of  
8 chemicals as P, B, or T, showing support for the use of  
9 risk assessment for pesticides with PBT like  
10 characteristics. We also believe that screening  
11 criteria that EPA cites from Wyckert on page 18 serves  
12 as a first step in PBT evaluation. The direct share is  
13 exceeded for all three aspects of PBT, just in case  
14 that is a tail PBT related problem formulation be  
15 conducted.

16 We also believe there are good modeling  
17 approaches available that allow higher tier refinement  
18 of exposure risk assessments for reputed PBT chemicals.  
19 Recently refined risk assessment will allow EPA to more  
20 clearly define potential for risk so that it can be  
21 appropriately compared with benefits as required under  
22 FIFRA.

23 We commend EPA for promoting the use of  
24 these tools during this SAP. Some additional comments  
25 or general comments, we agree upon and understand the



1 criteria for each component of the classification. We  
2 also need to agree upon and understand test methods and  
3 calculations. For example, if we're going to use DT 50  
4 or half life as a criteria for determining if a  
5 chemical is persistent, then we need to know exactly  
6 how we're supposed to measure the DT 50 or half life,  
7 whether we're supposed to use lab data or higher tier  
8 methods to predict these values.

9           Also threshold values should trigger  
10 further investigation and not trigger restrictions or  
11 bans. I really believe that a tiered approach should be  
12 used such that higher tier studies can be used to, need  
13 to be incorporated such that if lower tier studies  
14 cause exceedances of LOCs we can look at all data  
15 available to make a better judgment about risk.

16           We believe that a chemical must exceed  
17 all reasonable criteria to trigger further PBT  
18 evaluation and guide the problem formulation. Some  
19 specific comments on assessing persistence and some of  
20 these are redundant but just to reiterate we need  
21 agreement on methods for calculating segregation of  
22 dissipation kinetics for soil, water and sediment that  
23 are based on best available science. We need to  
24 understand if a P trigger would be based on lab data or  
25 tempered by more realistic higher tiered studies and



1 field data.

2 Registrant and regulators need a clearer  
3 understanding of P triggers to further evaluate the  
4 flow of water and sediment. Precision is only relevant  
5 to risk assessments for the target organisms where  
6 exposure will occur. For example, here pelagic  
7 organisms will not receive chronic water fate exposure  
8 from compounds which very rapidly dissipate from the  
9 water column into sediment and thus organism behavior  
10 and chemical transport conceptual models must be  
11 matched in the problem formulation step.

12 Another one of those that doesn't fit  
13 under P, we do want to address that, we need an  
14 agreement on methods and that's the exposure  
15 concentrations for total residues of concerns. So  
16 specific comments on assessing toxicity there are  
17 multiple guidelines today that generate toxicity end  
18 points. These end points can be used to assess  
19 toxicity risk of compounds that may bioaccumulate or  
20 bioconcentrate.

21 Again we want to stress we feel it's  
22 more appropriate to use a risk based approach when  
23 assessing toxicity and sort of propose that the level  
24 of accumulation of various trophic levels can be  
25 compared to known effects levels for focus species in



1 the food chain and this is gone, getting back to the  
2 idea of looking at bioaccumulation through aquatic food  
3 web such that forage fish and piscivorous fish which  
4 are then eaten by piscivorous birds or mammals and then  
5 those residue levels are transferred into the  
6 terrestrial system.

7                   The comparison there between what's  
8 transferred from the aquatic to the terrestrial  
9 comparing that to LOELs and NOELs that are derived or  
10 produced for terrestrial organisms need to be clearly  
11 thought through and investigated more thoroughly before  
12 those locations are used.

13                   Roughly that refinements should be  
14 allowed. We're thinking perhaps a chemical has  
15 multiple crop uses but with refinement it can be shown  
16 that only one of the crop uses that may have twice the  
17 application rate or maybe it's used four times in the  
18 application where another one might only have two  
19 applications, those type of adjustments can be used  
20 looking at LOC exceedances.

21                   And we talked about stressing a tiered  
22 approach for PBT evaluations and risk assessments, got  
23 more detail here. Again tier one studies are basically  
24 guideline studies with modeling leading to comparison  
25 data with extreme criteria. If we get exceedances with





1 the Tier 1, we can go to higher tiered studies which is  
2 Tier 2, which is a simple nine guideline study with  
3 modeling typically incorporating additional media such  
4 as instead of just water by itself with water and  
5 sediment.

6 Tier 3 study is a little bit more  
7 complex, nine guidelines, modeling and again, in  
8 addition to the multimedia, we're also looking at  
9 multi-trophic, we're not looking at just one species  
10 but multiple species within the system.

11 With Tier 4 looking at some of the data  
12 plus probabilistic modeling approaches and the data  
13 here is we can get a weight of evidence approach such  
14 that we incorporate all the data that we have to make  
15 appropriate decisions.

16 We heard quite a bit about probabilistic  
17 model in yesterday's discussions. Just to briefly go  
18 over these. This type of modeling allows especially  
19 different crops, water bodies and water conditions in  
20 aquatic food webs. It allows the evaluation of  
21 mitigation practices such as reducing off charted spray  
22 drift and vegetative filter strips.

23 Food web modeling allows the exploration  
24 of the water in sediment compartments into value  
25 potential impacts to different trophic levels.



1 Compartment specific data can be incorporated into  
2 model assessments through fine exposures and resulting  
3 risks.

4                   Here's a...to give an example of how  
5 higher tier studies can be used. The Tier 1 are a  
6 basic bio concentration study here done with fish. It  
7 was brought up yesterday that this was probably not a  
8 very good test to use for these PBT like chemicals  
9 because these chemicals have high log KOWs are more  
10 likely going to dissipate out in the water and sediment  
11 so really as Dr. Gobas mentioned measuring the chemical  
12 properties of the fish as opposed to, the properties of  
13 the fish as opposed to the properties of the chemical.

14                   So we don't feel that data obtained from  
15 this type of study really is useful for PBT like  
16 chemicals. If we go to a higher tier study with  
17 probabilistic modeling such that we have a field model,  
18 a water body model, food web model, we can look at  
19 potentially with more detail how the chemicals are  
20 interacting within the food web. There's obviously more  
21 places for the chemical to be taken up or absorbed to  
22 such as the sediment in the different points in the  
23 food web.

24                   And we think that this model here can  
25 give us a better indication of what the final



1 concentration might be for these types of chemicals and  
2 this would be a much better predictor than say for  
3 instance looking at standard multiplication values for  
4 different trophic levels so we're looking at a whole  
5 system here as opposed to just factoring in  
6 concentration factors with increase in trophic  
7 position.

8                   Some comments on log KOW and dietary  
9 exposure for assessing bioaccumulation. Log KOW is a  
10 good screen since all substances known to bioaccumulate  
11 have a log KOW greater than five. However, not all  
12 substances that have a log KOW of 5 actually do  
13 bioaccumulate. There are many factors that determine  
14 whether a substance will bioaccumulate.

15                   You need to relate it to the chemical as  
16 well as to the organisms. Obviously log KOW is an  
17 important component, but there's also other factors  
18 such as PKA or molecular size that from a chemical  
19 standpoint could affect bioavailability and  
20 bioaccumulation. And from the organism things such as  
21 size or the sex of the organism can affect  
22 bioaccumulation.

23                   The series from food and media is a more  
24 complex process, made by things such as assimilation  
25 from the sea as well as metabolism. This graph here



1 illustrates the comparison with log KOW with  
2 bioaccumulation from food and this graph here  
3 represents a literature review of 656 studies.

4                   The main thing I wanted to point out  
5 here that if you look at the individual log KOW values  
6 especially around, like a KOW of around 7, you see that  
7 there's quite a bit of variation within the data there  
8 showing that in some instances a chemical with a log  
9 KOW of 7 would bioaccumulate and others that indicate  
10 that it will not bioaccumulate.

11                   So the main thing here is just to point  
12 out that strictly using log KOW as our indicator for  
13 criteria may not be that great but again it's  
14 definitely a component but other processes and  
15 parameters should be also considered.

16                   As far as terrestrial assessments and  
17 long range transport. We do not address terrestrial  
18 evaluation but would like to mention that there are  
19 some models of interest that Gobas et. al. have  
20 developed that might be useful and again support using  
21 models with a SWAT type approach to assist them. As  
22 far as long range transport we do see the use of models  
23 as helpful for this area of regulation. The available  
24 models should be fully explored again using a SWAT type  
25 of approach to start.



1                   So in summary Crop Life America  
2 recommends a tiered approach to characterization of  
3 chemicals as P, B, or T.       CLA supports a multi tier  
4 approach to ecological risk assessment of pesticides.  
5 Crop Life America recommends a weight of evidence  
6 approach to risk assessment based on multiple tiers of  
7 data and modeling.

8                   CLA commends EPA for continuing to  
9 support the use of risk assessment in this area of  
10 evaluation. We believe this area is more technically  
11 difficult to assess than other evaluations EPA  
12 currently utilizes for regulatory purposes. We believe  
13 there are good tools available that allow refinement in  
14 this area of risk assessment which will allow EPA to  
15 more clearly define risk versus benefit under FIFRA  
16 law. We commend EPA for knowing the use of these tools  
17 during this SAP. That's all I have. Thank you.

18                   **DR. HEERINGA:**       Thank you, Dr. Obermeyer.  
19 Are there questions, clarification for Dr. Obermeyer on  
20 his presentation? I don't see anything, thank you very  
21 much. Our next public commenter is Dr. Lynn McCarty  
22 who is representing Valent USA and Dr. McCarty, I'll  
23 let you introduce yourself.

24                   **DR. MCCARTY:**       Great, thank you. My  
25 name is Lynn McCarty. Just by way of background, I'm



1 an ecotoxicologist with a longstanding interest in  
2 residue based toxicity approaches which I think is  
3 quite appropriate for this meeting.

4 My co-author is John Arnot who is an  
5 environmental modeler with considerable experience and  
6 expertise in fate and exposure modeling to a wide  
7 variety of organic chemicals. You may recognize his  
8 name as the lead author on the bio food web model  
9 that's been used in the assessments here. You may also  
10 know of his association with Don Mackay.

11 I want to just point out that although  
12 this study was funded by Valent and the focus and  
13 clarity benefitted substantially by input from Valent  
14 staff, the report represents independent view opinions  
15 and the best professional judgments of the authors.

16 So what we're going to do is a very  
17 technical approach. We have been asked to do an  
18 ecological risk assessment for Pyridaben. This is  
19 chemical four in the White paper in case you're  
20 interested so that you can use, feel free to use any  
21 information to compare and contrast.

22 So just a quick overview of the  
23 presentation, it's pretty standard. We're going to  
24 have a background of Pyridaben's properties, some key  
25 points and some uncertainties I can just highlight of



1 the data and risk exposure modeling and the toxicity  
2 evaluation, a risk quotient analysis and some  
3 conclusions.

4 Now my co-author John Arnot made me  
5 promise that I would bring this up. It's in our  
6 report, and by the way the companion report for this  
7 presentation is a 101 page report which is on the  
8 public docket and I think the panel members can have  
9 it, probably have it already and anybody else who...it  
10 is a public document.

11 **DR. HEERINGA:** Panel members do have it  
12 and have seen it, thank you very much.

13 **DR. MCCARTY:** Mainly John wanted me to  
14 mention that in there we mention that we used a  
15 holistic modeling approach, and I am sure that I see  
16 people having visions of John and I sitting in front of  
17 our computers wearing our sandals, our hemp cloth  
18 shirts and eating or getting granola bars but that's  
19 not really what it means in this sense. What we meant  
20 by holistic modeling was that we used a comprehensive  
21 internally consistent treatment of the model systems as  
22 a whole rather than simply a group of various parts  
23 from pieces of information and various sources.

24 We recognize that the data comes from a  
25 variety of sources and may require interpretation or





1 adjustment for optimum use in any particular model.  
2 For example, we use, and this is one thing that John  
3 has spent his Ph.D. on, a part of it at least is using  
4 elementric adjustment for metabolic rates so that we,  
5 if we found something for an organism we made sure that  
6 if we used it for another phase that the, it was scaled  
7 properly to fit in so that's just an idea and we spent  
8 a great deal of time making sure everything fit  
9 properly and was, reflected our best judgment what the  
10 information should do.

11                   So just by way of background Pyridaben  
12 is an insecticide effective on laparodopolis larva and  
13 frips. It has recently been approved for the use in  
14 the USA in enclosed greenhouses.

15                   It has been the subject of some previous  
16 risk assessments which have concluded that health,  
17 human health risk is very low. It also was fairly good  
18 evidence to suggest, experimental evidence that  
19 suggests, available information that Pyridaben does not  
20 biomagnify in aquatic food chains and the key thing  
21 that we're going, the background issue here is that in  
22 a recent revised updated USEPA risk assessment for this  
23 chemical, they specifically requested more data  
24 evaluation and uncertainty reduction for body residue  
25 effect relationships for selected representative



1 aquatic species in particular daphnia carotenoids in  
2 fish which would be used to finalize the outdoor use  
3 registration process.

4                   So just a, for the chemists in the crowd  
5 and I know there are many of you, we just have a slide  
6 here with some of the basic chemical properties of this  
7 substance. The chemical structure, molecular weight, et  
8 al. I get to point out for the log Koc at the bottom  
9 there 6.1 was the log Koc that was used by EPA and  
10 available in previous studies.

11                   We looked at that. EPA classified this  
12 particular study this number came from as a secondary  
13 level quality data. We looked at this and John thought  
14 that the particular study wasn't quite what he had  
15 hoped for, it was, they used soil instead of sediment,  
16 they used was a low Koc content in the soil and it was  
17 a short term test so he went to the literature, Seth,  
18 et al., 1999 which is actually an update of Parakov1981  
19 which is a review of the relationship between KOW and  
20 Koc and using that he decided that we might want to  
21 look at using a log Koc of 7.6.

22                   As I'll mention later, we used this only  
23 for the aquatic phase not for the soil runoff part of  
24 the modeling. So the key points are that the key, the  
25 PRZM/EXAMS ACROBAT modeling assumption is steady state



1 bioaccumulation which is based on peak water and  
2 sediment levels and we are seriously worried about this  
3 as you, and you've heard this repeated a number of  
4 times before as high KOW compounds, we believe it may  
5 not be appropriate for pulse applications of  
6 pseudofibrophotic chemicals.

7 Water solubility in Pyridaben is very  
8 low, as you've seen here 0.15 micrograms per liter and  
9 a point that the toxicologists would probably jump on  
10 is that solvent is commonly used in toxicity  
11 accumulation experiments to increase the bioavailable  
12 concentration. It is my contention that the use of  
13 solvents could be found in toxicity and bioaccumulation  
14 test interpretation and we'll get into that in a little  
15 bit.

16 So we listed some uncertainties here  
17 since uncertainties is what we're trying to reduce here  
18 in this particular case, but we note that despite any  
19 uncertainties we might do there are a number of other  
20 uncertainties that remain, that are characteristics of  
21 the site. We've been talking about the nature of the  
22 pond and whether that was appropriate.

23 Label use versus model assumption.  
24 Sometimes the modeling that goes into the registration  
25 analysis is, pushes the limits of what the label might



1 suggest was appropriate. We have some uncertain  
2 chemical physical properties. It is a super  
3 hydrophobic chemical and whatnot.

4 I mean the last one I'll bring up,  
5 attention to is the assumption, we used the assumption  
6 that the total radio labeled residue, the equivalent to  
7 the total mass for Pyridaben in the organism was part  
8 of the effective dose so the measured data that we  
9 used, we had radio labeled material rather than  
10 traditional chemistry analysis.

11 However, we find out that these and  
12 other uncertainties and variabilities are typically  
13 encountered in pesticide risk assessment. They're not  
14 unique. Some of the, some of the emphasis may be a  
15 little different depending on what the KOW and the  
16 chemical is but I mean these are the, we could count on  
17 these all the time.

18 But our objective in this particular  
19 study is to reduce the uncertainty in fate exposure  
20 modeling and residue based toxicity variables as  
21 suggested in the most recent EPA risk assessment. So  
22 now you heard Donald Kise talk the other day and I  
23 believe the word essential came up with regards to  
24 using time dependent exposure. I think Don must have  
25 been really thinking very hard because we were



1 obviously channeling him and we did this having two  
2 models here without his input.

3                   We used, in this thing we ran two models  
4 in parallel. The PRZM/EXAMS ACROBAT model that EPA's  
5 been using and the PRZM/AGRO model which is QUASI and  
6 ACROBAT which Don and Frank Gobas talked about. We  
7 used this in three tiers of increasing sophistication.  
8 In Tier 1 we didn't have any biotransformation  
9 information included, so zero transformation,  
10 biotransformation.

11                   We used the log Koc value that was being  
12 used and no time dependent exposure and we ran both  
13 models. In Tier 2 we ran, we included now estimates of  
14 biotransformation. There's substantial and good  
15 evidence that this material is biotransformed and we  
16 selected a number of estimates of that to include in  
17 the model. We used the same log KOC, no time dependent  
18 exposure.

19                   It is not impossible or extremely  
20 difficult to get PRZM, or to get EXAMS to do all sorts.  
21 For three B we only use AGRO, the AGRO model, we  
22 continue to use PRZM at the bottom as we mentioned, but  
23 we can't do kind of an exposure but we also did two  
24 steps and the first part we included the  
25 biotransformation, we used the log Koc of 7.6 for



1 aquatic modeling and 6.1 for transfer runoff but no  
2 time dependent exposure and then in the most  
3 sophisticated tier, 3B 2 we turned on time dependent  
4 exposure and we're going to look at that and we'll be  
5 able to compare all these things and give you an idea  
6 of the influence of these various parameters as, if you  
7 will, a bit of a sensitivity not so much analysis but  
8 view.

9                   So the exposure modeling that John  
10 carried out, we did seven of the outdoor agricultural  
11 use scenarios as used by USEPA in 2008 and permitted by  
12 the proposed Pyridaben label and we used the USEPA fate  
13 modeling inputs unless we note otherwise. We used the  
14 actual water solubility of the chemical in the modeling  
15 and as you'll see later on, we're in the risk quotient  
16 analysis, I'm not going to present the details of that  
17 data. Those are in the report.

18                   Models A and B produced similar  
19 exposures for Tier 1 and Tier 2 so both of those models  
20 in these situations using the same thing, but give  
21 similar results of our model. The model B, AGRO, gives  
22 a little, tends to be a little bit lower but pretty  
23 close, pretty close.

24                   As a result of this we identified the  
25 worst, the worst case highest exposure situation which



1 was for North Carolina apples treated, using the ground  
2 application scenario. This was consisted of 60.4  
3 pounds for active ingredient per acre applications 14  
4 days apart.

5 I just want to point out that that's not  
6 typical of what this pesticide would be used for, it  
7 tended to be used in three treatments for growing  
8 season and in this area they have two growing seasons  
9 so you wouldn't typically put them, run six  
10 applications in a row but anyway, we used that anyway  
11 because that was what the previous assessment used.

12 So what we have here is a graphical  
13 output summarizing some of this information. I'll take  
14 a second to explain it. The first thing I want to  
15 point out is that the bulk water in blue is in  
16 nanograms per liter and the sediment concentration's in  
17 nanograms per gram so they're a thousand times  
18 different.

19 The log scale on the side is you just  
20 have to drop the units appropriately, we did that so  
21 that the graph would be a little more trackable because  
22 otherwise we'd have to shrink everything down so I  
23 think most of the people here can resolve that, but you  
24 can see comparing the steady state application exposure  
25 assumption versus a time dependent assumption that





1 there's quite a difference.

2                   This is a 25 year run, and I think two  
3 things that you want to take away here is that the  
4 first that there's a major difference between the  
5 steady state and the time dependent exposure modeling  
6 for water concentration and sediment concentrations and  
7 I think you also want to take away there's no evidence  
8 of year to year increases in environmental levels of  
9 Pyridaben based on 25 years of six times per year  
10 app... six applications per year.

11                   This is a similar sort of slide we've  
12 included here the study, we've taken out the water and  
13 sediment concentrations for the study's sake, but we  
14 have now included at the top and the horizontal lines a  
15 steady state estimated biological concentrations for  
16 azul plankton bred invertebrates and fish eating fish.

17                   You can see here and the rest of it for  
18 the time independent exposure we have a complete thing,  
19 water sediment and those three groups of organisms you  
20 can see the exposure happening, the very rapid change  
21 that occurred there and everything here in the season.  
22 This is a two year period, if you ran we've stretched  
23 it, we've gone into the two years so you can see that  
24 in a bit more detail the trend lines that are happening  
25 here and the big differences between steady state and



1 exposure and time dependent exposure but if you ran,  
2 you know, it looks very much the same as the previous  
3 graph if you ran it over, if you showed all thirty  
4 years.

5                   And again in this case you have to be  
6 careful with the water is in nanograms per liter and  
7 the remaining materials in nanograms per gram. So  
8 that was how we got to, how we developed some exposures  
9 and I'll talk a little bit later about the numbers we  
10 used for the organisms but that's the basis of the  
11 exposure.

12                   The toxicity assessment, we used the  
13 body residue rates alternative approach. This is  
14 agreed to as applicable by both USEPA and Valent so  
15 there was no disagreement on that at all. However, we,  
16 John and I did this, decided to do this independent and  
17 from scratch So we started from, break from all the  
18 data that was available and made our own decisions on  
19 this.

20                   So we really evaluated all of the  
21 available calculated and experimental residue data.  
22 The calculated residue data was judged to be uncertain  
23 due to the use of solvent in most of the experimental  
24 testing. I still cannot understand how people put  
25 solvent in things because if you put chemicals like



1 this in a water exposure immediately they don't cause  
2 any toxicity.

3                   If you put sediment, if you put solvent  
4 in, they cause toxicity but you have modified the  
5 system dramatically by increasing the bioavailability  
6 so of course that's true and of course the toxic effect  
7 does occur, but it means you can't compare that result  
8 against tests where you didn't do, where you didn't  
9 have solvent in them because you haven't quantified the  
10 influence of the solvent and you have to know that it's  
11 changed things.

12                   So it's not that solvent is necessarily  
13 unacceptable, it's that you must quantify the  
14 influence. I mean if I did this test at two degrees  
15 and a standard test was at twenty degrees, that  
16 wouldn't be allowed because we know that temperature  
17 has a difference. Well, solvent has the same sort of  
18 modifying factor on toxicity and unless it's quantified  
19 I don't believe that you can reliably use it and raise  
20 a great deal of uncertainty.

21                   So anyway, so we were left with an  
22 experimental body residue data which was measured. I  
23 went through a detailed analysis of that and there was  
24 a detailed justification for the selection of that data  
25 and it's in the appendix of the report if you want to



1 see it. I'll give you my conclusions here in a  
2 second.

3 So we determined the estimated residue,  
4 effect residue for the representative aquatic species,  
5 as we needed to do something, we needed to do the risk  
6 quotient analysis, so that value was set at 0.04  
7 millimoles per kilogram based on the highest no effect  
8 residue for the most extensive aquatic specifies which  
9 is daphnia.

10 And this just gives you an idea of what  
11 this, and it's a fairly detailed slide, I'll take a  
12 second on it. The, this part right here, this is the,  
13 this would be where the denominator, this is the value  
14 here that I chose the denominator and risk quotient  
15 analysis, but I have a bunch of organisms and groups  
16 here, and I have effect and no effect and you can see  
17 here I put narcosis up here just as a reference for  
18 organic chemicals.

19 This is the range that, of the  
20 calculated, EPA calculated values for fish minor, some  
21 effects and no effect levels here of that typical  
22 range. I think that was mentioned this morning. I'm  
23 not making much of it, but I don't have any other acute  
24 data but this is all no effect levels for fish.

25 This is effect level for daphnia and

1 these are no effect levels for daphnia and these are  
2 again measured data and this is effect levels for  
3 carotenoids and no effect levels for carotenoids, and  
4 some additional material here for other organisms.

5                   So what happens, this allows me to get  
6 an idea of where the border between effects and no  
7 effects occur on a residue basis and so again as a more  
8 detailed analysis of how we did this, but this .04 is  
9 the basis for your highest, just below the highest no  
10 effect level and again these are, I went into details  
11 of why I've done that.

12                   So we've chosen that as representative  
13 of all the organisms and that is, my est...that is  
14 actually an estimated steady state value for  
15 accumulation.

16                   So here's a summary of what we did. I  
17 talked about earlier we have the application models,  
18 the three organisms, remembering that we're using the  
19 daphnia effect level, critical effect level for all of  
20 the organisms so in Tier 1A and Tier 2B which is  
21 essentially the two different models doing exactly what  
22 EPA did, you can see that the risk goes into slightly  
23 above one.

24                   When you include biotransformation here  
25 in model, tier 2A and B in the two different models you



1 can see it neatly drops substantially below one so  
2 biotransformation is a significant determinant in the  
3 exposure of this organism and if you don't include it  
4 and it does happen if you don't include, it's likely  
5 that you'll overestimate the risk.

6 And now we weren't able to use the EXAMS  
7 model here so Tier 3B is out of the AGRO model only.  
8 In Tier B1 the only difference is we changed the Koc to  
9 7.6 for the aquatic fate determination and see, that  
10 lowers it a modest amount. It's not trivial but it's  
11 not huge either, but we think that was a refinement  
12 worthwhile and given the uncertainty in this we felt  
13 that that was a, reflected a better decision.

14 However, when we turn on the time  
15 dependent exposure in Tier 3B2 you can see that the  
16 risk quotient drops dramatically, so, and the risk  
17 quotient is based on the 90th percentile of the model  
18 exposure residue for the species divided by that  
19 environmental effect residue of 0.04.

20  
21 So I haven't given you, I mean the model numbers for  
22 the actual body residues are available in the report ,  
23 and you can, this is simply the risk quotient so you  
24 can, you can figure out matters if you want to look at  
25 the report and get the exact ones if you're interested.



1 Just a visual of this. Here's what it  
2 looks like. Here's, here's the organisms. They all put  
3 raw data. These are the numbers that we used to try to  
4 find some endpoint of interest but it was, came out  
5 without the model, and here are the organisms and here  
6 is the model organism residues for all the key  
7 organisms up here.

8 We used the highest fish one, not the  
9 lowest one, so you can see there's a big difference  
10 between where things might happen and where the best  
11 estimate, the best model, most refined model estimates  
12 would suggest the residues would be.

13 So conclusions. Two sets of  
14 conclusions, one is for exposure. For exposure  
15 assessment mass balance modeling was refined with  
16 measured laboratory and mesocosm bioaccumulation data  
17 and the inclusion of biotransformation is important in  
18 exposure modeling as it can significantly reduce  
19 exposure and the tiered modeling approach allows the  
20 effects of refinement to be followed and it's quite  
21 clear that the realistic time dependent exposure  
22 generates much lower residue concentrations than steady  
23 state exposure. I don't think I'm saying anything new  
24 there, we've heard that repeatedly in the previous  
25 talks.





1 So the toxicology conclusions.  
2 Environmental effect residue of 0.04 millimoles per  
3 kilogram was derived from measured experimental body  
4 residue effect data for the most sensitive species. We  
5 believe that the measured body residue effect values  
6 reduced toxicity uncertainty for the USEPA identified  
7 organisms of concern, I think daphnia carotenoids in  
8 fish and that the worst case application risk quotient  
9 values for the most refined exposure modeling, Tier  
10 3B2, using the daphnia EER are about forty to a hundred  
11 times or more below a risk quotient of one.

12 So I think, I think we, we believe that  
13 we've achieved our objective which is a substantial  
14 reduction in the uncertainty of both exposure and  
15 residue based toxicity and interpretation of Pyridaben  
16 in outdoor agricultural use. Thank you.

17 **DR. HEERINGA:** Thank you very much, Dr.  
18 McCarty. Questions? Dr. Simonich.

19 **DR. SIMONICH:** I have a few questions.  
20 What were the assumptions made for in terms of the  
21 environmental half lives for the various compartments?

22 **DR. MCCARTY:** Those are all documented  
23 in the book. To give you an idea of what we did is  
24 actually both John and I probably would have been on  
25 this thing, except we were working on this. And what,



1 I've been on previous ones and my objective in this was  
2 to prepare a report that would be like the report I  
3 would like to receive if I was on the committee. So if  
4 you look at our, our detailed report, there is a fairly  
5 extensive executive summary which summarizes all the  
6 details.

7                   There's a main part of the report which  
8 gives you a more detailed approach and there is a,  
9 almost half of the report is an appendix which is a  
10 very detailed presentation of all the data that was  
11 examined, what we did with it, and all the assumptions,  
12 all the data values we used in the modeling, whatnot,  
13 and all of the, every decision that we made we  
14 justified that, so there's a table of contents in the  
15 appendix where you can go and look for any of those  
16 questions and it will be, it should be in the table of  
17 contents and so I know those answers are in, in the  
18 report.

19                   **DR. SIMONICH:**       But you can't give those  
20 to me now?

21                   **DR. MCCARTY:**       You have the report.

22                   **DR. SIMONICH:**       I don't have the report  
23 right here at this moment.

24                   **DR. MCCARTY:**       Well, I don't have it,  
25 you know, I'm...



1 **DR. SIMONICH:** Okay, so you don't  
2 remember the values offhand?

3 **DR. MCCARTY:** No, I don't.

4 **DR. SIMONICH:** And then what is the  
5 major transformation reaction?

6 **DR. MCCARTY:** I'm not sure what you  
7 mean.

8 **DR. SIMONICH:** What are the...

9 **DR. MCCARTY:** Well, we, we don't...what  
10 we have is we have estimates of metabolic degradation.  
11 We don't know exactly what's happening, but the parent  
12 compound is, is, is changing.

13 **DR. SIMONICH:** Transformation reactions  
14 in the environmental compartment other than...

15 **DR. MCCARTY:** I'm not sure that we used,  
16 again, this is John's area of responsibility but  
17 again, the information is in the report. The main  
18 part, I'm not sure of whether we, exactly what was in  
19 it, but I know that there's for various organisms that  
20 were modeled, that's the main part of the metabolism  
21 we're considering, not, that's what we had data for  
22 which are fish invertebrates.

23 **DR. SIMONICH:** And what about the  
24 assessment of persistent degradation products?

25 **DR. MCCARTY:** We didn't do that.

1 **DR. SIMONICH:** Thank you.

2 **DR. MCCARTY:** The EPA has judged that  
3 the degradation products were not significant  
4 toxicological importance and so we tried the, I mean we  
5 are facing the same problem EPA has here in that we  
6 would like to have done more as well, just as they  
7 would have done, but you know, the result was a little  
8 bit about information that happens to be very  
9 fortunately more information for this particular  
10 chemical in that the work that was done used real label  
11 Pyridaben in experiments and so they were able to  
12 collect information on residues, whereas most of it,  
13 many chemicals don't have that sort of information so  
14 there's nothing. So we were very lucky to have  
15 something to work with when in fact typically you don't  
16 have very little.

17 **DR. HEERINGA:** Yes. Dr. Norstrom?

18 **DR. NORSTROM:** The, staying on the  
19 metabolite issue, do we actually know what the  
20 structure of the metabolites are?

21 **DR. MCCARTY:** There is some information  
22 on that, yes.

23 **DR. NORSTROM:** And they've been judged as  
24 not being persistent or not?

25 **DR. MCCARTY:** You'll have to check EPA's



1 thing. That's not within the scope of what we focused  
2 on.

3 **DR. NORSTROM:** So when you made those  
4 adjustments there, reducing whatever confirmed in the  
5 slide for the metabolism, is that based on radio label  
6 studies?

7 **DR. MCCARTY:** Yes.

8 **DR. NORSTROM:** So it's basically a  
9 decrease of the starting compound?

10 **DR. MCCARTY:** Yes.

11 **DR. NORSTROM:** And does this mean that  
12 the other radio labeled substances were missing? In  
13 other words they've been excreted or...

14 **DR. MCCARTY:** There's a variety of  
15 things that could have happened to them. Again this is,  
16 most of the information was not collected with the idea  
17 of having a detailed analysis of this type done so  
18 we've done the best that we could do with what we had.

19 **DR. NORSTROM:** I guess I'm asking what  
20 the experimental protocol for something like that was.  
21 Can we say whether or not any of the non-starting radio  
22 labeled stuff was still in fish, for example, or  
23 whether it was excreted or can we say that at all?

24 **DR. MCCARTY:** There is some information  
25 that indicates that and various things, it's a very



1 detailed thing which we did not address.

2                   Again there's only so much uncertainty  
3 reduction we can do, but I understand your points and  
4 they're all well taken but I mean after a while, we can  
5 do a great deal more of sophisticated work but not  
6 really get any farther ahead and I think that's the  
7 situation you're in here.

8                   We had enough information to improve the  
9 process but not to the level that you might like when  
10 you start to go down that improvement, but nonetheless  
11 it's better, I believe that this is much better, a much  
12 better evaluation and a much clearer picture than we  
13 would have had without those.

14                   **DR. NORSTROM:**           Yeah, I agree it's a  
15 great start. Thanks for providing the structure, by  
16 the way, which is where some of my questions are coming  
17 from. Some of the potential metabolites, just off the  
18 top of my head, could be persistent.

19                   **DR. MCCARTY:**       Well, we, our objective  
20 was not to do the per... I mean if you remember our  
21 objective, it was simply remove the uncertainty in the  
22 fate as we, fate and toxicity and the fate has to do  
23 with the toxicity part so we're not, I mean although  
24 this panel has a much broader mandate, what we did here  
25 was very narrowly focused and this chemical has been



1 under review for some time, it has received partial  
2 registration.

3 The, in the draft directive that we  
4 received from, that the company received from the EPA  
5 early this year is what we're addressing, so that the  
6 presumption that I would make is that the outer bounds  
7 have been dealt with.

8 Whether it's been to be satisfactory to  
9 your point of view or not I'm not sure, but that's not  
10 where again, we're not doing research here, we're  
11 trying to do focus on the regular activities but I want  
12 to make it very clear that we tried to put everything  
13 we possibly could in here to be.

14 So if you want, if you want to go into  
15 great detail and look at this, the material is there  
16 and it's clear as we could possibly make it and you  
17 should be able to find it easily and you may not  
18 necessarily agree with what we did, but you will know  
19 what we did which is I think one of the things that I  
20 always like to see and often don't get.

21 **DR. NORSTROM:** Thanks.

22 **DR. HEERINGA:** Just a note to the panel,  
23 too, the report on the Valent study, it was emailed by  
24 Myrta Christian to us, it was not part of the CD  
25 transmission.





1 Dr. Steenhuis?

2 **DR. STEENHUIS:** I would like to come  
3 back to the half life. We have pesticide four in the  
4 large....we have pesticide four in the, in our, in the  
5 white paper. It says half life ranging from 224 days  
6 'til 1,110 days in the sediment or in the soil and your  
7 simulation shows that it disappeared in no time and I  
8 don't completely, I don't understand that. There's no  
9 carrying over effect that we can show.

10 **DR. MCCARTY:** Well, the information that  
11 you're talking about there is from a, and this relates  
12 to the previous question. This is a general metabolism  
13 by the micro biota in the field essentially. It will  
14 for all fate and we're talking, the metabolism we're  
15 including is simply the metabolism of the organisms  
16 that were, their exposure was being modeled for so we  
17 didn't substantially include that.

18 So the other thing is, that if you look  
19 at the mesocosm data which has been collected in this,  
20 the material disappears very quickly under the water  
21 column so those things, I think a lot of those  
22 estimates you may, it depends on who's estimating and  
23 what they're looking for. You can get quite a  
24 difference, but I mean, I know that, for example, in  
25 the mesocosm, the water column concentration is ten



1 percent of initial concentration after twenty four  
2 hours.

3                   So I understand it's not the answer to  
4 your question, but there are some, this is actually one  
5 of the things I think we saw earlier that there's lots  
6 of, when we classified these things by these schemes,  
7 we use a bunch of assumptions. Those are models, very  
8 simple models and when the thing, if a thing meets  
9 assumption of the model then it's pretty good but this  
10 is a chemical that has some characteristics that fit  
11 into this category but there are some other things that  
12 modify that.

13                  I think Dr. Bidleman was talking about  
14 some of those things for long range transport. I think  
15 there are some other things in terms of fate and  
16 persistence that may well apply so I can't answer all  
17 the...I can't answer the details of that question and I  
18 understand your confusion but we have our justification  
19 for what we did is in the report and we used the  
20 numbers, the numbers are there and you can review those  
21 and make your own conclusions.

22                   **DR. HEERINGA:**       Yes, Dr. Doucette.

23                   **DR. DOUCETTE:**       Lynn, given the, the  
24 other questions you brought up, this is probably minor,  
25 but I was interested in your choice of Koc going from



1 and I realize that soil with low organic carbon is  
2 different than sediment, but you chose an estimated  
3 value over an experimental value and Koc is supposed to  
4 be a constant and it worked to the advantage of  
5 lowering the quotient. How do you justify something  
6 like that?

7 **DR. MCCARTY:** Well, I relied on, John  
8 and I had the detailed discussion of that and he felt  
9 that that compilation of things for a wide variety of  
10 organic chemicals, the correlation, this is basically  
11 QUASAR, if you will, he felt that that QUASAR better  
12 reflected the estimate of this and he's an expert in  
13 this field as you well know, he's graded some of  
14 the...appropriated some of the models that are used  
15 here and so he felt it was not our concern to consider.  
16 However, you'll note very deliberately the way it was  
17 presented.

18 If you believe that and I understand  
19 your concern, you can subtract that out from the risk  
20 quotient analysis and it's very easy to do and you can  
21 still come up with it and I think you'll find it still  
22 doesn't make a big difference but we were very  
23 deliberate to try and make it very clear for people to  
24 do exactly that analysis.

25 I mean, there's nothing, I mean, again,



1 there's nothing here to hide, we wanted to be  
2 completely as open as possible so that people could  
3 follow it and make their own decisions and so I think  
4 that we've allowed you to do that and that's why I feel  
5 as if we've achieved exactly what we set out to do .

6 **DR. HEERINGA:** Dr. Hickie?

7 **DR. HICKIE:** I'd just like to make a  
8 comment, Koc should be a constant provided the organic  
9 carbon's the dominant absorption factor and that it's  
10 constant in composition between locations.

11 **DR. HEERINGA:** Dr. Maddalena?

12 **DR. MADDALENA:** That was a nice case  
13 study and, and report, thanks for providing that. I  
14 want to talk a little bit hypothetically here and allow  
15 you to step out of your role for Valent and just be...  
16 As a scientist if you had this product and you were  
17 going to register it, what area would it be applied on  
18 roughly and knowing that area and mass that's applied,  
19 what fraction leaves that area? So in other words is  
20 this for cumquats or is it for wheat and corn and I  
21 think that would make a very big difference in its  
22 ultimate fate.

23 **DR. MCCARTY:** Well, I mean, again, the  
24 scenarios were specified by the EPA for analysis and  
25 those are available in the Anderson, et al. 2008 report



1 on this so I...you're asking me to give a personal  
2 opinion about a regulatory decision, I don't feel very  
3 comfortable doing that.

4 I mean, we used, in fact, for example,  
5 we used six, six applications in a row, fourteen days  
6 apart which is normally spent to be three applications  
7 over two seasons so there would be quite a different  
8 exposure scenario as a result of that assumption. We  
9 use that assumption although I don't think it's  
10 realistic so simply because we're trying to be as close  
11 as possible to what EPA has done because then if we  
12 question all those things then we get into a great big  
13 discussion.

14 What we tried to do was to refine the  
15 estimates of these things as they specifically  
16 requested to try and show that perhaps there was a  
17 better way of doing it and that with very modest  
18 justifiable changes, we could demonstrate something  
19 different and actually I wasn't sure that that was  
20 going to happen. I mean we didn't have a preconceived  
21 outcome.

22 We did these things and this is  
23 literally what happened so I mean it could have been,  
24 it could have gone the other way and I might not be  
25 sitting here so you understand you're asking me a



1 question that really isn't in my purview to change.

2 **DR. MADDALENA:** Okay. I, I understand  
3 that...

4 **DR. HEERINGA:** Dr. McCarty, I agree on  
5 that too and let's make sure that we focus on the  
6 science and the report as it's presented, I don't think  
7 we need to cross examine.

8 **DR. MADDALENA:** Okay, I'm not cross  
9 examining. I appreciate it. It was a very good report.  
10 The point I'm trying to get at is whether we're looking  
11 for the keys under the street light. Where we're  
12 looking at it, this is an entirely different class of  
13 chemicals that you guys are having to deal with now and  
14 the fact that we did a really good job with the pond  
15 and with this assessment doesn't give me a lot of  
16 comfort in the long term and that is what I was asking  
17 you.

18 **DR. MCCARTY:** Okay, well, I understand,  
19 that's why the panel's here and I'm not sure I have the  
20 answer either on this, but I mean I think that this is  
21 the, this is the difficulty of being in transition here  
22 because this company is trying to register something  
23 when things are or the ground is shifting.

24 So I think that's why we focused very  
25 narrowly on answering the question, because I couldn't



1 anticipate what I need to do to try and assess that  
2 question but if you, if the panel comes up with  
3 something that decides you should do something  
4 different, I'm sure that the registrants will be, will  
5 do that when it's defined to be done.

6 I think you know, I mean, stepping  
7 outside my role and speaking for Valent here, I was  
8 very impressed that they were willing to put this on  
9 the public record

10 You know, this is pretty remarkable as far as I'm  
11 concerned in my experience and so, but they obviously  
12 have some confidence on this thing and they  
13 volunteered, they're being, as they say in government  
14 circles in Canada, at least open and transparent.

15 So I think that, you know, that to me is  
16 very, so they're trying to follow the rules as best  
17 they can and if the rules change I believe that these  
18 and other companies will try to do the same things so I  
19 think the opportunity here, I'm particularly pleased  
20 that the EPA is looking in this direction, I think it's  
21 the way to go, I think there's a lot of the devil's in  
22 the details but nonetheless the concepts, I don't have  
23 any problems with the concepts. Like you I'm not sure  
24 what the details will bring, but you know, let's see  
25 what happens.





1 **DR. HEERINGA:** Dr. Delorme?

2 **DR. DELORME:** Perhaps a minor point,  
3 Lynn, but with respect to your comments on solubility,  
4 one of the things we have to recognize is at the time  
5 of application there's a certain fraction that drifts  
6 into a water body possibly and that's in a formulated  
7 product which also often includes other things to keep  
8 it in solution. So completely dismissing the use of  
9 co-solvents I think is a little bit dangerous at  
10 times...

11 **DR. MCCARTY:** I didn't  
12 completely...being very careful there...

13 **DR. DELORME:** But there are situations  
14 where the compound may be more bioavailable...

15 **DR. MCCARTY:** Absolutely.

16 **DR. DELORME:** ...and the impact that  
17 that has, I'm not sure, it may be minor...

18 **DR. MCCARTY:** No, no, I'm sure you're  
19 right, but for what we were doing in trying to  
20 interpret a toxicity test where I do not know what the  
21 solvent did to mod...I mean I know the end result.  
22 They made something that when I put in the water  
23 normally was nontoxic that made it toxic, okay, so it  
24 clearly did something and I don't know how much of  
25 whatever it did, it did.



1 DR. DELORME: Right.

2 DR. MCCARTY: And so therefore I can't,  
3 I can't correct that, now fortunately if I had  
4 residues, if they had collected residues from this  
5 study when they were doing that, I could have, I could  
6 have figured out and fortunately there was some, there  
7 were a number of experimental, experiments carried out  
8 where they did, where they did this and I was able to  
9 do that and I did away with all that stuff.

10 And went strictly to the residue and  
11 tried to make sure it was that steady state so it was  
12 something I could, you know, the body residue was a  
13 steady state within the body compartment, and use that  
14 directly, but no, I mean to me they've done...when you  
15 use solvents in a toxicity testing it's only half the  
16 thing, because if you, you need to know what the effect  
17 is.

18 It's like saying, well, I did a test  
19 that, for a chemical physical property but I didn't  
20 correct the systemic temperature and pressure, nobody  
21 would do that and that's the equivalent of what we're  
22 doing here. We're doing something that we know is  
23 wrong and we're not collecting information to correct  
24 it, but I agree with you and that that's an issue.

25 In fact what you might end up doing in



1 toxicity testing is sometimes is actually collect that  
2 information with and without, so that you'll have an  
3 understanding of what the co-solvents and....

4 **DR. DELORME:** Or include the end use  
5 product as well.

6 **DR. MCCARTY:** Or test the product. In  
7 some cases the product was tested, but no, it is a good  
8 point, but again I didn't throw the baby out with the  
9 bath water, okay.

10 **DR. HEERINGA:** Okay, two more questions.  
11 Dr. Steenhuis and Dr. Simonich.

12 **DR. STEENHUIS:** Hi, my name is Thomas  
13 Steenhuis, I would like, I mean, I don't have time to  
14 read the whole paper in just five minutes. What you  
15 have here are sedimentation and deposition rates for  
16 the part, how did you determine that?

17 **DR. MCCARTY:** That I believe is EPA  
18 models. So sedimentation rate, that is AGRO, that's  
19 the AGRO model, and I'm told that that particular  
20 sedimentation rate is quite low as sedimentation rates  
21 go. Now this is, this is John's area of expertise but  
22 I asked Frank Gobas to be sure about that and Frank  
23 told me that, he looked at the number because I asked  
24 him that question just to reassure myself and he said,  
25 well, you know, and we've had this discussion about the



1 sedimentation rate in AGRO versus EXAMS so it is there,  
2 but it is low.

3 **DR. STEENHUIS:** I do agree with that,  
4 it's 1.5 centimeters when you calculate that, but how  
5 about you have also this type of sediment deposition  
6 and sediment resuspension range...

7 **DR. MCCARTY:** Again, I believe those are  
8 the model, what's in the model and you would have to  
9 ask John why he chose those if it's not there.

10 **DR. STEENHUIS:** I know, I didn't have  
11 time to read it.

12 **DR. MCCARTY:** Yeah. I understand, but  
13 I mean, again, we tried to provide that information,  
14 the details, so that if you, I can't always answer the  
15 question right away but it allows you to be able to ask  
16 the question.

17 **DR. STEENHUIS:** Absolutely, you're  
18 right.

19 **DR. HEERINGA:** Dr. McCarty, thank you  
20 very much, we appreciate the presentation. We have one  
21 more scheduled public presentation and it's by Dr.  
22 Stuart Cohen who is here representing, make sure I get  
23 this right, Amvac Chemical and let Dr. Cohen introduce  
24 himself.

25 **DR. COHEN:** Hi, my name is Stuart Cohen.



1 I'm with Environmental Turf Services in Maryland,  
2 excuse me, I'm representing Amvac Chemical.

3 First of all I want to start off by  
4 commending EPA to put together this package, it's such  
5 a complex subject, it's truly interdisciplinary to put  
6 all this together and I think Keith, you've probably  
7 been with pesticides less than two years and to do all  
8 this and present it in such a format to deal with a lot  
9 of cutting edge issues, is pretty commendable, and the  
10 White paper was put together very clearly and the  
11 presentations very, as the Chairman acknowledged, were  
12 very crisp and to the point.

13 The outline of my very brief  
14 presentation is I want to first talk about the time to  
15 reach equilibrium for food web modeling and then I want  
16 to address the need to address... I want to discuss the  
17 need to address metabolism in food web modeling and  
18 then talk about long range transport prevention and at  
19 the end I have a summary slide.

20 So in the past OPP has taken the single  
21 data, the upper 90th percentile of the worst day in the  
22 thirty year period for its bioaccumulation assessments.  
23 Okay, so that's a single day number, the upper 90th  
24 percentile, and has run that through food web models.  
25 Now this approach ignores the time for aquatic biologic



1 systems to reach equilibrium and this issue was  
2 addressed yesterday by Drs. Mackay and Gobas and just  
3 about everybody in between.

4 But in the White paper OPP presents the  
5 use of sixty day average concentrations which often  
6 allow to achieve a system equilibrium. OPP I don't  
7 think has said what the policy will be, but certainly  
8 by showing these two examples, that is preferable and  
9 we agree. Sixty is better than one for very high KOW  
10 and persistent chemicals. Greater than 60 days is  
11 probably even more appropriate for the system to reach  
12 equilibrium.

13 In fact if you run the CABAN model and  
14 you substitute in for the, you know, using the lumped  
15 first order rate constants for a case of metabolism in  
16 gill elimination et cetera, et cetera, I think you  
17 could find that for a Koc of, KOW, log KOW of around  
18 five or so, I think you'll find that it takes longer  
19 than even a hundred days to reach equilibrium.

20 But the point is that OPP with this  
21 White paper and with this new initiative is definitely  
22 on the right track and we totally support that. Now  
23 the need to address metabolism. OPP typically assumes  
24 no in vivo metabolism in its bioaccumulation  
25 assessments. This is mentioned in pages 105 and 110 of



1 the White paper.

2 Now of course this is incorporated, this  
3 is an integral part of the empirical data but in terms  
4 of modeling when it came, a Km metabolism rate constant  
5 has to be assumed it's assumed generally it's nulled  
6 out, it's assumed to be zero.

7 Data, in EPA's defense data on Km,  
8 metabolism rate constant, is almost always lacking in  
9 the studies that it seeks. On the other hand OPP  
10 generally gets depuration rates from the standard FIFRA  
11 guideline studies. So the K depuration is a summation  
12 of the four rate constants which we've seen Arnot and  
13 Gobas mention many times, it's just one of many  
14 documents that summarize what goes into that overall  
15 lumped rate constant, so Km is metabolism, let me get  
16 my glasses on so I can see that, okay, that's much  
17 better. Okay, Kb is fecal elimination, Kg is solution  
18 through growth and K2 is loss through respiration,  
19 mostly through the gills and I guess to some extent  
20 through the skin.

21 So one could back out of Km because, is  
22 there a pointer here, all right, so the CABAN model  
23 that EPA is putting forth, the Arnot and Gobas model,  
24 calculates these three parameters so if you get, and  
25 there is a reasonable data base on this and certainly





1 Frank Gobas could speak to this imminently better than  
2 I could, but I believe there's a reasonable data base  
3 underlying the calculations behind these so if you  
4 calculate this from that, you can get a Km, so let's  
5 talk about this a little bit.

6 In the pesticide four example, which you  
7 just had identified to you by the previous speaker, it  
8 examines, demonstrates the pitfalls ignoring  
9 metabolism. So initially calculating the kinetics  
10 based on the KOW presented some very, very high  
11 residues of pesticide four, Pyridaben, whatever it is,  
12 in fish but then when they went back in and put in the  
13 empirical data they showed much lower residues.

14 Okay, so even though that chemical has a  
15 log KOW of eight or so, whatever it is, you may think  
16 that's an extreme case. Pesticide two, that is PCNB,  
17 penta-chloro-nitro-benzene and you know, we're  
18 identifying that too, that has a log KOW of 4.6 and Km  
19 is also an issue there, not as dramatic an issue as for  
20 pesticide four but it's an issue as well.

21 So this plot, actually Dr. Norstrom, I  
22 believe you did some work with Derek Mure in this about  
23 ten years ago. You did a similar analysis, sorry for  
24 not citing you, but what this plot does, Fitz, Fitz was  
25 the lead author? Okay. What this plot shows is that



1 you have, and sorry for the PDF, it's right from the  
2 journal article.

3                   The log of the depuration half life on  
4 the Y axis plotted against the log at KOW, the  
5 equation that is presented for you there, the  
6 regression equation, the r squared is reasonable and  
7 what this shows is that if you've got a chemical, let's  
8 say the half life is up here, and the KOW is down here,  
9 let's say flat KOW four, and a half life of about  
10 twenty days.

11                   All right, that's above the line. That  
12 means that that chemical is being actually bioformed,  
13 it's incorporated into the organism but if it's below  
14 the ninety-fifth percentile, ninety-five percent  
15 confidence limit down here, then that means you've got  
16 a chemical that's being metabolized, so even though EPA  
17 struggles, as it said in the White paper it struggles,  
18 in the examples it gave, it doesn't always give high  
19 credibility to all the depuration data and the problems  
20 with the kinetics, you can see here, you can use this  
21 as a semi-quantitative approach to determine when the  
22 Km, metabolism might be significant.

23                   Vanderlindy did something analogous with  
24 a much broader base of chemicals and he looked at many  
25 taxa, he looked at insects, he looked at mollusks, this



1 is a fish based data base. So this could be a useful  
2 tool when specific metabolism kinetics data are lacking  
3 or equivocal and I'm not saying you have to use the  
4 Konwick et al paper, you know, look at everything, it's  
5 not best case or worst case, it's all cases.

6 You know, look at perhaps some of Fitz  
7 et als past work, as Dr. Norstrom was just whispering  
8 to me. Vanderlindy et al 's model with many taxa and  
9 also I suggest, I was talking to, you know, with Dr.  
10 Gobas yesterday about the Km data base underlying the  
11 development of his model with John Arnot and you know,  
12 he was saying that it was developed by and for  
13 chemicals that largely are not metabolized.

14 We did a little bit of playing around  
15 with it and we feel that Km doesn't have the right  
16 place in that model. We found that the bioaccumulation  
17 with Km zeroed out was reasonable so if we put Km into  
18 it, it would even show less bioaccumulation as  
19 indicated by empirical data. So I think the robustness  
20 of the Arnot and Gobas model should be tested with more  
21 chemicals that need to be metabolized when there's good  
22 data that either can be obtained directly or at a  
23 minimum backed out.

24 Next topic, long range transport  
25 potential. So here I'm going to be commenting on,



1 well, all my comments have to do with the process but  
2 it also has to do with not only the process today.

3           The last couple of days the focus has  
4 been on the processes. Now as Don Mackay said  
5 yesterday, don't be conservative on the processes, be  
6 conservative on the interpretation of the results.

7           I'm going to talk for the first time I  
8 think about input. You know, once you get the  
9 processes right then you've got to make sure you're  
10 doing a good job on the input, so I'm going to use  
11 PCNB, pesticide two, but this goes the way that OPP is  
12 overall applying a long range transport assessment.  
13 I'm also going to suggest an alternative model.

14           First right off the bat we cannot  
15 reproduce the results in the White paper that you saw  
16 earlier today for pesticide two. That, we use the same  
17 exact input parameters and I'll talk about those input  
18 parameters in a minute, we use the exact same input  
19 parameters, it's around page, I think it's around 162,  
20 I think it's table 6.1 and we use the same model that  
21 EPA used and for example, for transfer efficiency, EPA  
22 said that PCNB pesticide two transfer efficiency is 457  
23 percent. I got 201 percent, I didn't change anything.

24           Earlier this morning you showed that a  
25 POV and overall persistence half life was 599 days, I



1 got 312 days without changing anything so there's some  
2 things, there's a little bit of a disconnect there and  
3 I don't know if that's just a simple matter of typos,  
4 you know, input error or if there's something more  
5 fundamental, but that needs to be looked at.

6 Now an alternative, so the screening  
7 level model, and OPP didn't present this as any more or  
8 less than it is. It's an OECD decision tool that is  
9 used for comparing chemicals. I'd like to propose that  
10 OPP consider something.

11 I'm not endorsing Vonya's model, I'm  
12 simply saying it goes to quantitation, because you  
13 can't have risk assessment without quantitation and  
14 just comparing one chemical against another is great  
15 for triage, it's great for priority setting, maybe  
16 setting priorities for monitoring if you're expending  
17 monitoring resources.

18 And you don't have, I'm going to talk a  
19 little bit about Vonya's model, global pop, but and you  
20 don't have to be wedded to this, what I'm saying is  
21 start considering at least a semi-quantitative  
22 approach. So Frank Vonya set forth the global pop  
23 model, initially in 2003 publication I think in ES&T,  
24 Environmental Science and Technology. Vonya and Mackay  
25 talked about the processes that go into this in 1999.



1 Fender Adele is mentioned once or twice in the White  
2 paper and again today by Dr. Kan as an overall  
3 comprehensive comparison of the models.

4 Vonya's global pop model estimates  
5 arctic contamination potential based on pesticide  
6 e-fate chemistry. It is a zonally averaged multi-media  
7 model designed for the global fate of pops, that's what  
8 it's designed for. So why do we care about arctic?  
9 Well, arctic is, obviously there's good ecological  
10 reasons to care about arctic, but also it's kind of  
11 like the ultimate long range transport, so I'm not  
12 endorsing it, I'm saying just evaluate it, consider it,  
13 and consider possibly other semi-quantitative or  
14 quantitative approaches.

15 Now for pesticide two globe pop predicts  
16 much less than one tenth of one percent of globally  
17 emitted PCMB when presented in arctic surface media  
18 over ten year period of emission and equilibration.  
19 Yet OPP, now I'm coming back to the comparison  
20 tool....yet OPP....oh, and to put that into perspective  
21 if you look at Vonya's work I would believe that for  
22 the ACP 10 the emitted fraction for a ten year period,  
23 a typical problem chemical would be in a couple percent  
24 range, okay.

25 So we're talking about PCNB would be

1 about two orders of magnitude lower than the more  
2 problematic chemicals. I didn't run lindane through  
3 the process but you know, I think Dr. Bidleman's  
4 published work in this area. You know, people know  
5 that lindane is out there and around, certainly in the  
6 DDT analogs and PCNB would be about two orders of  
7 magnitude lower than those.

8                   Yet, when OPP presented its application  
9 of an OECD tool, it said that PCNB has much greater  
10 long range transport potential than DDT, aldrin and  
11 dieldrin, much greater. So when I saw that I said, huh,  
12 how did this happen? 'Cause I'm taking a common sense  
13 thirty thousand foot approach, how's that possible?

14                   So it's an issue of apples and oranges  
15 so what OPP did was in, I'm not sure when Ron Parker  
16 gave his presentation yesterday, I'm not sure what came  
17 across in the specific input modeling guidance that OPP  
18 typically uses the upper 90th percentile for say the  
19 aerobic zone metabolism half life as an example, and  
20 that's been discussed and evaluated and people know  
21 that going in, that's been aired out, and it is  
22 implemented science policy.

23                   For runoff modeling, for storm water  
24 runoff modeling, use as an example the upper 90th  
25 percentile of the aerobic zone metabolism half life.





1 Similar numbers go into aerobic aquatic metabolism but  
2 this is something different. This is long range  
3 transport potential assessment and all the papers I've  
4 seen and if you look at the actual OECD tool, what they  
5 talk about are reasonable numbers not the upper 90th  
6 percentile.

7 In fact I said in the beginning is it  
8 best case or the worst case, it should be all cases and  
9 I steal that line from a, I think his name was Dennis  
10 Kozlowski, he was a Dow scientist from the 1980s, a  
11 very top notch scientist, I may have his name wrong,  
12 but anyway so what the OECD tool does it presents, when  
13 it presents its reference chemicals. It doesn't  
14 present one number for water half life for aldrin, or  
15 one number for water half life for DDT. It presents a  
16 series of numbers. In fact it doesn't even present it  
17 for DDT. The reference chemicals it says it's supposed  
18 to be used wasn't used by OPP in its presentation or in  
19 its White paper.

20 The referenced chemicals for comparing  
21 something, for determining whether it's a PBT, are  
22 carbon tetrachloride, PCB analogs, hexachlorobenzene  
23 and lindane and its analog. Those weren't referred to,  
24 what was referred to are chemicals like aldrin isn't  
25 found out there but dieldrin is, there's an interesting



1 version. DDT is usually not found but DDE is and what  
2 the OECD tool says is you should use a range of input  
3 parameters and in fact it has a Monte Carlo module that  
4 you can run and that's the example. You do best case  
5 or do worst case, you do all cases.

6 So our concern is not with the OECD  
7 tool. Our concern is the way it was presented, applied  
8 in this White paper and I think the OECD tool could be  
9 very valuable for setting priorities and triage et  
10 cetera, but I would recommend that OPP also start going  
11 towards a semi-quantitative or quantitative risk  
12 assessment approach as well.

13 Now as Dr. Bidleman said earlier we also  
14 have concerns that in all of these models, in all these  
15 models, they don't consider, first of all they're not  
16 necessarily designed for pesticides, but they don't  
17 consider the pesticide application method, if it was  
18 soil incorporation versus air blasts in the orchard.  
19 It seems to me you have a lot different initial percent  
20 of emissions being kicked off into the atmosphere if  
21 you compare those two methods.

22 Also the volume, Dr. Maddalena I think  
23 it was, was questioning whether the volume used in  
24 here, production volume, there's a big difference in  
25 chemicals that only have a couple million pounds a year

1 globally versus those that are tens or hundreds of  
2 millions of pounds per year, so I'd recommend those  
3 refinements to this process.

4                   Then picking, then picking up PCNB in  
5 reverse, it was said in today, earlier today's  
6 presentation that the presence of, there was two  
7 pesticides so they listed pesticide two and I don't  
8 remember whatever else, it was well defined. That's  
9 hardly the case, it couldn't be less the case. In the  
10 White paper it says one of the most common pollutants  
11 found in arctic snow was a metabolite of pesticide two  
12 slash PCNB.

13                   This first appeared in an EPA document I  
14 think it was 2004. We immediately corrected EPA, EPA  
15 acknowledged in writing that this is wrong,  
16 acknowledged it and verbally and it's still appearing.  
17 A metabolite of PCNB has never been found in arctic  
18 snow. It was a table that had an abbreviation for an  
19 acronym for a different metabolite that's unrelated to  
20 PCNB. All you had to do was look at the footnote of  
21 the table or look at the text and you'd see it was a  
22 different chemical.

23                   So not in arctic snow. Also it says in  
24 the atmosphere of areas in which pesticide was not  
25 used, I believe it's talking about a Saskatchewan study



1 maybe in China, I'm not sure but in the study, the PCNB  
2 target crops were in the area, sod, grass seed, grass  
3 for seed and cabbage, so it's not known that PCNB  
4 wasn't used in that area and in fact the way you use  
5 some of these models, there was a big assumption it's  
6 in the vapor phase.

7                   In fact that was stated here and there  
8 was one study where the sampling points were a couple  
9 of miles away from where PCNB was used and the only,  
10 the only sample that had it was with a puff plug, a  
11 polyurethane phone plug, so it was trapping in this  
12 case because they also did air, but they were doing  
13 particular traps. The only PCNB residue was in one  
14 sample in a particulate filter.

15                   So my point, for VAF assessment one day,  
16 no, many days, yes. OPP's initial examples are sixty  
17 days, that's a great start. Expand use of Km and  
18 evaluate the Arnot and Gobas model regarding this  
19 parameter. Consider the use of log Koa. I did not  
20 talk about this because this is human bioaccumulation,  
21 this is supposed to be an eco assessment meeting, but  
22 we are top predators and that's kind of like the  
23 ultimate in bioaccumulation.

24                   Caruso et al, what they did was they  
25 studied mothers who were pregnant and following the



1 kids through about four longitudinal sites. They were  
2 about four years old or something like that, and they  
3 determined that chemicals with a log Koa greater than  
4 about eight was a concern for the study population. I  
5 know PCNB has a log Koa of about 6.3 or so. Anyway,  
6 log Koa was discussed earlier, I can't remember who,  
7 and the question from the panel and the response was it  
8 goes to clearance, the ability to clear out the  
9 chemical.

10 So I'm just chiming in to consider the  
11 use of log Koa either in human bioaccumulation  
12 potential or in mammalian terrestrial crafts. Evaluate  
13 global pop for potential use. Again, this is not an  
14 endorsement, it's a suggestion that you evaluate it or  
15 something analogous.

16 Integrate consideration for production  
17 by an application method into the LRTP assessments.  
18 Speaks for itself. And finally use appropriate model  
19 input, this meeting is focused on the processes and  
20 that's good, in a sediment burial et cetera, et cetera,  
21 but once you get a really good model, the output is  
22 only as good as the input. So you've got some  
23 references and we've got hard copies of that too. And  
24 I thank you for your time and I'd be happy to answer  
25 any questions.



1                   **DR. HEERINGA:**     Thank you very much, Dr.  
2 Cohen, and Dr. Simonich has an opening question.

3                   **DR. SIMONICH:**    Thank you for your  
4 presentation, and I appreciate your perspective. So am  
5 I to understand that you didn't run PDT eldrin or  
6 endron in global pop, and as you've shown,  
7 unfortunately, sometimes the use of models in the  
8 outputs might vary user to user so you did not run  
9 those, is that correct?

10                  **DR. COHEN:**     We did not run dieldrin,  
11 eldrin, endrin in global pop, no, but what Vonya did  
12 was run the perfect, they call them perfectly  
13 persistent chemicals, PPCs and to the extent that they,  
14 in global pop the PPCs come out at a few percent that  
15 the art of contamination potential for ten years that a  
16 few percent like between one and four percent of  
17 chemicals that would be in the range of not aldrin but  
18 probably dieldrin and probably DDE, that a few percent  
19 of what's admitted into the environment would...could  
20 then be deposited on an arctic surface and so that's in  
21 his paper.

22                  **DR. SIMONICH:**    Yeah, I'm aware of that  
23 paper.

24                  **DR. COHEN:**     I figured you were, all the  
25 research you've done.



1                   **DR. SIMONICH:**     But in fairness for  
2 direct comparison to EPA, they model DDT, eldrin and  
3 endrin.

4                   **DR. COHEN:**     Oh, now that's in the OECD  
5 tool.

6                   **DR. SIMONICH:**    Yes, I understand.

7                   **DR. COHEN:**     Oh, okay.

8                   **DR. SIMONICH:**     But I'm wondering where  
9 PCNB falls out compared to DDT, eldrin and endrin in  
10 global pop.

11                   **DR. COHEN:**     Oh, it was .0...oh, I ran  
12 that...oh, I'm sorry, we ran PCNB and it was .01  
13 percent to .03 percent depending on the input  
14 parameters and no, did not, did not run that, I just,  
15 because Vonya had the perfectly persistent chemicals in  
16 there.

17                   **DR. SIMONICH:**     Which may not be DDT,  
18 aldrin and endrin.

19                   **DR. COHEN:**     Would be, right, not,  
20 certainly not, certainly not aldrin.

21                   **DR. SIMONICH:**    So, also another question  
22 regarding your input parameters for PCNB and your  
23 critique of EPA's selection of parameters, what was the  
24 strategy you used to select your parameters?

25                   **DR. COHEN:**     I used their parameters,



1 well, to try to reproduce the work, I used the exact  
2 same parameters. Then and as an example of the  
3 transfer efficiency, let's see, what did I have the  
4 slide there...almost there, there we go, no, oh I know  
5 in the POV, the overall persistence, EPA reported today  
6 and I think in the White paper 599 days. When I used  
7 their input...

8 **DR. SIMONICH:** Just let me clarify, I  
9 mean with regard to global pops, what parameters did  
10 you select, it was the same as EPA's that was used....

11 **DR. COHEN:** Oh, oh, with global pop.  
12 When we ran what we think is reasonable input we came  
13 up with .01 percent but when we ran EPA's, definitely  
14 the aerobic soil metabolism half life that EPA first  
15 used for runoff modeling and I don't remember what we  
16 used for water. I think for water we used the same.  
17 We came up with .03 percent.

18 **DR. SIMONICH:** And how did you choose  
19 your reasonable values?

20 **DR. COHEN:** Based on, I mean this would  
21 take like two beers to explain the whole thing, but  
22 there has been a series of discussions back and forth,  
23 there is...

24 **DR. HEERINGA:** It sounds more reasonable  
25 with time.



1 **DR. COHEN:** Yes, there's, there's  
2 dispute...I mean this is a side issue here, but there's  
3 dispute about the appropriate aerobic flow of  
4 metabolism half life because some volatiles were lost  
5 during the study and EPA put them back in. When EPA put  
6 them back in, the half life went way back, way up and  
7 the R squared went way down so when you just let the  
8 volatile scope that we lost at the beginning, the R  
9 squared was very good.

10 The first order rate constant was very  
11 good and the half lives were short and there's been  
12 discussions back and forth and then there was a couple  
13 of studies and then so we took the mean, I don't  
14 remember if we took the mean or the worst one but then  
15 EPA takes the two, uses the C and T value and then  
16 derives the upper 90th percentile, separate issue.

17 It, both sides respectfully disagree but  
18 that's a separate issue so we ran it both ways, we ran  
19 global pop with what we thought was reasonable and with  
20 what EPA does in its runoff model.

21 **DR. SIMONICH:** Okay, so some of the  
22 differences between your discussion of the OECD tools  
23 and global pop, is that we're not doing an apple to  
24 apple, orange, orange comparison because we're not  
25 benchmarking the PCNB to DDT, aldrin, endrin. That



1 looks like was done in the OECD tool. We're also, the  
2 selection of the input parameters are also very  
3 different. I appreciate your points but...there's  
4 various aspects that don't make it a direct comparison.

5 **DR. COHEN:** Yeah, it's, that's right,  
6 so what we were trying...what we did, what OPP did was  
7 took the worst case examples of PCNB and like the DDT  
8 half life that...I'm sorry, I didn't mention this. The  
9 DDT half-life that was put in there, that is lower than  
10 I think USDA people would be aware of Don Walkups  
11 pesticide properties data base and Janice Chambers, you  
12 may even know about that.

13 There's a standard kind of like Bible  
14 for field half lives. The number that OPP used for the  
15 DDT soil half life was significantly lower than the  
16 number in the pesticide property data base, that half  
17 life. So here EPA took worst case for PCNB, compared  
18 it against reasonable or best case for DDT and that's  
19 the....I was simply trying to use that as an example of  
20 the input misrepresenting the results.

21 **DR. HEERINGA:** Other questions from the  
22 panel? Well, thank you very much, Dr. Cohen. Since  
23 there have been no other requests for public comment, I  
24 think we're ready to move on to the charge questions  
25 but before we do that I'd like to turn to the panel,



1 we've had a large number of presentations and we've had  
2 a chance to ask questions but maybe inadequate time or  
3 you formulated a question afterward, I'd just like to  
4 open the floor at this point to panel members to ask  
5 any other questions and I presume Dr. Brady, we could  
6 call up the relevant staff scientists to answer these.  
7 Are there any outstanding questions on the White paper,  
8 on the presentation material? Yes, Dr. Doucette?  
9 Maybe you could identify the topic area to us.

10 **DR. DOUCETTE:** The topic area would be  
11 degradation data that's submitted and I'm not sure who  
12 would be best to answer that but I've looked at the  
13 standard method and I'm still, I guess I would like to  
14 get a feel for when you receive a data package that  
15 looks at degradation and metabolism, what actually do  
16 you see and how comparable is that data from one study  
17 to another, how much flexibility is there in the data  
18 that's submitted, required to be submitted for the  
19 degradation part of it?

20 **DR. HETRICK:** I'm going to give you the  
21 short answer on this okay, number one, just to set the  
22 stage a little bit. When we see a....the registrants  
23 are normally just requested to submit one aerobic soil  
24 metabolism study to support a registration, one.

25 That doesn't give you a lot of leeway to



1 look at variations from one study to the other. Now in  
2 all fairness, more recently we've been getting more  
3 studies submitted to support registrations and that  
4 does help us to look at variations from soil to soil  
5 and across different matrices so you know, it can vary  
6 quite a bit. I've seen studies where we have half  
7 lives that range from 60 days up to 500 days and the  
8 tendency is that normally one would throw out that 500  
9 days as an outlier.

10 I personally don't see that, I don't  
11 think that's appropriate to do that, to throw data out  
12 just for the sake of, it just doesn't fit the norm but  
13 there's that tendency to want to do that.

14 **DR. DOUCETTE:** And as a follow up, how  
15 about in terms of the transformation products that are  
16 identified or aren't identified?

17 **DR. HETRICK:** The, normally when you  
18 start looking amongst the different soils, I'm speaking  
19 just on a soils basis, normally you see pretty  
20 consistently the profiles look fairly consistent from  
21 soil to soil.

22 With the caveat that if there's a pH  
23 dependence type of, some type of process going on there  
24 that may create a unique soil product or hydrolysis  
25 product. That might differ with, according to the pH



1 of the soil so the point is that normally for, from a  
2 biological perspective the metabolites are generally  
3 fairly consistent from soil to soil.

4 **DR. DOUCETTE:** In what level do  
5 they...I mean there was the ten percent level is I mean  
6 do you see things ranging down to percent levels, I  
7 mean it depends...

8 **DR. HETRICK:** Yes, yes, and we can track  
9 that because we have radio labeled studies and in  
10 thank God for that because if we didn't have that  
11 capability we probably would miss quite a bit.

12 **DR. DOUCETTE:** And of those, and in the  
13 radio labeled studies that just gives you an indication  
14 that there is label there, are the specific metabolic  
15 products always identified?

16 **DR. HETRICK:** Normally the registrants  
17 go to great efforts to identify any residues that they  
18 extract and you know, I've got to give them kudos for  
19 they make a noble attempt to try to identify any  
20 residues that are extracted from soil.

21 **DR. DOUCETTE:** Thank you.

22 **DR. HEERINGA:** Other questions from the  
23 panel? We'll have the opportunity if you require  
24 clarification during the charge questions we can do  
25 that, but I prefer that when we enter the charge



1 questions that we have most of these clarifications out  
2 of the way. Yes, Dr. Delorme?

3 **DR. DELORME:** Jim, maybe you can answer  
4 the question. I was just looking for clarification on  
5 what, when you're looking at a whole system half life  
6 for an aquatic system, what impact does that have on  
7 your modeling?

8 **DR. HETRICK:** Well, actually when you  
9 start looking at the PRZM/EXAMS model when we, I'm  
10 going to break this down between PRZM and EXAMS because  
11 I think there's an important differentiation here. The  
12 model's fairly sensitive to the aerobic aquatic  
13 metabolism study, or half life, and what, the way we  
14 use the data in this case for our modeling purposes is  
15 we use the total system half life from the aerobic  
16 aquatic metabolism studies to represent the water phase  
17 degradation.

18 For the sediment phase degradation, we  
19 use the anaerobic aquatic metabolism total system half  
20 life and so therefore, we're not biasing that process  
21 either way by doing that. For the...and the  
22 degradation half life, the sensitivity of the  
23 PRZM/EXAMS modeling as far as the PRZM, the aerobic  
24 soil metabolism half life, is we make the assumption  
25 that again we're using a lump degradation half life





1 that represents the comparable metabolism in soil  
2 solution as well as what's on the soil colloid and that  
3 when we go back and do a sensitivity analysis.

4 We only...the only time you really see  
5 major differences in the output as far as the EECs in  
6 the pond, are only really have half lives that are  
7 fairly rapid on the orders of probably ten days and if  
8 we go from ten to twenty days you see some pretty big  
9 differences in your EECs but if you were to go from 100  
10 days to 400 days, you might not see much difference.

11 Does that answer your questions?

12 **DR. HEERINGA:** Dr. Doucette?

13 **DR. DOUCETTE:** You mentioned ionizable  
14 chemicals, I've got that down on my list. Can you give  
15 me a feel for the percentage of ionizable chemicals or  
16 chemicals that would be ionized in environmentally  
17 relevant pHs that you deal with? Would it be 30 or  
18 half?

19 **DR. HETRICK:** No, I would say that they  
20 are probably about thirty percent.

21 **DR. DOUCETTE:** Thirty percent?

22 **DR. HETRICK:** Yeah, they're basically  
23 neutral organics that we're dealing with.

24 **DR. DOUCETTE:** Okay, for the ionizable  
25 compounds then how do you deal with Koc and sorption in



1 modeling especially those that are negative?

2 **DR. HETRICK:** That's a good question. We  
3 don't go through and do any speciation so we, that's  
4 generally not included in our modeling so we don't look  
5 at what's ionized versus what's not ionized. You know,  
6 so we don't really go through and do that speciation in  
7 the modeling.

8 As far as the Koc issue is concerned, we  
9 just do our Koc analysis on a range of soil types,  
10 making sure one of those soil types is actually a  
11 fairly low organic matter soil with a sand texture,  
12 either loamy sand or sand texture.

13 **DR. DOUCETTE:** So in a particular  
14 scenario if I've got an ionizable chemical that is  
15 let's say negatively charged at most environmentally  
16 relevant pHs, and I do that on a low organic carbon  
17 soil, probably isn't going to make any difference, it's  
18 probably not going to sorb either way?

19 **DR. HETRICK:** That's, that's correct.

20 **DR. DOUCETTE:** And so I still calculate  
21 a Koc based on that?

22 **DR. HETRICK:** Well, we have the  
23 capability of actually using a Kd or a Koc depending on  
24 what that relationship looks like. The first thing we  
25 normally do before we go through the Koc model,



1 partitioning model is we look to see if there's a  
2 relationship, a correlation between organic carbon and  
3 Kd and we don't go forward with that. If there is  
4 another relationship, we use a Kd type of estimate.

5 **DR. DOUCETTE:** And you'll use that all  
6 the way through PRZM and...

7 **DR. HETRICK:** Right, right.

8 **DR. DOUCETTE:** Thank you.

9 **DR. HEERINGA:** Dr. Gan?

10 **DR. GAN:** Just a little bit more  
11 clarification on question two, the persistence  
12 question. You just mentioned that for the water column  
13 half life, the members coming from the aerobic whole  
14 system half life for sediment it's going to be from the  
15 anaerobic...

16 **DR. HETRICK:** That's correct.

17 **DR. GAN:** So the whole system of half  
18 life approach will apply to both sediment and water?

19 **DR. HETRICK :** Right, right.

20 **DR. GAN:** Thank you.

21 **DR. HEERINGA:** Dr. Steenhuis?

22 **DR. STEENHUIS:** Can I ask a question  
23 about the AGRO model?

24 **DR HEERINGA:** Certainly.

25 **DR. STEENHUIS:** In order to evaluate the



1 model and which one is better, is it important to know  
2 what how the input parameters are determined and  
3 especially the sediment depth, the benthic zone depth  
4 and the resuspension rate? It seems that the results  
5 of these simulations are extremely sensitive to it,  
6 especially with regard to what we heard about pesticide  
7 four.

8 **DR. HEERINGA:** This goes back to your  
9 specific question to Dr. McCarty but we're talking now  
10 about the AGRO model in general?

11 **DR STEENHUIS:** The AGRO model how the  
12 input parameters are determined?

13 **DR. HEERINGA:** Keith, are you able to  
14 address that or if you would like to....

15 **MR. SAPPINGTON:** I've run the AGRO model  
16 and done some sensitivity analysis with it, but I think  
17 this question would be more appropriately directed to  
18 then developers of the model.

19 In terms of sensitivity it is, the runs  
20 that I've done it's sensitive to the rates of the  
21 deposition and the burial and resuspension and the  
22 other parameters that I mentioned in my presentation  
23 yesterday. I did not vary sediment depth so I don't  
24 know how sensitive it is as to the depth of the  
25 sediment. Organic carbon compound is quite sensitive



1 to that and what other parameters?

2 **DR. STEENHUIS:** Actually I mean how do  
3 you set those parameters? Do you know that? I mean  
4 they need to be set at some point and how will we make  
5 a choice, it seems one centimeter depth for the benthic  
6 zone or five centimeters like is used in EXAMS.

7 **DR. HETRICK:** I guess the question I  
8 have is are the deposition rates, resuspension rates in  
9 AGRO hard wired or can you change those?

10 **MR. SAPPINGTON:** You can definitely  
11 change those rates, and in fact the version that I used  
12 had constant rates and my understanding of the newer  
13 version uses PRZM to determine in some fashion those  
14 rates, so you would have a temporal variability as well  
15 as regional to that.

16 But in terms of defining the sediment  
17 layer at least in the comparisons that we did, we  
18 simply equated them to what we normally did in EXAMS so  
19 the information I was showing you about yesterday about  
20 EXAMS versus AGRO results, we kept as many of the  
21 parameters the same as we could including the sediment  
22 data.

23 **DR. HEERINGA:** Dr. Oris?

24 **DR. ORIS:** Yes, I was wondering if the  
25 EPA would like to respond to Dr. Cohen's comments on



1 input values or in the discrepancy between modeling  
2 that was done?

3 **DR. RUHMAN:** I have to check it myself  
4 to know what he's talking about, but these parameters  
5 that we have dealt with, we exactly use the same  
6 parameters the way we use for water modeling, we do not  
7 deviate from the water modeling but that is up to you  
8 and the panel how we, you know, proceed, you know, to  
9 use these parameters.

10 That was one of our questions but we  
11 use, this is for example purposes we did use exactly  
12 the same process of 90th percentile. We did some of  
13 the time we have five, six, you know, data points and  
14 how you use, you know, like Jim was talking about like  
15 we had a fifty and five hundred, you know, what do you  
16 use then? Do you use the average value or do you use  
17 the 90th percentile, and that's where we stayed with  
18 our normal procedures for the 90th percentile.

19 **DR. HEERINGA:** Dr. Oris, do you think  
20 that rectifying this discrepancy is important for your  
21 interpretation and response to the charge questions?

22 **DR. ORIS:** Well, I think that it would  
23 be helpful for some of the long range transport issues  
24 for sure, because there was a huge discrepancy there  
25 so, or, and comparison to values that came up for DDT



1 and dieldrin and eldrin I think that was the other  
2 thing that just seemed in the idea of comparing apples  
3 to apples and oranges to oranges I think. And I also  
4 wanted the EPA to have a chance to actually respond to  
5 that if they wanted to.

6 **DR. HEERINGA:** Sure.

7 **DR. RUHMAN:** Especially those, the  
8 values of the reference chemicals is already in the  
9 tool. I did not invent those. I just used the values  
10 from the tool.

11 **DR. HEERINGA:** Dr. Brady and Dr. Gan, I  
12 wonder if on this issue if you wanted to give it some  
13 thought, maybe even compare notes with Dr. Cohen if it  
14 is a matter of rectifying a discrepancy that's  
15 important. If it required a little time maybe to come  
16 back to us tomorrow or so if, you know, I don't want to  
17 put you on the spot with that but apparently I think it  
18 does come into play here.

19 **DR. BRADY:** Yeah, I think we'd like a  
20 little time...

21 **DR. HEERINGA:** Sure.

22 **DR. BRADY:** To do that and come back,  
23 thank you.

24 **DR. HEERINGA:** Yes, Keith Sappington.

25 **MR. SAPPINGTON:** I was just handed a





1 presentation of Drs. Mackay and Gobas yesterday where  
2 there was apparently a slide presented that compared  
3 the different outputs from different sediments.

4 **DR. HEERINGA:** Sediment depths, yes, I  
5 remember that chart, about five different sediment  
6 depths. Just a comment I think and going back to my  
7 interchange with Dr. Maddalena before, too. I don't  
8 want to cut people off with regard to these specific  
9 case studies, but my concern is that we are not  
10 reviewing risk assessments for these two chemicals,  
11 these case studies were inserted to demonstrate  
12 capabilities of the current system, the process of the  
13 current system.

14 And I recognize that it's very valuable  
15 to understand in the context of a specific chemical  
16 which you know much more about than certainly myself  
17 and many other people here, that they may inform the  
18 properties, they may inform the weaknesses of the  
19 approaches.

20 But I think we want to sort of back away  
21 a little bit from treating it as two known and two  
22 unknown specific risk assessments and that was my only  
23 concern there, so again, I don't want to restrict the  
24 panel's interpretation of that data but we want to keep  
25 it in the context of the four case studies rather than



1 four independent risk assessments and their validity or  
2 lack of validity at this point. It's just a comment.  
3 Again, you should feel free to make comments if you  
4 want to on each of those studies. I didn't mean to  
5 interfere that way. Any other questions?  
6 Clarification?

7                               What I would suggest that we do is that  
8 we take a fifteen minute break now before we begin the  
9 process of responding to the charge questions and we're  
10 right on schedule, if not a little ahead of schedule,  
11 and we'll try to entertain charge questions number one  
12 and two after our break. So let's plan to reconvene at  
13 3:00 p.m.

14 **(WHEREUPON,** a brief recess was taken.)

15                               **DR. HEERINGA:** Okay, if we could move to  
16 get underway, please.

17                               Welcome back, everyone, to the second  
18 half of our second day afternoon session, the FIFRA SAP  
19 meeting. At this point in the process we have, we're  
20 about to begin the panel's response to the charge  
21 questions that have been posed to us. Dr. Hickie, do  
22 you have....okay, we can, if any additional questions  
23 or clarification do come up as part of the discussion,  
24 we'll certainly permit it in this particular session so  
25 at this point in time I suggest that we move on to



1 charge question number one, and Don, can you read it  
2 into the record, please?

3 **DR. BRADY:** Absolutely. This is charge  
4 question one addressing exposure to parent and  
5 degradation products. When assessing the potential  
6 ecological risks of proposed pesticide uses, the Agency  
7 is charged with considering both parent compounds and  
8 any degradation products of concern.

9 In several of the case studies presented  
10 in the White paper, the Agency has illustrated three  
11 approaches for assessing the PBT characteristics and  
12 exposure to parent and degradation products.

13 When parent and degradates are  
14 considered sufficiently similar in their environmental  
15 base and toxicological properties and when these  
16 properties were unknown for the degradates the Agency  
17 has used the total residue method, i.e. the Agency  
18 model that combined parent and degradate using a common  
19 set of environmental fate and toxicological data.

20 In situations where the environmental  
21 fate and toxicological properties of the parent and  
22 degradate are available and considered sufficiently  
23 dissimilar, the Agency has modeled the environmental  
24 fate separately using the residue summation or  
25 formation degradation kinetics methods, i.e. modeling



1 individual residues from the parent and degradation  
2 products.

3 Please comment on the Agency's  
4 characterization of the strengths and limitations of  
5 these methods and the conditions under which each  
6 method should be applied. To what extent does the  
7 Agency's use of the total residue and individual  
8 residue methods reflect the current state of the  
9 science for assessing exposure to combined parent and  
10 degradate compounds?

11 **DR. HEERINGA:** I think there is one  
12 additional bullet.

13 **DR. BRADY:** Okay, please identify any  
14 methods the staff would recommend for addressing  
15 combined exposure to parent and degradate compounds  
16 based on the data typically available for pesticide  
17 ecological risk assessments as described in the White  
18 paper.

19 **DR. HEERINGA:** Dr. Doucette is our lead  
20 discussant and I'll leave it to him as to whether to I  
21 think address these three questions together or  
22 separately in order?

23 **DR. DOUCETTE:** We, our group of  
24 evaluators met last night and I was peer pressured  
25 into, I put together a couple of Power Point slides



1 with some discussion items to follow the lead, so it's  
2 on that machine and I'm happy to go over there and  
3 drive or sit here if somebody's willing...

4 **DR. HEERINGA:** I think Dr. Hetrick can  
5 drive for you.

6 **DR. DOUCETTE:** It's just in the folder  
7 under panel and with my name Doucette and there's only  
8 four or five and it's just to give us some discussion.

9 **DR. HEERINGA:** Give him a moment to  
10 bring them up then.

11 **DR. DOUCETTE:** Thank you, okay, we just  
12 went through reading the question and the discussants  
13 are listed there so you can go ahead to the first slide  
14 and I thought it was helpful for me to make sure that I  
15 understood the approach and I tried to summarize that  
16 as best I could. The total residue assumes that the,  
17 the total residue approach assumes that the parent and  
18 degradation products are equal in terms of fate and  
19 toxicity, and I'm paraphrasing and it is the approach  
20 that requires the least amount of data and at least in  
21 what was shown on the examples it's the most  
22 conservative.

23 The individual residue methods are  
24 divided in two categories, the residue summation or RS  
25 method and both parent and degradation product fate and



1 toxicity data are required, but in this particular case  
2 we know that the degradation products are there but we  
3 consider both the parent and degradation products  
4 applied at the same time and that eliminates the need  
5 for some of the kinetic transformation data through  
6 information that would be needed in the next approach  
7 and it through the examples, the effective  
8 environmental concentrations predicted were closer to  
9 the, I'm sorry, that should read FD method than the TR  
10 method.

11 So the final method is the formation  
12 degradation kinetics method which ideally should be the  
13 most in depth approach to solving this problem and  
14 again both parent and degradation product fates and  
15 toxicity data are required and it looks at the  
16 formation of the degradation products as the parent  
17 degrades, and hopefully I summarized that okay.

18 If I didn't, this would be a good time  
19 to correct me.

20 **DR. RUHMAN:** I think so, except that for  
21 the formation and decline methods you need to also to  
22 look at the transformation pathway, you need to have  
23 the transformation pathways, and sometimes the  
24 transformation pathway goes from one degradate to  
25 another. One degradate goes to the other and...



1                   **DR. DOUCETTE:**     Right, right, and I'm  
2 trying to paraphrase that, right, okay, thank you.

3                   **DR. RUHMAN:**     More complex. But what you  
4 said there is okay.

5                   **DR. DOUCETTE:**     Next slide, please. And  
6 hopefully this is just repeating the first question.  
7 It looks like my selection of fonts did not work out  
8 too well and this is our response, and again as we sat  
9 together as a group we felt that this was a tough  
10 question because really we thought that the White paper  
11 really answered the question, and by illustration, and  
12 we felt that the strengths and the limitations of the  
13 approach was really pretty well defined by the Agency  
14 in the White paper and we agreed that FD was more  
15 realistic than RS and TR and I think based on the  
16 examples it did seem that the TR approach, total  
17 residue approach, was most conservative but maybe less  
18 realistic.

19                                 And we also agreed that the data  
20 availability really does drive the choice and that's  
21 just the way it is and there was a question and one of  
22 the discussants brought up the point, well, why can't  
23 sufficient data always be obtained to allow the most  
24 realistic approach, and that's, you know, it's just a  
25 broad open question realizing that you don't get all





1 the data but you know, could more data be required in  
2 order to do that and we feel that that, the cost  
3 associated with obtaining the data that would allow the  
4 most realistic scenario is worth the cost and maybe  
5 that is on a chemical to chemical basis.

6                   Okay, and I'm just going to try to go  
7 through these very quickly and then there's, I've got  
8 some discussion points that hopefully the panel can,  
9 the rest of the panel can chime in. This is the second  
10 question, how does this approach really reflect the  
11 current state of the science for both the parent and  
12 degradate?

13                   We felt in terms of the transport part  
14 of it, treating them either way was probably  
15 appropriate since low concentrations of compounds  
16 generally, and certainly there are some exceptions to  
17 that, behave independently in terms of their transport.  
18 There was a lack of information on the approach used  
19 to, at least we didn't...we weren't able to get that  
20 information from the White paper on the approach used  
21 to assess the toxicity slash, you know, biological  
22 impacts of the mixture of exposure and I think that's  
23 an interesting and appropriate area to look at is, how  
24 do these things interact as a mixture in both those?

25                   And then finally I don't know if that



1 last one got cut off, I've got it on my screen, it  
2 seems to show up fine.

3 Let me see here, response one, response  
4 two and down there there's a couple of bullets it just  
5 says the mixtures and then in order to do that there  
6 also needs to be consideration, and this was brought up  
7 a couple of times, in order to look at how similar the  
8 degradate is to the parent compound especially in terms  
9 of toxicity is getting back to that mode of action  
10 question.

11 And the process at least in my opinion  
12 and in general the members of our little group, maybe  
13 it isn't as transparent as it could be in other words,  
14 how do you determine how similar a degradate is to the  
15 parent and do you actually look at and based on the  
16 discussions I believe you do, it just was not apparent  
17 in the White paper, how do you determine mode of action  
18 and the difference between parent and degradate?

19 Okay, and then the third question is  
20 there and we can just read that and really our response  
21 is given the limitations sometimes associated with the  
22 availability of the data or at least checking the data,  
23 we were wondering if you've considered using some  
24 estimation tools like Cannonball which is a really  
25 interesting program and my understanding is since I was

1 on the epi suite review panel about a year ago is one  
2 that they are either in the process of strongly  
3 considering incorporating into the epi suite program  
4 and it predicts metabolic pathways, intermediates and  
5 half lives and again, it gives a range of  
6 probabilities, it also, I have some information there  
7 on the properties, of predicting the properties of  
8 those intermediates and so it may be a potential tool  
9 when data is lacking or at least in pre-screening some  
10 of these chemicals where you're waiting for data, you  
11 can start looking ahead of time, being proactive and  
12 looking at compounds that may actually be a problem or  
13 have problematic degradates.

14           Again, my understanding is that it is  
15 going to be combined eventually, at least most of it  
16 with epi suite, which is something that's available to  
17 everyone, and this one should also be. One of the  
18 discussants, I think it was Dan, mentioned that if  
19 metabolic data was not available from the traditional  
20 studies you might be able to use in vitro  
21 transformation assays that, you know, typically are  
22 conducted for the identification of persistent  
23 metabolites in human studies and I think as a group we  
24 felt fairly strongly that this whole idea of how things  
25 behave as a mixture is very important in an approach to



1 somehow incorporate that into the risk assessment is  
2 important.

3                   And then finally there's some just I  
4 guess broader discussion points that I just threw out  
5 there because I didn't know how to put them in a  
6 category and again, it looks fine on my screen, I  
7 apologize for the font choice. And I think this was  
8 discussed several times in different charge areas but  
9 the idea of being able to improve and evaluate the  
10 current approach just by using representative slash  
11 benchmark chemicals where considerable data exists is a  
12 useful exercise and we felt as a group that it was.  
13 The impact of parality or stereo-selective processes,  
14 important consideration in terms of toxicity and that  
15 wasn't directly alluded to, or it was alluded to but  
16 not directly addressed.

17                   I wasn't clear and this is my question,  
18 not necessarily one of the group, I noticed in the list  
19 of information that was required, there is information  
20 on the photochemical degradation products and I assume  
21 that those are taken through the whole process in terms  
22 of their fate. I didn't see anything on hydrolysis  
23 products. Are they also transferred through and I may  
24 have just missed that. Do you get information on  
25 specific hydrolysis products that are formed and follow



1 those then through the process?

2 **DR. HETRICK:** Yes, but normally, yes, we  
3 do.

4 **DR. DOUCETTE:** So my ignorance then or  
5 my misinterpretation. The other thing that was brought  
6 up briefly was the, you know and actually this has come  
7 up quite a bit in terms of pesticide formulations and  
8 its potential impact on the solubility and those sorts  
9 of things but being on several panels, several of us  
10 mentioned the fact that there's some  
11 micro-encapsulation or nano-particle distribution  
12 methods that are being discussed and how that might  
13 affect fate and transport and availability is something  
14 that may be coming down the road.

15 One of the themes that I have that kind  
16 of was recurrent through several of these was again the  
17 transparency, and there was a lot of discussion on  
18 assumptions and inputs associated with a lot of the  
19 models and I don't, based on the discussions that we  
20 heard from all the different staff members, I think  
21 there's a lot of discussion internally, but it didn't  
22 necessarily come across until everyone discussed it and  
23 it didn't seem to be clarified in the White paper and I  
24 think that would make things easier.

25 Estimated versus model versus measured



1 in range we had an example that one of the public  
2 members gave about the sensitivity of the input  
3 parameters, and I got the impression sometimes that  
4 measured values are nice, but if they didn't seem to  
5 fit a conceptual model then sometimes we used the model  
6 values and correct me if I'm wrong there but sometimes  
7 we flip back and forth between measured input and  
8 estimated input even though there might be measured  
9 values available.

10 For some reason we decided that the  
11 measured value was not necessarily reflective of what  
12 was going on, and I don't know that that's necessarily  
13 wrong but it you know, coming from a measurer I tend to  
14 prefer measured values and if the measured values  
15 deviate a lot then I think it's appropriate to look at  
16 ranges rather than, you know, selectively choosing one  
17 value or another.

18 Several brought up just the general  
19 concept of uncertainty which is really associated with  
20 the model output and the model input, and I think what  
21 we in general did a lot of times on our own was look at  
22 and tried to get a feel for sensitivity analysis, what  
23 properties or processes or inputs really drive the  
24 ultimate assessment and allow us to focus on those  
25 particular areas.



1 Do we look at a best case or a worst  
2 case of range, all those things were discussed, and  
3 it's more just topics and then I had mentioned, really  
4 hadn't discussed ionizable chemicals and how you  
5 actually deal with those in terms of pH and whether or  
6 not they're ionized or neutral and some of those I  
7 just, I admit I threw in on my own without discussing  
8 with the rest of the panel members, so those are  
9 discussion points.

10 **DR. HEERINGA:** Thank you very much, Dr.  
11 Doucette. I'd like to, I know that you had  
12 considerable input from associate discussants in  
13 formulating this, but I'd like to open it up now to the  
14 associate discussants. I'll just go through them in  
15 order, Dr. Gan, do you have additional comments that  
16 you'd like to add?

17 Dr. Donnelly.

18 **DR. DONNELLY:** I think that pretty well  
19 summarizes it. The only comment I have is...you know  
20 it is important to recognize that there are examples  
21 where the metabolizing degradation are both more  
22 soluble and more toxic than the parent compound. And I  
23 think the 3 methods that are available...the FD is  
24 probably the most accurate, but in a lot of situations,  
25 given the amount of data that can be available, almost





1 by default you end up using PR. I think that was  
2 pretty much covered in the discussion when we had that.

3 **DR. HEERINGA:** Danny? Tammo?

4 **DR. STEENHUIS:** This is not my  
5 speciality, but I do remember where Agent Orange, about  
6 chemical compounds which were much more toxic than the  
7 rest, and I think we should watch out for those.

8 **DR. HEERINGA:** That's reinforcing Dr.  
9 Donnelly's point. Other members of the panel who would  
10 like to weigh in on this particular question? Dr.  
11 Delorme.

12 **DR. DELORME:** As per usual, those of you  
13 that know me know I can't keep my mouth shut on these  
14 things. Just couple of points, and again, I come at  
15 this from a risk assessment perspective, not  
16 necessarily an expertise. I agree that the FD is  
17 probably the gold standard of what you want to take. I  
18 also want to mention that it's probably not only  
19 optimal to PPT's, you can use it for other chemicals as  
20 well.

21 I think you have to be careful, or we  
22 have to be careful, because obviously we do this kind  
23 of modeling too up in Canada, the same kinds of models.  
24 When you have differential transformation processes  
25 dominating in soil and water you could get formation of



1 different degradates in the soil or in the water. So  
2 when considering the TR's, the RS approach and  
3 subsequent modeling you've got to be careful.

4 If you have something that's primarily  
5 formed in water you shouldn't be putting that on the  
6 field, okay? You have to find a way of putting it just  
7 in the water. And we've actually run into a couple of  
8 cases where we've had to find a workaround. You have  
9 to be, you know, cognizant of that.

10 With respect to using the formation  
11 decline method, I agree with KT. It's going to be a  
12 challenge, especially when you get into the re-eval,  
13 where you may not have the database. And one thing you  
14 might want to do is compare results with a range of  
15 chemicals, get an idea of the variability of the  
16 uncertainty, so that when you are doing that you can  
17 characterize that. I think it's important to do.

18 But I think you probably have enough  
19 chemicals from recent stuff you can take a look across  
20 the race chem sheet and see what the implications are,  
21 see what kind of variability you've got, okay. So mine  
22 your data a little bit. The other thing is just a  
23 minor point. When using residue summation, you might  
24 want to consider a temporal offset when you are summing  
25 things up. So you can either do that in your



1 application files for PRZM EXAMs, or you can just  
2 offset it when you go do the additions.

3 **DR. HEERINGA:** Thank you very much. Yes,  
4 Dr. Norstrom.

5 **DR. NORSTROM:** I'm trying to compose a  
6 coherent statement here, I was going to read it. My  
7 suspicion is that usefulness of the GR method may be  
8 moot, because I suspect we don't often run into  
9 chemicals where the degradates have similar properties  
10 and toxicity to pesticides.

11 Most degradation has moved chemicals  
12 less to more polar compounds which can be eliminated or  
13 mineralized. This is especially true of PV compounds.  
14 Given that toxicity and mode of action are likely to  
15 change with functional group alteration, addativity  
16 can't be assumed in these cases anyway. That being  
17 said, if the properties, including toxic actions are  
18 the same that reasonably are supposed to additive, then  
19 the toxic equivalents approach could be taken.

20 Also if the degradates are not toxic, or  
21 if they have a very low bio-accumulation potential  
22 maybe they can just be ignored altogether. But I think  
23 I don't know, any idea what proportion of the  
24 pesticides you're dealing with actually have degradates  
25 that are very similar property to the starting



1 compound. I suspect pesticide 1, which I think I'd  
2 guess is probably an unusual case. Is that safe to  
3 say?

4 So I really honestly thing that it is  
5 almost a moot question. Most of the degradates are not  
6 going to be similar enough that you can actually use  
7 that approach, but maybe you can ignore them. I'm just  
8 guessing, that's just generic.

9 **DR. HEERINGA:** We'll certainly include  
10 your point of view in. Other comments from the panel  
11 in response to this particular question? Randy.

12 **DR. MADDALENA:** I was kind of hoping  
13 other people would talk so I would have a chance to  
14 formulate this a little more in my mind.

15 What I would like to see in this  
16 question is somewhat of a microcosm of what you are  
17 dealing with in the whole process. This is a choice  
18 between 3 different models, and varying from relatively  
19 simple to relatively complex. Easy to use, difficult  
20 to use, fairly easy to interpret, but not very relevant  
21 to the environment, sometimes hard to interpret, but  
22 you get my point.

23 And this process represents the bigger  
24 picture of what you are working to now, which is  
25 developing an overarching model on how to deal with OPS



1 or these PBTs. So what I would suggest is that you  
2 follow a pretty well developed pathway to do this, and  
3 counsel, the DBA counsel on regulatory, environmental  
4 models recently put a document through the Science  
5 Advisory Board that talks about this process in great  
6 detail.

7                   Transparency, sensitivity analysis,  
8 uncertainty analysis, things that showed up on Dr.  
9 Gobas's final slide, as far as how to use the model  
10 once you develop the model. So I would strongly  
11 recommend that that be looked at, and that would save a  
12 lot of words in our report on how to use, how to go  
13 about this process. From these small choices or focus  
14 choices on specific pathways to the whole process of  
15 building a model and putting in the applications.

16                   **DR. HEERINGA:** Thank you Randy. Other  
17 comments, with respect to charge question number 1?  
18 I'd like to turn to Dr. Grady to see if your team feels  
19 that this question has been addressed, or whether there  
20 are any clarifications or-

21                   **DR. HETRICK:** I have one clarification.  
22 You mentioned Cataball and the ability to estimate half  
23 life. We have Cataball, we've played with Cataball.  
24 One of the issues that we have with it is that it's  
25 really based on a...you have to have populate it with



1 the appropriate data to be able to make those  
2 estimations, that's number 1. Number 2 is that I  
3 wasn't aware of the fact that you could actually  
4 estimate half lives out of it. If I'm mistaken on that  
5 I would appreciate some clarification on that.

6 **DR. DOUCETTE:** A point of clarification.  
7 I guess in terms of half life, it's something  
8 we've...that was discussed that it was going to be  
9 added. I'm not sure it's actually there yet. Right  
10 now it's just looking at biological oxygen demand and  
11 that's it. But there may be a way to actually use that  
12 information to give relative half life I think, based  
13 on an aerobic scenario. So I should have made that  
14 more clear.

15 **DR. HETRICK:** I want to just make sure I  
16 was clear on that.

17 **DR. DOUCETTE:** I have a question for you.  
18 What do you feel about the utility of a tool like that  
19 in a regulatory setting?

20 **DR. HETRICK:** We actually work with  
21 Yuranis, the person who actually designed Cataball, and  
22 I did an analysis of Cataball on probably about 10  
23 different compounds and we looked at what we actually  
24 saw in the...what we found in the metabolism studies  
25 versus what Cataball predicted.



1 And really how you parameterize and set  
2 that model up really determines what metabolites you  
3 see. So you have to be careful with that, and you  
4 really have to understand the nuances of that model  
5 before you start just go down the path of just thinking  
6 it's going to predict all the degradation products that  
7 you could possibly form, that was our take home  
8 message.

9 I think it has a lot of promise, I think  
10 it's going to take a lot of work to get the data to  
11 build a reasonable database to be able to start to draw  
12 from. Right now it's using the Midi data - I think  
13 it's on sewage sludge - to make the predictions. We  
14 are trying to, we've been talking to Duluth, who is  
15 actually been working with Uvanus and I think in the  
16 future there is going to be an attempt to try to pull  
17 in metabolite maps from our aerobic soil metabolism  
18 data and feed it into the Cataball program.

19 **DR. DOUCETTE:** And that's an excellent  
20 point, because we talked about that in the  
21 International Qsar Foundation sponsored a review of  
22 Cataball, and that was the one thing that was  
23 mentioned. Yes, it uses that database, and that's  
24 interesting, but there is so much other data out there  
25 that we could use to incorporate into Cataball and add





1 those metabolic pathways, which would be great.

2 **DR. HEERINGA:** Any other items? Dr.  
3 Ruhman? Panel members, any last comments on this  
4 particular charge question? Again, we'll have a chance  
5 to revisit it at the end if there is anything that  
6 you...comes to mind as we proceed. Well at this point,  
7 Dr. Brady why don't we move on to charge question  
8 number 2.

9 **DR. BRADY:** Charge question number 2.  
10 Interpretation of aquatic degradation rates for  
11 persistent pesticides with high sediment absorption  
12 coefficients. Environmental fate of pesticides with  
13 high sediment coefficient, often influenced by  
14 dissipation processes rather than degradation  
15 processes. An aquatic metabolism study the absorption  
16 process can be a most important process in removing  
17 pesticides from the water column.

18 This removal process however is not  
19 considered that the degradation pathway, because the  
20 pesticide is simply transferred from the water column  
21 to the sediment. Therefor the total system half life  
22 of the pesticide in aquatic metabolism studies is used  
23 to represent the most accurate degradation rate in  
24 aquatic environments.

25 Considering the environment fate data



1 typically available to support pesticide registration  
2 decisions, please comment on the strengths and  
3 limitations of the Agency's approach of using total  
4 system half life for assessing pesticide persistence in  
5 aquatic metabolism studies.

6 **DR. HEERINGA:** Dr. Gan, our lead  
7 discussant on this question.

8 **DR. GAN:** Yeah, I have a few slides also.  
9 My slides are better I think.

10 **DR. HEERINGA:** We'll acknowledge that,  
11 without a doubt.

12 **DR. GAN:** Okay, my fellow discussants  
13 include Professor Willy Lick, Professor Bill Dorset,  
14 Professor Tammo Steenhuis, and Professor Louis  
15 Thibodeaux. And looking the question again, I think  
16 the keyword here is really total system half life.  
17 Coming from a University environment, it took me a  
18 while...trying to understand some of the problems that  
19 are being discussed here.

20 This is from the article I guess, I  
21 lifted from the PFD file I was given. I have seen a  
22 similar set up. I have used a similar set up. The key  
23 here is really, if you can click up one more time, you  
24 have a system basically that has a layer of sediment,  
25 which is covered with a layer of water, and we'll spike



1 the pesticide into the water to start your experiment.

2 And of course what happens, is at the  
3 beginning the pesticide will glume to the sediment, but  
4 you are taking samples from both water phase and  
5 sediment phase. And at the beginning the water phase  
6 contributions will be greatly influenced by that  
7 absorption process.

8 Again, you have seen this chart, the  
9 black line is the water phase completion/dissipation  
10 curve, and the red line is the pesticide concentration  
11 in sediment. And the green line is really the total  
12 system concentration. You add the sediment and water  
13 concentrations together and my understanding is you can  
14 potentially use the black curve to derive DG 50 or half  
15 life, apparently that's what's being done.

16 And of course, as I just mentioned, a  
17 couple of people mentioned, the first part was really  
18 inaccurate, because you have both processes going on,  
19 the face partitioning as well as degradation happening.  
20 I think mostly PBT chemicals, the partitioning will  
21 dominate for the first pure of time.

22 However, if you add these together, of  
23 course you get the green curve, and in my mind that  
24 really would reflect the half life, the whole system  
25 half life, next one, this slide really summarizes what



1 my understanding is, and maybe some of my fellow  
2 discussants understanding here, because we don't  
3 normally do this kind of work. Again, you know, try to  
4 understand this graphic.

5                   So the original OECD protocol calls for  
6 constitution measurement in both water and sediment  
7 phases, and as I say, the water phase concentrations  
8 are greatly influenced by partitioning during the  
9 initial stage. The complication is that without the  
10 non-proven conditions...immediately after pesticide  
11 addition, the fraction of the composition should depend  
12 on the Koc, but with PBT that should be pretty  
13 significant.

14                   The complication is that effect, in my  
15 mind of experimental design. Maybe we have inherited  
16 it from 20 years ago, right? And also, you can also  
17 quite misinterpretation of the data. You can also call  
18 a lack of purity in terms definition. I think one of  
19 the public commentators mentioned that, which I agree.

20                   And really this boils down to last  
21 conclusion, that is the fact that this partition should  
22 be excluded from calculating half life. That's what  
23 the proposed approach is, we tend to agree with that.  
24 So this is to reaffirm this approach.

25                   The proposed approach will effectively



1 eliminate any effect of absorption on the measured half  
2 life. This approach will look more closely at  
3 proximate, the true half life for the whole system of  
4 the PPB chemicals, because sediment is dominant. The  
5 whole system half life is a useful parameter for  
6 describing persistence in the whole system. And the  
7 proposed approach will better fit.

8                   Because otherwise you have this so  
9 called heart-stick-shape, and the first water fit is  
10 not good. So you have a better quality of half life  
11 than that, in my mind.

12                   And in my mind, compared to the current  
13 practice that poses the half life in a more  
14 conservative approach from water column exposures,  
15 because half life generated by this approach should  
16 increase significantly over the current data, most  
17 likely.

18                   Okay, my last slide is just a few  
19 suggestions on confidence, because many of these points  
20 you guys have already considered. For example the  
21 first one is whole system half life should not be used  
22 for describing systems before the equipment has  
23 established. I think that's a valid comment.

24                   The whole system half life should be  
25 used for describing the whole system persistence, but



1 really not for short term exposure through the water  
2 column. For example, right after the drift, I mean you  
3 do have this short period of time, that of non-premium.  
4 It is essential to introduce a mechanism based on  
5 conditioning to address the transient exposure scenario  
6 you have built.

7 I think that you guys mentioned that the  
8 current modeling practice has taken that into  
9 consideration. Has both phase petitioning and half  
10 life as the input parameters. And again, it's worth  
11 cautioning here, the best approach may be still to  
12 understand each individual process for information  
13 again from 1 study. For example, from the aquatic  
14 metabolism study, can be used for other scenarios.  
15 Well that's all I have, thank you.

16 **DR. HEERINGA:** Thank you very much, Dr.  
17 Gan. Let's go to the associate discussants to see if  
18 they would like to add comments, or thoughts. Dr.  
19 Lick, you're up.

20 **DR. LICK:** I'm very-

21 **DR. HEERINGA:** Your microphone.

22 **DR. LICK:** I've been looking at this  
23 experiment, and Im thinking of how I would possibly  
24 interpret the results, because you introduce the  
25 chemical into the water, somehow it defuses into



1 sediment and partitions into the sediment. For a very  
2 hydrophobic chemical, this is a very, very slow  
3 process.

4 And for very hydrophobic chemical, all  
5 chemicals would go into the sediment. And then, let's  
6 say there is very slow degradation, the slower in  
7 bottom sediments with a lot of water. You have this  
8 chemical sitting in the bottom for a very, very long  
9 time as slowly, by molecular diffusion, defusing into  
10 the overlying water, where it presumably degrades.

11 But this again is a very slow process,  
12 because you have to diffuse all of this chemical, a  
13 huge amount of chemical from the sediment into the  
14 overlying water. So the...I don't know what you would  
15 deduce from this. You can't...from that experiment  
16 alone, you can't get the degradation rate in the water.  
17 You can't get it in the sediment, and what you do get  
18 is very difficult to interpret.

19 **DR. HEERINGA:** Dr. Doucette.

20 **DR. DOUCETTE:** I tend to agree with  
21 Willy's assessment, but I also see the need for a  
22 standardized approach for generating the data to run  
23 the scenarios.

24 I did have a question in terms of...I  
25 don't remember, I quickly glanced through the procedure





1 on the choice of sediment in that particular study.

2 How is that determined, or how is that made, or what is  
3 the standard scenario?

4 **DR. GAN:** Coming from a river system, or  
5 a lake system? It's real, real water.

6 **DR. DOUCETTE:** And what characterization  
7 of the solid phase do you get, other than organic  
8 carbons? Do you get everything? And have you looked  
9 at - and this is really related to my broad question  
10 that crosses a couple of groups on KOC, and absorption,  
11 - have you gathered enough data for a variety of soil  
12 or sediment types to start looking at cases where  
13 the...you know you mentioned that you have the ability  
14 to use KD rather than KOC. Have you go to the point  
15 where you've actually got enough data that you can look  
16 at other parameters, other than KOC to understand  
17 absorption?

18 **DR. RUHMAN:** Yes, all the time we looked  
19 at the clay ponds with the KD, what's the relationship,  
20 and also organic matter content, and we looked at the  
21 PH also.

22 **DR. DOUCETTE:** And do you now have  
23 internal relationships that look at other sort of  
24 properties, you know, to estimate or extrapolate out  
25 when you are starting to look at this now, other than



1 KOC?

2 **DR. RUHMAN:** We have all the soil  
3 properties. It has to be the right texture, organic  
4 matter, PH, everything about the soil. So we relayed  
5 the KOC, I mean the KD absorb to this for a meter.

6 **DR. DOUCETTE:** I guess maybe I didn't  
7 explain that very well. Do you have any other internal  
8 quasars that look at something besides organic carbon  
9 to predict absorption? It sounds like you have the data  
10 available.

11 **DR. HETRICK:** A little clarification  
12 here, some additional information. When we get a batch  
13 equilibrium study that comes in, normally there's  
14 probably about 4 or 5 soils, maybe 6 soils that are,  
15 that range in both organic matter and texture. And  
16 what normally happens, is that as I said before, we did  
17 a correlation between the KD and the organic carbon to  
18 see if there was any relationship there. But also  
19 there is additional statistical...some regress...some  
20 fairly basic regression to see if there is any kind of  
21 relationships between PH, clay and in some case they  
22 even do some specific surface. Not very often. And  
23 absorption.

24 But those are done on a...you know  
25 they're not done on the same set of soils, and you know



1 you have all kinds of issues there, but the point is  
2 that for each compound that's generally...those  
3 relationships are looked for. So that's a possibility  
4 to use that information to make some better  
5 predictions.

6 **DR. DOUCETTE:** And the final  
7 clarification, the 6 soils or sediments that you use,  
8 or you get information on for absorption are not  
9 necessarily or probably are not the soil that you use  
10 in the biodegradation?

11 **DR. HETRICK:** Yes, as Dr. Ruhman said,  
12 normally the sediment that is selected for these  
13 aquatic metabolism studies are natural sentiments, and  
14 normally we don't see the batch equilibriums, those are  
15 generally not conducted on those.

16 **DR. RUHMAN:** But sometimes we get also a  
17 sediment KOC.

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

20 **DR. LICK:** I have one problem, that's the  
21 second part. I have another problem with this, and  
22 that is worrying about chemicals with different  
23 partition coefficients. The amount of sediment in the  
24 system will effect the results, and that effects  
25 absorption time.



1                   So there again I don't know how to  
2 interpret this. I have now a question though. Why do  
3 that experiment? Why not do the degradation in the  
4 water, and do the degradation in the sediment. Why mix  
5 them together? You get 2 experiments, you get 2  
6 results.

7                   **DR. RUHMAN:** I think what we are trying  
8 to imitate is an aquatic system in time. I agree with  
9 Dr. Chambers.

10                  **DR. HEERINGA:** James.

11                  **DR. HETRICK:** I agree with Dr. Ruhman's  
12 assessment. I think we have to remember that the  
13 guidelines for this study were designed in 1982. Not  
14 that science just started in 1982, but the point is I  
15 think we progressed for longer than that. And actually  
16 in all fairness, back when this first started that was  
17 probably appropriate. But because the exposure models  
18 really weren't at the point that they are today, and  
19 so, good point.

20                  **DR. LICK:** And for most partition  
21 coefficients that probably wasn't that bad a problem.  
22 But now when we get the high partition coefficients  
23 it's an enormous problem, and you're right, it's now  
24 2008.

25                  **DR. HEERINGA:** Let's move on to our next



1 associate discussant, Dr. Steenhuis.

2 **DR. STEENHUIS:** I can not add anything to  
3 that.

4 **DR. HEERINGA:** Satisfied with the  
5 previous comments? Dr. Thibodeaux?

6 **DR. THIBODEAUX :** I agree with all the  
7 previous discussants. In this methodology is the 7 to  
8 1 ratio kept constant?

9 **DR. HETRICK:** Yes.

10 **DR. THIBODEAUX:** Is that apparatus that  
11 was shown typically used it's a bubble apparatus?

12 **DR. HETRICK:** That's correct, it  
13 normally...for anaerobic systems it bubbles nitrogen,  
14 for aerobic systems they are bubbling oxygen into the  
15 system.

16 **DR. THIBODEAUX:** What about vaporization?  
17 Is that somehow-

18 **DR. HETRICK:** Generally they are trapping  
19 the volatile.

20 **DR. THIBODEAUX:** And how is this  
21 information is in the model for example?

22 **DR. HETRICK:** As I eluded to earlier when  
23 that question was asked, we take the total system half  
24 life for the aerobic aquatic metabolisms study, which  
25 is the aerobic study, and we take that total system



1 half life and use that for our water column degradation  
2 rate.

3 **DR. THIBODEAUX:** In EXAMS?

4 **DR. HETRICK:** In EXAMS, that's exactly  
5 right. For the sediment degradation rate, we use the  
6 anaerobic aquatic metabolism total system half life.  
7 And that is for EXAMS.

8 **DR. THIBODEAUX:** For EXAMS?

9 **DR. HETRICK:** Right.

10 **DR. THIBODEAUX:** Thank you.

11 **DR. HEERINGA:** Other members? Back to  
12 Dr. Gan.

13 **DR. GAN:** You just mentioned that this  
14 protocol was invented in 1982, and just for an  
15 outsider, if you want, if EPA wants to modify  
16 something, does that mean you have to start from  
17 scratch again to reevaluate all the chemicals or how is  
18 this for you to change or modify some protocols?

19 **DR. HETRICK:** My experience has been that  
20 it's difficult. We actually have a revised OECD  
21 guidelines that we've adopted. But really it still  
22 falls within the same framework as this study design.  
23 It doesn't separate the water phase from the sediment.  
24 It mixes it and puts it into a total system. So your  
25 point is well taken.



1                   **DR. HEERINGA:**     Contributions from any  
2 other member of the panel?   Okay, Peter, you're up.

3                   **DR. DELORME:**     Just a couple of points.  
4 Ultimately the problem here is that when you are  
5 calculating your EEC's and water or sediment you want  
6 to have something that's reasonably...that's  
7 reasonable, that reflects reality.   So if you are using  
8 a whole system half life that's driven by sediment  
9 processes, then that might not be reflected in your  
10 EEC's, correct?

11                  **DR. HETRICK:**     Well one could argue that.  
12 We're making the assumption here that we have  
13 essentially a stratified re-dox situation in that  
14 environment.   And normally if you look at the read-outs  
15 potential in these studies, the sediment is generally  
16 fairly reduced and the overlying water is more toxic,  
17 that's for sure.

18                  **DR. DELORME:**     I may be dating myself, but  
19 I seem to recall that there are protocols out there for  
20 water only, aerobic bio-transformation studies, so-

21                  **DR. HETRICK:**     No, I agree with you.

22                  **DR. DELORME:**     So one of the potential  
23 approaches that could be taken as to...is to get both  
24 studies.   But to get away from the problem with  
25 the...that dynamic at the beginning, to use a site





1 sediment for example, when you are trying to get at  
2 degradation of sediment. That way, I understand from  
3 talking to Dirk earlier, that EXAMS can put in separate  
4 degradation rates, and you already do that.

5                   So there are possible other things. That  
6 may be a longer term solution, but in the shorter term,  
7 if you do have a compound that goes to sediment, the  
8 reality is you may want to be focusing your risk  
9 assessment on sediment dwelling organisms as well. We  
10 need to make sure that you are picking the appropriate  
11 organisms. There are a few things to consider when you  
12 get into comparing toxicity.

13                   **DR. HEERINGA:**     Okay, Dr. Mehta.

14                   **DR. MEHTA:**     I was wondering what kind of  
15 sediment you used in the test.

16                   **DR. RUHMAN:**     From either river system or  
17 lake, and it's usually taken from an area where the  
18 pesticide is going to be used.

19                   **DR. MEHTA:**     There could be a wide range,  
20 even within a single river, and the permeability of  
21 sand, silt and shale is widely different. There are  
22 several orders of magnitude of karst that you...I was  
23 wondering if...how do you sample I guess you go to the  
24 nearest basin and sample it, or how do you do that?

25                   **DR. RUHMAN:**     I redesigned that myself, so



1 I sampled soils but there is no...there is no specific  
2 depth. You have to get a sample for the sediment, you  
3 have to get a sample for the water, then you have to  
4 characterize each. You get characterization of the  
5 sediment, that there is texture, clay, sand, silt, PH  
6 and organic matter. And sometimes there is oxygen,  
7 they also do that. So we get these data for those 2  
8 compartments.

9 **DR. HEERINGA:** Dr. Norstrom.

10 **DR. NORSTROM:** Just a brief comment. I  
11 know we've talked...somebody mentioned it earlier, the  
12 whole business about bound residues. Is the Panel, did  
13 they consider that at all? What the importance of long  
14 term...if you're going to model these things over 10  
15 years or something like that, you might have a portion  
16 of that residue that's locked up and not really  
17 bio-available.

18 **DR. HEERINGA:** Microphone, Dr. Lick.

19 **DR. LICK:** We are going to talk about  
20 that in question 3, which deals with a lot of these  
21 processes. And I think it makes more sense to do it  
22 all at once, if you don't mind.

23 **DR. HEERINGA:** Dr. Delorme.

24 **DR. DELORME:** I just had an additional  
25 point to make. With respect to doing a study with a



1 spiked sediment, if in the answer to question 3 we are  
2 going to, if you are going to start considering  
3 sediment dynamics, and actually brining in soil and  
4 have it go to the bottom, that might be a little bit  
5 more realistic as well. There are a couple of reasons  
6 why you might want to consider that.

7 **DR. HEERINGA:** Turn to Dr. Ruhman and Dr.  
8 Hetrick to see if you feel this particular charge  
9 question has been addressed? Or whether you have any  
10 clarifications that you would like to request?

11 **DR. HETRICK:** I'm fine.

12 **DR. HEERINGA:** Okay.

13 **DR. RUHMAN:** It's a very simple question.

14 **DR. HEERINGA:** A simple question, but the  
15 answer is a little bit difficult, that's the way it  
16 works. Okay, we are the point in the agenda where we  
17 should be at 6:00 p.m. and adjourning, but this is a  
18 floating agenda, and I would like to move on, if  
19 possible to charge question 3, but let me just first of  
20 all turn to Dr. Brady to make sure that since there is  
21 a published agenda, whether there is anyone on your  
22 team that is not here that should be here?

23 **DR. BRADY:** I think we're able to  
24 proceed, yes.

25 **DR. HEERINGA:** Okay, and just out of



1 courtesy, general public, is there anybody aware of  
2 somebody who is absolutely critical to hear this? They  
3 can obviously hear it or read it in the final report.  
4 Seeing nothing, I am prepared, and the panel agrees, to  
5 move ahead with charge question 3. Dr. Lick is the  
6 lead discussant, and he is ready to go. So why don't  
7 we plan to do that? Dr. Brady, if you would please  
8 read charge question number 3 into the record.

9 **DR. BRADY:** Charge question 3, sediment  
10 dynamics. As part of its baseline ecological risk  
11 assessment process OPP uses Environmental Fate and  
12 transport computer models to generate estimated  
13 environmental concentrations of a pesticide in surface  
14 water, pool water and sediment. The EEC's are  
15 generated using the EXAMS model parameterized to  
16 represent a static farm pond receiving pesticide mass  
17 in run off from a treated agricultural field simulated  
18 by PRZM.

19 It is assumed by OPP that EEC's  
20 generated from this scenario are conservative  
21 representations of expected pesticide concentrations,  
22 not only in this farm pond but also in small first and  
23 second order streams that receive run off containing  
24 pesticide residues from many fields. Currently, the  
25 OPP modeling approach accounts for movement of



1 pesticide mass between water column and benthic region,  
2 using a set of lumped parameters and a mass transfer  
3 co-efficient.

4                   These parameters are intended to  
5 implicitly account for pesticide mass transfer due to  
6 processes such as diffusion, settling, re-suspension  
7 and other processes that tend to make the sediment  
8 layer with the water column. The current OPP modeling  
9 approach does not include inflow of sediment to the  
10 water body, which could lead to burial of sediment  
11 containing pesticide in deposition.

12                   Please comment on the strengths and  
13 limitations of OPP's current approach for modeling  
14 pesticide transport between the water column and  
15 benthic region, which relies on the use of lumped  
16 parameters to represent multiple transport mechanisms  
17 to static ponds.

18                   In the context of screening level and  
19 refined assessment, please comment on the strengths and  
20 limitations of simulating pesticide burial by sediment  
21 in static ponds as a process that renders pesticide  
22 permanently unavailable for biologic interaction.  
23 Please comment on the strengths and limitations of  
24 models described in the white paper with respect to  
25 modeling pesticide transport via sediment dynamic.



1 Which processes associated with sediment based  
2 pesticide transport, PG, sediment enrichment, settling,  
3 re-suspension, burial, bio-purgation, poor water  
4 diffusion, scour, bank erosion would be most important  
5 to consider in static ponds. Which processes would be  
6 most important in flowing water systems?

7 **DR. HEERINGA:** Thank you very much, Dr  
8 Brady. This is obviously a multi-part question, and  
9 Dr. Lick is the lead discussant on this, and I think  
10 you have a presentation that you want to.

11 **DR. LICK:** Well I think as you can see  
12 from the question itself, it's a very broad question.  
13 And before we actually got into the... answering  
14 specific parts of the question, I thought it would be  
15 worthwhile to talk about some of these processes, which  
16 we have eluded to over the last 2 days but never really  
17 talked about.

18 And if I could have the first slide,  
19 this is the description of the pond by standard...oops,  
20 well, that's okay. The part that we want to emphasize  
21 is the sediment water interactions, and here it has the  
22 re-suspension deposition.

23 Then there is this other thing on the  
24 left which is aquius mixing, which includes all the  
25 processes that effect the sediment water interaction,



1 including molecular diffusion, bio-turbation, and  
2 ground water flow. Two most significant ones there are  
3 molecular diffusion and bio-turbation. Ground water  
4 may not be important at some times.

5           The other thing, besides talking about  
6 those processes intimate to all those processes is the  
7 question absorption. And it's been assumed throughout,  
8 in all our talks and with all water quality models that  
9 absorption is fast, and therefore that we can assume  
10 equilibrium absorption. I want to question that  
11 assumption.

12           The other thing on the right there you  
13 see this sediment bed layer, benthic later. This  
14 is...the thickness of this layer is absolutely crucial  
15 to these water quality models. Very simply, if we turn  
16 off all the input into a pond, and then ask how long  
17 does it take for a pond to come to some clean state,  
18 we're going to get chemicals coming out of the bottom  
19 sediment.

20           If I assume this bottom benthic layer is  
21 3 centimeters thick, I'm going to get one result. If I  
22 assume 6 centimeters I'm going to get twice that time,  
23 and if I assume 12 centimeters it's going to be 4 times  
24 that time. How the hell do you pick this number?  
25 That's a problem, and I've seen numbers anywhere from 3





1 up to 15 centimeters; that's a problem. Okay, next  
2 slide.

3 Just look at the bottom part. I  
4 apologize for these slides, this is a last minute thing  
5 and I threw together some stuff, and the staff was very  
6 willing to help me out and make, scan these things and  
7 put them in, but anyway. This is desorption of 3  
8 different chemicals, 2 PCB's and hexachlorobenzene. MCB  
9 is a monochlorobiphenyl. HPCB is a PCB with six  
10 chlorines.

11 The partition coefficient for MCB is  
12 1/10th of 1/3rd, for HCB is 10 to the fourth, HTCB is 5  
13 times 10 to the fourth. This is a percent...we first  
14 equilibrated these things by letting them absorb for a  
15 long periods of time, like months, and then we  
16 desorbed. The first thing you noticed, desorption is  
17 slow. Eighty percent desorption is, oh 5 to 10 days  
18 for MCB, more like 30 days for HCB, and something like  
19 150 days for HPCB. So these are slow processes. By  
20 slow, I mean by comparison with the transit time for  
21 particles.

22 In other words you take a particle and  
23 dump it into a pond, it will drop out in minutes to at  
24 most an hour or so. These are orders of magnitude  
25 longer than that time. So in that period of time the



1 chemical absorbed into the particle and just goes down  
2 to the bottom, and that's it.

3                   The other thing I'd like to comment on  
4 is there is no indication of a labile, and non-labile  
5 or a labile and irreversible fraction, and in fact  
6 we've done dozens of experiments like that, and in  
7 every case the amount of chemical that has been  
8 absorbed also desorbs.

9                   The process is reversible. All the  
10 chemical comes out if you wait long enough. I mean,  
11 this is a graduate student here. She waited a long  
12 time for this, but she, you know, she had 2 children,  
13 she had a job, so we quit after 200 days or so. But  
14 all the chemicals, except for that one, are absolutely  
15 reversible.

16                  Okay, next slide. The other thing that's  
17 important, and I think is the most important process in  
18 most situations is the re-suspension or erosion  
19 deposition process, especially the erosion process.  
20 That's highly variable, depending on the sediment. We  
21 can have coarse sediments, we can have fine grain  
22 sediments which are consolidated, or we can have fine  
23 grain sediments which are non-consolidated. These  
24 erosion rates depend on the particle size, the  
25 mineralogy, the organic content, temperature, gas.



1 No one th th inks about this, but in any  
2 sediment that people in this room are concerned about,  
3 you probably have a lot of organic matter, means you  
4 have a lot of gas. The sediments, not the person, just  
5 the sediments. So you have to worry about that. You  
6 can not predict the properties of these sediments with  
7 theoretical consideration, but you can measure them,  
8 and these are some measured results.

9 What you see here is a sediment which  
10 has fairly uniform properties with depth. Never the  
11 less, it does consolidate, so the density of the  
12 sediment increases with depth. Erosion rates change  
13 from whatever the number is there, down by 2 orders of  
14 magnitude here. This is a long plot, it's not trivial.  
15 There are huge changes in erosion rates.

16 Next slide. That was from a core in the  
17 Detroit River, this is another core in the Detroit  
18 River. This is a layered sediment, so again you have  
19 erosion rates changing enormously from one layer to  
20 another and within, you know, 1 or 2 centimeters. It  
21 depends on how fine that interface is, next.

22 Just the tope one here. I just wanted  
23 to show this one, because this is 1 out of 32 cores  
24 that we took from the Kalamazoo River. Erosion rates  
25 are on the left, but in the middle is the...oops, no,



1 no, yeah, that's okay. Right there is the density as a  
2 function of depth, and the density is fairly constant  
3 in this top layer and then it decreases fairly rapidly.  
4 Erosion rates are fairly constant in this top layer,  
5 and then they decrease very rapidly.

6 This is the layer about 8 to 10  
7 centimeters deep. This has nothing whatsoever to do  
8 with bio-turbation. There are no organisms in this  
9 core. What it is, is the fact that you have a huge  
10 storm in 1986, eroded a lot of sediment as the flood  
11 ended, the sediment dropped out and you've got this  
12 layer, 5 to 10 centimeters deep throughout the  
13 Kalamazoo River. This is fairly common.

14 While we're commenting on this, we have  
15 32 cores and as we went through we weren't really  
16 looking for organisms, but we look at these cores as we  
17 go along. There were only 2 cores out of the 32 that  
18 had any organisms in them. Of those 2 cores, only  
19 possibly 1 did we say that there bio-turbated layer  
20 there. In other words there was a little thickness  
21 change in the density in 1 or 2 centimeters near the  
22 surface.

23 Next, yeah, all the way down. Most  
24 people will ignore molecular diffusion, because it's  
25 presumably not important. But we decided to do



1 experiments on the molecular diffusion of various  
2 organic chemicals, and this is Hexachlorabenzine, but  
3 we used other chemicals, all with partition  
4 coefficients that went from 5 meters per kilogram all  
5 the way up to 5 times 10 to the fourth meters per  
6 kilogram. Of course the answer does depend on the  
7 partition coefficient.

8 But the interesting thing here is the  
9 experiment ran for 512 days, another good graduate  
10 student here. But the Hexachlorabenzine, that's  
11 millimeters, in other words the Hexachlorabenzine  
12 that's centimeters?

13 No, no, that's millimeters, in other  
14 words the chemical only defused a few millimeters in a  
15 year and a half. And that's what we found with all the  
16 organic chemicals. The higher the absorption  
17 coefficient, the closer the chemical is bound to the  
18 interface. As the partition coefficient went down,  
19 then it was able to defuse into the interior. And it's  
20 fairly clear what's happening.

21 You have huge partition coefficients, so  
22 the chemical defuses into the sediment, it gets  
23 immediately sucked up by the particles, or the organic  
24 carbon in the sediment. So it can defuse until some  
25 more chemicals come in. But there are huge amounts of

1 chemical on the sediment, as compared to what's in the  
2 water. This the amount of chemical on the sediment.

3 Can we have next? We couldn't measure  
4 what was in the water, but we could calculate what was  
5 in the water. By the way, the solid lines in the  
6 previous result were the modeling result. From using  
7 that model, we calculated what the chemical  
8 concentration in the water was.

9 And first of all, if there were  
10 equilibrium,  $C_{sub S}$  would be equal to  $KTCW$ . Obviously  
11 it isn't true. I mean we're off by almost an order of  
12 magnitude near the surface. And then this is the right  
13 scale here, it's centimeters, so it's millimeters where  
14 the chemical is absorbed. Next.

15 Okay, based on those results for, oh, a  
16 dozen chemicals, we developed a numerical model and  
17 this shows the flux or the mass transfer coefficient  
18 for these different chemicals. First, the top line is  
19 the partition coefficient of 10 to the 6th, then 10 to  
20 the 5th, 10 to the 4th, and so on. The units there are  
21 10 to the minus 6 centimeters per second. If we get it  
22 into the units of the white paper that's 10 to the  
23 minus 6, about a tenth of a centimeter per day.

24 So all these mass transfer coefficients  
25 run from about .1 centimeters per day, up to 1

1 centimeter per day. The white paper poses a transfer  
2 coefficient of .1, which is at the lower end here, so I  
3 think molecular diffusion is much larger than what is  
4 being used in the model.

5 And this is the lower limit, remember,  
6 anything else is going to raise the mass transfer. But  
7 molecular diffusion is always there, while the other  
8 processes may not be.

9 Okay, next, keep going. Okay, then we  
10 did some experiments with bioturbation to look at  
11 organisms, and how they distributed chemicals. And  
12 this is a problem where we had 3 different organisms,  
13 separate experiments. This is lumbriculus, which is a  
14 vertical feeder where we keep, feeds at that, passes  
15 the food up through the gut and deposits fecal pellets  
16 at the surface.

17 The others were more horizontal mixers,  
18 or just mixers in general. These are the chemicals at  
19 the surface, being transported down into the interior  
20 by a convection diffusion process. In other words, the  
21 passing of food through the gut and around is a  
22 convection process, but the organism also disturbs the  
23 sediment.

24 That's a mechanical diffusion process.  
25 Okay, so these are 90 day experiments, the solid lines



1 are the mathematical model, and everything else is the  
2 experimental results.

3                   Next. We took that model, - that's  
4 fine, - and we decided to run it, to see how these  
5 organisms would behave over a very long time. So the  
6 experimental results are the 90 day results on the  
7 left, and then we see results from 1, 3, 5 and 10  
8 years. Eventually you get something like a well mixed  
9 layer, which is what is universally assumed by my  
10 modelers. A well mixed layer of constant thickness.

11                   Well I don't know how to define that, I  
12 don't think it's well mixed, and it certainly isn't a  
13 constant thickness. Because that one year it may be a  
14 little less than 2 centimeters, and it keeps changing  
15 until 10 years is about 3 centimeters. So, I'm sorry?

16                   **DR. BRADY:** This one is centimeters, and  
17 not millimeters?

18                   **DR. LICK:** Yes, this one is centimeters.  
19 Bio-turbation of course has...I mean it will generally  
20 mix or transport sediment roughly comparable to the  
21 depths of the organisms themselves.

22                   The next slide is important, but you  
23 don't have it, so I'll tell you what it is. It's,  
24 based on this and the experiments, we calculated the  
25 flux. The flux of chemicals due to organisms is now up



1 to about 1 to 10 centimeters per day.

2 As compared to molecular diffusion,  
3 which is .1 to 1 centimeter per day. Now this is two  
4 of Fitz's, the vertical feeder, and at 10 to the 4th  
5 organisms per square meter.

6 Which is a fairly large density.  
7 Occasionally you'll find things up to several times,  
8 times ten to the fourth but more often than not in the  
9 Great Lakes, for instance, they'll tend to be between  
10 ten to the third, ten to the fourth. Sometimes in Lake  
11 Superior, it will be less than that and of course the  
12 flux decreases from that, so we're talking about  
13 organisms having mass transfer co-efficient usually  
14 between one to ten but certainly could be less than  
15 that and molecular diffusion between .1 and one.

16 I think that's all I have as far as  
17 description of the processes.

18 **DR. HEERINGA:** Thank you very much, Dr.  
19 Lick. Would you want to go on to actually take this  
20 and address the other question or shall we go to the  
21 associate discussant?

22 **DR. LICK:** I think it might be  
23 worthwhile if people had questions now.

24 **DR. HEERINGA:** Okay, well, let's,  
25 yeah...fair enough, that's, Dr. Parker and any others



1 on the material that Dr. Lick has presented, as  
2 background question three, any questions on....

3 **DR. BRADY:** Yes, I didn't understand the  
4 erosion rate coming from the sediment pores, how is  
5 that, so you're not talking about erosion rate coming  
6 off of an agricultural field.

7 **DR. LICK:** No, no.

8 **DR. BRADY:** Is it settling at the  
9 bottom?

10 **DR. LICK:** Bottom sediments. Okay, we  
11 have, I made, what we wanted to do was not only measure  
12 erosion rates of surficial sediments but because in big  
13 storms you can erode huge amounts of sediments, tens of  
14 centimeters quite often so we also wanted to know not  
15 only how fast sediments erode at the surface but after  
16 they're eroded how fast do they erode at ten, twenty,  
17 thirty, centimeters down.

18 **DR. BRADY:** So this is erosion from the  
19 bottom of a moving stream?

20 **DR. LICK:** Of a moving stream or near  
21 shore of a lake or something like that, so what we do  
22 is take coarse, put it into this plume and then erode  
23 the surface until we get down to a certain  
24 depth...well, we take measurements all the way along  
25 but we can go down to as much as a meter and measure



1 that.

2 **DR. BRADY:** Okay.

3 **DR. HEERINGA:** Additional questions, Dr.  
4 Parker, anyone else? Dr. Steenhuis.

5 **DR. STEENHUIS:** I understand the  
6 velocities, but your velocity is not for a mixed  
7 system, your velocity is I think for moving pollutants  
8 out throughout the whole.

9 **DR. LICK:** It's a mass transfer  
10 co-efficient. What it says is the rate at which mass  
11 is transferred is proportioned to the co-efficient  
12 times the difference in chemical concentration between  
13 two layers.

14 **DR. STEENHUIS:** That is actually, the  
15 concentration in the sediment is in the EXAM model is  
16 uniform over the top five centimeters, and what kind of  
17 concentration do you take?

18 **DR. LICK:** At the surface?

19 **DR. STEENHUIS:** You have not a mixed  
20 system, you have a system which has a gradient in it.

21 **DR. LICK:** Right, and these are, adds  
22 are from the experiment so we've normalized it with the  
23 concentration in the overlying water.

24 **DR. STEENHUIS:** What do you use for the  
25 concentration in the sediment?



1                   **DR. LICK:**       We don't. In other words,  
2 that's just the flux on the basis of the overlying  
3 water, that's why it decreases with time, because the  
4 flux does decrease with time, but we don't take into  
5 account, because I don't know how to define a chemical  
6 concentration in the benthic layer.

7                   **DR. STEENHUIS:**    I think we should talk  
8 after the meeting about it because I'm confused.

9                   **DR. LICK:**       Well, the problem this well  
10 mixed benthic layer really is something that was  
11 invented by modelers. It is not there, we have never  
12 observed a...well, except for the well mixed or mixed  
13 layer due to deposition, but otherwise we have never  
14 observed a well mixed layer, so I don't know how to  
15 define the well mixed layer, the thickness of the well  
16 mixed layer in the real world.

17                  **DR. STEENHUIS:**   Mathematically your  
18 problems can be just as well described as a mixed  
19 layer. It is a well defined mathematical problem I  
20 think. You can also calculate the diffusions of the top  
21 layer.

22                  **DR. LICK:**       I'm sorry, I didn't...

23                  **DR. STEENHUIS:**    I mean your, the problem  
24 you present without mixing can be described  
25 mathematically, too, just like you can describe a mixed



1 layer so you can just take, I mean as an alternative  
2 for this mixed layer you can also take your set of  
3 equations in order to predict the flux, too.

4 I mean you did not show the equation for  
5 calculating the fluxes, but there is a set of equations  
6 that you used to calculate the fluxes in the overlying  
7 layers which are different than the mixed layers.

8 **DR. LICK:** Oh, yeah.

9 **DR. STEENHUIS:** A set of equations, and  
10 simply what I'm trying to say is that your set of  
11 equations can be used to instead of this mixed layer  
12 and that gets you out of the problem of defining what  
13 the size of this mixed layer is.

14 **DR. LICK:** Yes, what we've used are  
15 continuum equations, we've described how chemicals are  
16 transported through the sediment column due to  
17 diffusion, convection modified by absorption. They are  
18 continuing, I mean they are differential equations  
19 rather than the mass transfer equations.

20 They, I mean at the very end of this  
21 talk what I would like to suggest is that we modify the  
22 EXAMS or similar water quality model by treating the  
23 sediment layer in several discrete levels and actually  
24 doing a one dimensional time dependent model which  
25 would treat each one of these processes independently



1 and that would give us a much better description of  
2 what's happening in this, in this, any system.

3 **DR. HEERINGA:** Dr. Lick, I think you've  
4 actually in your last comment moved on to actually  
5 responding to this question and I think if we could  
6 turn to that, I think you've made your first  
7 recommendation there.

8 **DR. LICK:** Well, okay, before we get  
9 there, I mean, there were several sub-questions here,  
10 the first one please comment on the strength and  
11 limitations and so on on the use of lumped parameters.  
12 I think we've sort of said something about the use of  
13 lumped parameters already.

14 The main thing there is each of these  
15 processes, erosion deposition, molecular diffusion, and  
16 bioturbation behave in a different way and therefore  
17 they have to be modeled in a different way and the  
18 reason you do that is that you can use a mass transfer  
19 co-efficient to, and calibrate it to your data, but if  
20 you're trying to actually predict something, the time  
21 dependence of the three different processes are  
22 different and they're different from what would be  
23 predicted by the mass transfer co-efficient.

24 So if I'm going forward in time, I can't  
25 really, I think it would be much better to deal with





1 each of these processes independently especially if  
2 you're looking at a variety of ponds where you may  
3 have organisms, you may not have organisms, you may  
4 have erosion, each one would act differently.

5           And the other thing was this parameter  
6 curve in, I think I sort of referred to that already  
7 but again, if you had very slow absorption, the  
8 chemical is going to stay with the particle, go from  
9 the surface, plot on the bottom, curve in as one,  
10 that's it. On the other hand, if I have low partition  
11 co-efficients, slow absorption, I mean fast absorption  
12 which goes along with low partition co-efficient, then  
13 all the chemical dissolves into the water, the  
14 particles goes down to the bottom but there's nothing  
15 on the particle any longer, and so in that case curve  
16 in is zero.

17           And you can make estimates of this, you  
18 don't have to assume 0.5 and that was the first  
19 sub-question so maybe there's questions at this point.

20           **DR. HEERINGA:**     Dr. Hetrick.

21           **DR. HETRICK:**     Getting back to your  
22 molecular diffusion co-efficients, that's going to be  
23 dependent on what compound you're talking about, right,  
24 so that's....

25           **DR. LICK:**        Yes, the partition



1 co-efficient.

2 **DR. HETRICK:** Well, the partition...

3 **DR. LICK:** Primarily on the partition  
4 co-efficient.

5 **DR. HETRICK:** Yeah, okay.

6 **DR. LICK:** It's primarily the partition  
7 co-efficient and I think secondarily depending on the  
8 diffusion co-efficient or the molecular weight of the  
9 chemical.

10 **DR. HETRICK:** Okay, okay.

11 **DR. LICK:** Because I say I think because  
12 it's so overwhelmingly on the basis of a partition  
13 co-efficient.

14 **DR. HETRICK:** Okay, I was just...

15 **DR. LICK:** The rest of it is almost  
16 noise.

17 **DR. HETRICK:** I was just wondering if  
18 it's really, it becomes an issue then of this could  
19 actually be a variable that needs to be dependent on  
20 the properties of the pesticide that are being  
21 considered and do you recommend that type of analysis,  
22 that type of approach?

23 **DR. LICK:** On the basis of what we know  
24 now, or on the basis of these experiments, the first  
25 approximation would be just the partition co-efficient,



1 period, and then you could, I mean we have a formula  
2 for the, I mean again we have a mathematic model which  
3 we have used without changing, without fiddling with  
4 the co-efficient, in other words just using that  
5 expression and we've used it for, I don't know, six or  
6 eight different organic chemicals and it sits, okay,  
7 and it takes into account the partition co-efficient  
8 and the change in the molecular diffusion co-efficient  
9 of that chemical.

10 **DR. PARKER:** Actually I have another  
11 question as well.

12 **DR. HEERINGA:** Sure, Dr. Parker.

13 **DR. PARKER:** Looking at our two meter  
14 depth static pond, would the partitioning books say we  
15 have a pyrethroid coming in with spray drift. Would you  
16 expect the partition co-efficient itself would put most  
17 of the chemical on the sediment somewhat  
18 instantaneously in a two meter pond or does that take  
19 some time?

20 **DR. LICK:** A two meter pond only takes,  
21 you know, you know, minutes or maybe an hour for the  
22 very finest particles to drift down to the bottom.  
23 Particles settle out fairly rapidly.

24 **DR. PARKER:** So the PR ben doesn't  
25 really serve any purpose if it's, if the high KOC is



1 doing that by itself?

2 **DR. LICK:** I'll just talk about the  
3 science.

4 **DR. PARKER:** Okay.

5 **DR. HEERINGA:** Dr. Lick, I wonder if we  
6 could get your views on the second bullet then, that is  
7 the burial.

8 **DR. LICK:** Oh, yes, this is the fun one.  
9 Please comment on the strength and limitations of  
10 simulating pesticide burial by sediment in static ponds  
11 as a process that renders pesticides permanently  
12 unavailable for biological interaction.

13 I think it's fairly clear from all of  
14 the discussions that we've had that burial is  
15 absolutely essential if you, within the water quality  
16 model if you don't have burial, the chemical keeps  
17 concentrating in that layer and you get erroneous  
18 results. I mean think of a simple system where I have  
19 a sediment layer and I put in a pesticide with the  
20 runoff, mass particle runoff, that has a certain  
21 chemical concentration as it deposits on the bottom.

22 Later I have another storm and that  
23 layer, puts down another layer of the same  
24 concentration. The chemical concentration doesn't  
25 increase by all these processes, it stays the same



1 because the amount of pesticide increases at the same  
2 rate as the thickness of this layer. On the other  
3 hand, if I forced a constant layer of sediment, the  
4 water quality model wouldn't tell me that the pesticide  
5 concentration is increasing here, which is just not  
6 true and I think that showed up in a lot of the water  
7 quality models that have already been shown.

8                   The other thing where it might come in  
9 is you have to, as far as fluxes are concerned, you  
10 have to compare the rate of deposition with the rate at  
11 which all these other processes behave. In other words  
12 you have deposition about let's say one centimeter per  
13 year or maybe a couple centimeters per year. Now that  
14 amount of deposition is certainly comparable to  
15 anything that molecular diffusion or bioturbation can  
16 have so that would dominate the whole flux process, and  
17 so again you have to consider this not only as far as  
18 burial is concerned but as far as the flux processes.

19                   **DR. HEERINGA:**       So on this third point  
20 that asks about these processes and their impact in  
21 static ponds and then separately in flowing water, your  
22 view would be that the sedimentation burial process  
23 dominates some of these other processes in terms of the  
24 modeling impacts?

25                   **DR. LICK:**       Well, what our experience,



1 I'm aware of a lot of the work that goes on in the  
2 Passaic and some of these other large rivers which are  
3 heavily contaminated with PCBs in the sediments, I  
4 mean, don't worry about stuff coming in, it's the PCBs  
5 in the bottom sediments that are important. If you  
6 look and estimate all the processes that might be  
7 important, you figure out that if you really wanted a  
8 first approximation all you would care about is  
9 absorption rate and erosion deposition, period.

10 You wouldn't worry about volatilization,  
11 bioturbation, molecular diffusion, all of that is  
12 irrelevant. I would get a really good answer if I just  
13 knew erosion deposition absorption.

14 **DR. HEERINGA:** You feel that would apply  
15 both in static and flowing systems in the Detroit River  
16 or Trenton Channel that's moving right along.

17 **DR. LICK:** Well, the river, yeah, the  
18 Trenton Channel, the Passaic River is there, you know,  
19 they move. No, a pond would be different, but you would  
20 still have the deposition problem, you might not have  
21 the erosion problem.

22 **DR. HEERINGA:** Right. Okay. What I'd  
23 like to do is I'd like to give the associate  
24 discussants a chance to weigh in here and the first  
25 associate discussant is Dr. Mehta.



1                   **DR. MEHTA:**       And what I'm going to do is  
2 go through these three comments and one of the, there  
3 are two parts to the transport problem. One is forcing  
4 and one is response and the models at present and the  
5 one that was presented by Arnot and Gobas, they look at  
6 the response but in fact we know that when you have, if  
7 you have a static pond as Dr. Lick said, you wouldn't  
8 have any resuspension, so if you are dealing with  
9 resuspension in a static pond then it is not a static  
10 pond.

11                   Am I right or how would you get  
12 resuspension if it's a static pond, you would just  
13 think you'd have deposition.

14                   **DR. BRADY:**       Well, you wouldn't have  
15 dep... you wouldn't have resuspension through flow,  
16 we've considered that you might have some bioturbation  
17 that would continuously cause some mixing of the  
18 chemical with the benthic layer.

19                   **DR. MEHTA:**       But the erosion deposition  
20 function that having put up have to do with some soil  
21 factor on the bottom and you know I've never seen a  
22 pond that doesn't have it, it always does and you also  
23 have wind, so wind dries the surface water as you all  
24 know, but it introduces vorticity so as a result of  
25 that you have a stress on the water and when you have





1 even the slightest amount of wind driven net current,  
2 it actually completely modulates the effect of the  
3 waves below.

4                   So it surprises me that, you know, we  
5 would consider even distant stress level models that  
6 don't include some causative factors of resuspension  
7 other than bioturbation.

8                   **DR. LICK:**     Well, let me...I look at farm  
9 ponds. What is quite often the case is that you have  
10 shallow, in very shallow areas and banks and your waves  
11 can erode sediments in these shallow areas and you get  
12 muddy water in there which diffuses out into the  
13 interior. And occasionally some bank erosion, but  
14 that's relatively small.

15                  **DR. MEHTA:**     Which one, the bank erosion  
16 ?

17                  **DR. LICK:**     Yeah.

18                  **DR. MEHTA:**     So the other thing is that  
19 on the response side, you know, that was why I asked  
20 the question about what kind of sediment is being used  
21 to test the absorption and you know, there is sand that  
22 is silt and that is clear, as Dr. Lick said, and they  
23 are quite different as we know. Sand has a high  
24 permeability and there is poor water motion or there  
25 can be. In silt less so and in clays it fluctuates.



1                   There is very little poor water motion  
2 because of permeability of ten to the power minus nine  
3 and so on so any model that simply creates, calls  
4 sediment sediment, you know, I don't see the meaning of  
5 doing any particular kind of transport simulation  
6 because I think that the result would be totally  
7 spurious in that sense.

8                   Now there are one V models available.  
9 Dr. Lick mentioned one V vertical model that had been  
10 used for the screen testing and I was a little bit  
11 surprised that they're not being used here at EPA even  
12 at level next to the one that was presented like EXAM  
13 and so on because I think even the no and robust model  
14 is deficient in terms of forcing and in terms of what  
15 is resuspense?

16                  For example, as he said resuspension  
17 rates can vary over five or six orders of magnitude,  
18 but there are reasons for it. There can be a density  
19 effect or organic sediment or all kinds of other  
20 things. There can be gas in the sediment.

21                  Similarly, the settling rate velocity  
22 can vary over five orders of magnitude because it can  
23 have cloth or you can have individual particles or if  
24 you have sub-micron particles then they simply don't  
25 settle basically. They stay in suspension. So the



1 other comment I had was that when I look at the high  
2 end model as it is called, if you look at the  
3 presentation, all the relationships mentioned there are  
4 from the 1980s and early 1990s.

5 Now in the last ten years a substantial  
6 additional amount of work has been done in improving  
7 all of those relationships with the effect of an  
8 interaction between the turbulence or the boundary  
9 effect and settling boundary and erosion and so on and  
10 so forth.

11 So I think that even the high end model  
12 is, it requires a substantial upgrading and finally I  
13 think that just a couple of comments I had is that the  
14 way burial was presented was in the following way.

15 That if you have a pulse of contaminant  
16 going into water and then you have no pulse beyond  
17 that, then burial does have an effect because you reduce  
18 the concentration, but of course if you have and that  
19 was, for example, what happened in San Francisco Bay  
20 has a lot of contaminations from the ships and oil and  
21 petrol chemicals but the sediment that arrives, clean  
22 sediment from the Sacramento, San Joaquin delta, there  
23 is a sediment and surprisingly the rate at which the  
24 sediment has been coming in that way is also the rate  
25 at which sea level is rising so the depths of water



1 have remained more or less the same but you have this  
2 burial effect which causes sediment to get buried.

3 But on the other hand, burial doesn't  
4 mean that the sediment will be buried forever, you  
5 could have a big hundred year or a thousand year storm  
6 and it could get resuspended. One example is the  
7 burial of DDT by Los Verdes as a result of the outfall  
8 and then they started, they reduced the amount of clean  
9 sediment in the outfall and there was erosion and the  
10 DDT started coming up.

11 So that is an example where burial has  
12 to be tracked, and burial is not just a static  
13 phenomenon where you can think of it as something  
14 that's disappearing from the water column because there  
15 are decisive biological effects that are consolidation  
16 effects.

17 So one has to track the density and the  
18 strength of the soil with time and for example, if a  
19 soil stays somewhere for a very long time, it would  
20 harden to a point where it doesn't resuspend it to.  
21 The effect of waves has really not been treated even in  
22 the high end model.

23 And next month there is an EDU chaplain  
24 meeting that will be dealing with really very high  
25 level modeling of waves and sediments and that is not

1 to say that all of that needs to go into testing  
2 procedures at this point in time but I was a little bit  
3 surprised by the fact that water waves are not  
4 considered and in a static pond with waves, if you go  
5 into a static pond, you'll find that as a result of  
6 wave action there's always a fluff layer at the bottom  
7 and that being the case, sometimes the flux of  
8 constituents from the sediment into the water column  
9 increases quite a bit more than molecular diffusion  
10 because of heating of this material.

11 And it turns out that that flux can be  
12 related to a dimensionless equation to the wave height  
13 and so on and so forth, but I think that when, for  
14 doubling, you look at subvariant going to Florida Bay,  
15 and we do have, this is the bay, and this static pond  
16 idea simply does not cover all that situation.

17 And finally I'd like to say that in  
18 this, in the modeling of sediment transport, the United  
19 States is far behind some of our colleagues in Europe.  
20 One of two other countries that have very advanced  
21 modeling is especially Holland and Denmark and you find  
22 that while Government agencies in the U.S. use some of  
23 their own models, most of the consultants actually do  
24 not, they use a mic 3 and mic 21 in doing another  
25 model.



1                   And I think the reason for that is that  
2 these models have not seriously been looked at in terms  
3 of upgrading their technology, the technology we use in  
4 this model is fairly old. We can see that not only from  
5 the citations that were given, but also the proteins  
6 that are being used right here in EPA. So I think that  
7 those are my comments so far.

8                   **DR. HEERINGA:**       Thank you very much, Dr.  
9 Mehta. I'd like to go on to the other associate  
10 discussants. What I may do is go through the associate  
11 discussants this afternoon and then adjourn for the day  
12 and maybe we'll pick up some final discussion on this  
13 tomorrow morning before we begin charge question four,  
14 but right now Dr. Steenhuis is our next associate  
15 discussant. Your mike, would you pull it really close  
16 to you, too, Tammo, we've got this huge fan that's  
17 running here and I've got a little white noise problem.

18                   **DR. STEENHUIS:**       And I have an accent,  
19 too. In order to try to better understand what was  
20 going on with sedimentation rate, I tried to simulate  
21 it, and I would like to show that and I have some  
22 interesting aspects.

23 **(WHEREUPON,**       there was a pause in the proceedings.)

24                   I have my, I call it the modern EXAM  
25 slide because it doesn't have all the processes. The



1 next one.

2 And although after Dr. Lick I would have  
3 changed my model significantly, this other model is in  
4 instant equilibrium. Instead of all the processes on  
5 top I added the same amount and that gets, the  
6 advantage of that is you can exactly see what happens  
7 to the sedimentation rate and instead of a mass rate, I  
8 assumed actually between the water phase and I only  
9 assume degradation in the benthic, lake benthic area.  
10 Next slide.

11 It is more or less the same font model,  
12 it's the same effects. I assumed the ten hector pew,  
13 the one hector font, out of that two meters, five  
14 centimeters benthic zone is the same as the EXAMS model  
15 and initially I said the half life of a thousand days  
16 of sediment which is somewhat equal to pesticide four  
17 but there are partition coefficients of hundred  
18 kilograms per liter, really doesn't have an effect but  
19 absorption partition coefficient case and the  
20 concentration changes by number but the effects are the  
21 same and I have some sedimentation rate of zero, 0.6  
22 and 1.2 centimeter per year and applied monthly and two  
23 applications per year of 100 grams. Next one.

24 And like you see over here is the  
25 sediment concentrations for different application





1 rates, the depth below the pond so that from zero to  
2 five centimeters that is the mixing or the benthic zone  
3 and in EXAM it is completely mixed so we see the same  
4 concentration and by adding sediment, the pesticide  
5 will be pushed down, so the blue line is after ten  
6 years of simulation and you see the sediment to 16  
7 centimeters depth. And for 0.6 centimeters after ten  
8 years it is approximately of ten centimeters depth and,  
9 but there's no sediment concentration, you see that the  
10 sediment stays in the top five centimeters.

11 If you integrate another curve, if you  
12 see how much area is below the curve, you see that  
13 there's much more pesticide in the layer for the, where  
14 there is sediment concentration, where there is the  
15 highest rate of sedimentation. The lowest amount of  
16 sediment, the lowest amount of pesticide in the  
17 sediment is no sedimentation.

18 If you look to the bar, the next slide,  
19 the concentration of the water of course is opposite  
20 the highest sedimentation rate. The blue line has the  
21 lowest concentration in the sediment and the no  
22 sediment has the highest concentration water and is  
23 exactly consistent to what you saw before.

24 And on the conclusion based on this is  
25 the next one, is that increasing sediment concentration



1 rate indeed gets lower concentration in the water. All  
2 these models are completely consistent about that.

3                   What he didn't...what is different or  
4 what I did not, what I didn't understand yesterday, but  
5 after modeling, the higher the sediment rate, the more  
6 pesticide are in the total body of water and that has  
7 an effect on if it is being remobilized. It's sediment,  
8 when it's on the bottom, it's not out of mind out of  
9 sight, it was kept mixed up like anything, a cow in the  
10 stream. What we see in New York, all kinds of cows in  
11 this thing, they will mix it up, people in the stream  
12 but also getting the flow system is still available.

13                   Next one. Actually this was done out of  
14 pure, pure interest because before with previous  
15 sediment, with previous panels you didn't have any of  
16 the actions against that the sediment was not included.  
17 And the previous panel quite concerned about pesticide  
18 within a very short degradation life so I did the same  
19 analysis for a pesticide with a half life of thirty  
20 days, which one, which is aldecarb or something like  
21 that. You're talking partition coefficient would be  
22 lower, but it really doesn't affect and again  
23 sedimentation rate of zero centimeters up through 1.2  
24 centimeters.

25                   And the next slide we see the



1 concentration in the water and the rest is for, it's  
2 for 1.2 centimeters per year and the other  
3 concentration was exactly the same is for zero  
4 centimeters per year and if you, and the next one is  
5 the same slide for high application rate, with a  
6 thousand days you see a big difference.

7                   Next. So essentially if you had, if what  
8 was done before the approach of a static pond without  
9 concealing the sediment concentration mixing layer  
10 absolutely completely okay, but if you want to simulate  
11 pesticide with high index with lower degradation rate,  
12 you need to have a different modeling approach as the  
13 one before.

14                   Next one, this is essentially to show  
15 the effect of half life of concentration of water and  
16 concentration of sediment, so I assume the  
17 sedimentation of 1.2 centimeters per year and then  
18 essentially we see what happens if you change the  
19 concentration of the half life. Next one.

20                   This is the concentration in the water  
21 and of course the lower, the higher, the red one is  
22 2000 day half life and you find the higher  
23 concentration, which is completely logical, but why you  
24 find the concentration in the bottom of the sediment  
25 and not in the top of these two but there are really



1 sedimentation increases total amount of pesticides in  
2 the soil, anyway you look at it. That is, contaminated  
3 sediment. If you have clean sediment like you were  
4 talking before then it is the opposite effect, but it  
5 is adding dirty sediment and pesticide and the  
6 concentration of the water is the next one.

7           The pesticide concentration of course is  
8 the highest, that is the red line, for the lowest, for  
9 the highest half life which makes completely sense, and  
10 also the interesting thing is they all got to  
11 equilibrium and the same amount disappear each year in  
12 each half year independent of the half life in the  
13 sense that that is the way it works out. I mean, in  
14 equilibrium we have to remove the same amount as you  
15 add, so that is correct what you see over here. The  
16 squiggles are left in the beginning and the squiggles  
17 at the end are exactly the same.

18           Next one, despite a concentration of  
19 water, greater half life, greater concentration of all  
20 the sediments, the amount of sediment added has no  
21 effect in pesticide concentration of water for non  
22 pest, persistent pesticides but I would like to add to  
23 by changing the mass flux rate I can actually get a  
24 completely different answer if I mean I didn't have  
25 time before that because we do it right now what I



1 would have done is tonight after this panel, is  
2 changing the assumptions about the mass flux rate and  
3 the depth of the mass flux rate, and I can get  
4 different results.

5                   So the point is that it's the  
6 assumptions about mass flux and the depth of the layer,  
7 depth of the benthic layer, it can affect. I mean,  
8 although I didn't do it and we saw that before too and  
9 in extremely sensitive parameter and we need to know  
10 the, we need to know the parameters in order to  
11 simulate this realistically.

12                   **DR. HEERINGA:**       Thank you, Dr. Steenhuis.  
13 I'd like to ask Dr. Thibodeaux to weigh in on this  
14 question.

15                   **DR. THIBODEAUX:**    Yes, turning to the  
16 first question, the strengths and limitations of OPP's  
17 current approach. I think you alluded to it indirectly  
18 when you, and here I'm talking about prism's coupled to  
19 exams, that we're on our way to a different methodology  
20 when you invited Dr. Mackay to present parko and I  
21 think that is a step in the right direction. The  
22 transport of pesticides between a water column and as  
23 Dr. Lick has pointed out so nicely, is a very  
24 complicated process. It changes with time, it changes  
25 with layers of the sediment.



1                   He and I are very aware of the high end  
2 models that are currently being used to assist this  
3 assigned release of PCB releases from the northern  
4 rivers. Those high-end models have a lot to say and we  
5 have learned a lot over the last ten years about this.  
6 It's very clear from the model that Dr. Mackay has  
7 begun to come off of that one month parameter that's  
8 trying to represent all of these mechanisms. And of  
9 course, that's a very good first step.

10                  You have to realize, since the exam was  
11 created, which was several years back, and it has been  
12 modified, with it's time for a vision, I think the  
13 article moves in the right direction. It should be an  
14 option of the operator to select processes that more  
15 nearly fit the receiving strength. I would recommend  
16 the pond be replaced by three options. The pond being  
17 one, but another being the flowing stream and possible  
18 a third which was an estuary. It seems to me if we use  
19 the model as an option for screening of other models,  
20 depending on the locale of the pesticide use and where  
21 it may end up, then that might be an important first  
22 step.

23                  Dr. Lick was correct in the vertical, I  
24 think that layers should be created, there should be a,  
25 I don't like to use the word completely mixed, because



1 I agree with Dr. Lick, I don't think there's a  
2 completely mixed layer. There is enhanced mixing in  
3 the surface layer in the top, say roughly 10  
4 centimeters, but as you go down, the process changes.  
5 That mixing occurs for a lot of reasons. Bio-turbation  
6 being one.

7                   So I think that's one thing that the  
8 structure of the model and the transport processes  
9 would be a good first step and we've learned this from  
10 these more advanced models and I think it's time to  
11 start. And I think ARGO is a big first step in  
12 bringing this into the system. Of course, we want to  
13 retain the ability to look at transit conditions. I  
14 think that has been very clear through this  
15 presentation that steady state is sort of passe and we  
16 really need to look at the variations with time. The  
17 application and the response. So that pretty well  
18 covers my first point, chairman.

19                   The next thing, the context of screening  
20 level and refined assessment. Please comment on the  
21 screening question#2 with simulated pesticide in  
22 varial and static ponds and processes that move the  
23 pesticide permanently, if you look at the overall fate  
24 balance and neglect the varial process, then there's  
25 something wrong with your model. In the case of ponds,





1 and again that's why I think we need 3 different  
2 possibly similar scenarios. Ponds, streams and marine  
3 estuaries. Very clearly, we would not have a  
4 contaminated sediment problem that's been brewing for  
5 the last half-century in the United States,  
6 particularly with PCB's in the Northern rivers, if it  
7 were not for varial.

8                   So varial is a process that has to be in  
9 the model. Particularly in some of those models that  
10 we know where deposition overrides resuspension. So  
11 there's no doubt it. You'd have to consider that part.  
12 So I guess my answer for that one is back to my  
13 recommendation for #1 is. On question #3, I guess the  
14 answer is yes. Which process is, of course all of  
15 these, sediment enrichment, sediment resuspension,  
16 varial, bio-turbation, -- that's what the soil  
17 scientists called it.

18                   Polar diffusion, scour and bank erosion  
19 cannot be present in all aquatic systems. Bank  
20 erosion, for example, is something quite common in  
21 streams because of the meander. So I think user should  
22 be given the choice of some of these options as well.  
23 So what I'm saying, for uses for screening at this  
24 level, I think it's time to make changes and I think  
25 from what we've learned in the last 10 or 20 years on



1 sediments, should allow you to start to develop  
2 compartment models, I think would be the right word.  
3 And that's what ARGO is.

4 Realizing that number is in your cases  
5 with site specific studies, in which we're looking at a  
6 generic type of application. I think even those can  
7 retain a lot of the realism that Dr. Lick talked about.  
8 And also the sediment transport. Can we put anything  
9 in a more realistic fashion than it is now? That's my  
10 comments, Mr. Chairman.

11 **DR. HEERINGA:** Thank you very much Dr.  
12 Thibodeaux. At this point, what I'd like to do today,  
13 is to, Will Doucette is the last associate discussant  
14 on this question and I'd like to give him a chance to  
15 give his comments and then I think I'll wrap up for the  
16 day. I know that Staci has one thing she wants to  
17 introduce. We'll do that before the end of the  
18 meeting. But Will, if you want to do your comments?

19 **DR. DOUCETTE:** It's easy going last,  
20 there's not much left, especially at this point in the  
21 day. I agree with the previous discussion of best not  
22 to use lump parameters because they vary both with site  
23 and chemical properties. I also agree with the  
24 absolute need to consider varial, so I really don't  
25 have anything more to add other than reiterating the



1 importance of what's been said.

2 **DR. HEERINGA:** What I'd like to do to  
3 make sure that those who have to travel locally can  
4 make their commuting connections and so on, I'd like to  
5 adjourn for today and we'll pick up again tomorrow  
6 morning and we need just a charge or request of the  
7 discussants on this.

8 Thinking about this whole issue about  
9 first priorities and longer term, I very much, the  
10 discussion that we heard is very valuable and there's  
11 been a lot of contribution here, but maybe when we  
12 return tomorrow morning, give this some thought, if you  
13 have a set of priorities, not only on the compartments,  
14 but on the mechanisms, how would you prioritize them  
15 out or develop them? And I think that would be  
16 valuable.

17 We'll give everyone on the panel a  
18 chance to comment on charge question# 3 tomorrow  
19 morning too. Staci. Dr. Simonich?

20 **DR. SIMONICH:** This is with regard to  
21 the discussion we had earlier today regarding the long  
22 range transport potential of pentachloronitrobenzene  
23 and I just realized this over the last few hours. But  
24 I wanted to call to Dr. Cohen and EPA's attention the  
25 recent publication by Trevor Brown and Frank Wania,



1 it's Environmental Science & Technology 2008, issue 42,  
2 pages 5202 through 5209, screening chemicals for the  
3 potential to be persistent organic pollutants, a case  
4 study of arctic contaminants.

5 Are you aware of that? Okay. So I  
6 would point out that in this publication that Dr. Wania  
7 used global pop to estimate the elevated arctic  
8 contamination and bio-accumulation potentials of over  
9 100,000 distinct industrial chemicals. And 120 of  
10 those 100,000 chemicals were determined to have an  
11 elevated arctic contamination and bio-accumulation  
12 potential. And in that list is pentachloronitrobenzene  
13 and also in that list is --DDT.

14 So I would like to point that out, that  
15 Dr. Wania's use of global top suggests an elevated  
16 arctic contamination and bio-accumulation potential for  
17 pentachloronitrobenzene. I'd also like to point out to  
18 EPA that in this list includes other registered current  
19 use pesticides that might be of interest.

20 **DR. HEERINGA:** Thank you very much, Dr.  
21 Simonich. Dr. Lick?

22 **DR. LICK:** If I could have one minute.

23 **DR. HEERINGA:** You certainly can have one  
24 minute, use your microphone.

25 **DR. LICK:** I'd like to make two proposals



1 to the panel and to EPA. One is to develop a  
2 one-dimensional, time dependent model of these  
3 processes. One with your idea of what's important,  
4 what's not important. The second thing is, how the  
5 hell are we going to verify this? Suppose we do some  
6 field studies with ponds, different types throughout  
7 the country which have different characteristics.

8 **DR. HEERINGA:** I appreciate you bringing  
9 up the Kalamazoo River, I grew up in Kalamazoo, you  
10 brought me home.

11 Dr. Parker?

12 **DR. PARKER:** If I could throw out a  
13 couple more issues for the panel to think about, if we  
14 could muddy the waters a little bit if that's  
15 appropriate. I might also ask that the discussants  
16 think about tiering, in terms of a simple system that  
17 can be run quickly and easily and efficiently that  
18 gives us some bang for our buck without going with  
19 something entirely complex.

20 **DR. HEERINGA:** Well you've got another  
21 dimension. It's not only prioritization and the  
22 difficulty of development, but how it would fit into a  
23 tiered system of assessment. Dr. Bradbury?

24 **DR. BRADBURY:** If I can buy a minute.  
25 To follow up on Dr. Lick's concepts of how would you



1 evaluate whether or not the models were working and Dr.  
2 Mackay brought that up yesterday as well. I'm  
3 wondering if there isn't some semi-quantitative if not  
4 qualitative ways we might think about some pesticides  
5 of the past, psychodynes for example that we think had  
6 moved around past the site of application, be it long  
7 range transport through the air or maybe sediments  
8 moving around was our way to do a mental exercise of  
9 how this would all work.

10 If we put in dieldrin, even if we don't  
11 know what dieldren did, what would we conclude with the  
12 current models we have or what some of the iterations  
13 of the future may hold. Would they predict that aldrin  
14 is ending up in places that are far removed from where  
15 they were applied in cornfields in the midwest. Could  
16 it have been long range transport, could it have been  
17 movement of sediments to different basins or different  
18 rivers and systems.

19 It seems as if our constructs aren't  
20 sort of doing what we knew happened with those older  
21 pesticides, they'd give us some insights into what  
22 we're getting right and what we're getting wrong as we  
23 go forward. So one other way is to use old data to  
24 give us insights to know where we are and where we're  
25 heading.



1                   **DR. HEERINGA:**     Okay. I think we'll have  
2 a chance to revisit this all tomorrow morning, maybe a  
3 little refreshed. I'd like to turn then to Myrta  
4 Christian, the Designated Federal Official to see if  
5 she has any last minute announcements for today.

6                   **MRS. CHRISTIAN:**    No, we don't have any  
7 new announcements, but I do expect to see everyone  
8 tomorrow morning at 8:30.

9                   **DR. HEERINGA:**     Thank you very much  
10 everybody, have a great evening, and we'll see you  
11 tomorrow morning.

12 **(WHEREUPON, the MEETING adjourned at 5:15 p.m.)**  
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## CAPTION

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

It was requested that the matter be taken by the reporter and that the same be reduced to typewritten form.

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.

## 1 CERTIFICATE OF REPORTER

2 COMMONWEALTH OF VIRGINIA

3 AT LARGE:

4 I do hereby certify that the witness in the foregoing  
5 transcript was taken on the date, and at the time and  
6 place set out on the Title page hereof by me after  
7 first being duly sworn to testify the truth, the whole  
8 truth, and nothing but the truth; and that the said  
9 matter was recorded stenographically and mechanically  
10 by me and then reduced to typewritten form under my  
11 direction, and constitutes a true record of the  
12 transcript as taken, all to the best of my skill and  
13 ability.

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

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

20  
21  
22  
23  
24 MARK REIF, COURT REPORTER / NOTARY

25 SUBMITTED ON OCTOBER 29, 2008



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