

US EPA ARCHIVE DOCUMENT

FIFRA SCIENTIFIC ADVISORY PANEL  
OPEN MEETING

REVIEW OF WORKER EXPOSURE  
ASSESSMENT METHODS

U.S. ENVIRONMENTAL PROTECTION AGENCY  
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FIFRA SCIENTIFIC ADVISORY PANEL (SAP)  
Review of Worker Exposure Assessment Methods  
January 10, 2007  
Morning Session

DR. HEERINGA: I'd like to welcome everyone back to the second of four days in our scheduled FIFRA Scientific Advisory Panel Meeting on the topic of a Review of Worker Exposure Assessment Methods.

I am Steve Heeringa of the University of Michigan. I'm an applied statistician. I currently Chair the FIFRA SAP and will serve as the General Chair for the meetings today, tomorrow and Friday morning as needed.

I want to make one administrative note. I do have a teaching obligation this afternoon at the University of Maryland and I'll be away and Doctor Portier will be assuming duties for chairing the session just for this afternoon. I'll be back tomorrow morning.

What I'd like to do before we turn to the morning proceedings is to again thank members of the panel for committing time at a very early part in their academic or research year here to come to D.C. for this very, very important session. And I'd like these

1 individuals to introduce themselves and provide some  
2 background on the affiliation and relevant expertise.  
3 Ken.

4 DR. PORTIER: I'm Ken Portier, Director of  
5 Statistics at the American Cancer Society National Home  
6 Office in Atlanta. And my interest is in probabilistic  
7 issues in risk assessment.

8 DR. HANDWERGER: Good morning, I'm Stuart  
9 Handwerger from the Departments of Pediatrics and Cell  
10 and Cancer Biology in the College of Medicine at the  
11 University of Cincinnati. My clinical expertise is in  
12 pediatric endocrinology and my research is in  
13 developmental endocrinology.

14 DR. CHAMBERS: I'm Jan Chambers with the  
15 College of Veterinary Medicine at Mississippi State  
16 University. My area of expertise is pesticide  
17 toxicology. I'm a member of the permanent SAP and I'm  
18 also a member of the EPA's Human Studies Review Board.

19 DR. BUCHER: I'm John Bucher, I'm with the  
20 National Toxicology Program at the National Institute  
21 of Environmental Health Sciences. I have an interest  
22 in carcinogenesis bioassays and the development of new  
23 toxicology methods.

24 DR. HINES: My name is Cynthia Hines. I'm  
25 a research industrial hygienist with the National

1 Institute for Occupational Safety and Health. My  
2 research areas are in occupational exposure assessment  
3 studies, including a number of pesticide field studies.

4 DR. JOHNSON: My name is Dallas Johnson.  
5 I'm retired recently from Kansas State University where  
6 I served in the Department of Statistics and as a  
7 consultant for the Agricultural Experiment Station for  
8 more than 30 years.

9 DR. APPLETON: I'm Hank Appleton with the  
10 U.S. Forest Service. I'm a pesticide toxicologist and  
11 I prepare exposure assessments and risk assessments for  
12 the pesticides that we use in our pest management  
13 programs.

14 DR. KIM: I'm David Kim from the  
15 Department of Environmental Health at the Harvard  
16 School of Public Health. And my work is in the human  
17 exposure assessment and pharmacokinetics.

18 DR. BARR: I'm Dana Barr, I'm from the  
19 Centers for Disease Control and Prevention in Atlanta.  
20 I'm the Chief of the Pesticide Laboratory. And my  
21 research interest is in human exposure assessment,  
22 primarily through bio-monitoring.

23 DR. LU: Good morning, Alex Lu from the  
24 Rollins School of Public Health at Emory University.  
25 My interest is in using biomarkers to assess pesticide

1 exposure and use the pharmacokinetic model to interpret  
2 those biomarker results.

3 DR. HUGHES: My name is Brian Hughes, I'm  
4 a toxicologist. I work with the Michigan Department of  
5 Agriculture in the pesticide section with my interests  
6 being in the risk assessment, cooperating a lot with  
7 Michigan State University doing field studies for  
8 occupational risk assessment for ag. workers.

9 DR. LANDERS: My name is Andrew Landers.  
10 I head the Application Technology Group at Cornell  
11 University. Our interest in the team is to look at  
12 engineering ways of reducing operator contamination in  
13 environmental pollution.

14 MS. MCCARTHY: My name is Peter MacDonald,  
15 I am Professor of Mathematics and Statistics at  
16 McMaster University in Canada. General expertise in  
17 applied statistics and this is my seventh year on FIFRA  
18 panels.

19 DR. HAMEY: Good morning. I'm Paul Hamey,  
20 I'm from the U.K. where I work with the U.K.  
21 government's Pesticide Safety Directorate which is our  
22 regulatory agency for agricultural pesticides.

23 DR. ROBSON: Good morning, I'm Mark  
24 Robson, I'm the Director of the New Jersey Agricultural  
25 Experiment Station and Professor of Entomology at

1 Rutgers and Professor of Environmental Health at UMD.  
2 My research interest is to look at pesticide exposure  
3 to farmers, and most recently to pesticide exposure to  
4 children.

5 DR. POPENDORF: And I'm Will Popendorf,  
6 Professor of Industrial Hygiene at Utah State  
7 University. My specialty area is exposure modeling and  
8 control and I have probably 30 years experience in  
9 pesticide exposure assessment.

10 DR. CURWIN: Hi, I'm Brian Curwin with the  
11 National Institute for Occupational Safety and Health.  
12 I'm a research industrial hygienist, conducting  
13 occupational exposure assessment studies for pesticides  
14 generally.

15 DR. HEERINGA: Thank you again, panel  
16 members. At this point in time I'd like to introduce  
17 the Designated Federal Official for today's meeting and  
18 the balance of the meeting, Myrta Christian.

19 MS. CHRISTIAN: Thank you, Doctor  
20 Heeringa, good morning. I would like to welcome  
21 everyone to today's meeting to consider the review of  
22 worker exposure assessment methods.

23 Again I would like to thank the panel, the  
24 presenters and the public for participating in this  
25 meeting.

1           Also, I would like to remind everyone that  
2 all the documents related to this SAP meeting are  
3 available in the EPA docket and in the SAP website.

4           I look forward to another day filled with  
5 lively discussion and great panel participation.

6           DR. HEERINGA: Thank you. Just to recap  
7 where we are, yesterday's session was primarily an  
8 information and presentation session. We heard in the  
9 morning an introduction and overview on worker  
10 assessment methods within the EPA in general and  
11 elsewhere from Jeff Evans and an historical perspective  
12 on the worker exposure assessment from John Worgan of  
13 Health Canada, the Pest Management Regulatory Agency.  
14 We also heard case studies, just sort of a general  
15 introduction as to how EPA uses the data from the PHED  
16 system currently and a discussion from Cassi Walls of  
17 the Antimicrobial Division on how the Antimicrobial  
18 Division would potentially incorporate findings and  
19 recommendations that came forward from these panel  
20 meetings. Then in the afternoon we had a presentation  
21 from the AG. Handlers and the Antimicrobial Exposure  
22 Task Forces from industry and we had a period of public  
23 comment.

24           And I wanted to make a note for the record  
25 that we did receive yesterday a written comment from



1 Doctor Richard Fenski of the University of Washington.  
2 That comment, the panel has copies of that two page  
3 written submission and it will be placed on the docket  
4 for this session as well. So just in the interest of  
5 full disclosure that is also available to the panel.

6 Okay, what we would typically do in these  
7 multi day sessions is to include in the first session  
8 each morning sort of recapping events of the previous  
9 day and provide the EPA scientific staff a chance to  
10 sort of update or maybe amend or extend some of the  
11 information that was provided yesterday.

12 So at this point in time I'd like to turn it  
13 over to Jeff Dawson and Jeff Evans of the Health  
14 Effects Division of the Office of Pesticide Programs.

15 MR. EVANS: Thanks, Doctor Heeringa.  
16 We've got two items for followup from yesterday, one a  
17 clarification from a representative of the Agricultural  
18 Handlers Exposure Task Force regarding one of the  
19 slides addressing data generation and Jeff Dawson some  
20 corrections to announce.

21 MR. DAWSON: Believe or not we made an  
22 error. Just for clarification since we're on the  
23 agenda today, we're talking about the biological  
24 monitoring issues. In the background document one of  
25 the ratios which we've calculated is in error so I

1 don't, I'm not sure that we're presenting it today but  
2 we can have copies made of the corrected page and  
3 distribute them to the panel.

4 And specifically it's on the Table 3.2 for  
5 Malonate and the ratios there are incorrect because we  
6 made a math error.

7 DR. HEERINGA: Thank you very much for  
8 citing the Table too, that's now part of the record as  
9 well.

10 Any additional introductory comments? I  
11 understand, Mr. Dawson, that we also will have Doctor  
12 Collier is going to, from the AG. Handlers Task Force  
13 is going to have a few additional comments to follow up  
14 on yesterday.

15 DR. COLLIER: Thank you. I'm Richard  
16 Collier, the current Chairman of the Administrative  
17 Committee of the AG. Handlers Task Force.

18 It's come to my attention that there might be  
19 some lack of clarity about one of the slides that I  
20 presented yesterday, specifically slide 16 which was  
21 entitled PHED's data dilemma. One of the bullet points  
22 on that slide indicated that some 100 studies have been  
23 submitted since 1995 that are not included in the PHED  
24 database and the final slide there indicates no  
25 incentive to industry to submit new studies. That may

1 seem to be an inconsistency. The intent of the last  
2 bullet was to indicate that there was no incentive for  
3 industry to submit new studies for inclusion in the  
4 PHED database. Many studies were submitted, more than  
5 100 since 1995 in response to product specific data  
6 requirements of the Agency, but those studies were not  
7 submitted by the industry for inclusion in the PHED  
8 database because of the data compensation issue. I  
9 just want to clarify that point.

10 DR. HEERINGA: Thank you very much, Doctor  
11 Collier. Any questions from the panel on either of  
12 these two items?

13 Okay, well let's get underway with today's  
14 program. The first presentation we have is going to be  
15 given by Doctor Sheryl Beauvais of the California EPA  
16 Department of Pesticide Regulation. Doctor Beauvais.

17 DR. BEAUVAIS: Good morning, I'm going to  
18 be talking about I'm getting feedback, are you also?  
19 Okay, don't worry about it, okay.

20 This morning I'll be talking about  
21 comparisons between biological monitoring and passive  
22 dosimetry. Basically we've got a database out there  
23 that consists of studies done by one or both methods  
24 and what we've done, EPA's done a lot of this work,  
25 other researchers have done work and I'm going to be

1 presenting some of that with the intent of showing  
2 that, if we compare results from these diverse methods,  
3 and they generally are converging on similar values,  
4 then that suggest to us that we might, that these  
5 methods are somewhat supportive of one another. May I  
6 have the first slide please. Thank you.

7 On the background, this, materials in the  
8 background, Section 3 of the background document, I'm  
9 going to be covering the majority of Section 3 and then  
10 the last part of that with the hand exposure methods.  
11 Jeff Dawson and Jeff Evans will be presenting  
12 afterwards. And in that Section 3 of the background  
13 document we discuss three key issues, there's a section  
14 in there that talks about that, and four key issues are  
15 listed, I've got three of them on the slide here.

16 The first one the main concern that we have  
17 here is we want to be sure that there is not a  
18 potential for a systemic bias, that there's not  
19 evidence to suggest that and possibly evidence to  
20 suggest that there is not a systemic, systematic bias,  
21 sorry, between biomonitoring and passive dosimetry  
22 methods. And then the other three key issues that were  
23 identified are really subsets of that. We're concerned  
24 very much that passive dosimetry not underestimate  
25 exposure because the bulk of those studies in, no, all

1 studies in generic databases and the bulk of the  
2 studies that we use in exposure assessment rely on  
3 passive dosimetry, and if it's underestimating exposure  
4 that's a concern.

5 And so the other issues deal with ways in  
6 which, or proposed ways, mechanisms by which passive  
7 dosimetry might underestimate exposure. And the second  
8 bullet there is the first of these which is dermal  
9 absorption. There is concern that residue may be  
10 absorbed dermally during attempts to remove it. And  
11 I'll talk more about that in a little bit. But  
12 essentially that would result in a positive, possible  
13 negative bias if in, while attempting to remove the  
14 residue we are actually encouraging it to absorb  
15 through the skin or fail to collect it, then that can  
16 result in an underestimate.

17 And then the other one generally is residue  
18 breakthrough from whole body dosimeters. And I'll talk  
19 more about that shortly. And again that can result in  
20 a positive, possible negative bias. And the other one  
21 has to do with hand exposure methods and I'll defer  
22 that to the next presentation. Next slide please.

23 Okay, one way to think about passive  
24 dosimetry in biomonitoring here, I'm going to start at  
25 the lower left of the slide, is essentially pesticides

1 are contacting the skin, contacting the body surface  
2 during a person's workday and they are absorbed,  
3 metabolized, distributed through the body and excreted  
4 ultimately.

5 And moving you up to the upper right, the  
6 active compound, the active, whether it's the pesticide  
7 or it's metabolite, whatever it is that's  
8 toxicologically active, the moiety, when it reaches its  
9 target, whether it's an enzyme or other type of tissue  
10 is basically if we had a way to look at that, if we  
11 had for example a Star Trek Tricorder where you could  
12 wave it in front of the person and say, yes, there's  
13 this much damage happening right, if we could actually  
14 see that in the compound episode of injury and know  
15 quantitatively what was happening we would have.

16 And if we could do the same thing in  
17 toxicology studies in animal data where you could say,  
18 yes, this is, you know, if this dose is happening at  
19 that site, this is the damage that's occurring and we  
20 could compare those two numbers, we would have perfect  
21 risk estimates.

22 But we don't have that, so instead we have a  
23 couple of surrogate approaches that we can use. And  
24 with passive dosimetry, essentially we're trapping the  
25 pesticide before it reaches the body, either on

1 clothing, on patches or we are removing pesticide  
2 before it's been absorbed if we're doing a dermal  
3 absorption removal. In the case of inhalation we're  
4 trapping pesticide in the breathing zone area.

5 So that's one approach is we're quantifying  
6 the amount of pesticide reaching the individual.

7 The second approach is down in the lower  
8 right, is biomonitoring where we're actually  
9 quantifying residues that are excreted or are in the  
10 system in blood or other tissues. So we're actually  
11 taking the amount that's absorbed and that has been  
12 metabolized or processed or is, and is actually in the  
13 system itself.

14 Generally we're taking urine sample, excreted  
15 amounts and we're quantifying that so this is so we  
16 have sort of the before and after. These are both  
17 surrogate approaches to get us, for what it is we  
18 really would like to have in a perfect world where we  
19 know exactly what the toxicologically active amount is  
20 at the target site. Next slide please.

21 So we've talked about, a couple of  
22 presentations yesterday talked about passive dosimetry,  
23 so I'm going to quickly go through these again in just  
24 another perspective. It measures the amount of the  
25 pesticide that's impinging on the surface of the skin

1 or the amount available for inhalation. So we're  
2 either absorbing or removing dermal residues or we're  
3 trapping residues in the breathing zone in the case of  
4 inhalation.

5 We'll talk an awful lot about dermal exposure  
6 because dermal is, in most scenarios the dominant  
7 exposure route unless you're dealing with a volatile  
8 compound like a fumigant for example. Next slide  
9 please.

10 And we, you've seen some, already some slides  
11 on monitoring dermal exposure.. This fellow who is all  
12 dressed up here has, these are patches and they show  
13 those. That's one common methodology. And I wanted to  
14 show, this is slide that you wouldn't have seen before,  
15 we talked, we're going to talk in a minute here about  
16 the backing that, about an impervious barrier and  
17 that's kind of small but that's, what you have is  
18 absorbent material and then an impervious backing  
19 behind it. And this patch when it's torn away a little  
20 bit you can see that. So that we have, the patches  
21 that are placed at various locations on the body and in  
22 the case of each patch you're assuming that, and  
23 extrapolating the residues found on the patch to a  
24 certain region of the body. The arm for example, the  
25 leg, the chest, whatever.



1           In contrast, the whole body dosimetry, we  
2 have, and this is a whole body, the photo is of a study  
3 that was done to measure residential exposure but this  
4 is a full body dosimeter and give you the sense of what  
5 that is, and you've seen photos of this yesterday as  
6 well, but it's a garment that covers the body basically  
7 from the shoulders to the ankles. It does not have an  
8 impervious backing obviously. And so one of the  
9 concerns that we have is about the potential for  
10 pesticides to pass through that barrier and fail to be  
11 measured for that reason. Next slide please.

12           When we're talking about, when we monitor  
13 exposure to the head and the hands now; when, the slide  
14 that I just showed you we had, all we were talking  
15 about were trapping methods when you're talking about  
16 the majority of the body. We don't do residue removals  
17 in anywhere except pretty much the head and the hands  
18 in general. And so in each case we have a trapping  
19 method and a residue removal method so that a trapping  
20 method might be gloves or a patch, you can put patches  
21 on the head, attached to a hat perhaps and some studies  
22 have used headbands or hats, you could have a collar  
23 patch for example. So there are many approaches that  
24 way.

25           The most common way that's currently being

1 used are face and neck wipes and this is a residue  
2 removal method where you are soaking some sort of an  
3 absorbent pad with a solvent or a surfactant solution  
4 and wiping as much of the exposed, ideally wiping the  
5 entire exposed area. And this is, we have concerns  
6 about residue removals methods because there's a  
7 question about whether you were actually getting all  
8 the residue that's on the skin. And again that's a  
9 concern because of the potential to underestimate  
10 exposure if you don't get that because you're analyzing  
11 what you've removed.

12 Again with hands you've got gloves that would  
13 trap residues or rinses or hand, hand rinses, hand  
14 washes, hand wipes where the residue that's on the,  
15 their hands is wiped away or rinsed away and you're  
16 measuring the amount that's been removed from the  
17 hands.

18 So when we take those, in yesterday's slides  
19 you saw a couple of times in yesterday's presentations  
20 the equations that are used to estimate total exposure,  
21 dermal exposure from these methods. We essentially  
22 take, when you're talking about dermal exposure we take  
23 the residue from the dosimeters, whatever has been  
24 removed and combined with other factors such as dermal  
25 absorption which comes from animal or human data, an

1 estimate of the body's surface area if you had patches,  
2 and then any sort of protection factors. If you were  
3 measuring outside clothing but the person was, would be  
4 wearing clothing then you might incorporate protection  
5 factors into your estimates. Each of those is,  
6 incorporates its own assumptions or defaults and those  
7 again are potentials for error in the passive dosimetry  
8 based estimates.

9 And with inhalation exposure we trap residues  
10 in the breathing zone, this is the predominant way that  
11 this, that inhalation exposure is estimated. You see  
12 this fellow here with the sampling pump on his,  
13 attached to his belt and then a tube that runs up over  
14 his shoulder and then the end of that sampling tube is  
15 pointed downwards from his shoulder. And this is, it's  
16 intentionally facing downwards so that it's not  
17 contaminated with deposition pesticide settling out  
18 from the air.

19 The sampling pump is running at a fairly low  
20 rate, something like 2 liters per minute which is less  
21 than the breathing rate, so you're going to have, so we  
22 do a calculation for that as we make an estimate of the  
23 breathing rate that the person might have had from,  
24 depending on their level of activity, their age and so  
25 forth. But, oh, in, and then, also, I'm sorry, at the

1 top of the tube here is where the sampler, the material  
2 that's going to collect the residue is located, it's a  
3 resin charcoal or something like that up in the sampler  
4 tube. And that's what's analyzed, the sampling tube  
5 is, the material within that is extracted and analyzed.

6 And again in, using this in, to estimate  
7 inhalation exposure we would deal with inhalation rate.  
8 Absorption factors, we have very little data on that,  
9 we generally assume 100% absorption. If it's available  
10 in the breathing zone we assume that they've inhaled  
11 it. And then protection factors for a respirator if  
12 the, if they're required to wear one in that scenario.

13 So we have several assumptions with passive  
14 dosimetry. We assume that the residues that we measure  
15 are meaningful indicators of exposure, we assume that  
16 those, the residues that we've measured that are on the  
17 skin surface or trapped in dosimeters and so forth are  
18 available for absorption, that's one assumption. We  
19 also assume either that the, we assume if the duration  
20 of the monitoring differs from the duration of actual,  
21 the scenario that we're trying, the working interval,  
22 whatever, that that doesn't matter. Now we do have  
23 data that suggests that shorter intervals will tend to,  
24 you'll tend to get higher exposure estimates than if  
25 you measure over longer intervals. So that in general

1 we try to have the monitoring intervals match the  
2 intervals of the scenario that we're trying to estimate  
3 exposure for. So in most cases it's a full workday for  
4 occupational exposure.

5 We also assume that the dose that is absorbed  
6 through skin, the dermal absorption, whatever value  
7 we're using, we're assuming that that can be  
8 extrapolated from the laboratory data, whether it was  
9 in, from human volunteer studies or from animal data,  
10 that that's a meaningful number. And then finally if  
11 we uses patches and we've done an extrapolation we're  
12 assuming that the residue on the patch really could be  
13 generalized to the entire region. Or that that  
14 extrapolation is valid.

15 Passive dosimetry gives, has several  
16 advantages which is why it's so widely used. It allows  
17 the differentiation of exposure for one thing. You can  
18 tell what part of the body if, how much of this was  
19 dermal, how much of it was inhalation. It allows you  
20 to differentiate between activities in a workday if a  
21 person can switch, can change clothing for example.  
22 You can monitor a portion of their workday only. And  
23 also because it allows you to differentiate between  
24 body parts, it allows you to evaluate measurements that  
25 would be, tend to reduce exposure. For example, if

1 there is a great deal of exposure on the hands then we  
2 could evaluate the use of gloves, how much that affects  
3 it. Because the monitoring is occurring during the  
4 working interval you can supervise the subjects during  
5 the entire period that you're collecting the data. And  
6 because of the assumptions that were discussed  
7 yesterday that for handlers, that exposure is  
8 independent of the, largely independent of the chemical  
9 characteristics of whatever the active ingredient is,  
10 you can use studies, surrogate data from one study to,  
11 form one chemical to estimate exposure to another.

12 Disadvantages of passive dosimetry is that it  
13 requires an estimate of dermal penetration and that's a  
14 big one, that's, we need to use surrogate data from  
15 laboratory animals a lot of times, many active  
16 ingredients don't have data from human volunteers and  
17 also there are studies that suggest that dermal  
18 absorption varies with the amount of the pesticide  
19 that's on the skin, which makes sense. If you load a  
20 great deal of pesticide on, or a great deal of material  
21 on the skin, proportionately less of it gets absorbed.  
22 The absolute absorption may be higher but  
23 proportionately less of it is absorbed. And we also  
24 have uncertainty because we have various methods of  
25 estimating dermal exposure so that you, if you're

1 comparing between studies you may have one study, and  
2 this was discussed yesterday where the patches were  
3 placed in one location and another study where they  
4 were placed in another, so that that, there's  
5 variability between studies.

6 Biological monitoring is essentially an  
7 estimate of the internal dose, how much was absorbed.  
8 And it, to do that we, to the, to collect those data  
9 we're measuring the body burden of a chemical, either  
10 the pesticide itself or the metabolites of the  
11 pesticide in selected tissues such as blood or the  
12 amount that's excreted from the body of the, either the  
13 pesticide or its metabolites. For practical reasons,  
14 because it's just very, it's much easier to get people  
15 to collect urine than it is to draw blood and it's just  
16 much easier to go with urine samples. And so that's  
17 the majority of what we're talking about when we talk  
18 about biomonitoring, this is usually urinary. Next  
19 slide please.

20 Biomonitoring also has several assumptions.  
21 We, it assumes that the urine is the major route of, is  
22 a major elimination route for the pesticide or its  
23 metabolites. To the extent that it isn't you're  
24 dealing with extrapolation errors. It's also assuming  
25 that the residues that are in the urine were entirely

1 due to the pesticide that was absorbed during the  
2 activity that you were monitoring. So during that work  
3 shift. If there are other ways for the metabolite or  
4 for that pesticide if there was exposure outside of  
5 that, if you have a metabolite that's common to other  
6 compounds besides the pesticide of interest, then  
7 you'll have, that undermines that assumption. And also  
8 we assume that pharmacokinetics can be extrapolated  
9 from laboratory studies and that it's relatively  
10 consistent between individuals, that the data that we  
11 get again from the laboratory are meaningful out in the  
12 real world.

13 And biomonitoring offers the advantage that  
14 it's integrating exposure across all routes. It  
15 doesn't matter whether the dose was absorbed dermally  
16 or by inhalation or by ingestion. Assuming that we  
17 have sufficient pharmacokinetic information we can get  
18 a good absorbed dose estimate. And we also do not need  
19 an estimate of dermal absorption with biomonitoring  
20 which is a good advantage of that.

21 It has disadvantages as well and the biggest  
22 one for that is that we require the pharmacokinetic  
23 studies in order for this, these data to be useful.  
24 And also there is some inherent variability in  
25 pharmacokinetics. We metabolize, pesticide might be



1 metabolized and absorbed at different rates between  
2 people and at different times within the same person.  
3 It also requires a greater degree of, biomonitoring  
4 requires a greater degree of cooperation from the study  
5 participants because they need to save their urine and  
6 they need to be honest about the extent to which  
7 they've saved it because we generally are operating off  
8 of 24 hour samples. And also the results can be  
9 absorbed by, can be affected by other absorbed  
10 materials. Again if they've been exposed to the  
11 pesticide at other times or if they've been exposed to  
12 something that gives the same metabolite as the one  
13 that we're monitoring.

14           And also we mentioned the characteristics.  
15 If we had the ideal target compound for biomonitoring,  
16 these are the characteristics it would have, it should  
17 be either the pesticide itself if it is excreted  
18 unchanged or a major metabolite of the pesticide. And  
19 again that's to minimize the errors of extrapolation.  
20 If you're dealing with something that's 10% or less of  
21 the absorbed dose, then you're extrapolating, you know,  
22 an order of magnitude or more. We also want it to be  
23 ideally specific to the pesticide of interest. If it's  
24 a metabolite common to a lot of compounds it's much  
25 less useful. And we want it to have a valid analytical

1 method obviously and it should be stable so that it's  
2 actually present throughout the sampling interval and  
3 up until the point of analysis. So the example that  
4 I've shown up there is the one that's the classic, the  
5 346 Trichloropyr and all the TCP that's the metabolite  
6 of Chlorpyrofos.

7           So I'm going to talk about some comparisons  
8 now between biomonitoring and passive dosimetry. And  
9 the rationale again for our comparisons is that we have  
10 these two very diverse methods that are used too  
11 estimate exposure. There, we have good data, a  
12 substantial database for both that would give us good  
13 data for comparisons and each method, although each  
14 method has its advantages and disadvantages, you know,  
15 the, they, together we can, if they converge again on  
16 the same values then we have greater confidence in the  
17 values that there, both methods are reporting for us.

18           So first there are two different approaches  
19 that were taken in these comparisons. The first is  
20 concurrent studies, those are studies with simultaneous  
21 monitoring of passive dosimetry while collecting  
22 biomonitoring samples as well. So that the subjects  
23 wear the dosimeters and so forth and provide the  
24 samples. We're comparing the amounts calculated from  
25 passive dosimetry and biomonitoring and that's usually

1 the absorbed dose or it can be residues collected in  
2 urine and residues analyzed on the dosimeters and  
3 passive dosimetry. Next slide please.

4           There are uncertainties associated with  
5 passive dosimetry that will potentially affect these  
6 comparisons. One is if you have inconsistent  
7 techniques within a study. For example, variable patch  
8 placement, one person is wearing different types of  
9 PPE, et cetera that can affect those comparisons.  
10 Also, the use of fixed dermal absorption. As I  
11 mentioned before the amount of pesticide that's  
12 absorbed will vary with, can vary with the amount  
13 that's on the skin and we generally select a fixed  
14 value. For example, 3%, we say 3% of the Chlorpyrifos  
15 residue on the skin we assume to be absorbed and so  
16 we're using that as a fixed value and that can, that  
17 adds to the uncertainty of our estimate. Next slide  
18 please.

19           There are also uncertainties in the  
20 biological monitoring component of these comparisons.  
21 The accuracy and the variability of the  
22 pharmacokinetics, again that's an area that can add to  
23 our uncertainty, depending on the, how variable it is  
24 and how accurately we have estimated. If there are  
25 incomplete urine collections from the test subjects.

1 Also if there were previous unreported exposure to the  
2 same pesticide. To minimize the chance of that  
3 affecting the estimates most biological monitoring  
4 studies incorporate a pre-exposure urinary sample where  
5 they ask the test subjects to collect their urine 24  
6 hours before they're exposed and then that gives you  
7 the idea of the background levels. And finally there  
8 is concern about if you, if whatever residues the  
9 passive dosimetry has intercepted are residues that  
10 weren't absorbed obviously, if they were collected on  
11 the skin they weren't absorbed through.

12 So the majority of these studies involved,  
13 with the concurrent monitoring involved chlorpyrifos  
14 and again that's because it has a really nice  
15 metabolite which is the TCP metabolite. There are many  
16 comparisons available of absorbed dose. The TCP is  
17 estimated to, roughly 70% of the absorbed chlorpyrifos  
18 is estimated to be excreted as TCP in these biological  
19 monitoring comparisons. We also have some samples of  
20 other organophosphate pesticides and some non-OP  
21 pesticides as well. In most of those cases we're  
22 correlating the residues rather than getting absorbed  
23 dose estimates.

24 So the first set of comparisons, these are  
25 ones that were reported by Fenske and Day. They were

1 reported by them from calculations that were made by  
2 Layton at EPA in the exposure assessment for  
3 chlorpyrifos and what you're looking at here is, across  
4 the bottom are just basically scenario numbers, these  
5 are just distinct handler scenarios. And there's a key  
6 up in the upper right here that would, that tells you  
7 which, the first two are mixer/loaders, applicators and  
8 so forth. And then on the, this, we're getting  
9 absorbed dose estimates or we're getting, I'm sorry,  
10 unit dose, unit exposure estimates, micrograms per  
11 kilogram of active ingredient handled. So these are  
12 actually the, what we call unit exposure rather than  
13 absorbed dose estimates. Each of the points on this  
14 graph is an arithmetic mean, arrow bars are standard  
15 deviation. And the main point that this makes for us  
16 is that in each of these comparisons the doses don't  
17 stray very far. The yellow is the biomonitoring  
18 estimate and the red is the passive dosimetry. And  
19 those are fairly similar. Next slide.

20 You see the same thing with, these are  
21 reentry studies, the last slide was handler exposures.  
22 And in this case our estimate is the total absorbed  
23 dose in this case, micrograms per kilogram body weight  
24 per day. And again, red is the passive dosimetry,  
25 yellow is the biomonitoring and each point in this, on

1 this one, these data are, were summarized by Honicutt,  
2 et al and I've simply graphed their estimates here.  
3 Each point is the geometric mean with the arrow bars  
4 being the standard deviation and these are four  
5 different scenarios of, and during which they had  
6 concurrent biomonitoring of passive dosimetry.

7 There are also several other studies  
8 available that are reported in the literature. And  
9 some of those did have compound specific metabolites, a  
10 metabolite that was specific to the active ingredient  
11 being monitored. In a lot of cases for  
12 organophosphates what's monitored instead are  
13 metabolites that are common to many OPs, dialkyl  
14 phosphate metabolites for example, where you can  
15 monitor for multiple organophosphates at the same time.  
16 And there are numerous studies where those sorts of  
17 monitoring were done.

18 On this slide I mention a couple of examples  
19 of comparisons that have been reported. These  
20 generally are reporting correlations because you're not  
21 getting absorbed dose estimates off those. You can't  
22 assign the metabolites to a specific pesticide so we  
23 don't have absorbed dose estimates for specific  
24 pesticides so that they're not always calculated. But  
25 the correlations did involve a range of exposures and

1 the correlations are, can be fairly, fairly good. Next  
2 slide please.

3 So these had good to moderate correlations in  
4 some of these studies. For example, when they were  
5 estimating absorbed doses and excreted alkyl phosphates  
6 for the applicators that were spraying Dimethoate in  
7 olive trees they recorded a correlation of  $r$  squared of  
8 .65 between the absorbed dose estimate in which they  
9 calculated by assuming a 10% dermal absorption, 100%  
10 inhalation. And then they correlated that with the  
11 alkyl phosphates excreted in the urine.

12 In some studies there were poorer  
13 correlations, although in many of those studies they  
14 had small sample sizes or they had documented previous  
15 exposures to the pesticide outside the interval that  
16 they were monitoring with the passive dosimetry. In  
17 complete passive dosimetry perhaps they were only  
18 monitoring the hands for example, or they had short  
19 intervals for biomonitoring. Biomonitoring need to be  
20 carried out for at least a few half lives of the  
21 compound to, you want to get a quantitative recovery of  
22 the compound.

23 There are also some correlations reported  
24 with pesticides that are not organophosphates.  
25 Dyfioppyr is an example of a compound that's had

1 concurrent dosimetry and biomonitoring done and they  
2 found, they had poor recovery in the biomonitoring  
3 samples unfortunately. There's also studies that have  
4 reported biomonitoring and passive dosimetry for  
5 Captan. Unfortunately Captan has a metabolite that's a  
6 very small portion of the absorbed dose so those  
7 studies generally haven't resulted in good  
8 correlations.

9 EPA put together some tables and those are  
10 the tables that Jeff Dawson mentioned before we began.  
11 There were two tables in this background document. The  
12 first is the 3-1 which is a report of ratios of passive  
13 dosimetry to biomonitoring estimates that were reported  
14 in EPA exposure estimates. These are essentially  
15 preliminary ratios. There wasn't any processing of  
16 these numbers, they're just reported as they were  
17 reported in the risk assessments. And they're, so  
18 they're ratios of passive dosimetry to biomonitoring  
19 and they've dealt with either absorbed doses or unit  
20 exposures.

21 The absorbed dose would be micrograms per  
22 kilogram body weight and unit exposure would be for the  
23 handlers, milligrams per pound AI handled. These, some  
24 of these were ratios of arithmetic means rather than  
25 geometric means. If we were to really put some work



1 into this we would actually want to do comparisons of  
2 all geometric means. But for, as ballpark estimates  
3 these ratios can give us sort of a sense of how well  
4 passive dosimetry and biomonitoring correlated and we  
5 had a range of ratios which actually, as I'm reporting  
6 on the slide, the lowest one was .01 and the highest is  
7 5.73. Now as I understand it the .01 number is going  
8 to be somewhat in dispute, that's coming from Propinyl.  
9 And I think the AG. Handler Exposure Task Force has  
10 something to say about that in a little bit.

11 But at any rate the important takeaway that  
12 we took from this is that neither method consistently  
13 overestimated or underestimated in that you didn't have  
14 consistently higher estimates for passive dosimetry or  
15 biomonitoring. And that they were all fairly close to  
16 1 and they're all within an order of magnitude of 1,  
17 with the exception of the two numbers from Propinyl.

18 Another approach for comparisons of passive  
19 dosimetry and biomonitoring are what we're calling the  
20 retrospective analysis. These are where you have  
21 separate studies or separate monitoring events. They  
22 can be within the same study where you have workers  
23 doing passive, doing an activity and being monitored  
24 with passive dosimetry one time and then later, or  
25 earlier by quite a lot, being monitored by biological

1 monitoring. The other approach, another approach you  
2 can do is have a surrogate estimate for the passive  
3 dosimetry from the PHED and compare those to  
4 biomonitoring.

5 For these comparisons we have the same  
6 uncertainties in the passive dosimetry as I mentioned  
7 in the concurrent. And then also, you can also,  
8 because we're comparing numbers, or exposure estimates  
9 that were happening at different times, different study  
10 conditions can affect these. For example, different  
11 equipment types or differences in personal protective  
12 equipment and differences in the product concentrations  
13 or the dilute spray concentrations for applicators.  
14 There are also uncertainties, biological monitoring  
15 that can affect these comparisons.

16 Unlike the concurrent analysis we don't have  
17 the concurrent passive dosimetry so you don't have to  
18 worry about interception by the dosimeter, but you have  
19 the other factors from, that were, had been listed  
20 previously. And then also if they were, again with  
21 the, if the passive dosimetry techniques were varied  
22 between studies, patches versus whole body dosimeters,  
23 those add to the uncertainty of the estimates. And in  
24 some cases there are no, the, if the patches for  
25 example are on the outside and we use clothing

1 penetration factors, those add to the uncertainty of  
2 the estimates as well.

3 This is an example of a nonconcurrent  
4 monitoring that was conducted in the same, within the  
5 same study with fluazifop-butyl, this is from Chester  
6 and Hart in 1986 where two separate applications were  
7 monitored. The first one was with biomonitoring, they  
8 monitored 13 mixer/loader applicators applying this  
9 herbicide with vehicle mounted sprayers and each  
10 mixer/loader/applicator was monitored, first with  
11 biomonitoring where they had 24 hour samples for 2 days  
12 pre-exposure and then 7 days post-exposure and then  
13 after that 7 days they had another monitoring event  
14 where they monitored them with passive dosimetry.

15 And they compared those, so what you're  
16 seeing here, each dot is a single worker and the amount  
17 of fluazifop that was recovered from the urine, and  
18 fluazifop is a major metabolite from the fluazifop-  
19 butyl and then the estimated dermal exposure in  
20 milligrams total over the body from the dosimetry. So  
21 the  $r$  squared, if you correlate those two is fairly  
22 good. These are log, a log-log plot of the original  
23 numbers that they reported and then which this equation  
24 up here is the log transformed, is the regression of  
25 the log transformed data.

1           And again Table 3-2 in the background  
2 document, EPA reported comparisons. In this case they  
3 used dermal absorption, or I'm sorry, passive dosimetry  
4 estimates from the Pesticide Handler Exposure Database,  
5 PHED, and in the risk assessments, any biomonitoring  
6 used in the risk assessments. So the range of ratios  
7 is much larger than in, when we had concurrent  
8 monitoring, but half of them were still within an order  
9 of magnitude of 1 and that's considered pretty good  
10 because of all of the, anytime you're dealing with  
11 field studies you have a lot of uncontrolled variables  
12 and so there's a lot of variability within studies.

13           So that to get comparisons that are within an  
14 order of magnitude are considered pretty good. So  
15 basically in this case most of the passive dosimetry  
16 estimates were higher than the biomonitoring, but not  
17 all of them.

18           And so the take home that we, what we took  
19 away from that is that while the passive dosimetry  
20 didn't consistently estimate, overestimate exposure,  
21 they tended to be higher in most of these comparisons,  
22 but that they were still fairly close to the  
23 biomonitoring estimates in these comparisons.

24           So in conclusion the comparisons that we did,  
25 or that we have reviewed here suggest that we get

1 either similar or correlated results for both the  
2 concurrent studies and the retrospective analyses. In  
3 may cases we had insufficient information to do  
4 absorbed dose estimates and so we ended with just  
5 simply looking at correlations instead. A lot of times  
6 we're missing, for example the amount of pesticide that  
7 was handled in the study so we can't do an absorbed  
8 dose. Or we don't have the information we would need  
9 for a full absorbed dose.

10 Also because of the variability of field  
11 studies the results that are differing by less than an  
12 order magnitude we would still consider pretty close.  
13 And we did see greater differences in the retrospective  
14 than in the concurrent monitoring. But what we also  
15 felt was that there was not a systematic bias shown in  
16 these comparisons.

17 We didn't have a consistent overestimate with  
18 one or the other and in particular we were comfortable  
19 that passive dosimetry probably wasn't consistently  
20 underestimating exposure which was a concern that we  
21 were most concerned about.

22 Because these methods are coming at it again  
23 from the diverse approaches to exposure, we take, we  
24 find this is supporting evidence of exposure and that's  
25 actually one of the questions you're going to be asked

1 about and we felt that there wasn't a substantial  
2 underestimate of exposure. And that's my last slide.  
3 Any questions?

4 DR. HEERINGA: Thank you very much, Doctor  
5 Beauvais. Members of the panel, any questions or  
6 points of clarification on Doctor Beauvais'  
7 presentation? Doctor Lu?

8 DR. LU: How do you calculate absorbed  
9 dose using biological data?

10 DR. BEAUVAIS: As in biomonitoring?

11 DR. LU: Yeah.

12 DR. BEAUVAIS: First of all you quantitate  
13 the residues in the urine and so you say, okay, this is  
14 how much, how many milligrams of my metabolite, and  
15 that is in sequential sample usually, so we'd say in  
16 sequential 24 hour samples I had a total of, you know,  
17 so many milligrams in the urine. Then we relate that  
18 to, if it's a metabolite, you relate metrically, you  
19 say, okay, that, what's because I have this many  
20 milligrams I need to convert it to how many milligrams  
21 of the parent compound if it's a metabolite.

22 DR. LU: No, I guess my question is this.  
23 Say for example you have seven urine samples

24 DR. BEAUVAIS: Okay.

25 DR. LU: on one particular day from

1 DR. BEAUVAIS: Yes.

2 DR. LU: particular workers

3 DR. BEAUVAIS: Yeah.

4 DR. LU: do you analyze separately? Or  
5 do you pool the sample?

6 DR. BEAUVAIS: They're pooled.

7 DR. LU: Okay.

8 DR. BEAUVAIS: The samples are pooled.

9 DR. LU: So you pool the samples together  
10 and you got a number

11 DR. BEAUVAIS: Yes.

12 DR. LU: and then you have multiple day  
13 results

14 DR. BEAUVAIS: Yes.

15 DR. LU: assuming, and then you sum them  
16 together?

17 DR. BEAUVAIS: Yes. So we're getting a  
18 summary number at the end.

19 DR. LU: And normalize by the volume? And  
20 then you

21 DR. BEAUVAIS: Yeah, exactly.

22 DR. LU: do the calculation.

23 DR. BEAUVAIS: Yeah.

24 DR. LU: Okay. Aren't you worried about  
25 the volume dilution? Say for example you have seven

1 urine samples

2 DR. BEAUVAIS: Uh-huh.

3 DR. LU: and each gives you 200  
4 microliters, or 500 mil, do you add them up together  
5 assuming that each one of them you're analyzing  
6 individually

7 DR. BEAUVAIS: Yes.

8 DR. LU: they'll come up very close the  
9 limit of detection level. And all of a sudden you pull  
10 them together because of huge volume

11 DR. BEAUVAIS: Oh, we

12 DR. LU: the composite sample becomes  
13 non-detect.

14 MR. DAWSON: Typically you wouldn't pull  
15 like if you had a time course where you're measuring,  
16 let's say 5 days worth of 24 hour urines, you would  
17 analyze each one separately

18 DR. LU: Right.

19 MR. DAWSON: and take the

20 DR. LU: Okay.

21 MR. DAWSON: the calculated residue from  
22 each sample and add it together. And generally the way  
23 these studies are done well, it depends upon how  
24 you're doing them of course, but let's say it's a  
25 single exposure event day that's monitored and then



1 you're looking at the time course of excretion after  
2 that, you would add those all together because it would  
3 represent that single day of

4 DR. LU: Uh-huh.

5 MR. DAWSON: exposure, even though it  
6 took 4 or 5 days or whatever for the residues to  
7 completely be excreted.

8 DR. LU: Okay.

9 MR. DAWSON: So we want to make sure we  
10 capture that.

11 DR. LU: Okay, good.

12 DR. HEERINGA: Doctor Hanwerger.

13 DR. HANDWERGER: As an endocrinologist I  
14 frequently rely on urinary excretion of hormones to  
15 tell whether patients are in a hyper-secretitory or a  
16 hypo-secretitory state and I find the collection of  
17 urine to be one of the most frustrating things I have  
18 to rely on because the data is invariably poor. It's  
19 very hard to get people to collect a 24 hour urine and  
20 have consistent 24 hour as judged by something like  
21 urinary creatinine.

22 Do you use a measure of creatinine or  
23 something else to really tell you whether this is a 24  
24 hour urine? I can see somebody walking out on a field  
25 wearing this space outfit that you have and is not

1 going to worry so much about, you know, how he's going  
2 to collect his urine if the bucket is sitting far away  
3 and he's got to go, it's easier to just move over  
4 somewhere else in the field and take a leak.

5 So I would think that 24 hour urine from  
6 somebody under those conditions would not be the most  
7 reliable and I certainly wouldn't want to make a  
8 clinical diagnosis of Cushing's Disease or Addison's  
9 Disease based on a 24 urine of somebody out in field  
10 spraying pesticides. So I mean I think you, and I'm  
11 not surprised that your correlation isn't perfect, I  
12 think it's superb considering the fact that there is so  
13 much variability. I think so often non-clinicians  
14 think that a 24 hour urine is a 24 urine, but it's not.

15 DR. HEERINGA: Mr. Dawson.

16 MR. DAWSON: I'm sorry, Jeff Dawson, HED,  
17 one comment, we have the same frustration and what we  
18 try to do on our protocols is to, A, build in some  
19 observational component to make sure, you know, that  
20 people are trying to, during the field work and such  
21 and some of our recording aspects, but then also look  
22 at creatinine and, you know, urine volume outputs,  
23 anything we can use to get a handle on the fact that,  
24 the completeness of the sample.

25 DR. HEERINGA: Yes, Cynthia Hines.

1 DR. HINES: Just a comment on the previous  
2 comment and then another question. I'm not sure how  
3 other people do their 24 hour urine field study but you  
4 raise a good point and what we do in our studies  
5 anyway, is we try to make that as easy for the field  
6 workers as possible and they actually have urine kits  
7 and bottles with them in a convenient portable way so  
8 that if they're out in the field and have to take a  
9 leak, they don't have to go anywhere to get their  
10 bottle, they have it with them.

11 So I mean your point is well taken, you  
12 always never know if you've really got it but we do do  
13 the 24 hour creatinine and are trying to check for  
14 that. And it's always a worry but we do what we can to  
15 make that as easy for the worker as possible.

16 So, the my other question is, I don't know if  
17 you've had a chance to read Richard Fenske's comments  
18 yet. He raises a point on the comparison of passive  
19 dosimetry and biomonitoring that had occurred to me,  
20 and that is, how sensitive is this analysis that you're  
21 doing to the choice of the compounds that you have  
22 selected here?

23 Essentially, and when you get a chance to  
24 look at this, he breaks down this data into looking at  
25 Chlorpyrifos separately from Atrazine. And then there

1 looks like, and I haven't had a chance to rigorously  
2 look at this, but it looks maybe a little more  
3 systematic bias may be introduced, that there may be  
4 some compound dependent results. So could you perhaps  
5 comment on that?

6 DR. BEAUVAIS: Well that was the intent in  
7 looking at a variety of compounds and, yeah, certainly.  
8 And in the Tables 3-1 and 3-2 one of the things that  
9 EPA was doing when they were looking at these was they  
10 were looking at the effect of dermal absorption. In  
11 some cases you'll see that in looking at those tables  
12 that more than one dermal absorption value is used and  
13 just to show, here's what happens to the ration. And  
14 basically the ratio is proportional to the amount of  
15 dermal absorption. If you assume twice as much  
16 absorption your ration doubles.

17 And, yes, absolutely these ratios are  
18 sensitive to all the assumptions that we're making  
19 about dermal absorption. And with regard to the  
20 passive dosimetry and about the percent metabolite  
21 that's recovered, so when I was saying that, you know,  
22 70% of Chlorpyrifos is assumed to be recovered as TCP,  
23 because we take that number, they yeah, absolutely.  
24 It's compound specific and it is sensitive to the  
25 compounds. And the best that we can do is look at a

1 variety of compounds. Anything to add?

2 MR. DAWSON: Just one other, Jeff Dawson  
3 again, HED, one other comment. When we try to prepare  
4 those tables we just tried to capture as much as we  
5 could, you know, in the time frame we had to we  
6 basically just opened up the cupboard and took what was  
7 there. So the lack of a certain chemical whatever, we  
8 may not have had the information for a variety of  
9 chemicals.

10 DR. HEERINGA: Doctor Chambers.

11 DR. CHAMBERS: A couple of questions.  
12 The people that are in the moon suits like that that  
13 you showed a picture of, are they actually expected to  
14 do their normal tasks suited up like that?

15 DR. BEAUVAIS: Yes.

16 DR. CHAMBERS: Really?

17 DR. BEAUVAIS: Yeah. When they're suited  
18 up like that, that's because they're applying suited up  
19 like that. That moon suit is not the dosimeter, that  
20 is actually what they're wearing.

21 DR. CHAMBERS: Oh, no, no, I know that's  
22 not the dosimeter but it just seems like it's awfully  
23 cumbersome to do their normal tasks. They can handle  
24 that?

25 DR. BEAUVAIS: Uh-huh.

1 DR. CHAMBERS: Okay, all right.

2 DR. BEAUVAIS: Well, and that's when, in  
3 yesterday's discussion they were making the point that  
4 they want to have, in the AHETF studies they're looking  
5 for the minimal toxicity compounds or the or, excuse  
6 me, minimal toxicity formulations to work with because  
7 they don't want people dressed up in moon suits. And,  
8 by yeah, if you're applying something that's terribly  
9 toxic you're going to, in some of these OPs you're  
10 going to be wearing that stuff.

11 DR. CHAMBERS: Okay. Another concern  
12 that I've had is with the whole body dosimeters, the  
13 underwear type thing. The studies that you've looked  
14 at that have included that, have there been concurrent  
15 urinary samples at the same time? Because it seems  
16 like with a whole body dosimeter you're certainly going  
17 to get some interception, that's the point of the

18 DR. BEAUVAIS: Yes.

19 DR. CHAMBERS: dosimeter.

20 DR. BEAUVAIS: Yeah, and the way that they  
21 get around that is, is the dosimeter is actually acting  
22 as another, as a layer of clothing. So they're wearing  
23 the t-shirt that is going to be used as a dosimeter in  
24 lieu of the t-shirt that they would normally wear. So  
25 that essentially it's replacing their clothing instead

1 of in addition to.

2 DR. CHAMBERS: But are there studies  
3 that are looking at biomonitoring concurrently?

4 DR. BEAUVAIS: Yeah.

5 DR. CHAMBERS: Because those would  
6 necessarily, the urine samples necessarily would have  
7 less there because you know you're intercepting some  
8 from the

9 DR. BEAUVAIS: Yes and --

10 DR. CHAMBERS: dosimeter.

11 DR. BEAUVAIS: and what, and our  
12 assumption that we're using in those is that whether it  
13 was intercepted by the dosimeter is what the person's  
14 clothing would normally intercept.

15 DR. CHAMBERS: So you're adjusting?

16 DR. BEAUVAIS: No, we're let's see how  
17 to

18 DR. CHAMBERS: Are you adding that  
19 amount to the urine then to try to come up with a total  
20

21 DR. BEAUVAIS: No.

22 DR. CHAMBERS: total body dose?

23 DR. BEAUVAIS: Okay. I can tell you that  
24 we're not and, because we're assuming it wasn't  
25 absorbed. Again it, because the person is, if the

1 person weren't wearing the t-shirt that was being used  
2 as a dosimeter they would be wearing a different t-  
3 shirt, so that dose would not be absorbed because of  
4 the clothing, it would be trapped in the clothing.

5 DR. CHAMBERS: So the whole body  
6 dosimeter is not an additional layer of clothing then?

7 DR. BEAUVAIS: No, that's

8 DR. CHAMBERS: I thought it was.

9 DR. BEAUVAIS: yeah, exactly. In these  
10 concurrent studies that's what they're

11 DR. CHAMBERS: It's not an

12 DR. BEAUVAIS: that's how they yes.

13 DR. CHAMBERS: And the other concern  
14 that I've had for many years with these kinds of  
15 studies as well as with the residentials from surfaces  
16 and so forth is, does anybody every monitor how much of  
17 the breakdown products are out there on the skin that  
18 are actually just passing through into the urine? You  
19 know, certainly where the organophosphates

20 DR. BEAUVAIS: Uh-huh.

21 DR. CHAMBERS: the breakdown products,  
22 TCP or whatever, that's going to be the same thing  
23 breaking down in the environment as is showing up in  
24 the urine through metabolism.

25 DR. BEAUVAIS: Uh-huh.



1 DR. CHAMBERS: And so are you getting  
2 some urinary metabolite presumably that's really  
3 nothing more than an environmental breakdown product  
4 passing through?

5 DR. BEAUVAIS: Yeah, and that's actually,  
6 there are a couple of recent studies that have looked  
7 at that and, yeah, found that there is some of that  
8 happening. But I'd say probably not a lot. But again  
9 that's going to be compound specific. But yes, that is  
10 an issue that people are aware of and that there is  
11 actually studies where they're trying to investigate  
12 that.

13 DR. HEERINGA: Doctor Portier and then  
14 Doctor Appleton.

15 DR. PORTIER: I was looking at your  
16 figures on slides 22 and 23 and trying to understand  
17 what the arrow bars, I mean it says standard deviation,  
18 that means that for each of these handler tasks there's  
19 multiple people that did concurrent sampling. Is that  
20 what that means?

21 DR. BEAUVAIS: Yes. Yeah, so these are  
22 the geometric mean of individual results, yes.

23 DR. PORTIER: Okay. It would have been  
24 better if you plotted the differences, right? Because  
25 of, between the

1 DR. BEAUVAIS: Yes.

2 DR. PORTIER: between the concurrent  
3 estimate and the biomonitoring estimate, so I could

4 DR. BEAUVAIS: Okay.

5 DR. PORTIER: figure out what the real  
6 variability, and the uncertainty on the difference is  
7 what I'm more interested in than the differences of the  
8 means. It's just a minor point that would

9 DR. BEAUVAIS: Okay.

10 DR. PORTIER: have helped. Especially  
11 on that slide where you're trying to figure out for  
12 situation 3, whether that's really different or not.

13 DR. BEAUVAIS: Uh-huh, okay.

14 DR. HEERINGA: Doctor Appleton.

15 DR. APPLETON: Yeah, I gather you're still  
16 using DPR and I address this to the EPA colleagues as  
17 well. You're using fixed values for dermal absorption

18

19 DR. BEAUVAIS: Yes.

20 DR. APPLETON: exclusively to go from  
21 passive dosimetry for externally deposited residue and  
22 there's no

23 MR. DAWSON: Yes, that's correct. We're  
24 still using

25 DR. APPLETON: there's no temporal

1 input.

2 MR. DAWSON: No, we have

3 DR. APPLETON: So you're sticking with  
4 saturation.

5 MR. DAWSON: we're still that's  
6 correct.

7 DR. APPLETON: Okay, I was going to talk  
8 more about that this afternoon for data needs but I  
9 just wanted to confirm that. Thank you.

10 DR. HEERINGA: Steve Heeringa. I have a  
11 question to follow up on Ken's question on slide number  
12 22. There's sort of a remarkable correspondence  
13 between the means on the passive dosimetry and the  
14 biomonitoring. There's a transfer coefficient in the  
15 absorption under the passive dosimetry or does that not  
16 factor in here? In other words did you have to  
17 calibrate these two graphs by choosing a transfer  
18 coefficient to get the same?

19 DR. BEAUVAIS: No, no, the

20 DR. HEERINGA: You just chose a constant  
21 and it worked out so these things map onto each that  
22 closely?

23 DR. BEAUVAIS: Yeah, these, for handler  
24 exposures we don't have transfer coefficients and these  
25 are the amount that's absorbed on the dosimeter while

1 the person is spraying or mixing and loading. Transfer  
2 coefficients are used in reentry exposure, or is that

3 DR. HEERINGA: No, I mean the dermal  
4 transfer across skin, through skin transfer.

5 DR. BEAUVAIS: Oh, oh, I see what you're  
6 saying, yes. So, oh, so the question is

7 DR. HEERINGA: Absorption.

8 DR. BEAUVAIS: are they coming from the  
9 same study, is that

10 DR. HEERINGA: No, did you have to

11 DR. BEAUVAIS: Yes, oh there's

12 DR. HEERINGA: Those range of values

13 DR. BEAUVAIS: These, okay.

14 DR. HEERINGA: 2% to 10%, did you have  
15 to calibrate that value to get these two curves to  
16 correspond that closely?

17 DR. BEAUVAIS: Just a second, we're  
18 yeah, Tim Leighton can answer that.

19 DR. HEERINGA: Sure, Doctor Leighton.

20 DR. LEIGHTON: Although this seems to be a  
21 lifetime ago and I'm in a different job now, when we  
22 worked on this we used a 3% dermal absorption.

23 DR. HEERINGA: Okay.

24 DR. LEIGHTON: As a constant.

25 DR. HEERINGA: You just chose a constant

1 and

2 DR. LEIGHTON: That's right.

3 DR. HEERINGA: which is good. Thank you  
4 very much, Doctor Leighton.

5 DR. LU: 3% across all the pesticides.

6 DR. LEIGHTON: For Chlorpyrifos.

7 DR. LU: How about Atrazine?

8 DR. LEIGHTON: That one I'm not sure of.

9 MR. DAWSON: Jeff Dawson again. What we  
10 would do in these cases is for all the variety of  
11 chemicals in the risk assessments we would have taken  
12 the dermal absorption factor specific to that chemical  
13 and they could have been derived from a variety of  
14 things but most of the time they're, you know, dermal  
15 absorption studies.

16 DR. LU: Yeah, as I recall there is a  
17 table in the document that shows different absorption  
18 for different pesticides, right? Like 24D and

19 MR. DAWSON: Right.

20 DR. LU: Okay.

21 DR. HEERINGA: Thank you very much. It  
22 just sort of struck me that several of these points  
23 lined up nicely and I think a typical trip, given you  
24 have a component like that is to essentially calibrate  
25 these variables until you get sort of a maximum overlap

1 at several points.

2 Yes, Doctor Bucher.

3 DR. BUCHER: So I'm not an expert in this  
4 area at all so I can ask a very naive question. I  
5 thought I understood what was going on now and I'm  
6 confused about something and that is the fact that with  
7 these whole body exposure suits, if they are in fact  
8 simply replacing the clothing that they would normally  
9 wear, how is what is absorbed on those whole body  
10 patches related to what is absorbed, what is available  
11 for absorption on the skin?

12 DR. BEAUVAIS: Yeah, that's actually one  
13 of the questions, one of the reasons why we have  
14 questions, or one of the uncertainties related to  
15 passive dosimetry, because at the same time that it's  
16 serving that purpose it's also serving as a surrogate  
17 skin. And in the case where the dosimeter is below the  
18 clothing, then that, it is serving as a surrogate skin.  
19 If you have a dosimeter that's outside the clothing  
20 you're using a clothing penetration factor. And, yeah?

21 DR. BUCHER: So I would think that either  
22 one of those situations would be better than using it  
23 to replace normal clothing.

24 MR. DAWSON: One clarification. For most  
25 of these kinds of studies for occupational studies, the

1 dosimeter would be placed between what an individual  
2 would normally wear as their clothing and their skin.  
3 So it would be intercepting the residues after it would  
4 pass through their particular normal work clothing  
5 before it deposited on the skin.

6 DR. HEERINGA: Yes, Doctor Hughes.

7 DR. HUGHES: One quick question which is a  
8 follow up. With regard to environmental breakdown  
9 products that might interfere with the dosimetry  
10 analysis, you did a collection beforehand. And did you  
11 actually eliminate subjects that might have sprayed  
12 recently? Was that an assessment of what they might  
13 have picked up in the environment or was that an  
14 assessment of what they might have sprayed in an  
15 instance or event that occurred previous to your  
16 monitoring event?

17 DR. BEAUVAIS: Well these are a  
18 correlation of studies that other people were doing and  
19 in general when, I would say that in general you'd  
20 probably want to eliminate that person. But I've also  
21 seen studies where they simply report that, you know,  
22 this one was high going into it.

23 DR. HEERINGA: Time for a few more  
24 questions before we Doctor MacDonald.

25 DR. MACDONALD: Yeah, my concerns are very

1 much like Doctor Bucher's, that just the relationship  
2 between the normal work clothing and the clothing worn  
3 during the study and so on. At one point I thought  
4 well if you put everything on the outside you're  
5 measuring the exposure of a worker who worked naked and  
6 then you would have to interpret that for an actual  
7 scenario by putting clothing on and determining how  
8 much it's keeping out. And there's something about  
9 the, some of the case studies that are being done, it  
10 seems to be the way you're doing it.

11 But I also would like some clarification as  
12 to how the pesticides are actually getting in. Is the  
13 major source through the protective clothing or normal  
14 work clothing or are there also exposed areas like the  
15 back of the neck or face and so on, and in fact most of  
16 the pesticide is getting in through the small exposed  
17 areas? Do we know this?

18 MR. DAWSON: Jeff Dawson, HED, it's very  
19 scenario dependent, so depending on the activity. For  
20 example if you consider let's say a mixing/loading  
21 activity where, you know, you're doing a lot of this  
22 stuff right in front of you it could be around the  
23 seams of the shirt and that area, it could be actually,  
24 if it's loaded enough it could actually penetrate  
25 through the fabric, it could go through the buttonholes



1 and such of the garment. If you're doing a, let's say  
2 a different activity such as air blast applications we  
3 tend to see, and this is borne out in the data, where a  
4 lot of the residues are on the, you know, the back of  
5 the head and the back itself and such.

6 So that's why we're, we talked to someone  
7 yesterday about like segmenting the whole body  
8 dosimeters and collecting patches from different  
9 regions. We're interested in understanding the total  
10 loading for the individuals, but also how the loading  
11 occurs and it gives us better insights into how we  
12 might manage those exposure levels.

13 DR. MACDONALD: Yeah, just to follow up  
14 too, just looking, the pictures have really helped but  
15 I could see that, I would expect a tremendous amount of  
16 variability between workers, just in the way they put  
17 their clothing on, the kind of clothing available to  
18 them, and with certain especially where you don't have  
19 machines and pumps and so on, just how clumsy they are  
20 in handling the product. So I would certainly expect  
21 some scenarios to have extremely high worker to worker  
22 variation or even a high variation in applications  
23 within the same worker.

24 And just a related matter too, it's not clear  
25 how much information you have on variability within

1 worker doing essentially the same task under the same  
2 conditions.

3 MS. DAVIS: Absolutely we have the same  
4 concerns and inherent in the data there is extensive  
5 variability. And actually we're going to be talking  
6 about the inter and intra-variability in one of the  
7 charge questions later this week because it is an issue  
8 for us, right.

9 DR. HEERINGA: Okay, thank you everyone.  
10 We'll have a chance to return to this general topic I  
11 think later in the morning when the Agricultural  
12 Handlers Task Force does their presentation as well.

13 But at this point I think on the agenda we're  
14 scheduled for Jeff Dawson and Jeff Evans of Health  
15 Effects Division to do a presentation on methods for  
16 handling, for measuring hand exposures.

17 MR. EVANS: Thank you very much, Doctor  
18 Heeringa. My name is Jeff Evans of the Health Effects  
19 Division. I'd also like to have Phillip Villanueva  
20 join us for any statistical questions that may arise  
21 from this discussion.

22 As you probably gather from the background  
23 and our discussions and comments, that the hand rinse  
24 versus cotton glove performance issue is very important  
25 to us with respect to developing generic databases. So

1 if we could approach this program with starting simple  
2 and getting more complicated as we get through this.

3 The current approach of course is the most  
4 simple and our mechanistic analysis is another kind way  
5 of saying, whatever we could find from the available  
6 literature and I do this with some trepidation knowing  
7 that some authors are present on this panel and I  
8 apologize in advance for any misinterpretations. Also  
9 I did try to faithfully in the background document  
10 reproduce what I had found in those papers and again I  
11 apologize if there is any inconsistencies in the, in  
12 what I put in those tables and if I captured your  
13 information correctly.

14 And the finally we're going to also look at  
15 the performance or comparisons of measurements in the  
16 data in PHED using the case studies that Jeff Dawson  
17 described yesterday. So we're going to certainly look  
18 at what we have now to approach this issue. And of  
19 course this augments our discussions with respect to  
20 biological monitoring and passive dosimetry comparisons  
21 overall as Sheryl presented this morning and the task  
22 force will address this afternoon.

23 So our current practice as I pointed out is  
24 very simple. We're just assuming that the two are  
25 interchangeable and we have to date not made any

1 corrections based on methods within the Pesticide  
2 Handlers Exposure Database.

3           So again our analysis of the literature, we  
4 certainly came away with I think several is a  
5 charitable way to put all the variables and factors  
6 that impact what you may be measuring on hands to  
7 consider. There's a number of different study design  
8 issues that complicate matters. We have test tube  
9 grabs, some of a mass balance approach and other  
10 methods, you know, spiking skins of individuals who are  
11 in vitro, porcine skin. So, and I think it's important  
12 to point out that there has not to date been a  
13 comprehensive study that really looks at this sort of  
14 holistically. And so we're relying on what's available  
15 in the literature and what we have in PHED at the  
16 moment. Next slide please.

17           So, to start off I think the seminal paper  
18 that addresses this and probably got everybody going on  
19 the relative comparison, was Davis back in 1983. He  
20 reported that hand measurements based on the use of  
21 cotton gloves to be considerably higher than hand  
22 measures using ethanol rinses and this was apple  
23 thinners reentering field treated with azinphos-methyl.  
24 Richard Fenske a few years later also reported  
25 measurements with gloves to be higher at short

1 monitoring periods, 1 and .5 hours and also at, these  
2 began to notice smaller differences observed when the  
3 monitoring periods were longer and this one 1.5 to 3  
4 hours, so the differences started to diminish somewhat  
5 as the monitoring period increased. He also noted some  
6 breakthrough of the lightweight cotton gloves which may  
7 have certainly impacted the results and had speculated  
8 that in the Davis study they may have used a heavier  
9 weight cotton gloves. So there are always, there's  
10 always something complicating, you know, a very simple  
11 read for a regulatory scientist. So Fenske has looked  
12 at this issue quite a bit. And another study reported  
13 hand measurements again for workers reentry fields  
14 treated with azinphos-methyl and thinning apples, that  
15 cotton gloves were 3.5 times the measurements using  
16 hand rinses. And again I think I should not that the  
17 apple thinners were monitored for two hours and I think  
18 this is where, you know, we have certainly got the  
19 notion of perhaps making some sort of correction factor  
20 for the hand rinse method from this paper where he had  
21 had a hand rinse correction factor from a compound  
22 having a similar LOGKOW to account for perhaps losses  
23 from the hand rinse method.

24 And in the next slide you'll see some  
25 summaries from those data. There's the original study

1 looking at the differences in the hours and that  
2 certainly got us thinking about exposure duration and  
3 other literature studies also seem to hint at that  
4 possibility.

5 And then in the table below is the azinphos-  
6 methyl study where he had gloves and washes. That 68%  
7 is based on a correction from captan, with captan and  
8 azinphos having similar chemical properties. I also  
9 included the wipe there, you know, Richard has pointed  
10 out many times that the wipe method is a very poor  
11 performer and I think it was mentioned yesterday in one  
12 of the public comments, that the wipe is also a very  
13 performance issue.

14 I don't know of any studies conducted by any  
15 task forces or signatory to our agency for occupational  
16 exposures where they relied on the wipe for measuring  
17 hands. I do know that this wipe is used for the face  
18 and neck and so I think that certainly has some impact  
19 on our thoughts regarding that method for the face and  
20 neck wipes. Next slide please.

21 So I probably should have stopped there  
22 because that certainly gave me a nice handy way to  
23 proceed with correcting for hand rinses and perhaps  
24 solving a problem, but the more you read, the more  
25 complicated it seemed to us and the more things entered

1 the picture. Certainly as investigators we're  
2 interested in different items of concern.

3 So to summarize some of the things that  
4 struck us on these data was that when you're looking at  
5 hand rinse performance, certainly the physical chemical  
6 properties of the pesticide, its solubility, optimal  
7 water partition coefficient strikes us as very  
8 important. Also perhaps molecular weight. Some of  
9 them also looked at the residence time on skin,  
10 acknowledging the differences in logistical  
11 considerations of field studies. So you might have  
12 some subjects waiting for periods of time and that  
13 might impact on that performance so they incorporated  
14 immediate rinsing and perhaps waiting periods of up to  
15 an hour.

16 Over the years, perhaps based on chemical  
17 performance methods, investigators selected alcohols  
18 and soap and water so there's a wide variety of  
19 solvents that have been used in these hand rinses.  
20 Concentration appears to have some impact on removal.  
21 As you have additional layering on the skin maybe it  
22 becomes easier to remove as you have more on the skin,  
23 that first little bit being absorbed and perhaps tying  
24 up that mechanism. The duration of exposure of the  
25 monitoring period also as we saw earlier in the

1 presentation, that might have some impact on the  
2 performance of hand rinses, whether it was a short or a  
3 long period of duration. And the nature of the residue  
4 I think is something that we may to also consider since  
5 we have several task forces and several different  
6 concerns.

7 We have exposure to different types of  
8 residues for reentry into pesticide treated fields.  
9 The residues may be more complex. They're complicated  
10 by being bound with soil or plant waxes and plant uses  
11 and other articles. When you have sprayers they're  
12 primarily exposed to a dilute concentration that's  
13 perhaps more uniformly spread over the body. And then  
14 you have mixer/loaders that are exposed to  
15 concentrates, getting concentrated splashes. So  
16 there's certainly a lot more going on than in my  
17 simplistically evaluated, or simple algorithms. But of  
18 course once again, the more you look at it the more  
19 complicated it got and I certainly wish I'd stopped at  
20 the first two studies, but I didn't.

21 So just some additional comments on some of  
22 those items I highlighted previously. The physical  
23 chemical properties of the pesticide and we really do  
24 think indeed if it is determined that it's important to  
25 correct for hand rinse performance, that we really do



1 think that looking at a physical chemical with  
2 properties of the surrogate compounds is a very  
3 important and perhaps a practical solution for a  
4 regulatory solution.

5 The performance in the hand rinse  
6 efficiencies have been reported in a number of studies.  
7 Richard Fenske and his colleague in Washington at the  
8 time, Alex Lu and Brian Curwin looked at some field  
9 reentry studies and tobacco fields treated with a water  
10 soluble compound and Campbell looked at the performance  
11 of different solvents on chemicals having very  
12 different water solubilities on the porcine skin.

13 And again I think that these studies I think  
14 can give us some of the basis for thinking about making  
15 the corrections. They do contain a lot of these  
16 surrogate chemicals that are used in generic database  
17 studies. And, you know, we had started to put together  
18 some regression equations comparing solubility, and the  
19 measurements of those, we just didn't have time to do  
20 that for this presentation but it's some we are  
21 certainly thinking about. And one of our colleagues at  
22 PMRA also thought that dermal absorption studies where  
23 they measure wash off after certain durations might  
24 also be an important component to consider in that  
25 analysis.

1           Of course performing these studies is a very  
2 difficult and maddening affair at times as pointed out  
3 by some of the panel members this morning and certainly  
4 that's not to be underestimated. And in doing so many  
5 of the investigators did incorporate a waiting period  
6 of sometimes an hour or 90 minutes, something like  
7 that. And others were able to capture the residues  
8 immediately after the exposure, particularly the test  
9 tube grabs where they had more of a mass balance  
10 approach. And in general, not always, but in general  
11 it seemed to us that the longer the waiting period the  
12 lower the rinse efficiency. So that would certainly be  
13 a study design consideration from our perspective and I  
14 certainly prevail upon the task forces to include a  
15 collection time of hand rinses immediately upon  
16 returning of the subjects from the field or study site.  
17 Next slide please.

18           The impact of the rinsing solutions, we have  
19 seen in a lot of the studies presented already, and  
20 we'll see certainly more later in this presentation  
21 where there is a wide variety of solutions that have  
22 been selected. Again, a lot of it might have to do  
23 with the thoughts about the method validation for the  
24 hand rinse. However, it should be noted that the soap  
25 and water solutions are currently used by all the task

1 forces, that does seem to be the preference. I had  
2 read in some of the literature that there were concerns  
3 for the subjects of the studies using, oh, I don't  
4 know, 50% methanol might be an issue deliquifying those  
5 hands after awhile, it may be enhancing the absorption  
6 of the pesticides that they were exposed to in that  
7 study. So for a variety of reasons it seems as though  
8 the state of the art as it were has focused on the use  
9 of more soap and water oriented washes.

10 And so I think the key studies that sort of  
11 address the different kinds of rinse efficiencies was  
12 the Brewer which was a compilation of many studies  
13 where they spiked hands of different solutions of many  
14 different pesticides, some of which are surrogate  
15 compounds. And those also include the Fenske and Lu  
16 data.

17 The 22% value you see there is for  
18 chlorpyrifos and I always think about that when I look  
19 at some of those chlorpyrifos biological monitoring  
20 studies. Perhaps, and I'm speculating here out loud,  
21 that, you know, in the mixer/loader/applicator ones  
22 where there are gloves it might not have been as much  
23 of an issue, but if you have reentry exposed to  
24 chlorpyrifos residues and you're having a poor  
25 performance, that might explain some of the differences

1 seen in the reentry compared to the mixer/loader. I'm  
2 simply speculating here but just some food for thought.

3 In the compilation study discussed in Brewer  
4 there was a high range, all the way up to 96% with a  
5 mean of 73% reported. In the study where they looked  
6 at the spiked porcine skin, the Propinyl certainly  
7 performed the best but I was struck by the fact that  
8 the soap and water rinses were the most consistent for  
9 this wide range of chemicals. That actually was the  
10 tightest range of percents. And I think both of the  
11 papers provided clues regarding the impact of skin  
12 concentration. Most definitely the Campbell asserted  
13 so and I think the Brewer paper was not as, it didn't  
14 seem as clear to us as we had read through that,  
15 Propoxur being the curious one in there. Next slide  
16 please.

17 So again as I pointed out Campbell saw  
18 definitely an increased efficiency with higher  
19 concentrations on the skin and again the Brewer study  
20 presented a little more mixed results.

21 And once again, bless them all, the study  
22 investigators used different solvents, different  
23 procedures, have different views on capturing and  
24 perhaps that may have complicated some of the results  
25 presented in that paper.

1           When we looked at studies that really focused  
2   on reentry, again having longer durations, it does seem  
3   that there is the potential for equilibrium or perhaps  
4   some layering going on as you have long exposure  
5   durations and you can mitigate perhaps some of the  
6   concerns about losses due to binding of the skin or  
7   absorption by having a longer study, and thus you may  
8   have a layering effect or some kind of equilibrium  
9   going on.

10           So that studies that may be conducted for  
11   short durations might overestimate exposures for maybe  
12   8 or 10 hour periods. It's a two way street and so the  
13   values from an 8 or 10 hour study may actually  
14   underestimate an exposure scenario where you're looking  
15   at a 1 or 2 hour exposure. So it does seem to be a  
16   complicated matter to us. Slide please.

17           And these studies that look at longer term  
18   contact with residues, at least as far as I was able to  
19   tell, were largely studies looking at reentry exposure.  
20   And again that's where you have maybe a more  
21   complicated residue pattern being developed because of  
22   the other active soil and plant waxes and the like.

23           So in Fenske in early '89 we began to see  
24   perhaps a difference between short and long durations.  
25   Derkin out of Syracuse looked at some earlier reentry

1 studies and compared the concentration of the residues  
2 on the leaves to the concentration of the residues on  
3 the hands, making some assumptions about the surface  
4 area of the hand and established a fairly nice  
5 relationship between the DFR, which is measured in  
6 micrograms per square centimeter and then the  
7 micrograms per square centimeter captured on the hands  
8 of the reentry workers. Of course in those studies  
9 there was gloves and hand rinses so we thank them for  
10 that.

11           Spencer I think also had a very nice analysis  
12 of the differences between long and short durations and  
13 again described that loading seen in the first two  
14 hours. And I think that's a really important thing to  
15 consider in a study for a number of reasons. One is  
16 for the handler studies the detection issue and then  
17 making sure that we get good measurements on the hands.  
18 And, you know, it suggests to us that maybe there is  
19 some concept in some of the situations, particularly  
20 reentry, where there may be equilibrium established  
21 after repeated contacts. And so longer study exposure  
22 durations are important in field study designs. Next  
23 slide please.

24           And some final thoughts, at least from, you  
25 know, our read of these studies, Jeff's going to get

1 into a few more after he looks at the case study data,  
2 but it seems to us worth considering some sort of  
3 relationship anyway between the efficiencies that are  
4 reported in studies, perhaps considering laboratory  
5 penetration studies, some sort of relationship between  
6 physical chemical properties and the rinse efficiencies  
7 that have been reported.

8 To play the devil's advocate with the task  
9 forces which I enjoy doing, as part of a field study  
10 design, perhaps select a surrogate chemical with a  
11 known and reliable biomarker and adding any remaining  
12 residues based on what is found in the urine. Maybe  
13 making adjustments for inhalation. You know, we have a  
14 lot of thoughts about comparing biological monitoring  
15 and the impact of the whole body dosimetry. I mean  
16 ideally you would have a study maybe collecting  
17 measurements with patches but if indeed the methods are  
18 capturing everything, then whatever you do collect in  
19 urine should either be small or be of low significance  
20 to your final unit exposure estimate.

21 And as some might conclude, make not  
22 adjustments at all to these surrogate data based on the  
23 conclusions of the passive dosimetry and biological  
24 monitoring comparisons.

25 And with that I'll hand it off to Jeff Dawson

1 who's going to describe additional analysis with the  
2 data in the PHED.

3 DR. HEERINGA: Thank you. Mr. Dawson  
4 we're at about 10:05. I don't want to rush your  
5 presentation. I think what I, my view is we'll go  
6 ahead with your presentation. We may have to take a  
7 break right after your presentation before you take  
8 questions if that's okay with you. Please proceed.

9 MR. DAWSON: Thank you. I'm just going to  
10 introduce the summary of the data and then I'm going to  
11 pass it over to Doctor Phillip Villanueva who dealt  
12 with the analysis of these data so I'll only talk for a  
13 couple of slides.

14 So basically yesterday I introduced the case  
15 study information for the six scenarios from PHED and  
16 our thought was, in addition to the analyses that Jeff  
17 just described, why not also take a look at the actual  
18 field monitoring data that we had to see how these  
19 methods have performed under field conditions.

20 So basically what this slide shows is the  
21 distribution of the different types of data that we had  
22 to work with based on what was in the case study. And  
23 so across the y axis here is just the number of data  
24 points that we have and the x axis here is just the  
25 varying combinations of sampling methodologies and



1 whether or not the monitored individuals were wearing  
2 protective gloves of some sort. So the blue bars here  
3 represent those individuals who were working with bare  
4 hands and then the red bars represent individuals who  
5 were wearing some sort of protective glove over the top  
6 of their hands.

7 And then each of the bars represents, well,  
8 and then the varying bars across the bottom represent  
9 the various sampling methodologies. For example, in  
10 the first bar right here the hand sampling was done  
11 with an acetone wash, straight acetone. In that one  
12 they were wearing protective gloves. In this one here  
13 the individuals were barehanded but they were, the  
14 sampling was done by collecting it with a soap  
15 solution. This bar here again was also a soap solution  
16 but in that case the individuals were also wearing a  
17 protective glove to reduce the exposures.

18 So from the case study this was essentially  
19 totaled up to 513 data points and there are 12  
20 different combinations of sampling methods and whether  
21 or not they wore protective gloves.

22 And then basically this slide just represents  
23 those data points and the code kind of carries through  
24 here, the various combinations of the sampling media  
25 and whether or not they were barehanded or wore

1 protective gloves. And on the x axis here you have the  
2 total amount of active ingredient that they handled and  
3 here was the total amount of residues in micrograms  
4 that were measured on those hands. And keep in mind  
5 this is for the 6 case study scenario so it's mixing,  
6 loading and applicators and it's different forms of  
7 pesticide.

8 So in some cases for the applicators it would  
9 be a dilute spray but, and for the let's say people  
10 loading granules it would be a, you know, a  
11 concentrated solid material so all the variety of  
12 pesticide antagonists or whatever you want to call it  
13 is also reflected in this slide.

14 And then on this slide, just to show how once  
15 you start segmenting the data down based on different  
16 scenarios and such, how you reduce the number. So, and  
17 this particular slide represents applicators who were  
18 wearing protective gloves and you can see instead of  
19 the 12 different combinations all of a sudden you're  
20 down to 4 different combinations. This is the soap  
21 solution where they were wearing a protective glove and  
22 ethanol with a protective glove and cotton gloves as a  
23 sampler with a protective glove over that and then  
24 isopropenyl. And here you, just by segmenting the  
25 database on whether or not they were a mixer, loader or

1 an applicator and whether or not they wore protective  
2 gloves, you go from 513 data points to 73.

3 So we did a series of analyses based on this  
4 and what I'd like to do is to hand the presentation  
5 over to Doctor Phillip Villanueva who actually did that  
6 part of the analyses.

7 MR. VILLANUEVA: Just a quick  
8 clarification, Mr. Villanueva, I'm not a doctor, but  
9 thanks.

10 So anyways we're, if we can go back to the  
11 previous slide I just want to talk a little bit about  
12 that.

13 So Jeff's team, one of the questions they had  
14 was, do certain hand monitoring methods result in  
15 consistently better recoveries? In other words, are  
16 the unit exposure values consistently higher?  
17 Depending on whether it's a removal or a trapping, so  
18 whichever type of hand monitoring method we're talking  
19 about. Next slide.

20 So we looked at various scenarios, 6 in total  
21 so there were applicators versus mixer/loaders, solid  
22 versus liquid formulation and then of course as Jeff  
23 just mentioned, protective glove versus bare hands. So  
24 we looked at each one of these 6 scenarios separately,  
25 ensuring that we had comparable unit exposure values.

1 And again the goal was just to determine if some of  
2 these different hand monitoring methods that we have  
3 consistently produced higher unit exposure values  
4 across these 6 different scenarios.

5 Again we segmented the data into 4 different  
6 categories for the hand monitoring methods. Some of  
7 them being trappings, others being removal. Cotton  
8 gloves, then soap solutions and then various alcohols  
9 and acetone and then the tie back gloves and other  
10 types of hand monitoring methods.

11 So initially this was meant to be an  
12 exploratory analysis, just kind of getting a feel for  
13 the data, just a simple Anova approach was performed on  
14 the log of the unit exposure values and there are  
15 couple of assumptions, a couple of underlying  
16 assumptions whenever you're performing this type of  
17 analysis.

18 In this case the log transform data are  
19 normally distributed is one of the assumptions. So  
20 whatever transform you have to use but basically you  
21 want to convert the data and make it's normally  
22 distributed before analyzing it. Also, the different  
23 group variances are equal, and that's one of the  
24 underlying assumptions so that's something we need to  
25 check later on also. And the observations are

1 independent so there's not going to be any type of  
2 correlation between the monitoring units, which of  
3 course I think you've guessed from some of the previous  
4 presentations that that's not the case.

5 But part of this, in addition to the Anova  
6 was a graphical evaluation of the data. So just  
7 looking at scatter plots and the probability plots give  
8 us a good idea if the data is lognormally distributed  
9 or if the variances are approximately equal and just an  
10 idea of where the group means lie in relation to one  
11 another.

12 So this is just one of the examples, this is  
13 the one I believe was included in the document  
14 submitted to the panel members. Again we did all 6  
15 different scenarios. In some cases the sample sizes  
16 were kind of small. I'm just going to spend a little  
17 bit of time explaining this graph. In each one of  
18 these cases again we have the different hand monitoring  
19 methods here.

20 In some cases not all 4 were available,  
21 depending on the exact scenario. In this case these  
22 were applicators wearing protective gloves with liquid  
23 sprays. So here in this case we have cotton, soap and  
24 wash and also the symbols here represent different  
25 studies so these are the monitoring units within each

1 individual study. So for these scatter plots you can  
2 already see that there's some evidence that there's  
3 quite a bit of clustering. So in this case what we  
4 have would be the, within study variability, I'm sorry,  
5 the within study, I'm sorry, yeah, the, with, in this  
6 case we'd have a correlation between the within study  
7 samples.

8 So here you can see they are tending to clump  
9 up here so that's already kind of undermining the  
10 assumption that the samples are independently sampled.  
11 And again, we don't take that into account with a  
12 simple Anova analysis. So you have some monitoring  
13 units down here so keep in mind some of these may, in  
14 some cases may be individuals monitored multiple times.  
15 In other studies they might have distinct individuals  
16 for each monitoring unit.

17 Over here we have the probability plots and  
18 this gives us a good idea of the, of whether our  
19 assumption or normality is being met. Again this is a  
20 log scale, we're looking at the los of the unit  
21 exposure value, so looking at this normal probability  
22 plot is the same as assessing the appropriateness of  
23 the lognormality assumption for the original data.

24 So here you can see with the points lying on  
25 these lines here that the assumption of lognormality is

1 met. You could also do, instead of a visual inspection  
2 of that there are statistics that you can use such as  
3 the Shapiro-Wilkes to determine if that assumption is  
4 being met. But generally what we saw in all 6 cases,  
5 and I'll summarize from this later on also, is that  
6 that assumption seemed to hold so log transforming the  
7 data effectively converted the unit exposure values to  
8 normal distributions.

9 Another nice handy feature of these  
10 probability plots is that you can also assess whether  
11 or not the group variances are approximately equal. So  
12 in this case the slopes of these lines are an  
13 indication of the variability in the data, so if  
14 they're approximately parallel then you can say that  
15 the group variances are equal.

16 So it seems to be the case for these two  
17 groups right here, but not the case here for a wash,  
18 there seems to be a smaller variability in that case or  
19 a less steep slope. And so again, keep in mind that  
20 was another underlying assumption of a simple Anova  
21 approach. So I think that's all I wanted to say about  
22 that slide, yeah.

23 As I mentioned before, we looked at 6  
24 separate scenarios, this is just a summary of the one  
25 way Anova approach here and we have the different, this

1 is a sample size for the monitoring units. Again, keep  
2 in mind that some individuals were monitored multiple  
3 times depending on the study. And then in some cases  
4 we have some very small sample sizes so you have to be  
5 very cautious about, well, in addition to the  
6 assumptions that are violated you also have to be  
7 cautious about the sample sizes we're considering.

8 And these are the hand monitoring methods  
9 that are available for these various scenarios. And  
10 just a quick look at the significant differences that  
11 we saw here. In some cases you'd have cotton being  
12 less than wash, in other cases it would be larger, the  
13 unit exposure values are, rather the logs of the unit  
14 exposure values. So there weren't any consistent  
15 results but again this was exploratory, keeping in mind  
16 that there are certain assumptions in using this type  
17 of approach that are being violated.

18 And just a quick summary of all 6 of these  
19 different scenarios. As I mentioned previously, log  
20 transforming the data effectively converted those to  
21 normal distributions. I hate to use the term  
22 normalize, we tend to use that a lot with this group  
23 for different things. So instead I say convert to,  
24 convert the data to normal distributions effectively.

25 Generally there was at least one group



1 variance that was not equal to the others when looking  
2 at these 6 different scenarios, so that was a problem  
3 as far as interpreting the results of an Anova  
4 analysis. And of course the sample were not  
5 independent because of the study design. Basically we  
6 expect studies, measurements from within the same  
7 studies to be more similar than methods from different  
8 studies. So that's a violation of the independence.

9           So two of the primary assumptions of this  
10 type of approach have been violated but the scatter  
11 plots do indicate that the study to study variation is  
12 greater than the method to method variation, which  
13 would imply that basically we would have to find much  
14 larger differences than we've observed so far to  
15 conclude that certain hand monitoring methods perform  
16 better than others. And then of course that wasn't the  
17 only goal, we still to determine if one consistently  
18 outperforms others. But basically just based on this  
19 simple approach it seems obviously that there's no  
20 method that consistently results in higher unit  
21 exposure values.

22           As far as possible future analytical  
23 approaches, we know there are better methods available  
24 out there to take into account these unequal group  
25 variances and also the types of non-independence that

1 we're seeing with these measurements. Some of the  
2 approaches we're talking about would be nested Anova  
3 which you consider as a subset of a mixed linear model  
4 approach.

5           These, as I mentioned can appropriately model  
6 the nesting that we're seeing with the measurements.  
7 For instance, you'd want to consider the nesting of  
8 measurements within workers so some workers being  
9 sampled times and then the workers within the studies.  
10 And also again the unequal variance can be modeled more  
11 appropriately. We do have some preliminary results  
12 from running hierarchical linear models or HLM that  
13 we've had time to do between the time of finalizing the  
14 document and preparing for this SAP. And we think  
15 that, even though I'm going to provide some of the  
16 preliminary results, there are even further refinements  
17 we can do using such an approach, using HLM.

18           We can include dummy variables or additional  
19 covariates, if we were to use the KOW and consider  
20 interaction terms. So we can more appropriately take  
21 into account some of the physical chemical properties  
22 instead of repeatedly sub-setting the data.

23           And this is just a comparison of the results  
24 I showed earlier from our one way Anova and then the  
25 results from the HLM analysis. Again some of this, we

1 don't see anything here that conflicts with what we saw  
2 with the one way Anova, but as I mentioned before,  
3 since some of these differences between the hand  
4 monitoring methods aren't very large, then some of the  
5 significant differences we saw on the one way Anova  
6 don't hold when we look at a more complex model that  
7 appropriately considers the nesting and unequal  
8 variance that we've observed in the data. But again,  
9 even based on the significant differences that we do  
10 find there doesn't seem to be any significant results,  
11 I'm sorry, any consistent results that we see from one  
12 scenario to the next. And again many of the  
13 significant differences that we saw on the one way  
14 Anova don't hold for this type of more appropriate  
15 approach to looking at the data. I think that's it.

16 MR. DAWSON: And then just to wrap things  
17 up, kind of where we are in conclusion with this  
18 presentation is that we're left with basically two  
19 options. One is to adjust the results or not and  
20 basically a couple of options we thought of, to  
21 possibly adjust the results we're looking at log KOW,  
22 adjustments based on log KOW or other physical chemical  
23 properties or, depending upon, you know, what the  
24 outcome is, is to the comparison of, or biomonitoring  
25 analysis that we talked about earlier, maybe adjust

1 based on that. And conversely, not adjusting hand  
2 measurements, again depending upon the biological  
3 monitoring analysis and the passive dosimetry  
4 comparison we talked about earlier and also the results  
5 of this field performance analysis that we just talked  
6 about.

7 And I think as Jeff Evans alluded to earlier,  
8 some kind of controlled designed experiment to better  
9 specifically address this issue would also be very  
10 useful.

11 DR. HEERINGA: Thank you very much for  
12 these presentations. We're at about 22 minutes after  
13 10:00 and I think it's about time that we should take a  
14 break. But are there any pressing questions? I'll  
15 return after the break, but any pressing questions that  
16 anyone would like to ask before we move to a break here  
17 with regard to this presentation?

18 Okay, I guess we'll have a little time over  
19 the break to consider any questions.

20 For the next presenters, which I think are  
21 the AG. Exposure Task Force Group, we'll probably allow  
22 15 to 20 minutes for questions after the break so we'll  
23 get a little bit later start than the agenda shows, but  
24 let's plan to reconvene here at 20 minutes of 11:00  
25 please.

1 (WHEREUPON, there was a recess).

2 DR. HEERINGA: Okay, welcome back  
3 everybody to the second half of our second morning  
4 session of the FIFRA Science Advisory Panel meetings on  
5 the topic of Review of Worker Exposure Assessment  
6 Methods.

7 We've just completed a presentation by Jeff  
8 Evans and Jeff Dawson and Mr. Villanueva regarding the  
9 Agency methods for hand exposure assessments. And  
10 before we move on to the next scheduled presentation  
11 I'd like to give the panel an opportunity for a few  
12 clarifying questions on this presentation.

13 Are there any questions that the panel has on  
14 the material that Jeff Evans or Jeff Dawson or Mr.  
15 Villanueva presented? Yes, Doctor Bucher.

16 DR. BUCHER: This question really isn't  
17 specifically related to what you presented but I'm  
18 curious as to the relationship between the questions  
19 you're raising about how you would possibly utilize  
20 information from the existing database in relation to  
21 the rest of the context of this meeting about the  
22 future studies that are being put together. Is there a  
23 relationship between these or are you simply asking for  
24 the panel to respond to you about how you might  
25 retrospectively utilize the data that you already have

1 in a better way?

2 MR. EVANS: You know, certainly we would  
3 like both, but for this presentation this really has  
4 view towards how we would collect new data if we needed  
5 it, and I think also to help us make sense of what we  
6 do have since we have a mixture of methods for  
7 assessing that part of the body.

8 DR. HEERINGA: Doctor Johnson.

9 DR. JOHNSON: Yes. Have you looked at the  
10 correlations that might exist between the different  
11 measurements that you might have on the same  
12 individual? For example, how does the head and neck  
13 wipes correlate with the hand washing, how do those  
14 correlate with the patches, how do they correlate with  
15 the whole body dosimeter, et cetera?

16 MR. VILLANUEVA: No, I don't think we've  
17 specifically looked at how different measurements  
18 correlate within an individual measurement, within an  
19 individual that's been measured.

20 DR. HEERINGA: Do Lu.

21 DR. LU: Just a clarification question.  
22 How does the Agency define exposure versus dose?

23 MR. DAWSON: I guess the standard answer  
24 would be, based on what we have, what are included in  
25 the Agency wide Exposure Assessment Guidelines. So the

1 definition there of exposure would be, you know, what's  
2 deposited on the surface of the skin. Also, if you  
3 read that document it uses the term, and we kind of use  
4 it interchangeably, there's a little nuance to it but  
5 potential dose and then absorbed dose would be after it  
6 passes through the barrier.

7 DR. LU: And do you think it is adequate  
8 to say for example, dermal exposures? There is many  
9 ways to assess dermal exposures. And then you multiply  
10 by 3% in the case for chlorpyrifos and that number  
11 represents dose.

12 MR. DAWSON: That's correct, so in that  
13 particular case we would have calculated an absorbed  
14 dose estimate for the eventual calculation of a risk  
15 estimate. But how we do it varies depending upon the  
16 nature of the hazard information we have available.  
17 For example, in recent times, essentially what's been  
18 done related to these risk assessments is that large  
19 numbers of dermal administration toxicity studies have  
20 been developed, so there, instead of calculating  
21 absorbed dose estimates we would be using exposure  
22 estimates directly.

23 DR. LU: Right but I guess the question  
24 will be for me, is kind of looking at those data, the  
25 comparison that you presented in the last two hours,

1 are those numbers being calculated this way, that, the  
2 exposure amount times a certain fraction of the  
3 quotient and that resulting number will become dose and  
4 being manipulated in all the comparisons?

5 MR. DAWSON: Right, from the passive  
6 dosimetry estimates, that's how we'd be getting it.

7 DR. LU: All right. Thank you.

8 DR. HEERINGA: Cynthia Hines.

9 DR. HINES: Just one quick clarification.  
10 When you're presenting isoprophyl alcohol data and  
11 ethanol data, is that 100%, is that 10%, is there any  
12 water in those?

13 MR. DAWSON: Several of them were 100%,  
14 there were a few that were 50/50. I'd have to go back  
15 and look at the exact detail. Some of it exactly  
16 wasn't clear from the studies so it would

17 DR. HINES: Yeah, I might suggest some  
18 caution in combining handwash that may come from a  
19 straight ethanol or IPA with that that has a  
20 substantial amount of water in it because they will  
21 behave differently.

22 MR. DAWSON: Absolutely.

23 DR. HEERINGA: Yes, Doctor Kim.

24 DR. KIM: Just a follow up to that. I  
25 have a question about whether you're interested in, or



1 concerned about chemicals that are absorbed inside the  
2 skin and the date of that, so the time force behavior  
3 of chemicals that are inside the stratocore or in  
4 deeper layers of the skin? Because the effect of  
5 different washes can affect how that, affect the  
6 behavior of those chemicals, they may penetrate further  
7 or they may be, they may come to the surface of the  
8 skin, et cetera. So that would affect your internal  
9 dose estimates.

10 DR. HEERINGA: Presumably we'll have an  
11 opportunity to cover that in more detail as we get into  
12 responses. Doctor Pependorf.

13 DR. POPENDORF: Yes, I just I guess want  
14 to follow up on that too because I think the question  
15 was really, are you using the data or the data that you  
16 presented, was that exposure or dose? And my  
17 understanding was that you were presenting exposure  
18 without any adjustment for absorption. You'd  
19 eventually use it that way but that's not what you  
20 presented. Is that not correct or which is correct?

21 MR. DAWSON: On the hand data from the  
22 case study that I presented it's pure exposure, no  
23 adjustment for absorption in that. I'm sorry if there  
24 was a little bit of misleading with the conversation  
25 with Doctor Lu earlier.

1 DR. HEERINGA: Doctor Bucher.

2 DR. BUCHER: Sorry, I guess I'm again  
3 confused then because it seems to me like if you're  
4 going to be adjusting the handwash information for  
5 exposure based on KOW for example, that to ignore the  
6 possibility of utilizing that same kind of physical  
7 chemical information for estimating the amount that  
8 might be lost to the handwash recovery through  
9 absorption is lost information and it's a lost  
10 opportunity.

11 MR. DAWSON: I think we're open to all  
12 possibilities and suggestions that you may have for how  
13 to address these issues.

14 DR. HEERINGA: I'm quite sure we'll have  
15 ample discussion of this topic later on.

16 Okay, at this point I think it seems like  
17 we're reasonably comfortable, at least with the  
18 presentations and the information provided this  
19 morning. There may be additional questions and I guess  
20 it's always been our practice, and I think Ken will  
21 follow that this afternoon, that if there is in the  
22 course of the discussion need for clarification or what  
23 appears to be a clear misunderstanding we'll allow an  
24 opportunity for a correction or a clarification at that  
25 point too.

1           At this point then I would like to thank the  
2 presenters from the Health Effects Division for their  
3 discussion of the hand exposure measurements and that  
4 data. And I'd like to move on the next scheduled  
5 presentation on the agenda which is going to be  
6 presented by the Agricultural Handlers Exposure Task  
7 Force and the topic is a comparison of passive  
8 dosimetry in biological monitoring.

9           So we sort of go back to an industry  
10 evaluation of the topic that Doctor Beauvais covered  
11 this morning. And I think the scheduled initial  
12 discussion is Doctor John Ross if that's correct.  
13 Doctor Ross.

14           DR. ROSS: That's correct. Thank you, Mr.  
15 Chairman. I thank you for this opportunity to address  
16 this august body on behalf of the Agricultural Handlers  
17 Exposure Task Force. Can you hear me okay?

18           DR. HEERINGA: That's fine.

19           DR. ROSS: Today I'd like to talk about a  
20 comparison of human dosimetry as measured using passive  
21 dosimeters and biomonitoring. Next slide please.

22           I'd like to give a brief overview of what  
23 we're going to discuss today, starting with a history  
24 of worker exposure monitoring going back into time and  
25 then moving forward into the generic use of that

1 exposure in the form of the Pesticide Handlers Exposure  
2 Database, some of the attributes of passive dosimetry  
3 and biomonitoring and a review of studies that have  
4 been published as well as proprietary studies and some  
5 of the physical chemical properties, metabolism and  
6 things like that that are involved in comparing these  
7 different studies. Finally a statistical analysis,  
8 conclusions and some of the lessons that we've learned  
9 from these comparisons.

10 Passive dosimetry and biomonitoring go back  
11 to the mid-50s and correspond to the time of the  
12 introduction of the organophosphate insecticides where  
13 there was concern about acute toxicity:

14 These earliest measures of passive dosimetry  
15 and biomonitoring were industrial hygiene tools, they  
16 were done more qualitatively than quantitatively and  
17 that changed, the paradigm that we assessed risk with  
18 changed in 1983 with the issue of the National Academy  
19 of Science Report that established quantitative  
20 measures for exposure assessment. And we have gone  
21 from a time when we were trying to prevent acute  
22 toxicity now to preventing the possibility of no  
23 toxicity. We've gone from cases of toxicity in the  
24 field to a hundredfold below that with uncertainty for  
25 intra and interspecies factors, and are now entering a

1 new era where we're talking about looking at the 95th  
2 percentile at a hundredfold below the no affect level.  
3 Next slide.

4 Recently questions have been raised regarding  
5 the validity or the trueness of passive dosimetry as a  
6 measure of exposure. And I'd like to give an  
7 introduction to the generic use of passive dosimetry  
8 and a discussion of the criteria that we have used for  
9 biomonitoring, and then a comparison of the results of  
10 these two methods. Next.

11 The passive dosimetry methodologies have been  
12 codified, they were standardized starting here in 1975  
13 with patch dosimetry by the World Health Organization.  
14 It was updated in 1982 for whole body dosimetry and  
15 there have been a series of FIFRA guidelines  
16 established for passive dosimetry. In 1986 for handler  
17 or mixer/loader/applicator exposure monitoring. In  
18 1997 those guidelines were updated for reentry workers  
19 and residential exposure and in '97 the OECD issued  
20 guidance documents for passive dosimetry. Next.

21 The Pesticide Handlers Exposure Database has  
22 been discussed extensively today. So I'll try to  
23 minimize the reiteration here. But basically it was  
24 issued in 1992, reissued again with additional studies  
25 in '95 and these studies tended to be older, most of

1    them were non-GLP and as EPA has previously indicated  
2    there are 37 distinct exposure scenarios that are  
3    within the Pesticide Handlers Exposure Database.

4           The primary methods used for assessing dermal  
5    exposure was patch dosimetry and inhalation monitoring  
6    was typically done with personal inhalation monitors.  
7    Face and neck exposures were typically done with patch  
8    dosimetry in these studies and hand exposure as EPA has  
9    just discussed ran the gamut, there were a variety of  
10   methods. Hand washes with a variety of solvents,  
11   gloves, et cetera.

12           Now, one of the interesting things about the  
13   Pesticide Handlers Exposure Database is that two thirds  
14   of the dermal measures of exposure in that database are  
15   below the limit of quantification. The LOQ varied by a  
16   hundred thousand fold between these studies and  
17   reflected in part the age of the studies and the  
18   ability to detect different materials at the time the  
19   studies were conducted. Most of the studies didn't  
20   measure all body regions and as a result we, in trying  
21   to assess exposure, have added body parts from  
22   different individuals in order to come up with a whole  
23   body which we call composite bodies.

24           There are other synonyms for this. But the  
25   bottom line is that it's very difficult to get a useful

1 measure of variability from this type of data. So for  
2 the most part the Pesticide Handlers Exposure Database  
3 restricts the analysis to evaluation of central  
4 tendencies.

5 More recently the AG. Handlers Exposure Task  
6 Force has generated generic exposure data that follows  
7 many of the methods that have been established in the  
8 Pesticide Handlers Exposure Database, but improves on  
9 that paradigm. Next.

10 Now, basically for estimating total exposure  
11 in these passive studies, use the micrograms of  
12 exposure measured on a whole body inner dosimeter and  
13 the micrograms from the handwash, the amount of  
14 material from the head and neck and inhalation. Next.

15 Now absorbed dosage is calculated by adding  
16 in a compound specific dermal absorption fraction. So  
17 the data, whether it comes from the Pesticide Handlers  
18 Exposure Database or whether it comes from the AG.  
19 Handlers Exposure Database, is normalized dermal or  
20 inhalation to micrograms of exposure per pound of  
21 active ingredient applied. Multiply that by the pounds  
22 of active ingredient used in a particular study by the  
23 fraction of absorption through the skin, add to that  
24 the inhalation dosage which is also derived from a  
25 normalized value to pounds applied, and divide by body

1 weight to get absorbed dose.

2 Now, this is the critical comparison, this is  
3 what we use for comparison to biomonitoring which is  
4 also an absorbed dose. There are a number of exemplary  
5 passive dosimetry biomonitoring exposure studies that  
6 I'd like to overview today and show you the results  
7 from. These are a list of the studies in this slide.  
8 They include a variety of handler exposure monitoring  
9 studies, but they also include some reentry studies  
10 such as low crops, scouting, citrus pruning, citrus  
11 harvesting and an indoor study which is, actually two  
12 indoor studies which involved jazzercise. Next.

13 Now the requirements for a useful passive  
14 dosimetry study are ones that are able to measure both  
15 inhalation in the breathing zone of the individual  
16 that's being monitored as well as the dermal component  
17 which includes both a dermal dosimeter as well as hand  
18 washes and a measure of head exposure, head, neck and  
19 face exposure which can be done with either a patch or  
20 with washes and wipes.

21 We need to have an analytical standard and a  
22 good analytical method that allows low limits of  
23 detection. And it's important to emphasize that in  
24 these studies, especially where we're looking at  
25 concurrent passive dosimetry and biomonitoring, where



1 they are done at the same time, that there no  
2 additional layers of clothing beyond that required by  
3 the Worker Protection Standard or the label. Next.

4 Now for biomonitoring studies there are a  
5 number of desirable attributes and the ones that we've  
6 listed here we say are desirable, they're not absolutes  
7 but if we get outside of these parameters it becomes  
8 problematic. One thing that is required is a knowledge  
9 of the kinetics of excretion. We need to know what the  
10 metabolism and excretion is in humans or some higher  
11 primate. I can't tell you the number of times I have  
12 made the mistake of using rodent metabolites and trying  
13 to assess exposure. And this is a real problem when  
14 going to a higher mammal because sometimes the pathways  
15 for metabolism are radically different. It's helpful  
16 to have a urinary metabolite that's at least 30% of the  
17 absorbed dose. And we're going to discuss a few  
18 examples where we've got 8% to 12%. Those are still  
19 doable.

20 There are some examples that we have excluded  
21 that are as low as a tenth of a percent and we feel  
22 that those are not possible to make a reasonable  
23 comparison. Metabolite excretion has to take place  
24 over a relatively short interval, a half life of two  
25 days or less in order to capture a significant

1 proportion of the total excretion in a reasonable  
2 period of time. Especially if you're looking at 24  
3 hour collections.

4 This is an imposition on people that are  
5 doing these studies or involved in the studies,  
6 involved in the collection and you don't want to impose  
7 any longer than necessary. Now metabolites need to be  
8 stable in urine and we need to know how the exposure  
9 occurs. That is, were these exposures study state? In  
10 other words, we know the person was exposed before we  
11 began monitoring and they continued to be exposed  
12 through the monitoring period, or was their exposure  
13 limited to just the time that we started the  
14 collection?

15 Again for these biomonitoring studies it's  
16 very helpful to have no additional layers of clothing  
17 beyond what is normal. And what I'm going to describe  
18 are studies in which individuals have been monitored in  
19 these concurrent passive dosimetry and biomonitoring  
20 situations where they have their normal work clothing  
21 which is long sleeved shirt, long pants and briefs and  
22 a t-shirt as the inner dosimeter.

23 Alternatively we can take an outer dosimeter  
24 and apply a clothing protection factor or penetration  
25 factor to that to estimate the amount going through the

1 clothing. But either way we're using normal clothing,  
2 nothing beyond that with these passive dosimetry  
3 biomonitoring studies concurrently done. Next slide.

4 Now in addition to concurrent studies there  
5 are a couple that we're going to talk about today that  
6 were consecutively done where we had passive dosimetry  
7 done in the same cohort of individuals that  
8 subsequently had biomonitoring done. It's desirable  
9 from our perspective to do this concurrently because  
10 under concurrent conditions you know that these people  
11 are being exposed to the same dosing scenario, whether  
12 it's handling a chemical or post-application exposure.  
13 And we're capturing that exposure by the passive  
14 dosimetry and biomonitoring at the same time.  
15 Alternatively you can use individuals, the same  
16 individuals where you've measure them at one time with  
17 a passive dosimeter and you might want to do this, and  
18 there are a couple of cases we'll talk about, where  
19 we're interested in extrapolating this data to  
20 residential exposure.

21 And so we put two layers of dosimetry  
22 garments on the individuals in the consecutive case so  
23 that we can find out what went to all portions of the  
24 body and then subsequently did biomonitoring using  
25 normal clothing configuration. There's a little

1 greater uncertainty associated with passive dosimetry  
2 and biomonitoring that's done consecutively than done  
3 concurrently just because you can't assure that it was  
4 exactly the same exposure scenario. It might be very  
5 similar in handling the same amount of material and in  
6 trying to engage in the same activities, but it won't  
7 be exactly the same. Next.

8 Now the concurrent passive dosimetry and  
9 biomonitoring study designs involved primarily garment  
10 dosimeters. There is one case where we used a study  
11 that had patch dosimetry, I'll point that out. Most of  
12 these studies were done more recently, that is 1990  
13 vintage, plus. Virtually all of these studies that  
14 we're going to discuss that were passive dosimetry and  
15 biomonitoring concurrent, were done under good  
16 laboratory practices. Inhalation was monitored in the  
17 breathing zone for most of these studies, there are a  
18 few exceptions where exposure from the inhalation route  
19 was expected to be very low or nonexistent, and it  
20 wasn't taken. In virtually all cases face and neck  
21 wipes were used or occasionally hat patches. Hand  
22 washes were used in most cases. And in virtually all  
23 of these studies there was a high level of  
24 detectability, both in the urine as well as the passive  
25 dosimeters. Next.

1 Now of the 34 studies that we looked at, and  
2 these were both proprietary as well as published  
3 studies, 14 of the studies we found to meet the  
4 acceptability criteria that I outlined in the previous  
5 couple of slides. 9 of those were proprietary studies,  
6 5 were published studies and 13 out of 14 of these  
7 "acceptable" studies used dosimetry garments. One of  
8 them was a patch dosimeter study. And 12 out of 14  
9 were concurrent as opposed to consecutively monitored.  
10 Now, I'd also like to point out that in looking at  
11 these 34 studies there were other studies that were not  
12 included. One of those was the Propinyl study that EPA  
13 mentioned. In that particular study the metabolism was  
14 done in rodents and we felt that it was not a useful  
15 study for comparison to passive dosimetry. Next.

16 This slide outlines studies in the concurrent  
17 passive dosimetry and biomonitoring studies, the nature  
18 of the pesticide that was used in the left hand column,  
19 and then the next column over shows the human dermal  
20 absorption that was measured at the lowest dose in the  
21 studies where multiple dosages were measured. And as a  
22 comparison, the next column shows the rat dermal  
23 absorption for those same compounds and you'll not that  
24 as is typical, rats, when used as a model overestimate  
25 dermal absorption for humans, they tend to have more

1 permeable skin. In most cases the rat is the model of  
2 choice, that's what's used to generate regulatory data  
3 and so that represents one of the sources of  
4 conservatism when we estimate absorbed dosage from the  
5 existing data. We also show here the metabolite that  
6 was specifically collected in each one of these  
7 monitoring studies and in the far right hand column  
8 give an indication of the excretion after multiple half  
9 lives. Next.

10 Now, what we would like to discuss today is  
11 the validity of passive dosimetry as a measure of  
12 exposure. And Webster defines valid as having legal  
13 force, which is certainly useful in a regulatory  
14 setting or based on evidence or sound reasoning. A  
15 valid study or a valid methodology should give  
16 something that's reliable, that approaches reality,  
17 that's not overly conservative.

18 Now it's the AG. Handlers Task Force position  
19 that it's difficult if not impossible to isolate a  
20 particular portion of the body and validate exposure  
21 recovery to that portion. And that would be areas such  
22 as the hands, face or neck. The removal efficiency  
23 studies that are frequently done, some of those that  
24 have been recently cited in the literature, have  
25 problems with study designs.

1           They have short periods of application  
2 typically followed by wash off, they don't simulate  
3 what occurs in a working environment, they don't have  
4 some mitigating factors that would either prevent  
5 absorption, like the plant materials, grease, the  
6 equilibrium situation that occurs over an extended  
7 period when you're exposed to a recurring source. But  
8 all of these methodologies, the hand washes, the face  
9 wipes, the whole body dosimetry can be validated as a  
10 whole if we look at a comparison of concurrent passive  
11 dosimetry and biomonitoring. Next.

12           That is, if we look at biomonitoring and we  
13 find a dosage for a particular compound or a particular  
14 scenario, we compare that to the passive dosimetry dose  
15 estimated under that same set of conditions, applying a  
16 compound specific dermal absorption factor and they  
17 come out about the same, then we have a valid  
18 methodology. Next.

19           Now the method that was used for calculating  
20 dose for biomonitoring involved summing the amount of  
21 metabolite that was excreted and correcting for the  
22 stoichiometric difference between the molecular weight  
23 of the parent versus the metabolite, and correcting for  
24 the fraction excreted over the period of time for which  
25 the urine was collected and dividing by the body

1 weight. Next.

2 Now from the perspective of validating  
3 passive dosimetry with the concurrent biological  
4 monitoring we're going to look at ratios of central  
5 tendencies from each of these methodologies. We're  
6 also going to look at the possible influence of dermal  
7 absorption on this ratio of passive dosimetry to  
8 biological monitoring. And finally to look at the  
9 ratio over a number of different compounds and  
10 scenarios. Next.

11 Now the data that's shown in this graph are  
12 data from the Pesticide Handlers Exposure Database  
13 which is shown on the x axis and some data from the  
14 Outdoor Residential Exposure Task Force. These are  
15 central tendency values and they are compared to data  
16 from biological monitoring studies where the same  
17 amount of material was handled in both studies.

18 So the individuals, even though they came  
19 from different studies, the results were normalized to  
20 the same amount of material handled. And you can see  
21 the centerline, the solid line, which represents a 1 to  
22 1 correspondence of passive dosimetry to biomonitoring.  
23 The dotted lines represent a plus or minus 3x  
24 difference from that centerline of equivalence. Next.

25 Now in manipulating the data, standardizing



1 the data for biomonitoring studies, or passive  
2 dosimetry monitoring studies that were compared to  
3 biomonitoring, we made some modifications from the  
4 assumptions that were in the original papers that were  
5 either proprietary or published. And these are  
6 critical because some of them involved for example,  
7 respiration rate where we adjusted all of the  
8 respiration rates to a uniform value of 16.7 liters per  
9 minute. In the studies as they appeared, published or  
10 proprietary, they were 12 to 29 liters per minute.  
11 I'll just point out that at 29 liters per minute,  
12 someone sitting on a tractor would hyperventilate and  
13 would be incapable of performing their job. But this  
14 was a regulatory assumption that was in common use for  
15 a number of years.

16           Biomonitoring data were consistently  
17 estimated using a combination of stoichiometry as I  
18 indicated and a percent excreted in urine after  
19 multiple half lives. Dermal absorption was adjusted in  
20 the case of Chlorpyrifos to a single value of 3%,  
21 because in the studies as published or as printed they  
22 ranged for that particular compound from a low of 1% to  
23 a high of 9.6%, reflecting the opinions of the various  
24 authors. 3% is the value that's historically been used  
25 for regulatory purposes, that's the value that we used

1 for all of the studies involving Chlorpyrifos.

2 In two fo the studies where we had concurrent  
3 biomonitoring and passive dosimetry, where only an  
4 outer dosimeter was used and they wore underwear but we  
5 did not measure the exposure on that underwear, we only  
6 looked at the exposure on the outer dosimeter, a 10%  
7 clothing penetration value was assumed. This is very  
8 consistent with data that has been accumulated by the  
9 Antimicrobial Exposure Task Force which shows a range  
10 of 8% to 12%. So we took about the middle of that  
11 range. Next.

12 This graph shows the individual data points  
13 for concurrent passive dosimetry and biomonitoring  
14 where the exposure from biomonitoring is shown on the x  
15 axis from passive dosimetry on the y axis and each one  
16 of these points represents an individual. So this is  
17 all of the data from all of these studies combined and  
18 you'll see that they fall above and below this line of  
19 equivalence that's been drawn in where there would be,  
20 if it fell exactly on the line, the same dose derived  
21 from both methodologies. You can see that there's  
22 perhaps a slight bias to overestimate from passive  
23 dosimetry, but it falls on both sides of the line.  
24 Next.

25 If we look at the ratio of passive dosimetry

1 to biomonitoring for these studies, again by  
2 individual, as a function of the dermal absorption  
3 factor used for the different compounds that were  
4 involved in these studies, we can see again that  
5 there's data that falls above and below this line of  
6 equivalence, the geometric mean ratio for all of these  
7 data points is 1.2 so there's a slight tendency to  
8 overestimate from passive dosimetry. Next.

9 Listed in this slide are, again the ratio of  
10 passive dosimetry to biomonitoring and we've just shown  
11 chronologically, the studies and the individual data  
12 points from each one of those studies to demonstrate  
13 that there is no particular bias in the results for  
14 passive dosimetry to biomonitoring as a function of  
15 time or study. Next.

16 In conclusion we feel that the data  
17 demonstrate that passive dosimetry does not  
18 underestimate the actual absorption or exposure as  
19 demonstrated or as measured from biomonitoring. It's  
20 not biased and yields an estimate of absorbed does  
21 that's very similar to biomonitoring. As a result of  
22 that we feel that passive dosimetry as a whole has been  
23 validated. And again we reiterate that it would be  
24 very difficult, if not impossible, to validate these  
25 individual measures that are used in passive dosimetry,

1 such as handwash, face wipe, et cetera. Next.

2 And finally the lessons learned here,  
3 regardless of whether we're talking about passive  
4 dosimetry using patches, that is from the Pesticide  
5 Handlers Exposure Database or from one of the studies  
6 that we utilized in the concurrent passive dosimetry  
7 and biomonitoring, or using whole body dosimeters, the  
8 absorbed dose from biomonitoring and the absorbed dose  
9 from these passive dosimetry are very similar.  
10 Biomonitoring however can only be done with a very  
11 limited number of compounds because we only have a  
12 limited number for which we have complete absorption  
13 distribution, metabolism and excretion data.

14 Finally, the dermal route is the predominant  
15 route across a variety of compounds, a variety of  
16 scenarios. Approximately 70% of the absorbed dose is  
17 attributable to the dermal route of exposure for these  
18 relatively low vapor pressure compounds. Thank you.

19 DR. HEERINGA: Thank you very much Doctor  
20 Ross. And before we move on with the additional  
21 segments of the presentation I'd like to offer the  
22 opportunity for the panel members to ask a few  
23 questions. Doctor Handwerger.

24 DR. HANDWERGER: In your discussion you  
25 presented all people as equal, but I'm not convinced

1 that the biometabolism of a 60 year old African  
2 American male is the same as a 22 year old Hispanic  
3 American female. I'm also not convinced that a 25 year  
4 old male on anticonvulsions or antidepressants or any  
5 drug necessarily metabolizes a particular substance the  
6 same as someone who is not on the same drug. I think  
7 there are a lot of internal cellular variables that  
8 have not been taken into account. Though your  
9 distributions, your correlations are excellent when you  
10 look at hundreds of individuals there is a lot of  
11 scattering of the results. And do we know more about  
12 the people who don't correlate as well as those that  
13 do? I would hope that the database would include  
14 things such as sex, something about the medical  
15 history, the age and so forth, because I think in your  
16 analysis all people were treated as equal and all  
17 people are not equal.

18 DR. ROSS: That's a very good point. You  
19 know, in response to that I think it's, would be useful  
20 to point out that a high proportion of the individuals  
21 involved in these studies were males, and that  
22 typically for whatever reason in the absorption,  
23 distribution, metabolism and excretion that are done by  
24 industry anyway, most of the participants are also  
25 males of about the same age range as the workers.

1           They are also typically screened to not be  
2   metabolically induced so that we're not looking at  
3   people that are in any kind of heavy drug regimen, non-  
4   alcoholics, et cetera.

5           So some of that variability that you're  
6   concerned about I think is not there. But the sex and  
7   the age and to a degree the ethnicity of these  
8   individuals is known, it's recorded, I don't think that  
9   it's ever been looked at, you know, in any kind of  
10  systematic fashion.

11           DR. HEERINGA: Doctor Barr and Doctor  
12  Chambers.

13           DR. BARR: Thank you for that nice  
14  presentation. I actually want to reiterate what he  
15  says. I think in the real world you're going to find a  
16  lot more variability. These are controlled populations  
17  with, you know, a fairly small range of age and a small  
18  range of ethnicities and so I think that you're going  
19  to find a lot more variability in the real world.

20           I have a couple of questions regarding some  
21  of your slides. Most of the slides didn't have what  
22  chemical you were talking about on them. When you  
23  looked at the biomonitoring dose versus the passive  
24  dosimeter estimate, were those all TCPY or TCP  
25  Chlorpyrifos or were they a combination of those

1 chemicals that you had on one of the first slides in  
2 your presentation?

3 DR. ROSS: Those were a combination of all  
4 of the chemicals.

5 DR. BARR: So you applied the same  
6 correction factors to each chemical? Assuming, you  
7 know, assuming 10% breakthrough and all of this stuff  
8 to each chemical, for each different chemical?

9 DR. ROSS: In the case where we had a  
10 consecutive, or concurrent with the outer dosimeter

11 DR. BARR: Uh-huh.

12 DR. ROSS: there were two cases like  
13 that, we used 10%.

14 DR. BARR: Okay.

15 DR. ROSS: Regardless of the chemical.

16 DR. BARR: Okay.

17 DR. ROSS: But in each case we adjusted  
18 absorbed dose by the chemical

19 DR. BARR: And by the pharmacokinetics of  
20 that chemical?

21 DR. ROSS: Right, by the kinetics of that  
22 particular compound.

23 DR. BARR: Okay. A couple of other  
24 questions. For Atrazine you measured the  
25 chlorotriazines. I'm assuming then you measured just

1 the Atrazine and the doculation products and no other  
2 chemicals there when you used those estimates?

3 DR. ROSS: No, I believe there were three.

4 DR. BARR: Three, so three.

5 DR. ROSS: I think Mercapturate was one of  
6 them.

7 DR. BARR: Well there's a great deal of  
8 variability with Atrazine metabolism, depending upon  
9 the exposure scenario especially and I find it hard to  
10 believe that biomonitoring and passive dosimetry  
11 compared that well.

12 The other question I had is you had on one  
13 slide Cypermethrin for Cyfluthrin and then the  
14 metabolite was the 440 3pba and so were you using  
15 Cypermethrin pharmacokinetics? Yeah, pharmacokinetics  
16 to estimate Cyfluthrin exposure, is that

17 DR. ROSS: No, the other way, well, yes.  
18 We were using Cypermethrin pharmacokinetics

19 DR. BARR: Okay.

20 DR. ROSS: for Cyfluthrin, that's  
21 correct.

22 DR. BARR: Well I was just, I was amazed  
23 at the way you data greed because before I came to this  
24 meeting I have never seen biomonitoring data and  
25 passive dosimetry data agree so well. Those are my



1 comments.

2 DR. HEERINGA: Doctor Chambers, I believe  
3 you were

4 DR. CHAMBERS: Just to clarify, the  
5 fraction excreted data, that came from human ADME  
6 studies?

7 DR. ROSS: Yes.

8 DR. HEERINGA: Doctor Ross, I guess Doctor  
9 MacDonald has a question.

10 DR. MACDONALD: Yeah, the graph on slide  
11 22, is that in the advance material we were sent or is  
12 that something additional?

13 DR. ROSS: Oh, that is from another  
14 report. You were provided the report, let's see, the  
15 report is entitled, it's entitled, Passive Dosimetry  
16 Data Derived from Outdoor Residential Exposure Task  
17 Force and Pesticide Handler Exposure Databases,  
18 Comparisons to Biomonitoring Data. So it's an  
19 independent report.

20 DR. MACDONALD: Okay, and is, I think the,  
21 the two graphs showing the very strong correlation  
22 along the diagonal are very convincing arguments but  
23 like some other people here I'm a bit surprised at how  
24 good the agreement is, so I'd really like to see more  
25 documentation, in particular the, for example slide 22,

1 what was the sample size in each mean zone? Because  
2 that's also going to pull it into a more consistent  
3 pattern. So I would certainly like more documentation  
4 on those two pictures.

5 DR. HEERINGA: Doctor Ross, Steve Heeringa  
6 here, I'll just ask a question which I think probably  
7 needs to be asked in general scientifically. You went  
8 through a protocol, a process to review 34 studies and  
9 to choose 14 which show up in this graph and 20 were  
10 eliminated. Clearly in that review people knew or had  
11 information on what these relative dosimetry and  
12 biomonitoring values were.

13 How did you handle that in your review?  
14 I know I'm putting you on the spot but I think it's  
15 probably something 20 studies were eliminated from  
16 this graph

17 DR. ROSS: Uh-huh.

18 DR. HEERINGA: and in terms of criteria  
19 and scientific objectivity, how did the task force  
20 approach that?

21 DR. ROSS: That's a very fair question.  
22 Actually the summary of those studies that were  
23 eliminated for a variety of reasons is in Table 7 or  
24 the complete writeup.

25 DR. HEERINGA: Yes, uh-huh.

1 DR. ROSS: And, you know, the reason for  
2 exclusion is given in the far right hand column. And  
3 it varies. There were a number of studies that were  
4 excluded because there wasn't primate metabolism  
5 available.

6 DR. HEERINGA: Right.

7 DR. ROSS: You know, one of the studies  
8 that I did is included in that compilation. As I  
9 indicated previously I've been burned by assuming that  
10 primate and rodent metabolism are the same and only to  
11 find out later to my embarrassment that they are very  
12 different.

13 DR. HEERINGA: Okay, thank you for  
14 reminding me of that table. I actually did see that  
15 and I had forgotten I'd looked at that. So that, again  
16 I think it's just important to get that out here, to  
17 establish again the nature of those criteria for  
18 exclusion. Doctor Portier.

19 DR. PORTIER: If you could put up slide  
20 26. One of the parameters that could actually make  
21 this better, and the one that I have the least  
22 understanding of where it comes from is the fraction  
23 absorbed.

24 You know, if I went through there's like  
25 three or four of these studies that seem to be way off

1 the mark and I, you know, like the Humnicutt study and  
2 you ask, did they just get the fraction absorbed wrong?  
3 If I tweaked it up so all of those points would move  
4 right up the one or the other one? The other  
5 parameters in this comparison seem to have pretty firm  
6 foundations.

7 Can you explain a little bit more where the  
8 fraction observed numbers come from? The 10%, I mean,  
9 you know, maybe 10%'s not right for that chemical under  
10 those situations --

11 DR. ROSS: Well

12 DR. PORTIER: or is that, I'm missing  
13 something here?

14 DR. ROSS: I think there's some confusion  
15 here because the 10% was clothing penetration but we  
16 applied a dermal absorption fraction, that amount  
17 getting to the skin of anywhere from I think 1% to, I  
18 don't know what the high was

19 DR. PORTIER: 9%, 1% to 9%?

20 DR. ROSS: Right, we've got it in one of  
21 the earlier tables. And that was applied on a compound  
22 specific basis.

23 Now, in many of those cases there were  
24 multiple doses tested in the individuals where the  
25 dermal absorption was tested and we typically took the

1 highest dermal absorption value of two or three values  
2 that were tested.

3 And typically the testing is done to simulate  
4 a range of exposures that might occur in a working  
5 environment, all the way from, you know, a reentry  
6 situation to somebody handling a concentrate. And so  
7 the values that we used tended to bias the, if  
8 anything, bias the estimates of passive dosimetry a  
9 little high.

10 DR. PORTIER: I guess I need a little bit  
11 more. How did they actually determine that number?  
12 I'm not a toxicologist so maybe at lunch

13 DR. ROSS: Oh that, I'm sorry

14 DR. PORTIER: you know, what I'm saying  
15 because that seems like a hard thing to get there. I  
16 mean I could see from the biomonitoring you could kind  
17 of back calculate what, you know, and under a lot of  
18 controls, you could back calculate what was dermally  
19 absorbed but how do they get that number otherwise?

20 DR. ROSS: This number is taken directly  
21 from typically human purposeful application studies in  
22 which a known area is delineated, typically on the  
23 volar surface of the forearm and material applied in a  
24 known concentration, it's normally radial labeled,  
25 there are a few exceptions. Actually Chloropyrifos was

1 one of the exceptions. But in most cases it's radial  
2 labeled so that they can follow the dosage and, you  
3 know, account for everything that was applied, removed  
4 and excreted.

5 DR. HEERINGA: Cynthia Hines.

6 DR. HINES: I'm sorry to beat a dead horse  
7 here but I just want to be absolutely clear on how this  
8 passive dosimetry was conducted concurrently. So we  
9 have an inner dosimeter process and an outer dosimeter  
10 process. And would you state again for the inner  
11 process what the worker was actually wearing and what  
12 items were then analyzed for the dermal exposure for  
13 both the inner and outer process?

14 DR. ROSS: Okay, that's a very good  
15 question. For the workers concurrently monitored with  
16 an inner dosimeter, the dosimeter that was analyzed for  
17 the skin surrogate was the t-shirt and briefs, okay?  
18 In addition to that I also looked at the area from the  
19 sleeve down, so the upper arm and forearm, to which a  
20 clothing penetration factor was applied to get to the  
21 skin.

22 DR. HINES: Because they had long sleeved  
23 shirts on?

24 DR. ROSS: They had long sleeve shirts  
25 with a t-shirt underneath.

1 DR. HINES: Right.

2 DR. ROSS: So in those cases there was

3 DR. HINES: Is that how the legs were  
4 handled as well?

5 DR. ROSS: Correct, yes.

6 DR. HINES: Okay, now the outer, could you  
7 go through that?

8 DR. ROSS: For the outer dosimeter studies  
9 the entire outer dosimeter was analyzed and an assumed  
10 clothing penetration of 10% was applied to everything  
11 that was on the outer dosimeter.

12 DR. HINES: And they had their regular  
13 work clothes underneath?

14 DR. ROSS: Correct. Well, underwear, yes.

15 DR. HINES: Just underwear, no

16 DR. ROSS: Just underwear.

17 DR. HINES: Okay, so it was a dosimeter  
18 and underwear

19 DR. ROSS: Correct.

20 DR. HINES: no t-shirt. Okay. A full  
21 body dosimeter, their underwear and no t-shirt?

22 DR. ROSS: And no t-shirt.

23 DR. HINES: Right.

24 DR. ROSS: Right.

25 DR. HEERINGA: Doctor Lu.

1 DR. LU: Yes. I heard it said by Doctor  
2 Heeringa yesterday that all the discussions outside  
3 this room should be disclosed. And some of the panel  
4 members actually gathered together at the dinner table  
5 last night to continue the discussion and one of the  
6 topics was that we wonder how a so called generic  
7 database can be established for the purpose of these  
8 topics. By listening to your presentation, again this  
9 is my understanding, I just want to double, I don't  
10 want, I just want to make sure that that's correct, by  
11 comparing the passive dosimetry data to the  
12 biomonitoring data, regardless of how you do it, you  
13 find a very good consistent, you find a very good  
14 correlations, therefore the conclusion made by the task  
15 force is that we don't have to worry about individual  
16 locations of the passive dosimetry data as long as we  
17 use the whole body dosimetry, that number alone will be  
18 sufficient to say use for those calculations. Is that  
19 somewhat

20 DR. ROSS: That's

21 DR. LU: close enough?

22 DR. ROSS: That's correct.

23 DR. LU: Okay. The question is, yesterday  
24 somebody from your group presented the whole body  
25 dosimetry figures that kind of, you have 6 regions,



1 right? Like arms, back and my question to the Agency  
2 actually earlier prior to the presentation was, how are  
3 you going to process the samples? Say at the end of  
4 the study period the person has the whole body  
5 dosimetry and obviously the person has to take the  
6 dosimetry off, are you going to cut the 6 regions and  
7 analyze individually and add it together? Or

8 DR. ROSS: That's correct.

9 DR. LU: Okay, so the question is, it's a  
10 big surface area, it's made of cotton so it takes up a  
11 lot of solvent to extract a compound.

12 DR. ROSS: That's right.

13 DR. LU: Don't you worry about a limit of  
14 detection?

15 DR. ROSS: That's part of the methods  
16 development in choosing your surrogate compound. You  
17 have to be very careful in going into one of these  
18 studies that you can get down to the limit of detection  
19 that you need, knowing that when you extract these  
20 large surface areas and you're generating large volumes  
21 of solvent, that you can get down to these low levels  
22 of detection. I mean we're looking at nanogram per  
23 centimeter squared, or less, detection limits.

24 DR. LU: Well I think, well, we can talk  
25 about this later this afternoon during, in our

1 discussions.

2 DR. HEERINGA: We will have opportunity.  
3 Thank you, Doctor Lu. At this point I think what I'd  
4 like to do is to move on to make sure that we get in  
5 the balance of the components for the presentation.

6 And I think that Curt Lunchick is going  
7 to do the next segment of this presentation and then  
8 Doctor Baugher after that I believe.

9 MR. LUNCHICK: That's correct and I want  
10 to again thank the panel for the opportunity to present  
11 the Task Force position. I think the discussions that  
12 we've had so far this morning have been very  
13 enlightening and very good.

14 What I want to do is kind of move what we've  
15 been hearing into a regulatory risk assessment and how  
16 this type of information gets used and the Task Force's  
17 position on what we're hearing in regards to how our  
18 data would be used by the different agencies in North  
19 America to conduct a risk assessment and what we think  
20 the proper conclusions are. Go to the next slide.

21 The charge questions that we're looking at  
22 right now, in addition to whether there is a need for  
23 additional data, basically boil down to whether we  
24 should be adjusting any part, individual part of the  
25 passive dosimetry methodology, the hand monitoring, the

1 whole body dosimetry as your breakthrough.

2 We've looked at different studies, we've  
3 clearly looked at this comparison of passive dosimetry  
4 to biological monitoring to determine if the  
5 methodology as a whole is consistent and is not  
6 systematically underestimating what we consider to be  
7 the true absorbed dose measured through biological  
8 monitoring. And obviously one of the options that the  
9 Agency has presented is to make no adjustment based on  
10 this correlation that we are seeing. Next slide.

11 John raised this issue and I wanted to  
12 emphasize it because I think we need to make a very  
13 clear distinction between the issue of efficiency  
14 versus validation. We've seen data presented by the  
15 Agency, looking at the removal efficiency of pesticides  
16 from the hands with different techniques, be it rinse  
17 aids or touching tubes, et cetera.

18 That clearly gets in to whether the  
19 percentage of material you're removing is high, low or  
20 in between. What it does not get at is whether any one  
21 method is more or less accurate in regards to the  
22 prediction of the true absorbed dose. And I think as  
23 the panel deliberates the charges questions it needs to  
24 keep this in mind and differentiate between efficiency  
25 and validation. You can go to the next slide.

1           Clearly I think we saw, I think the Agency  
2 did a good job in its presentation that there's a lot  
3 of stuff going on when we're looking at what's going on  
4 in the field in hand rinses, glove dosimeters, whatever  
5 and if you look at the data as a whole it was hard to  
6 tell if there was any real consistent difference.

7 There's a tendency to think that cotton glove  
8 dosimeters give you slightly higher residues than a  
9 hand rinse which give a slightly higher residue than  
10 the hand wipe, but even that is questionable as to  
11 whether there's a difference of if it's consistent.  
12 And the Task Force, we have standardized our hand  
13 monitoring methodology with a hand wash which adds a  
14 physical removal process compared to a rinse where you  
15 may just pour water or whatever monitoring material  
16 over the hands.

17           That said, I think again one has to keep in  
18 mind, I know everybody including the Task Force wants  
19 to ensure that whatever our methods are, we are not  
20 underestimating the calculated absorbed dose and  
21 henceforth, risk. But we also have to be careful, and  
22 as Doctor Baugher is going to present, higher estimates  
23 through some of these methods may not actually be the  
24 best. Higher dermal residues may not be more accurate,  
25 they're definitely going to be higher and obviously

1 overestimate compared to others, but as Doctor Ross was  
2 showing, in validation you want some level of accuracy  
3 there.

4 And I think this is consistent with what the  
5 Agency has concluded too on page 82 of its submission,  
6 that if you look at these hand rinse efficiency  
7 studies, the results are equivocal in determining if  
8 one is better than the other, it consistently gives  
9 higher residues. And frankly that was consistent with  
10 our selection criteria we discussed yesterday where we  
11 did not make a preference in reviewing existing study  
12 data. Next slide.

13 Our position therefore is, and again this is  
14 the other important point, you have to look after what  
15 we are doing in estimating the total exposure in  
16 absorbed dose, that you've got to look at the  
17 methodologies combined, the whole body dosimetry, the  
18 face and neck wipes and the hand washes. Our methods  
19 follow, do follow the EPA Guidelines, we are providing  
20 consistency in our new studies that we're conducting  
21 with doing the handwash methodology.

22 And that, if you look at these comparisons of  
23 dermal exposure or the absorbed dose calculated from  
24 the combined dosimetry, hand washes and, or hand  
25 exposures and face and neck wipes, adjusting for human

1 dermal absorption, and it's important to note, remember  
2 that in these ratios you're seeing it is human dermal  
3 absorption we are using, that we are getting very good  
4 correlation with the absorbed dose calculated by the  
5 biological monitoring.

6 We found it interesting that the analysis we  
7 did was coming up with a ratio very similar to the one  
8 that the regulatory agencies did, although they were  
9 done independently. Which again raises the question,  
10 if the methodology as a whole is considered accurate  
11 for the purpose of calculating the total absorbed does,  
12 then why do an adjustment for hand exposure even if  
13 it's a small adjustment? The question needs to be  
14 considered, is it necessary?

15 That said, we think there may be situations  
16 where determining the hand rinse efficiency is  
17 important. They're not the situations the Task Force  
18 is going to primarily look at, but if one of the  
19 members is looking at hand exposure by itself for  
20 comparison of say exposure mitigation with different  
21 types of gloves or in other ways comparing just hand  
22 exposure, this issue of making sure those exposure  
23 values by themselves where you've got high efficiency  
24 of removal, that the values you're getting are  
25 reflective of what's on the skin, then we see

1 situations where looking at the hand rinse efficiency  
2 may be important.

3 But for what we're doing, again with total  
4 dermal exposure estimates we feel the methodology has  
5 been validated to a degree that we have confidence in  
6 its ability to predict the absorbed dose when adjusted  
7 with dermal, human dermal absorption.

8 The other issue that was raised is maybe to  
9 look at a well established chemical where we know the  
10 human ADME values and to determine if any breakthrough  
11 of the whole body dosimeter is occurring. This is an  
12 interesting idea I think conceptually, it makes sense.  
13 The problem is, and we saw this this morning in Doctor  
14 Beauvais' presentation and I think in some of the  
15 discussions that are being raised here. There is a lot  
16 of complexity in what's actually going on out in these  
17 fields.

18 This is not a controlled circumstance by any  
19 means when we go out and do a field study. Individual  
20 variability in how products are metabolized, I mean  
21 there's differences in the exposure to different parts  
22 of the body which would affect dermal absorption. I  
23 question whether we have enough accuracy to take the  
24 absorbed dose in this type of situation, subtract out  
25 inhalation exposure, account for the hand exposure and

1 face exposure and accurately determine whether there's  
2 any significant breakthrough coming unless it's pretty  
3 significant.

4 And frankly, with it being under the normal  
5 work attire and with the levels of exposure we're  
6 seeing, saturation or those type of situations really  
7 aren't occurring. So again, I think we concur with the  
8 Agency that on the whole the potential breakthrough of  
9 a whole body dosimeter is probably very small, it may  
10 occur to some degree, but with the overall accuracy  
11 that we're looking at here it probably does not require  
12 looking at concurrent biomonitoring to see if we could  
13 adjust. You can go to the next slide.

14 And I think the Agency concluded it very well  
15 in its submission where it states that, you know, the  
16 dermal absorption during sample collection and  
17 breakthrough through dermal dosimeters does not, you  
18 know, it's unlikely to contribute to a negative bias in  
19 any pragmatic application of the results in a risk  
20 assessment. And I think that's the key is the word,  
21 pragmatic. You know, for regulatory purposes whatever  
22 is occurring is so negligible as to, it's questionable  
23 whether you could measure it accurately and its impact  
24 on the exposure assessment is going to be minimal or  
25 unlikely.



1           Again, and I'm just going to quickly go  
2 through this because these points have been raised now  
3 several times, but an adjustment of the passive  
4 dosimetry techniques as a whole, and we emphasize on  
5 the whole, is unnecessary because we are seeing this  
6 concurrence with the biological monitoring. And what  
7 makes it even more important is, as Doctor Ross said,  
8 typically when we're doing a risk assessment we will  
9 take the data, the passive dosimetry.

10           We will not have human dermal absorption data  
11 and with the new human subjects rule I can guarantee  
12 you that it's going to be very unlikely there's going  
13 to be some extremely strong need before any of our  
14 companies conducts a human dermal absorption study.

15           So we're either going to be using rat dermal  
16 absorption data determined by guideline methodologies  
17 which as you saw in one of Doctor Ross' slides tends to  
18 be much higher than the human dermal absorption, or  
19 frankly there are times in the absence of even rodent  
20 data with the EPA, a default of 100% is used. So you  
21 have these confounding conservatisms to the passive  
22 dosimetry as we get into estimating absorbed dose to  
23 calculate the risk values.

24           I think basically this is again reiterating  
25 that we've seen no evidence from what the Agency has

1 presented and our own analysis, that the AHETF passive  
2 dosimetry methodology, frankly the guideline  
3 methodology taken as a whole, is systematically  
4 underestimating the absorbed dose. And if this panel  
5 agrees with this analysis, and again taking into effect  
6 also the fact that typically we're not going to use  
7 human dermal absorption, we're going to be  
8 overestimating based on rodent or 100% dermal  
9 absorption default, that the passive dosimetry  
10 methodology is sufficiently robust and accurate, that a  
11 correction factor is not needed for regulatory risk  
12 assessment. And I believe that's my, yeah, last slide.

13 DR. HEERINGA: Okay, thank you very much.  
14 At this point what I'd like to do, I will leave time  
15 for questions but I'd like to go on to Doctor Baugher's  
16 presentation and then we can return for general  
17 questions for Mr. Lunchick and Doctor Baugher. I hope  
18 I've pronounced the name correctly, I think I said it,  
19 Bauer, earlier but it's a hard G.

20 DR. BAUGHER: Thank you and I'm glad to be  
21 allowed to speak in this issue. My name is Doug  
22 Baugher, I'm a technical consultant to Gowen Company  
23 and represent them on the various ag. and residential  
24 exposure task forces. I've been deeply involved in  
25 pesticide exposure assessment and risk assessment since

1 1980.

2 Let's cut to the chase and go to slide number  
3 2. The issue underlying charge 2 is the adequacy of  
4 passive dermal dosimetry, specially, does it  
5 underestimate exposure? Or another way of putting it,  
6 are the methods sufficiently accurate for their  
7 intended purpose in risk assessment and risk  
8 management?

9 Give that concern, what can we do? We can  
10 validate methods, that's the dosimetry methods for the  
11 surrogates that we use. We could apply an arbitrary  
12 adjustment factor to the measured residues. We could  
13 biomonitor for residues not sampled. Or we could do  
14 nothing.

15 Except for the last action there are  
16 difficulties with the other three approaches. As other  
17 presenters have noted the dermal acquisition and  
18 retention of residues is a complex process that we  
19 really do not understand. And for that reason, here we  
20 are 30 years into it, we still do not have a validated  
21 protocol for even the simplest issue, residue recovery  
22 and efficiency.

23 And we have to note that truly validated  
24 methods would be much more than residue recovery  
25 efficiency, they would have to simulate the dynamic

1 processes occurring in the field. And we also note  
2 that developing such protocols would require  
3 intentional human dosing with a clear justification.  
4 We'll try to show you later that we do not believe  
5 there's a good argument for justification.

6           Biomonitoring to measure residues that escape  
7 capture by the dermal dosimetry could be useful but  
8 that would require human pharmacokinetics, discovery of  
9 good biomarkers and development of analytical methods  
10 for urinary metabolites and so forth. Because the  
11 current products for which we have such information are  
12 not our surrogates and are not suitable for surrogates,  
13 developing this data would be very expensive and  
14 probably not meet the test for justification.

15           Applying adjustment factors to the dosimetry  
16 methods has been suggested but as we have seen, the  
17 efficiency based factors would be all over the map and  
18 determining adjustment factors that satisfied the  
19 regulatory agencies, the scientific community, the  
20 public, the stakeholders would be very daunting.

21           In any case, the issue as it applies to  
22 exposure task force work is based on a simple model  
23 that we've seen before. Dermal exposure totaled equals  
24 the hand plus the body plus the face and neck and as we  
25 do it that's from hand washes, underwear and swabs.

1 The ultimate product of our model, if the ultimate  
2 product of our model was based only on these three  
3 parameters, then the measurement uncertainty would be a  
4 real concern. As an aside, the comparison of  
5 biomonitoring to passive dosimetry as presented earlier  
6 is a classic case of validation of the three parameter  
7 model. But the ultimate goal of our work is to produce  
8 an estimate of the absorbed dose for use in risk  
9 assessment and risk management and this is multi  
10 parameter.

11 This slide shows the usual parameters in that  
12 dermal exposure monitor, model. The column labeled,  
13 convention, shows the usual regulatory conventions and  
14 the column labeled, expected, shows parameter values  
15 likely to be found in the real world. Now this of  
16 course will vary product by product, though what I have  
17 shown here is typical of many orchard products. And  
18 I've selected open cab air blast application as the  
19 model here because it's a very high exposure scenario.  
20 In the regulatory convention the agencies would assume  
21 100% of the maximum labeled rate per acre.

22 Typically it's about half that and it can go  
23 greater or lower depending upon pest infestations. The  
24 Agency estimates 40 acres per day. I've talked with  
25 many growers and pest control operators and they're

1 very happy if they get 30 per day. And oftentimes only  
2 a single block may be treated with a product so it  
3 could be only 5 or 6 acres per day. The dermal  
4 milligrams per pound AI handled, the unit exposure  
5 we've talked about would be the arithmetic mean under  
6 convention.

7 We would probably use the geometric mean  
8 because the distribution is lognormal. The body weight  
9 conventionally is 70 kilograms. Our workers happen to  
10 be just a little bit heavier than that. In the AG.  
11 Handlers Air Blast Study which I've used here, they  
12 averaged 89 kilograms and over all the studies that  
13 we've done they 've averaged 89 kilograms. So when  
14 we're done we calculate dermal mgs. per kg per day in  
15 the usual fashion. And we see that the conventional  
16 calculation gives us a value approximately 5 times that  
17 of the expected value.

18 Now the next component in the model is dermal  
19 absorption. And typically when we have a lack of rat  
20 dermal absorption data we use a conventional 100%.  
21 Now, this does not account for the other important  
22 component which is the differential between the rat to  
23 human which is probably on the order of 2x to 10x and  
24 has been historically reported out at 5x. If we do  
25 have a rat dermal absorption study we use that data,

1 but again we don't account for the rat to human  
2 differential. And finally we might have in vivo human  
3 dermal absorption.

4 I'm going to look at how this use of dermal  
5 absorption really affects what happens to the entire  
6 multi parameter model. I'm going to label these  
7 conditions 1, 2, and 3. Condition 1, we have human  
8 dermal absorption, that's seldom the case. Condition  
9 2, we have rat dermal absorption, that is sometimes the  
10 case, and we can alternatively model the 5x rat to  
11 human difference. And finally condition 3, where we  
12 have no dermal absorption data the Agency assumes 100%  
13 rat dermal absorption. Here again we do have  
14 knowledge. California put together a review of I think  
15 42 rat dermal absorption studies and found that the  
16 mean absorption was 19% plus or minus 14% and they used  
17 that knowledge to establish their default at 50%.

18 So anyhow, if we apply these conditions to  
19 the conventional deterministic estimate we see that in  
20 condition 1, with known human dermal absorption the  
21 conventional model estimates absorbed doses 5 times  
22 greater than the expected model. Under condition 2  
23 with known rat dermal absorption the conventional model  
24 estimates absorbed doses 25 times greater than expected  
25 when the mean rat to human differential is factored in.

1 Under condition 3 with unknown rat dermal absorption  
2 the conventional model estimates absorbed doses 120  
3 times greater than expected when the mean rat to human  
4 differential and the historical mean absorption are  
5 factored in.

6 In short, the conventional approach to  
7 getting an absorbed dose yields estimates substantially  
8 greater than would be expected when other knowledge is  
9 factored in.

10 You may be wondering if I'm mixing apples and  
11 oranges here and so forth but I took another step. To  
12 assure myself that I had not fooled myself with these  
13 central tendency and high end estimates, I did a couple  
14 of simple probabilistic analyses and we'll go over the  
15 results of that in reverse order.

16 What I did was, I'm not going to show you the  
17 whole model because it's very simple, I accounted for  
18 handwash residue collection efficiencies of 60% to 95%  
19 which is based some work that Doctor Ross has done with  
20 rats and the removal in rat dermal penetration studies.  
21 Whole body dosimetry efficiency, I let it range from  
22 80% to 99%. Face wipe, 75% to 90%, 95%. In any case,  
23 when you look at all the input parameters, the bottom  
24 line is the driver was the unit exposure and the  
25 lognormally distributed milligrams per pound AI



1 handled.

2 Now where am I here, okay, so what we found  
3 is, factoring in the dosimetry and efficiencies had a  
4 very minimal impact at the high percentiles. For  
5 example, a 98th percentile dose, assuming 100%  
6 dosimetry efficiency might become a 96th percentile.  
7 So although these ranges of inefficiencies look pretty  
8 high, when you factor in everything you can that's  
9 going on they really don't have much of an impact.  
10 More importantly, no matter how you look at it the  
11 conventional estimate of absorbed dose always  
12 approached or exceeded the 95th percentile and many  
13 times it was at the 99th or higher.

14 Now, another important thing is, this is an  
15 exposure assessment based on acute exposure. This same  
16 value would be used for a long term exposure and when  
17 you compare that to the probabilistic overall mean it  
18 really vastly overestimates that exposure.

19 Okay. So to conclude, passive dermal  
20 dosimetry is only a component in the overall estimation  
21 of absorbed dose. When used with other model inputs  
22 conventional deterministic estimates give high  
23 percentiles even if you account for residue collection  
24 inefficiencies. And one again this is another  
25 confirmation of the phenomenon that we call compounding

1 conservativisms.

2 We admit that the current dermal dosimetry  
3 methods may have some minor limitations and we don't  
4 see that there is much benefit to be had by finding out  
5 what those limitations are. Therefore there is no  
6 meaningful benefit and therefore the intentional dosing  
7 for additional dosimetry method validation would not be  
8 justified. Applying the arbitrary adjustment factors  
9 would be inconsistent with the risk/benefit principle  
10 of FIFRA because there's no real benefit. So we take  
11 the recommendation of the fourth action which is no  
12 action. Thank you.

13 DR. HEERINGA: Thank you very much, Doctor  
14 Baugher. We are at 12:15 and I think in the interest  
15 we've made good progress here, I'd like to give the  
16 opportunity for panel members to ask a few questions  
17 before we break for the lunch. I think that as I  
18 mentioned this morning I need to go to College Park to  
19 teach this afternoon, but Doctor Portier will be  
20 assuming the role of the Chair and I think he'll leave  
21 an opportunity right at the start of the afternoon  
22 session for any questions that may arise over lunch.

23 Any questions at this point from the panel,  
24 questions of clarification? Ken.

25 DR. PORTIER: In your analysis you

1 adjusted for body weight by moving the kilogram body  
2 weight up from 70 to 89, right?

3 DR. BAUGHER: That's correct.

4 DR. PORTIER: I think that's on slide 7.

5 DR. BAUGHER: Yes.

6 DR. PORTIER: In estimating the dermal  
7 exposure did you change the biometrics to adjust for  
8 the higher weights? I mean, you know, body size, as  
9 you put on weight the skin surface area goes up as well  
10 so your exposure amounts subtract that a little bit as  
11 well. So did you back calculate that or did you use  
12 the standard biometrics?

13 DR. BAUGHER: I did not back calculate  
14 that but in other little numerical experiments I've  
15 done I've found that there's really not much  
16 correlation between body weight and between dermal  
17 exposure. Yes, intuitively bigger weight, bigger  
18 surface area but it just doesn't seem to work out that  
19 way.

20 DR. HEERINGA: Doctor Popendorf.

21 DR. POPENDORF: I've got, yeah, two  
22 questions that are just informational on John Ross on  
23 one. Your slide number 24 that showed those individual  
24 values comparing dosimetry and biomonitoring, did you  
25 happen to run a correlation coefficient for that slide?

1 DR. ROSS: Yes, and I believe that's in  
2 the writeup. It was, well, we didn't do a correlation  
3 coefficient per se but we did look for correlation.

4 DR. POPENDORF: Yeah.

5 DR. ROSS: And it is highly significant, I  
6 think less than 0005 and I believe that it's in the  
7 text of the article here.

8 DR. POPENDORF: Uh-huh, I, we, I can maybe  
9 look for that. The other question was a clarification  
10 I think on Curt information. A couple of you mentioned  
11 that when you were talking about that default  
12 absorption for, you know, when you don't have human  
13 data of 100%.

14 DR. ROSS: Uh-huh.

15 DR. POPENDORF: Now is that 100% of dose  
16 or 100% of the rat absorption fraction?

17 MR. LUNCHICK: Okay. Curt Lunchick.  
18 Typically what we do is, if there are no dermal  
19 absorption data whatsoever, rat or human, we will take  
20 the dermal exposure value and assume it's totally  
21 absorbed so it becomes equivalent to dose.

22 DR. HEERINGA: Doctor Landers, do you have  
23 a

24 DR. LANDERS: I have a question

25 DR. HEERINGA: Turn on your microphone

1 please.

2 DR. LANDERS: On Table 7 with the open cab  
3 air blast applicator, on that table I compliment you on  
4 choosing 30 acres a day as a more realistic output, I  
5 would agree. But I'm somewhat concerned about you  
6 taking 50% of the AI per acre. When were these trials  
7 conducted?

8 DR. BAUGHER: Could you go to my very last  
9 slide, I don't know if it's on there or not. In the  
10 probabilistic analysis I used as an example some  
11 various orchard products I've worked with and looked at  
12 the most likely use rate of being 50% of the maximum  
13 label oh, I'm sorry, I'm reading the wrong column  
14 here, if you go down to the pounds AI per acre

15 DR. LANDERS: Uh-huh.

16 DR. BAUGHER: you see that the product  
17 may be used at 1.5 to 3 pounds active per acre in that  
18 discreet distribution

19 DR. LANDERS: Yes.

20 DR. BAUGHER: and that 20% of the time  
21 it'll be the low rate and 50% of the time it'll be near  
22 the average and 20% of the time a little above and  
23 about 10% at the maximum. And that's based on  
24 experience with some of the products I've worked with.

25 DR. LANDERS: Right.

1 DR. BAUGHER: Now this would vary case by  
2 case.

3 DR. LANDERS: Yes, because it, for example  
4 in New York State until three years ago it was unlawful  
5 to go below the maximum rate. So, indeed, so this  
6 would not be acceptable to us on the east coast.

7 DR. BAUGHER: Unlawful to go below the  
8 maximum label rate?

9 DR. LANDERS: Yes. Correct.

10 DR. BAUGHER: I have never heard of that.

11 DR. LANDERS: And the reason for this is  
12 resistance.

13 DR. BAUGHER: Okay, then I guess I'll take  
14 New York out of my models.

15 DR. HEERINGA: Or put it in your fourth  
16 category. Yes, Doctor

17 DR. ROBSON: Hi, Mark Robson, just as an  
18 aside, under FIFRA, as somebody who been training  
19 pesticide applicators for years we always encourage  
20 below the rate, as does the Agency, and under FIFRA 2EE  
21 we, the farmer can legally do that. The registrant at  
22 times is anxious about efficacy and reminds of that,  
23 but at least in your neighbors in New Jersey we  
24 encourage below the label rate.

25 DR. HEERINGA: Doctor Hughes.

1 DR. HUGHES: Yeah, I'm, just a point of  
2 clarification, I'm assuming this is a sensitivity  
3 analysis as to which inputs would have greater impact  
4 in the probabilistic model. Have you ever done that  
5 for like residential or reentry models?

6 DR. BAUGHER: Yes, as a matter of fact I  
7 forgot to mention, I did a very similar analysis with  
8 reentry into treated orchards to hand harvest fruits,  
9 again factoring in residue collection inefficiencies  
10 and reached exactly the same conclusions. The drivers  
11 there happened to be a little different. One is the  
12 variance in the transfer coefficient and the other is  
13 the variance in the residue which depends upon the day  
14 of reentry. But again it's our unit exposure that the  
15 task forces have measured which is the most important  
16 component of the probabilistic models.

17 DR. HEERINGA: At this point I think I  
18 would like oh, Doctor Lunchick or Doctor Ross.

19 DR. ROSS: One response to Doctor  
20 Pependorf, the statistical correlation for that second  
21 figure with the scatter plot is located on page 33 of  
22 the report and we looked at the Spearman Rank  
23 correlation with a p less than 0001.

24 DR. POPENDORF: And that's, that I guess  
25 certainly is significant, I was just looking to see

1 what fraction of the overall variability was explained  
2 by the agreement or the difference, which is the square  
3 of the correlation coefficient so, but thank you.

4 DR. HEERINGA: Dallas.

5 DR. JOHNSON: Yes, significance in  
6 correlation is more a function of sample size in the  
7 actual value of the correlation. So could you tell us  
8 what the actual value of that correlation was for that  
9 picture?

10 DR. HEERINGA: It must be an r square for  
11 that regression line if it's a linear. I see .672.

12 DR. JOHNSON: I was going to say .7 just  
13 by looking at the picture so I was pretty close.

14 DR. HEERINGA: Okay, the interocular test  
15 here. At this point in time I think that I would like  
16 to call a break for lunch and again I think 1:30 Ken?

17 DR. PORTIER: Yeah.

18 DR. HEERINGA: Let's reconvene at 1:30 at  
19 which point Doctor Portier will be chairing. I want to  
20 make one comment before we break and that is, with  
21 regard to the proceedings I want to make sure that  
22 everybody is aware that there's a lot of material, we  
23 have broken up the presentations and the discussion of  
24 the charge questions, primarily so that I think all of  
25 us can stay a little more engaged. Because if we had



1 12 hours or presentations and then 12 hours of charge  
2 of charge question discussion it just would not be  
3 effective.

4 What is going to happen over the course of  
5 these four days is that we will discuss charge  
6 questions at the appropriate time frame following the  
7 scheduled presentations.

8 If there are additional thoughts or  
9 additional information comes forth as a result of  
10 future presentations or actually conversations such as  
11 we've had this morning, it will be possible to revisit  
12 for panel members a charge question I think. And we  
13 can do that at the beginning of each day just to make  
14 sure that as we proceed through Friday that if there  
15 are any changes or any additional information or  
16 comments pertaining to those charge questions, that  
17 that can be brought forward. I think that's only fair  
18 game in this process. And if not, we wouldn't sort of  
19 have a full exploration of the topic.

20 So hopefully everybody will be here for the  
21 four days, from the critical players to the public who  
22 has a vested interest, obviously from the task force  
23 and from the EPA staff. If for some reason key  
24 individuals will not be here over the course of the  
25 next two and a half days you may want to bring it just

1 to the attention of Myrta Christian and myself so we  
2 can accommodate that.

3 Okay everyone, have a good lunch and I think  
4 for panel members and others, I don't want to advertise  
5 a particular location but I think the Hyatt's expecting  
6 some people and has some tables reserved over there.

7 (WHEREUPON, the morning session was adjourned for  
8 lunch.)

FIFRA SCIENTIFIC ADVISORY PANEL (SAP)  
Review of Worker Exposure Assessment Methods  
January 10, 2007  
Afternoon Session

DR. PORTIER: So let's reconvene. This morning we had a good set of presentations and some good discussions. At this point, before we go into the charge questions I'll give the committee one last opportunity to ask any clarifying questions of the presenters from this morning.

Do we have any open questions, burning questions that were developed over lunch?

Yes, Doctor Appleton.

DR. APPLETON: Just something I forgot to ask yesterday. When does the task force anticipate the availability of a beta version of the AHED for public examination?

DR. PORTIER: Identify yourself.

MR. LUNCHICK: Yeah, I will, this is Curt Lunchick, Task Force Bearer Crop Science. It is available already with data that have been reviewed and frankly I could get you a copy, Hank, and if anybody else on this panel would like to see the database, I think maybe work through Steve Knot or somebody to get a list and the Task Force will distribute AHED. It's I

1 think build 3.6 for people that are curious.

2 DR. APPLETON: Can I, just one more quick  
3 one if I can remember it. Did you have any plans to, I  
4 hate to use the word validate, but like field validate  
5 the database once it's established in a form that  
6 everybody's comfortable with and come in with a study  
7 that's been designed according to your criteria and  
8 performed and just compare the outputs of the exposure  
9 between the two?

10 MR. LUNCHICK: Well the database, I'm not  
11 sure I got the question, the database is much like  
12 PHED, a compilation of existing study, or study data  
13 that it then does the algorithmic calculations. So I'm  
14 not quite sure what you were wanting us to validate it  
15 against. We are, just out of curiosity going to  
16 compare it to PHED estimates but

17 DR. APPLETON: Uh-huh.

18 MR. LUNCHICK: and it is there for  
19 somebody to, for instance, look at a scenario where you  
20 feel there is sufficient data and compare it to  
21 biological monitoring.

22 DR. APPLETON: Yeah, okay, just curious.  
23 Thank you.

24 DR. PORTIER: Okay, I guess we're done  
25 with the questions and it's time to move on to the

1 issues and the charge questions.

2 We're starting out here at around 1:40 and  
3 we're scheduled to go to 5:30, just to warn you, we're  
4 going to cover all three questions that are on there  
5 today so we may be running a little beyond the 5:30  
6 period but not much more than that. It all depends on  
7 how the conversation goes.

8 So with that I guess, Jeff Dawson, you're  
9 going to be reading the charge questions.

10 MR. DAWSON: Okay. Question 1, data  
11 needs. EPA believes that many studies within our  
12 current database have limitations. In some cases the  
13 Agency is lacking data to address modern pesticide  
14 application equipment and techniques. EPA believes  
15 that additional data could significantly improve our  
16 ability to estimate and better characterize the range  
17 of worker exposure with greater certainty. Please  
18 comment on these limitations and EPA's conclusions that  
19 additional data could improve significantly the  
20 Agency's ability to assess worker exposure. Also,  
21 please comment on the selection criteria proposed by  
22 the AHETF and AEATF and their respective submissions  
23 for evaluating the extent to which existing data would  
24 meet EPA's exposure assessment needs. Thanks.

25 DR. PORTIER: And our lead discussion on

1 that is Doctor Curwin.

2 DR. CURWIN: Okay, thanks. I'd just like  
3 to start off by summarizing a bit of what I understand  
4 are the limitations of PHED and the reasons for this  
5 first charge question.

6 Essentially from what I've read and heard,  
7 the PHED essentially has an inadequate number of  
8 measurements or at least quality measurements. In some  
9 cases inadequate QA/QC, use of older sampling  
10 methodology, for example the patch dosimeters versus  
11 using the whole body dosimeters, older analytical  
12 methods that may result in higher levels of detection  
13 with the resulting in high levels of censored data. I  
14 think one estimate was that there was two-thirds of the  
15 data in PHED are actually censored.

16 Lack of representativeness and by that I mean  
17 the older work practices that may no longer be used are  
18 in PHED and some new technologies and new practices  
19 aren't reflected in that database. As well a lack of  
20 diversity of test conditions and a lack of entire body  
21 dermal estimates.

22 So the EPA contends that these limitations  
23 decrease the confidence in the reliability in some of  
24 their exposure estimates for pesticide handlers that  
25 there are making for regulatory decisions.

1           Given these limitations I think that there's  
2   an impetus then to try to develop this new database  
3   that will address these limitations, however there are  
4   some people that have questioned the need to replace  
5   PHED or don't think it should be entirely replaced.  
6   The Farm Worker Justice presented yesterday as well as  
7   a comment by Doctor Richard Fenske suggests that PHED  
8   has 1,700 plus monitoring units and that the new  
9   database will only have about 600 monitoring units, and  
10   that therefore we shouldn't be abandoning PHED just  
11   yet.

12           To that I actually, and maybe the Agency  
13   might be able to help me on that, I've had some  
14   experience with PHED in the past and, although there  
15   may be 1,700 plus monitoring units, the actual number  
16   of units that are used in regulatory risk assessments  
17   is much, much smaller if you limit it to the grade A  
18   and grade B data. And so that is my assumption. So in  
19   that regard I'm not sure if it, if the number of  
20   monitoring units, how that will compare to then the new  
21   database.

22           But given that there is some useful data I  
23   think still in the PHED, and one of the comments that  
24   I've heard is that even though the newer technologies  
25   are maybe not captured in PHED and that the new

1 database will capture these, we don't want to lose the  
2 old technologies that are still being used in some  
3 cases, you know, particularly with certain types of  
4 tractors and things that can be used for many, many,  
5 many years.

6           It's my opinion, and this is just my personal  
7 opinion and it certainly isn't that of the panel, and  
8 we'll have this discussion about this, but I think that  
9 the EPA has clearly demonstrated that there is a need  
10 for new additional data. I think the limitations in  
11 PHED, and I've had the experience of using PHED for  
12 risk assessments, I think these limitations are valid,  
13 that the ability to conduct a worker exposure  
14 assessment is limited because of these limitations.  
15 And certainly by requiring additional data that will  
16 address these limitations will help I think the Agency  
17 is improving their risk assessment and their exposure  
18 assessment process.

19           Given that though, the new database certainly  
20 has to be designed such that it addresses these  
21 limitations that have been noted. I would also  
22 encourage that PHED isn't completely abandoned and I  
23 think this is being done but that's certainly, some of  
24 the data from that database is going to be incorporated  
25 into the new database and existing studies that are out



1 there now are going to be incorporated into the new  
2 database.

3 To comment on the criteria that was used by  
4 the two task forces in selecting data to go into the  
5 database, my assumption is that this is selection  
6 criteria for existing data, the criteria seems  
7 reasonable to me. I do have a couple of comments, one  
8 for each of them actually.

9 The AHETF in their criteria state that  
10 inhalation data is not required and this meeting so far  
11 has largely been speaking about dermal exposures and I  
12 understand that dermal exposure is a significant  
13 portion of exposure when we're talking about pesticide  
14 handlers, although inhalation still can be a  
15 significant contribution to exposure and we haven't  
16 addressed that in this meeting at all. I would think  
17 that part of the criteria for including data you would  
18 want to still include studies of having inhalation  
19 exposure.

20 With regards to the AEATF they state in their  
21 criteria document that they'll use biomonitoring data  
22 to populate a database, a generic database, provided  
23 that there is acceptable primate dermal exposure and  
24 pharmacokinetic data. I actually question the use of  
25 using biological or biomonitoring data to populate a

1 generic exposure database. You're going to have to  
2 back calculate to get your unit exposures which is  
3 going to introduce some error and uncertainty and then  
4 you're going to take this value and then apply a dermal  
5 absorption dose or some other metrics to come up with  
6 an absorbed dose, so you're actually doubling the error  
7 in some regards. At least figuratively if not  
8 literally. So I would question that, although I think  
9 biomonitoring data is is very useful and should be  
10 considered in certain instances. But I think to  
11 populate a generic database for developing unit  
12 exposures, I would caution against that because of this  
13 error.

14 That's all I had to say directly on this and  
15 I'd like to just open it up to the assistant  
16 discussants and have their opinions as well. If Doctor  
17 Appleton would like to start I'll just go in order on  
18 this sheet.

19 DR. PORTIER: Remember to speak up now.

20 DR. APPLETON: Yes sir, yeah, it turned  
21 itself off. Hank Appleton, Forest Service.

22 Okay, I guess my first comment would be to  
23 recommend that the EPA and the task forces examine the  
24 available methodology that is out there in the  
25 literature involving the use of physical chemical

1 properties to estimate dermal permeability constants  
2 with the pesticides of interest to these databases. It  
3 would be a first step towards using first order  
4 kinetics to examine absorption, systemic absorption and  
5 determining the absorbed fraction of residue, perhaps  
6 in terms of percent of external dose absorbed per hour.  
7 I think that would be injecting a little realism into  
8 the scenarios that we assess.

9           The second comment I had, now I may be  
10 mistaken, but in listening, particularly to the AEATF  
11 discussions of yesterday and today, there seems to be a  
12 proposed approach that will minimize variation between  
13 monitoring units or replicates as we used to call them.  
14 And that really wouldn't promote probabilistic  
15 approaches that the EPA is promoting right now and it  
16 really seems to me to be a compromise of realism for  
17 what may appear to be a cleaner study statistical  
18 design and result. That's a personal opinion rather  
19 than an observation.

20           And final well, I've got two more. With to  
21 hand residue collection, in view of the existing data  
22 and just the priority knowledge, with the existing data  
23 showing possible rapid absorption of some active  
24 ingredients in pesticidal formulations, the use of hand  
25 rinses is questioned by me and I think a number of

1 other people, including Howard Mybach, as a data  
2 collection technique.

3 And certainly for future studies we ought to  
4 determine whether or not we want to continue with the  
5 use of the rinses, whether it's because of the  
6 detergents in the alcohol can change the physiological  
7 nature of the epidermis or deeper layers. And  
8 particularly I hadn't really thought about the calls of  
9 nature too much, I was too hung up on the physical  
10 properties of chemicals and how they dermally absorb,  
11 but if there are going to be repeated hand washes  
12 within a study monitoring period then that, the  
13 possible changes in the skin properties that I think  
14 tend, would tend to accelerate dermal absorption may  
15 occur.

16 On the other hand longer term residences on  
17 the hand surface raises the possibility of dermal  
18 metabolism of residues and that would be a residue that  
19 you could lose over a four hour monitoring period. And  
20 then of course the obvious systemic absorption that  
21 could occur within that four hours.

22 And because of all these confounding factors  
23 that can go into the hand rinse technique, you know, my  
24 personal recommendation would be at least to reconsider  
25 hand rinsing techniques for the newer studies or lose

1    them and go with a cotton glove external dosimeter  
2    instead.  Maybe with frequent changes of gloves if  
3    you're worried about breakthrough.  But you'd have to  
4    consider the level of detection that you're working  
5    with.

6                   And everybody's going to talk about the  
7    statistical validity of 10 monitoring units per study  
8    but my personal opinion is I'd rather have 10 quality  
9    replicates to work with than 15 or 20 dubious results  
10   to play with.

11                   So with that I'll move on.

12                   DR. CURWIN: Doctor Hamey.

13                   DR. HAMEY: Thank you.  The reason for  
14   having exposure data is to be able to complete  
15   regulatory risk assessments to ensure there's a  
16   sufficient margin of exposure between the likely  
17   exposure and the toxicological end point of concern.  
18   Obviously there's a need that we have to do this  
19   consistently with a degree of confidence in order to  
20   protect the health of workers while permitting products  
21   to present acceptable risks into the market for the  
22   benefit of growers and industry.  I think we'd all  
23   agree on that.

24                   The question really then becomes, can this be  
25   adequately achieved with the PHED database?  To which I

1 think the answer is, not very well. For two reasons.  
2 The first is the structure of the database and the  
3 algorithms it uses to estimate exposure which reflect  
4 the fact that many of the original data come from  
5 studies where incomplete body parts were monitored. As  
6 a consequence this does not provide an understanding of  
7 the distribution of individual exposures so it's not  
8 possible to characterize a particular exposure  
9 statistic and the competence associated with that value.  
10 This is true for both central tendency and higher  
11 exposure values which are both of interest in the risk  
12 assessment. I think the AHED software does represent  
13 an opportunity to correct that, those problems.

14 The second problem relates to the actual data  
15 within the database. Having had personal experience  
16 with the PHED database and having for a number of years  
17 also been involved in a European project to build a  
18 similar database of studies relevant to European use,  
19 which was the Europe project that John Worgan  
20 mentioned yesterday, the deficiencies in the data I  
21 think are a serious concern. Because they fail to come  
22 up to modern standards there's actually an imbalance in  
23 the data quantity requirements on both sides of the  
24 risk assessment equation. Similar deficiencies in the  
25 hazard, i.e., the toxicology data, would not actually

1 be tolerated. Also, comparable shortcomings are not  
2 tolerated in other human exposure data and here I'm  
3 thinking of the residue data in treated crops that  
4 we've used in a dietary risk assessment.

5 The limitations have been I think correctly  
6 identified by the EPA and the issues that I believe are  
7 of particular relevance include the fact that a number  
8 of studies did not use representative workers, some of  
9 them were company employees, some we don't know  
10 actually what their employee status was. A number of  
11 the studies are only monitored for short durations and  
12 this was, as we've heard, a particular point that was  
13 discussed as a limitation during the development of the  
14 OECD guidance document on occupation exposure  
15 measurement in agricultural settings. And this causes  
16 considerable uncertainty when using the data for  
17 exposure assessments representative of real practice  
18 where workers work for a whole day.

19 Some records in the database have missing  
20 parameters so that work tasks, equipment or  
21 environmental conditions are not adequately described.  
22 This limits analysis of possible relationships between  
23 exposure in these parameters.

24 Pesticide product packing, application  
25 practices, handler training, stewardship and equipment

1 have probably shown changes in the last sort of 20, 30  
2 years. These are likely to result in improvements,  
3 i.e., lower exposures, but as we don't fully understand  
4 what the determinates of exposure are, there may be  
5 some changes that have inadvertently increased the risk  
6 of exposure and these aren't reflected in the data.

7 It's also worthwhile to note that the EPA  
8 have stated that it's their desire to utilize more  
9 sophisticated probabilistic analyses in their  
10 occupational risk assessments. Indeed there's a strong  
11 body of scientific opinion with much agreement at the  
12 international level that both the variability and  
13 uncertainty in exposure assessments, if not risk  
14 assessment totally, should be transparently  
15 characterized.

16 An international workshop in 2003 was  
17 conveying, bringing together exposure assessors,  
18 modelers, toxicologists and statisticians to consider  
19 how to do this for pesticide users. It became apparent  
20 during the discussions at that workshop when  
21 considering case studies that developed using PHED,  
22 that the database contained so much unexplained  
23 variation which was likely to be due to the limitations  
24 in the data and mixed study protocols, that this  
25 objective could not currently be achieved.



1 Consequently it was concluded that more robust  
2 representative data are required to attempt to fill  
3 this objective.

4 So the questions is, you know, will the  
5 additional data help to address this? I think they  
6 probably will if the study protocols except and avoid  
7 the earlier issues which have, the limitations which in  
8 the current data, which appears to be the case.

9 I think it's important that the intention is  
10 to have monitored a significant proportion of the  
11 working day. The uncertainty with extrapolation will  
12 be decreased so we'll have a better understanding if  
13 exposure is proportional to the amount of active  
14 ingredient handled as this will be based on the  
15 comparison of whole day uses rather than a mixture,  
16 what we have currently when we try to make this  
17 comparison of whole day and short period uses.

18 Now it's extremely important that the new  
19 data are representative. This will be achieved in part  
20 by ensuring that farmers and growers are the subjects.  
21 There's also a need to understand if the sample  
22 monitored reflects the variation that occurs in reality  
23 in this population and to characterize the associated  
24 uncertainties with this sampling and to understand if  
25 they produce any biases in exposure. I think this is

1 an issue which we will have to consider further  
2 tomorrow.

3 An aspect that does not appear to be  
4 addressed satisfactorily to my belief at the moment is  
5 the issue on intra-worker variability. And I think  
6 there is a need to explore this aspect further.

7 Regarding the selection criteria proposed to  
8 the existing data I'm reasonably satisfied with those.  
9 I did have a question about the use of PPE in old  
10 studies but we heard yesterday that it was being looked  
11 at by, in comparison to today's standards. That was  
12 answered for the AHETF but I think a similar question  
13 is also relevant to the AEATF which I didn't ask  
14 yesterday.

15 And while on the subject of the AEATF  
16 criteria, I note that they state that inhalation will  
17 only be considered if applications generate what  
18 they've defined, what they've called inspirable  
19 aerosols but they haven't actually defined what those  
20 are and I would have a suspicion that they may not  
21 include inhalation monitoring as a criterion when I  
22 think it may be required. And they should also  
23 remember that although large droplets and particles may  
24 not respired, they may be deposited in the nasal region  
25 or in the mouth and they may be available for oral

1 absorption, they might form part of the absorbed dust.  
2 Thank you.

3 DR. CURWIN: Who is next here? Doctor  
4 Kim.

5 DR. KIM: Most of my comments have been  
6 addressed by other members of the panel so I'm going to  
7 focus on a few comments that may be helpful.

8 In general I'm in agreement with the EPA's  
9 conclusion that additional data could improve  
10 significantly the Agency's ability to assess workers'  
11 exposures.

12 However one area of great data need is  
13 documentation of task and activities as well as  
14 meteorological, physical chemical conditions,  
15 meteorological conditions which can really affect your  
16 exposure estimates. And we know from pharmacokinetic  
17 that relate exposure and dose relationships, that  
18 exposure variables are, exposure estimates are very,  
19 very sensitive to being able to predict what the  
20 internal dose is. So the database could, somebody who  
21 is querying the database should be able to extract  
22 information such as the intensity of exposure, the  
23 frequency, identifying the duration of exposure, as  
24 well as other meteorological factors that could affect  
25 exposure.

1           Second comment is again directed toward EPA  
2 and the AHETF has identified this already, and the EPA  
3 should I think move toward a similar approach which is  
4 to standardize the use of patches, specifically the  
5 location of the patches. Using an approach that relies  
6 on the skills and observations of the researchers who  
7 are collecting the data introduces many biases, based  
8 on the skills of the researcher and results in a lack  
9 of consistency across the studies. So a movement  
10 toward standardizing the location of the patches would  
11 be very helpful in comparing the exposures of different  
12 exposure scenarios as well as compounds.

13           With regard to the two databases, AHETF's  
14 database, my main comment has to do with the monitoring  
15 duration. The Task Force says that they want to focus  
16 on studies that have measured dermal exposures for  
17 which the individuals or the workers were exposed for  
18 at least half a day. This may be a little too  
19 stringent. And I understand the limitations of the  
20 analytical limits of detection, the high limits of  
21 detection as well as, well, inconsistencies in the  
22 laboratory. But with regard to high intensity and  
23 short term dermal exposures, if we set a criteria that  
24 says that we are not going to consider any studies  
25 beyond half day worker exposure durations then we're

1 not going to be capturing those short term, high  
2 intense exposure scenarios.

3 With regard to the AEATF database my comments  
4 are directed toward the biomonitoring studies. The  
5 point is made that extrapolation parameters must be  
6 available for the study to be selected by the AEATF and  
7 a primate dermal absorption data is listed as one of  
8 the types of data that will qualify for inclusion by  
9 the AEATF.

10 However there is a paucity of studies that  
11 have human relevant extrapolation factors and most are  
12 estimated from rat and porcine models. And you can  
13 refer the work done by James McDougall and Jim Riviera,  
14 et cetera. And maybe we'll talk about this later on,  
15 but in terms of being able to predict that amount of  
16 chemical that is deposited on the skin that actually is  
17 absorbed and penetrates the skin, there are other  
18 alternatives that Doctor Appleton spoke of, mainly  
19 using the fixed law of diffusion. And using these  
20 models allows one to be able to extrapolate from rat  
21 and porcine data to human exposure scenarios. So there  
22 you go.

23 My last comment has to do with the percent  
24 absorbed, and this is related to my previous comment,  
25 and it just seems that percent absorbed dose is going

1 to give you some wrong answers because the percent,  
2 application of that percent absorbed dose is really  
3 dependent on the dermal exposure, the level of loading  
4 on the surface of the skin. And this is because of the  
5 differential surface tensions of the skin as well as  
6 the media that is placed on top of the skin.

7 So what happens is that it's the first layer  
8 of skin that is most important for predicting  
9 absorption and dose. And as you have more loading on  
10 top of the skin of course you're going to get lower  
11 percent absorption. Therefore using something like the  
12 fixed law of diffusion which treats the skin as a  
13 single membrane and describing that absorption and  
14 penetration process using permeability coefficients  
15 which are readily available from these dermal  
16 absorption studies, it's just a different way of  
17 analyzing the data, may give you better estimates of  
18 the dermal, percent of the dermal dose that has  
19 actually been absorbed. That's it.

20 DR. CURWIN: Doctor Popendorf.

21 DR. POPENDORF: Well, to some degree I  
22 agree that we've made, some of my points are, have been  
23 discussed earlier. But I'm going to try to talk about  
24 the issues of the quality of the existing PHED data and  
25 the nature of why it's probably not well characterized

1 in terms of its limitations. And I think both groups  
2 have, particularly I guess the EPA presentation has  
3 given many examples of why it's limited, but I think  
4 the biggest problem and the focus of what I'm going to  
5 talk about is that, like the output in terms of, sort  
6 of the printout or the results of using PHED, the user  
7 is really not given any, or the appropriate measures of  
8 quality. Basically we've got your grading which is  
9 only one, or is based on only one parameter. And even  
10 that I think I'm going to talk about some of its  
11 limitations, so that I think overall, although  
12 subjectively I think I would agree that the data is  
13 limited and should be expanded through the proposals  
14 that have been made here, but that we add a measure of  
15 quality or of a broader measure of quality so that you  
16 can actually show improvement and show the value to any  
17 user, including the human effects people of why this  
18 data would be better or be able to quantify some of the  
19 limitations.

20 I think as an example of the kinds of things  
21 that are not part of the grading system that have been  
22 mentioned here so far, the incompleteness of some of  
23 the body parts within any given scenario. There is  
24 really no measure of that in terms of output and that  
25 certainly should affect grade or the quality of the

1 result that you get from that. The number of non-  
2 detects, now that's being built into the new protocol.  
3 That could be an output of both the new and the old  
4 protocol because the example that was, just sort of  
5 came out in our, in the presentation of our information  
6 of the gloved and un-gloved hands, clearly the data is  
7 biased by that non-detect issue. And unless you had  
8 some intuitive way to look at those numbers there's no  
9 indication in terms of the, like a grading mechanism  
10 that would help to tell you that.

11 The short time periods, the limited or  
12 limitations in the range of the active ingredient  
13 handled would also be potential additives to that  
14 grade. Certainly if the intent, eventually one of the  
15 other questions that we'll talk about later is the  
16 linearization of the data through the use of the  
17 active, amount of active ingredient handled. And if  
18 that's in a very limited range, if the validity of that  
19 assumption has not been tested, that should be part of  
20 the grade.

21 The only real part of the grade that's in  
22 there right now is based on the two parameters  
23 separately. If you want to bring up that first figure  
24 I'll get an example of a couple of things to show you  
25 graphically of what this, what I'm going to be talking



1 about. This, okay, the top figure is basically the  
2 existing grading scheme based on the lab recovery, the  
3 percent lab recovery and the coefficient of variation  
4 for the lab recovery. And as you can see right now  
5 you're putting in for instance an A grade, has to be  
6 within a single limit set for each of those two  
7 parameters.

8 And if you look at it from a broader  
9 perspective, well what affect does that have in terms  
10 of the potential error if you will or the projected  
11 standard deviation of the result? What I've presented  
12 in the bottom figure is I think a better way to look at  
13 it of looking at basically the affect of the  
14 coefficient of variation as a measure of precision,  
15 divided by the percent lab recovery as a measure of  
16 accuracy. And the lower that percent recovery, thank  
17 you, the lower that percent recovery, the more of an  
18 affect it has on the coefficient of variation. So for  
19 instance, this single point, the limit for an A grade  
20 as presented is right here, is what I've presented is  
21 again the same kind of figure but everything below the  
22 red line has a probable error, what I'm calling a  
23 probable for lack of another term, probably standard  
24 deviation or whatever you might want to call it, of a  
25 multiplier of 1.17. So I mean you're looking at

1 basically, if you want to think of it as a percent, a  
2 17% probable error, a probable standard deviation is an  
3 A grade. And if you think of that in terms of all the  
4 uncertainties and variables that we've been talking  
5 about today, this is like the gold standard, I mean it  
6 is, you know, very, very precise and in fact overall by  
7 adjusting for the recovery it's also very accurate.

8 Similarly the B grade, et cetera is shown  
9 here and you can see where the D, I mean without having  
10 looked at it in this perspective, the difference  
11 between the C and D grade is simply based on the  
12 recovery efficiency for the same coefficient of  
13 variation.

14 So, you know, great concept and I think, you  
15 know, the idea of having a grade, A, B, C, D, that's  
16 good and that's simple and it's intuitive, it's  
17 certainly part of the data that goes into, or the, part  
18 of the data set that goes into the PHED, it's not,  
19 well, you can only select on it as an output which  
20 limits the numbers. And we talked about, I think you  
21 gave some good presentations of the results of, of what  
22 if you just want A and B grade you end up with some  
23 losses. But I think you might want to look at  
24 expanding the definition of that grading scheme to  
25 include some of these other parameters.

1 I think on the next figure no, let's move  
2 on to the next one, we don't need to talk about that  
3 now.

4 Well I guess we'll, I'm going to talk about  
5 these points later in other discussions but I think the  
6 point here really is that the A, B, C and even the D  
7 grade data that you have, when you look at it going  
8 back to that first slide, the overall accuracy, I mean  
9 the worst grade you have there is a D factor which is a  
10 55% variability in that data. And that's, if that were  
11 the only parameter that you used it looks pretty good  
12 in comparison to everything else.

13 I mean I think the thing that you really want  
14 to think about then is to go back to what I was saying  
15 earlier, to include issues of incompleteness, of the  
16 fraction of non-detects and the short period, adding  
17 that to those parameters that would allow it to be  
18 graded which would show the poor quality of some of  
19 that data, allow it to be used more effectively but I  
20 think also justify the addition of better data that is  
21 going to address all those issues that have been  
22 proposed in these two, by the two task forces.

23 DR. CURWIN: That's all the comments from  
24 the associate discussions for this charge and I would  
25 like to open it up to the rest of the panel for any

1 comments that they may have.

2 DR. PORTIER: Doctor Landers.

3 DR. LANDERS: Thank you Mr. Chairman. I  
4 have a few comments regarding what I regard as the  
5 limitations of the database and how I would suggest  
6 they could improve. Understandably they're all to do  
7 with application technology.

8 And so for example I feel that there is a  
9 lack of information on different types of application  
10 equipment. While a growing number of farmers and  
11 growers are in the fortunate position of owning new  
12 types of sprayers, there are a lot of antique tractors  
13 and sprayers in use. The dilemma for you of course is  
14 to which example do you use for the study tests. What  
15 is a typical sprayer?

16 Let's take an example, in orchards sprayers  
17 range from modern tower sprayers which direct the spray  
18 in a horizontal direction into the canopy. These are  
19 much favored by researchers, through to the traditional  
20 air blast sprayer which sprays the spray plume upwards  
21 and outwards, contaminating not only the trees but the  
22 neighbor's trees that is, not the target tree, the  
23 tractor and everyone else in the next county. It then  
24 moves to low volume atomizers and if you listen to some  
25 people in some universities there's a great trend

1 towards low volume atomizers. Therefore I suggest that  
2 a single study test, if for example you choose air  
3 blast sprayers this is not typical and it fails to  
4 address the concerns that I have.

5 Therefore my recommendation in this case is  
6 to categorize application techniques and test  
7 accordingly. And this could be applied to various  
8 other crops, not just apples.

9 The second area of my concern is that there's  
10 a dearth of information regarding the protection  
11 offered by engineering controls. It is now over 20  
12 years since the state of California introduced  
13 legislation concerning closed transfer devices. And in  
14 the mid-80s there was a little flurry of research  
15 coming out of California from UC Davis, looking at  
16 their effectiveness. But not much since. And we would  
17 really like to know that for one reason which I'll come  
18 to in a moment. Induction bowls for example which are  
19 mandatory on all new sprayers in Europe, not yet here  
20 in the U.S., offer great opportunity to reduce risk,  
21 filling the sprayer knee high rather than clambering  
22 onto the tank certainly reduces potential contamination  
23 to the operator and decreases potential for  
24 environmental pollution.

25 Why are we interested in this? Purely

1 because the question exists, if we can introduce more  
2 engineering controls, then can we reduce the amount of  
3 PPE that is required? Whilst on a nice cool day like  
4 this in Washington, D.C. the thought of wearing a Tivex  
5 suit is far away but in the hot humid days in the deep  
6 south I understand it's quite unpleasant to be spraying  
7 in midsummer. So we must be aware that if we can  
8 engineer away the risk it would help us reduce the  
9 wearing of these Tivex suits.

10 The third area I have concern with is a point  
11 that I alluded to yesterday and that is the condition  
12 of tractors and sprayers. Yesterday I mentioned  
13 tractors and how in our research at Cornell we've seen  
14 contamination of the operator's clothing due to the  
15 fine quality of the tractor seat. This is even of more  
16 concern where you have custom applicators using self-  
17 propelled sprayers who may spend 18 hours a day  
18 climbing in and out of cabs wearing contaminated  
19 clothing.

20 The condition of the sprayer is an area I'd  
21 to address today. Many surveys have shown sprayers to  
22 be in poor condition. Research shows that sometimes  
23 the outer side of the sprayer is as contaminated as the  
24 inside of the tank. There are ISO standards available  
25 concerning the tank cleanliness and I would recommend

1 the adoption of these standards as part of good  
2 practice. Study tests are conducted on an "as is"  
3 basis. They take the sprayer "as it" on the day of its  
4 operation and off they go. GLP is followed in the  
5 laboratory but what about the field? Are we starting  
6 off with a vessel that is contaminated? So for  
7 example, we put our operator in a dosimeter in some  
8 nice clothes and he immediately, he or she immediately  
9 lean over this scruffy sprayer and contaminate a  
10 dosimeter with product that may have been on there from  
11 yesterday or two days or whenever.

12 So new technology does exist. For example,  
13 low drift nozzles, air induction nozzles reduce drift  
14 considerably, not only from the target area but also  
15 contamination of the sprayer. So if we started off at  
16 base one with a clean sprayer I would recommend this as  
17 good practice for the tests. Thank you.

18 DR. PORTIER: Any additional questions?  
19 Doctor Johnson.

20 DR. JOHNSON: Well just a comment. Part  
21 of my career has been involved with coauthoring three  
22 books in statistics called, Analysis and Messy Data,  
23 Volume 1, Volume 2, Volume 3.

24 The data in the PHED database is messier than  
25 I'd want to include in any of those books. So the

1 point I want to make is the main thing that we're, that  
2 I think we're after is trying to predict risk and  
3 what's the relationship between what's observed and how  
4 does that relate to actual risk of the individual being  
5 measured?

6 And it seems to me that based on the data in  
7 the PHED database, given the problems that it has, that  
8 it makes this idea of trying to predict risk a very,  
9 very, very tough job and I think there is a need for  
10 new data and I would support the collection of that.

11 The second point that I wanted to make, I  
12 don't know whether this is the right place to make it,  
13 but it did ask about the way that the studies are being  
14 graded in terms of quality and that has to do with the  
15 coefficient, the way the coefficient or variation is  
16 measured. It seems that if the data have the lognormal  
17 distribution, then coefficient of variation maybe  
18 should be measured in terms of log units rather than in  
19 terms of the raw units. And I don't know where that, I  
20 can't tell for sure whether that's being done and where  
21 it's being done, but I would make that recommendation.  
22 That might be something that you'd want to do.

23 DR. PORTIER: Doctor MacDonald.

24 DR. MACDONALD: I think Doctor Landers'  
25 remarks were very interesting but I think that also



1 takes us off in a direction that we were really not  
2 asked to go.

3 And that is answering the question, does  
4 newer equipment substantially mitigate risk? I think  
5 that's a very important question.

6 But neither database that we're, the existing  
7 one or the ones we're looking at proposed are intended  
8 to answer that question. I think that's, that would  
9 require a completely different kind of study.

10 DR. PORTIER: And I guess I took his  
11 comments as being recommendations for additional  
12 information to be gathered at the time that these  
13 studies are done. Because if I remember correctly  
14 there's not a lot of equipment specific information in  
15 the scenario metadata.

16 DR. LANDERS: I agree with the Chairman.

17 DR. MACDONALD: Yeah, my concern though is  
18 that we're not going to get enough data from specific  
19 types of equipment to be able to make good use of the  
20 breakdown. We'll have another covariant in there but  
21 we won't have enough information to make use of it.

22 DR. PORTIER: And I guess, again I took  
23 his comments as something we're going to reevaluate in  
24 question 5 when we talk about study design issues as it  
25 relates not only to sample size but variability. And I

1 think you're, in that context the scenarios and what  
2 goes into describing a scenario is part of the  
3 equipment issue.

4 Yes, Doctor Barr.

5 DR. BARR: I'd like to speak a little bit  
6 about the issues that Doctor Pependorf brought up about  
7 data quality. And I think that you're moving in the  
8 right direction by trying to generate more data now  
9 because, not only has the farming technology and our  
10 ability to design studies improved over the last 20, 30  
11 years, so has our ability to detect the chemicals in  
12 the laboratory as well.

13 And so when you're going to talk about  
14 grading studies, the European Union actually has a  
15 system for grading them based upon their ability to  
16 confirm a chemical, a particular chemical for analysis  
17 and criteria about CVs and spiked recoveries. But I  
18 would think if you were going to collect new data that  
19 you would try and set a systematic guideline for levels  
20 where those data are collected because a CV can change  
21 as you go down lower in the level of detection. And so  
22 I think that these need to be standardized if it's  
23 going to be used as a quality criterion for grading  
24 studies.

25 DR. PORTIER: Doctor Hines.

1 DR. HINES: Well, I just wanted to add, I  
2 think one of the objectives in collecting new data is  
3 to better characterize our distribution of exposures.  
4 And for that purpose that's one of the reasons why  
5 there's a focus on getting a good range of amount of  
6 chemical use. And I think that also addresses why we  
7 want to see different types of equipment, because we  
8 may have some modern equipment designed to minimize  
9 exposure at the low end of our distribution but I  
10 heartily second your observation that we still have  
11 some very antiquated methods out there of applying  
12 pesticides in orchards. And that it may take some  
13 outreach to try and find those people who are doing  
14 those methods. And so we can get a better distribution  
15 and that may be the amount, it may be the equipment and  
16 there may be some other factors.

17 DR. PORTIER: Doctor Lu.

18 DR. LU: I was waiting for someone to  
19 bring up this issue so I don't have to provide a  
20 written statement, but

21 DR. PORTIER: You still have to provide a  
22 written statement.

23 DR. LU: I guess the missing part of this  
24 discussion is that both the Agency and the task force  
25 group kind of shy away from collecting additional

1 biomonitoring data. There are disadvantages that were  
2 presented by both parties in terms of, you know, the  
3 difficulty to do these kind of studies. There's a  
4 Human Subjects Review Board barrier they have to cross.  
5 I don't think those are the good reasons to not doing  
6 this type of work. And especially the issue related to  
7 the Human Subjects Review Board. I think their  
8 establishment is to help us to conduct robust human  
9 studies, not to prohibit us from doing this type of  
10 work.

11 As a matter of fact, I think people brought  
12 up European countries, I went to Warsaw a couple of  
13 months ago and I heard that they are going to set aside  
14 a huge chunk of money and then come out with an  
15 organization that deals with conducting biological  
16 monitoring studies in the European countries. So we,  
17 again we're far behind on this part.

18 Another ironic situation is that both parties  
19 identify the lack of pharmacokinetics and so and so  
20 forth, but both parties also provide data that shows  
21 that we're able to calculate the absorbed dose using  
22 biological data. Don't you think that's ironic? If  
23 you don't have the pharmacokinetics how can you do  
24 those calculations?

25 So again I understand the limitations but

1 since we're talking about what type of data is needed  
2 in the future I think it's almost impossible to ignore  
3 the importance of biological data. Now I have to write  
4 a statement.

5 DR. PORTIER: Alex, you know, when I look  
6 at what we're talking about here a lot of this is tier  
7 1 and tier 2 type studies and wouldn't you think that  
8 the biomonitoring study data is going to pertain more  
9 to these tier 3 kind of studies where there's much more  
10 need for that?

11 DR. LU: Well as a matter of fact I think  
12 when I was in the school I was taught that you should  
13 take the biological data first. If the level looked  
14 okay that means everything is fine in the field. If  
15 all of a sudden case A has such a high level then you  
16 want to know what happened. And that's why you conduct  
17 a dermal exposure assessment or inhalation, to find out  
18 the reason. And now we're going backward and going  
19 backward in a way that you don't even have a rear  
20 mirror so chances are you'll have an accident.

21 Anyway, it's very easy to do a biological  
22 monitoring study in an occupational setting because  
23 they tend to expose higher, the chances are we'd get a  
24 much better limit detection. I don't know about other  
25 people but I have a very limited field experience, I

1 think Cynthia Hines may be able to comment on this,  
2 that workers tend to be very cooperative in these types  
3 of studies. So I don't think there's a lot of  
4 logistical reasons that are put out by both parties are  
5 legitimate in the sense that, you know, based on our  
6 experience.

7 So I would say biological studies might be  
8 the tier 1 study, not tier 3.

9 DR. PORTIER: Doctor Chambers.

10 DR. CHAMBERS: This is Jan Chambers.  
11 Let me just clarify about the Human Studies Review  
12 Board. This board will be looking at all studies that  
13 are involving intentional dosing of humans whether it's  
14 passive dosimetry or biomonitoring, regardless of what  
15 the end point is.

16 DR. LU: This is Alex again. But the  
17 question is, what is intention dosing? I mean those  
18 are pesticide applicators, with or without a study that  
19 we impose on them. They still go out and spray  
20 pesticide for making a living. That's one argument.

21 The other argument is that sometimes the  
22 review board looks at the exposure level and says, oh,  
23 this might pose some significant risk. But if the  
24 level is comparable to the level that those people are  
25 going to experience in the field, they why are we still

1 allowing those pesticides to be used in the field but  
2 not in the human control study?

3 So those dilemmas need to worked out in the  
4 human subject level, but we should not be discouraged  
5 from doing this type of work. I mean it's part of our  
6 work to commicate with the Human Subjects Review Board  
7 but, you know, that should not be used as an excuse not  
8 to do biological monitoring studies.

9 DR. PORTIER: Point taken. Doctor Curwin.

10 DR. CURWIN: I have a couple of comments.  
11 One is to Alex actually. I think we can all agree that  
12 it's desirable to have biomonitoring studies but I  
13 think we need to put this into context with the  
14 regulatory agencies in that they want to develop a  
15 generic database so that they can do their exposure  
16 assessments without having to provide new data for each  
17 compound that is coming in for registration.

18 And I think that's difficult to do with a  
19 biomonitoring type approach because, you know, the  
20 nature of biomonitoring is you have to have chemical  
21 specific data. So while it would be highly desirable  
22 to have these, this information on each compound, if we  
23 really are, if we feel that the resources or  
24 limitations and that sort of thing that the regulatory  
25 agencies are under, and that the generic exposure

1 database is the way to go, I'm not sure that the  
2 biomonitoring then is going to apply here. That'll be  
3 discussed later this afternoon I do believe.

4 And then another comment, and I don't want to  
5 put Doctor Chambers on the spot but I'm going to a  
6 little bit, just because of your HSRB hat, and I could  
7 be wrong in this assumption. But I think one of the  
8 impetuses for this charge question was the recent HSRB  
9 review for the additional data and HSRB had said that  
10 there wasn't a clear indication that there is a need  
11 for data. From what I've been hearing in this  
12 discussion it seems like for the panel members who have  
13 spoken at least, that there is a consensus that the  
14 additional data is warranted due to the limitations of  
15 fed.

16 And I'm just curious because of your HSRB  
17 affiliation if you have a comment on that particular  
18 charge?

19 DR. CHAMBERS: Yes Doctor Curwin, this  
20 is Jan Chambers. That was one of the major concerns  
21 that HSRB had when we saw some of the protocols that  
22 were presented during the June meeting, that there  
23 really didn't seem to be sufficient evidence to the  
24 panel that was looking at that, that there was a need  
25 for new data.



1           And I'm just a little bit concerned actually  
2 about the fuzziness of what the goals of the HSRB are  
3 that are kind of floating around here right now. And  
4 I'm wondering if Jeff or Jeff or Bill Jordan or  
5 somebody might just give a brief overview of what the  
6 statutory need for the HSRB's activities are.

7           MR. DAWSON: I'll let Bill do that.

8           MR. JORDAN: Thanks, I'm Bill Jordan, I  
9 work for EPA's Pesticide Office and have worked with  
10 the Human Studies Review Board on their, fulfilling  
11 their responsibilities under the recently promulgated  
12 EPA regulation to improve protections for subjects of  
13 human research.

14           The board has a couple of different  
15 functions. The first of which is to review completed  
16 studies that involve intentional dosing of human  
17 subjects and there are different categories of such  
18 research. There are intentional dosing studies which  
19 are designed to measure a toxic affect. There are  
20 exposure studies such as the ones that we've been  
21 talking about today. And then there are things such as  
22 studies of insect repellant efficacy and so on. Not  
23 all of the completed studies need to go to the Human  
24 Studies Review Board under the regulation but ones done  
25 after April 2006 will, when they're completed and

1 submitted to EPA and EPA decides, yes, the data are  
2 something we want to use in our reviews, we'll send  
3 them to the board for a review. And when the board  
4 gets such studies they need to, under the charter and  
5 our regulations, give us feedback on two distinct but  
6 related aspects of the research.

7 The first of which is, are the data  
8 scientifically sound? And secondly, were they produced  
9 in a manner that is consistent with the ethical  
10 standards applicable to that research? For studies  
11 that have, are at the proposal stage, our regulation  
12 directs EPA to review proposals for research and once  
13 we at EPA have completed our review, to provide copies  
14 of the materials relating to these new protocols to the  
15 Human Studies Review Board and ask the Board's advice  
16 on the proposed research. Again, the Board is looking  
17 at two distinct but related aspects of the research.

18 The first of which is, will the data produce  
19 scientifically sound results? And secondly, will the  
20 data comply with or comport with the applicable ethical  
21 standards? And the ethical standards that apply for  
22 new research are the standards contained in the common  
23 rule and through EPA's new regulation, extended  
24 essentially comparable requirements to third party  
25 research. And so we'll be asking the board, do you

1 think under the common rule standards, that this new  
2 set of proposals for research that AG. Handler Exposure  
3 Task Force wants to do, do you think these studies are  
4 going to give us scientifically valid information and  
5 do you think they will comport with the ethical  
6 treatment of subjects?

7 So that's the thrust of what the Board is  
8 being asked to do.

9 The last thing that I'll mention is that on a  
10 case by case basis we at EPA can say there's some other  
11 questions we'd like to get the Board's advice on  
12 relating to the conduct of human research that may not  
13 focus on a specific study, either a proposed study or a  
14 completed study.

15 DR. PORTIER: Thank you. Doctor Hamey.

16 DR. HAMEY: Thank you. It was just a  
17 minor comment to what Doctor Curwin was saying in  
18 response to what Doctor Lu said. And regarding the use  
19 of biological monitoring as a sort of preferred  
20 approach to assessing exposure.

21 My understanding is a lot of the assessments  
22 the EPA are trying to make are before products are  
23 actually approved and allowed onto the market. So, you  
24 know, predictive estimates of exposure, so in order to  
25 decide whether it is acceptable for it to be used. So

1 there's a Catch 22 dilemma.

2 DR. PORTIER: Doctor Pependorf.

3 DR. POPENDORF: Yes, Bill or perhaps  
4 Janice, but I was caught by the phrase, intentional  
5 exposure, and to what would seem to be an  
6 interpretation of what intentional means, intention to  
7 expose someone who would not otherwise be exposed. And  
8 in this case or cases of air pollution health effects  
9 where people are being exposed, the issue of  
10 intentional exposure would seem not to apply. Is there  
11 another category in that evaluation or how is that  
12 being interpreted?

13 DR. PORTIER: I think we can have EPA's  
14 input on this.

15 MR. JORDAN: Okay, this is Bill Jordan  
16 again. The regulation applies to human research  
17 involving intentional exposure of subjects to a  
18 pesticide and there is a definition of intentional  
19 exposure. And it's perhaps a bit broader than you may  
20 be thinking of, Doctor Pependorf, and certainly we've  
21 had other people raise similar questions.

22 For purposes of the regulation, intentional  
23 exposure is defined to mean exposure that only occurs,  
24 that would not have occurred but for the person, the  
25 subject's participation in the research. And so let me

1 see if I can give some examples that might clarify how  
2 we at EPA think of the distinction. And I'll concede  
3 at the outset that there will be situations that'll be  
4 a gray area and will need to be looked at on a case by  
5 case basis.

6 If someone says to a subject, here,  
7 participate in this study and we're going to apply some  
8 chemical to your skin to see how much of that chemical  
9 crosses the skin barrier and we can then measure as a  
10 urinary metabolite. That's an intentional dosing  
11 study.

12 On the other hand if the researcher goes to a  
13 field and collects urine from people who are hired by a  
14 farmer completely apart from the research, gets consent  
15 from the participants and measures urinary metabolite  
16 levels, that would be an observational study.

17 The difference between those two situations  
18 is that the exposure experienced by the subjects occurs  
19 in the first instance as a consequence of participation  
20 in the research. In the second instance it's a  
21 consequence of the subject's voluntary choices about  
22 whether to go to work and what kinds of pesticides to  
23 use or his employer's choices about that.

24 There will be cases that are somewhat in a  
25 gray area but the kinds of scripted activities that are

1 called for in the AG. Handler Exposure Task Force  
2 protocols are ones which we deem, put it on the side of  
3 being an intentional exposure study.

4 DR. PORTIER: Doctor Chambers.

5 DR. CHAMBERS: I guess just to reiterate  
6 a little bit of the concerns that arose during HSRB  
7 meetings when this was first presented, is that partly  
8 what Bill Jordan just said about the scripting. There  
9 will be some, in some cases some scripting and not just  
10 absolutely regular activities. And then the other  
11 concern is that in some cases it will be surrogate  
12 compounds and not necessarily the ones I guess that  
13 were going to be used that day in the field anyway.  
14 And so that makes it kind of one of those gray area  
15 type studies I think. So sort of semi-natural but  
16 semi-scripted.

17 DR. PORTIER: Any additional questions,  
18 comments? I think this is probably a good place to  
19 break on this question and to take a short afternoon  
20 break. Mr. Dawson, did you get what you wanted to get  
21 out of this question or Mr. Evans? Do you guys have  
22 any additional questions that well, you can think  
23 about it. We'll revisit it after the break because I  
24 see a lot of people yawning, we need to get up and move  
25 around a little bit.

1           So we'll ask that question when we get back.  
2   I won't quite close the question until we get back from  
3   the break.

4           Let's take a 15 minute break, I have 2:40,  
5   that's puts us back at 2:55.  
6   (WHEREUPON, there was a recess).

7           DR. PORTIER:    Okay, it looks like we've  
8   got our panel back.   Maybe I should, I almost hesitate  
9   to ask if there's any additional panel questions at  
10   this point because I really want to go on to the next  
11   charge question.   But if there's a dying question among  
12   the panel I think we could consider it.   Did anybody  
13   come up with a   I'm not going to give you a lot of  
14   time to think about it.

15           Jeff and Jeff, it looks like, my take on this  
16   is I get a feeling that the panel feels that the  
17   additional data is justified.   I think that's part of  
18   the take home message.   The other message is that the  
19   selection criteria for the most part looks good but  
20   we're going to have a number of recommendations for  
21   additional data elements that we'd like to see recorded  
22   and some other side issues that are going to be  
23   discussed.

24           Is that kind of what you --

25           MR. EVANS: I would agree with that, we

1 were very happy with the answers and you gave us a lot  
2 of things to think about to enable us to press our case  
3 further and we very much appreciate that. And we are  
4 ready to move on to the next question if

5 DR. PORTIER: And Doctor Curwin, it's  
6 going to be interesting to see how you include the  
7 discussion on the Health Effects Committee. You asked  
8 that question.

9 Okay, I think we're ready to read to read the  
10 second charge question.

11 MR. EVANS: I'll be happy to do that. The  
12 common approach for conducting dermal exposure  
13 monitoring studies relies on the use of whole body  
14 dosimetry, hand washing and facial neck wipes. In some  
15 cases biological monitoring is also used as an  
16 alternative method. Exposure estimates and Agency risk  
17 assessments however typically rely on two of the skin  
18 measurements. For example, potential dose coupled with  
19 dermal absorption data or dermal toxicity studies in  
20 order to calculate risks. The Agency believes that  
21 these methods are complementary and that they can  
22 provide appropriate estimates for exposure assessment,  
23 but that the results directly related to the  
24 reliability of the inputs used.

25 Please comment on the Agency's conclusion



1 regarding passive dosimetry and biological monitoring,  
2 including whether a systematic bias exists in either  
3 approach.

4           Based on the information presented the Agency  
5 has particular concerns over three specific aspects of  
6 how these studies are conducted, including, 1, the  
7 possible need to correct for the efficiency of the  
8 handwash technique, 2, compensating for absorption of  
9 residues through the skin during sample collection  
10 periods and 3, the breakthrough of residues under whole  
11 body dosimeter garments. Please comment on the need to  
12 systematically account for residue losses due to these  
13 potential method biases. If there is a need, please  
14 describe how these corrections should be accomplished  
15 in a way that could reduce uncertainties in the  
16 resulting exposure estimates.

17           DR. PORTIER: Doctor Barr, it looks like  
18 there's a lot of comments. I guess you'll start us off  
19 on this.

20           DR. BARR: I'll start us off. First of  
21 all as a preface to my comments I'd like to say that  
22 the presentations that were given today were quite  
23 excellent and directly impact the charge of our working  
24 group. And so most of us kind of feel a little  
25 overwhelmed with the data that was presented. And so

1 we want an opportunity to digest the remarks and  
2 perhaps revisit some of these questions at a later date  
3 during the week.

4 The first question really wasn't a question  
5 but it was to ask our overall assessment of the passive  
6 dosimetry and biomonitoring data and whether there's a  
7 systematic bias between the two measures. From the  
8 information that we've been presented and given today,  
9 both from the EPA and from the task force, we don't see  
10 that a systematic bias exists.

11 Again we have some questions on how these  
12 comparisons were derived and would like to look more  
13 deeply into it tonight before we finalize that answer.

14 Since the last three questions are so closely  
15 linked and deal with the efficacy of passive dosimetry  
16 methods, whether they involve hand washing or whole  
17 body dosimeters to adequately estimate the external  
18 dose, we'll just treat them as one question and kind of  
19 try to address them all together.

20 I think existing data clearly indicate that  
21 for certain pesticides absorption of a pesticide on the  
22 skin or into the body can occur within a matter of  
23 minutes after the exposure has occurred. This  
24 absorption would be expected to be pesticide dependent  
25 and related to the ability of the particular pesticide

1 to penetrate the skin. In addition, variability in the  
2 amount absorbed would be expected based upon the time  
3 the pesticide remains on the skin prior to washing, the  
4 amount of pesticide that is actually on the skin and  
5 general inter-person variability. In addition, the  
6 ability of the solvent, and here several solvents were  
7 discussed, both alcohol, water and detergent based, to  
8 remove the chemical from the skin or promote its  
9 absorption into skin may vary based upon the physical  
10 and chemical properties of the pesticide and adherence  
11 to the standard hand washing protocols.

12 Most, but not all of these potential biases  
13 would most likely result in an underestimation of the  
14 amount of the pesticide present in the skin. For  
15 example, data presented in Fenske and Lu, 1994 show  
16 that several hand washing solvents recover less than  
17 50% of chlorpyrifos from the skin immediately after  
18 exposure and about 20% was recovered from the hands one  
19 hour after exposure.

20 Using dermal absorption factors based upon  
21 existing data such as the 3% factor based on Nolan et  
22 al's paper for chlorpyrifos should be used, although  
23 they don't necessarily reflect the various parameters  
24 that can affect dermal absorption.

25 I think correcting for these biases is going

1 to be difficult because no gold standard for comparison  
2 exists. The current comparisons that have been given  
3 to us compare biomonitoring against the dermal  
4 absorption and of course biomonitoring is not without  
5 its limitations as well. And we have to make several  
6 assumptions with biomonitoring as with dosimetry that  
7 gives both approaches some degree of uncertainty.

8 If correction methods can be derived that can  
9 significantly decrease the uncertainty at a reasonable  
10 cost then perhaps they should be applied. For example,  
11 the approach using the log  $K_{ow}$  that was mentioned  
12 earlier would be a possible solution if deemed  
13 appropriate and if it would have a significant impact  
14 on the overall exposure estimate.

15 A second approach of course which you also  
16 mentioned today would be to quantify the amount of  
17 absorbed dose based on excreted metabolites and  
18 pharmacokinetic information and add this to the passive  
19 dosimetry estimates. As biomonitoring provides data  
20 that are independent of the route of exposure, other  
21 routes of exposure would be included which might  
22 overestimate the total dermal dose. The biomonitoring  
23 approach may be difficult as well because many  
24 pesticides do not have reliable biomarkers and  
25 pharmacokinetic information is insufficient or largely

1 lacking for most pesticides. In addition, the burden  
2 to the participant becomes exponentially larger if 24  
3 hour urine samples are requested over a period of days.

4           However, the biomonitoring approach would  
5 likely be one of the few viable approaches acceptable  
6 to estimate the amount of breakthrough from whole body  
7 dosimeters. One cannot assume that you have a uniform  
8 breakthrough from a whole body dosimeter and there  
9 appears to be no reliable way of predicting the amount  
10 of body surface affected. Also, breakthrough is likely  
11 affected by the task being performed as well.

12           Some tasks may have minimal potential for  
13 breakthrough in which case no correction would be  
14 necessary. But for tasks where breakthrough is likely  
15 biomonitoring would complement the passive dosimetry  
16 data to estimate the external dose. Alternatively,  
17 some sort of patch placed under the whole body  
18 dosimeter may be able to provide some breakthrough  
19 information if those patches were strategically placed.

20           I believe the existing data demonstrates that  
21 some sort of correction should be applied or at least  
22 the uncertainty recognized and it should be chemical  
23 dependent. One thing that has been I think of concern  
24 to a lot of the people in our working group is trying  
25 to have something generic that doesn't use the chemical

1 and physical properties of each independent pesticide.

2 Before today I had seen no study in which  
3 biomonitoring results compared so well to passive  
4 dosimetry estimates which is why in part so many  
5 studies have coupled passive dosimetry an/or other  
6 environmental analyses with biomonitoringh to estimate  
7 total exposure. Likely, in my opinion, an approach  
8 using the chemical physical properties of the pesticide  
9 and wash solvent should be employed to derive a  
10 correction factor to correct for dermal absorption of  
11 the chemical when estimating hand exposure using  
12 passive dosimetry.

13 Biomonitoring is also viable but a more  
14 costly and cumbersome option and may overestimate the  
15 external dose if other routes of exposure are  
16 significant or if the selected biomarker is not  
17 selected for the exposure.

18 Again for the data provide it's just not  
19 clear to us whether a correction factor or compensating  
20 for breakthrough is necessary. However the panel feels  
21 strongly that the chemical and physical properties of  
22 each single chemical should be considered as a part of  
23 this generic database. We don't know from the data  
24 presented whether the agreement would hold if sorted by  
25 individual pesticides for example.

1           Also we think some attempt to include the  
2 studies that were excluded in the study presented by  
3 the task force should be done and clearly if some  
4 correction factor is adopted it should be chemical  
5 dependent.

6           I'd like to I guess invite the other  
7 associate discussants to give their opinions as well.

8           DR. PORTIER: Doctor Hines, Cynthia.

9           DR. HINES: Thank you Dana, that was very  
10 exhaustive, I'll see if I can find something to expand  
11 upon or add to that.

12           Taking the first question on whether or not  
13 there is a systematic bias in the passive dosimetry and  
14 the biological monitoring, I would concur with what  
15 Dana said, that given the data that we have been shown  
16 by EPA and by the Agricultural Handlers Exposure Task  
17 Force, as presented the data do not seem to show a  
18 systematic bias.

19           I do have some concern that there may be bias  
20 within individual chemicals. We haven't much time to  
21 really look at that. For me the implications of that  
22 extend to maybe new chemicals down the road or  
23 chemicals that we do additional biomonitoring on where  
24 we may learn something new about the relationship  
25 between passive dosimetry and dose through biological

1 monitoring. And I would hope that in the future if EPA  
2 were to come across a study that had concurrent  
3 biological monitoring and passive dosimetry, or one of  
4 these sequential studies and there was an obvious, in  
5 particular the passive dosimetry underestimated the  
6 biological monitoring that EPA would maybe take that  
7 into consideration and look at that and not just simply  
8 take what was in the database and ignore that and maybe  
9 that's your routine procedures.

10 The next question had to do with the possible  
11 need for correcting for efficiency of the hand washing  
12 technique. I think the challenge in that question is  
13 the word, need, versus the word, feasibility. Clearly  
14 there is quite a variation in the efficiency of removal  
15 in these hand washing techniques as we've seen from the  
16 data from substances that are recovered with, you know,  
17 in excess of 90% efficiency and then substances like  
18 Dana mentioned, chlorpyrifos that are less well  
19 recovered. And this may have a lot to do with both the  
20 techniques that were used in the studies and also the  
21 solvent systems, contact times, those kinds of things.

22 So having said that it would seem that in a  
23 sense when you have poor efficiency of removal that it  
24 would seem that you would need to do some kind of  
25 correction, although when I start thinking about the



1 feasibility of actually doing this and extending this  
2 across chemicals it becomes more problematic. Also,  
3 factoring into my thinking is that at least under the  
4 proposed Agricultural Handlers Exposure Task Force  
5 studies, participants will all be wearing gloves. And  
6 so hand loading may be very low to start with. And so  
7 the whole impact of this removal efficiency may really  
8 be not a significant element.

9           So I think on balance I'm not feeling that  
10 that is a, the correction is something that's highly  
11 needed. It might be, you know, when you're exploring  
12 data something you could do would be to see what if we  
13 corrected our doses for this, is it going to make much  
14 of an analysis difference or sensitivity difference in  
15 the whole body versus the dermal, those kinds of  
16 sensitivity analyses?

17           On the second question, absorption of  
18 residues through the skin during the sample collection  
19 periods, as Dana pointed out this is going to be highly  
20 chemical dependent and it's going to be dose dependent.  
21 And so there's a lot of factors in there. You know, I  
22 think my general impression is that probably that  
23 contribution to exposure will not be high and so I tend  
24 to think that probably there's not a great need for  
25 correction there as well.

1           Again I would hope that if EPA for a  
2 particular chemical as it is being registered or re-  
3 registered really shows an obvious deviation from this  
4 where you think that it's going to affect the whole  
5 risk assessment, that you would take any other data  
6 into account.

7           And finally the breakthrough of residues  
8 under whole body dosimeter garments, you know, what I'm  
9 most familiar with is, you know, when we do air  
10 sampling in industrial hygiene we always have a backup  
11 section and we can on every study know whether we've  
12 got breakthrough. And it's a technical challenge that  
13 we don't have that for whole body dosimetry or even for  
14 patch dosimetry, whereas we're conducting these studies  
15 to know whether or not we've had breakthrough. And if  
16 anyone could ever engineer a suit or a patch that would  
17 allow us to actually measure that during our sampling,  
18 that to me would be the ideal situation. So that we  
19 would know on a case by case basis whether we really  
20 needed to correct.

21           And as Dana pointed out the dilemma with  
22 breakthrough is that with pesticides you don't get this  
23 nice uniform deposition. You could have, you know, a  
24 leak along the sleeve and it gets saturated so you  
25 might have a breakthrough in one spot but not in 90% of

1 the rest of the garment. And I don't honestly know how  
2 you would deal with that. We discussed this  
3 possibility and maybe others have done this of  
4 selective patches that act as monitors underneath the  
5 dosimeter. So perhaps that could be explored or maybe  
6 has been discussed. But in the absence of any real  
7 sound way to do this I don't think that I would advise  
8 making that correction.

9 The one other comment I would make is this  
10 idea of maybe looking at the optimal water partition  
11 coefficient and its relationship to the removal  
12 efficiency, I thought was intriguing. There isn't a  
13 lot of data in there. That might be worth pursuing to  
14 see if you can, you know, get more data, I don't know  
15 if that's going to bring in human subjects issues, but  
16 of the different approaches that were suggested for  
17 looking at this problem of handwash or hand rinsing  
18 removal efficiency, that one to me seemed the most  
19 interesting.

20 DR. PORTIER: Very good. Doctor Hughes.

21 DR. HUGHES: Again I'll make my comments  
22 brief because I think Doctor Barr has pretty much done  
23 a good job of covering them. I'll also iterate what  
24 she said that we appreciate the industry's as well as  
25 EPA's efforts in giving us some comparisons between

1 passive dosimetry and the biomonitoring. The way I  
2 have looked at this is basically putting it into more  
3 of an epidemiological perspective and that is not  
4 uncommon when you conduct a case control study to look  
5 at the biases that impact the study to determine the  
6 nature and the magnitude of their affect on the result.  
7 In other words, if it overestimates and how much it  
8 overestimates. If it underestimates, how much it  
9 underestimates.

10 And then with the effect of looking at  
11 whether the result you get is generalizable. Okay,  
12 we've often mentioned the term accurate but I think  
13 it's more applicable for regulatory purposes to use  
14 that term generalizable. In the same way we have to  
15 look at the end result with regard to all the  
16 parameters, how they're going to overestimate and  
17 underestimate the possible results that you would get  
18 from any model that you have that predicts a risk.

19 When you look at the comparisons between  
20 passive and biological monitoring you see that the  
21 variability is an order of magnitude off, in my  
22 experience I agree with the Agency that that's  
23 acceptable. And so I go on and have to take a look at  
24 exactly what would hand washing mean and what are the  
25 variations? And I appreciate the industry's evaluation

1 of looking at risk assessments and taking a look at  
2 exactly what I would regard as a sensitivity analysis,  
3 looking at each one of those parameters and figuring  
4 out the variability in each one of those parameters and  
5 how much it would make a change to the overall result.

6 For the AHED database where actually one is  
7 using gloves and protecting the skin the dermal  
8 exposure on the hands is probably not as significant as  
9 it would be for other exposures, being the Residential  
10 Task Force or the Reentry Task Force. In studies that  
11 we had and the reentry study on blueberries that was  
12 mentioned by Doctor Olsen, we find that 50% of the  
13 exposure occurs on hands. And certainly that's not to  
14 be expected in AHED. And certainly with regard to  
15 looking at the model in more of a probabilistic  
16 determination one wouldn't expect that there would be  
17 much sensitivity to variations within looking at the  
18 efficiencies in hand washing and absorption thereof.

19 Nevertheless, when I say that I'm still a  
20 little bit concerned that looking at the possible need  
21 to correct the efficiency of hand washing techniques  
22 might be valuable in other situations. Again, where  
23 the hand is unprotected, where you might be in the  
24 agricultural, might look at the Agricultural Reentry  
25 Task Force data or the residential data, where hands

1 are unprotected where you might be dealing with young  
2 children. And I think that there is, as Doctor Barr  
3 suggested, some cause that we'd go ahead and take a,  
4 and look at the data and make the, and look at Doctor  
5 Fenske's data and assume or at least think that there  
6 is a probability that you're underestimating the  
7 estimate.

8 And to go ahead and find ways of compensating  
9 for that based on some biomonitoring data.

10 And so I just wanted to add some comments  
11 with regard to acknowledging the sensitivity based on  
12 the probabilistic study, but also saying that there  
13 might be occasions where we really do need to look at  
14 that and we can't quantify exactly what the absorption  
15 efficiencies are from the information on hand and we  
16 really do need to go one and look at a more  
17 comprehensive study, looking at not only the  
18 components, the kow's, we'll have to look at the  
19 concentrations, we'll have to look at the timing.

20 And also we have to look at the various  
21 protocols and make sure that what we're emulating with  
22 regard to biomonitoring with regard to whether it's a  
23 dried residue on a plant or actually direct application  
24 with the different formulations, that we have some  
25 comparisons there as well.

1 DR. PORTIER: Doctor Kim.

2 DR. KIM: So some of the biases in hand  
3 washing patch samplers and whole body dosimeters,  
4 they've been discussed by other members of the panel  
5 and they've been fairly discussed, thoroughly discussed  
6 in the literature so I won't really comment on them.  
7 But my only recommendation is that the uncertainties  
8 associated with each of the sampling techniques, they  
9 just be stated up front, they be incorporated into the  
10 databases and just, yeah, so it's stated. So not  
11 necessarily at this point correcting for any biases  
12 because there is, like Doctor Barr said, there is no  
13 gold standard to compare against.

14 My, most of my comments are going to focus on  
15 skin biology. You know, we've focused on, it's been  
16 said in the past that physical chemical properties of  
17 the exposure scenario are most important for predicting  
18 dermal, or measuring dermal exposure and predicting the  
19 internal dose that results from the dermal exposure.  
20 But I would argue that some of the skin biology or  
21 consideration of the skin biology is very important  
22 because if you look at an inhalation exposure study, a  
23 chemical that enters the alveolar region and it crosses  
24 that alveolar lining, it's, the diffusion is very rapid  
25 so it's not a diffusion limited uptake for inhalation

1 exposure to chemicals.

2 But for the skin, the skin is a very dense  
3 layer, it has all sorts of cornified cells, proteins,  
4 lipids, and this very messy matrix will affect how  
5 chemicals are absorbed or taken up into the body. So  
6 that in the skin sometimes what happens is that the  
7 skin holds on to these chemicals for fairly long  
8 periods of time. And understanding how the chemical  
9 behaves inside the skin is very important and this is  
10 very relevant, I mean it's been discussed fairly  
11 extensively by the FDA and in the pharmaceutical  
12 industry. So a patch dosimeter that better captures  
13 the level of chemical that is as close to the skin as  
14 possible is preferred. As well as when you're choosing  
15 or selecting the patch sampler it should have some  
16 characteristics that are similar to human skin. And  
17 there was a recent publication that came out of the IOM  
18 where they invented a sampler that had a charcoal  
19 backing and various layers that were able to better  
20 mimic uptake via the skin.

21 As for any of the residues that are, that  
22 result from breakthrough across a sampler, the EPA  
23 doesn't really talk about tape stripping which is a  
24 method that has been used by the FDA and pharmaceutical  
25 industries extensively to actually measure the chemical



1 concentration or the amount of chemical in the stratum  
2 corneum. And through successive tape strips you able  
3 to actually get at what the dose is and what the time  
4 course behavior of that chemical is within the stratum  
5 corneum because that's what drives ultimately what, how  
6 much of a chemical goes inside for systemic  
7 circulation.

8           The other comment has to do with the percent  
9 dermal, dermal absorption factor, And it's been  
10 demonstrated that this varies from the location of the,  
11 by location on the body. So for example a dermal  
12 absorption across the hands is going to be completely  
13 different because of the physiology of the skin  
14 relative to on the eyelids for example. So I think  
15 that is going to contribute to a lot of the  
16 uncertainties and there are techniques in place right  
17 now that do take into account the thickness of the skin  
18 at different layers for examining differences in the  
19 percent dermal absorption.

20           DR. PORTIER: Doctor Lu.

21           DR. LU: I think the question that's set  
22 out for the panel has been discussed thoroughly. I  
23 guess I kind of set a tone when I, you know, answered  
24 the question of the data needed that, you know, just  
25 stay away from this complicated dermal exposure

1 scenario and focus on something that may give you a  
2 better quality of the data. Those three questions are  
3 very significant.

4 And I want to echo the example that Cynthia  
5 Hines raised is the air sampling tube. There is the  
6 back end that will absorb the breakthrough. And as a  
7 matter of fact if I can recall, if you found 30% of  
8 breakthrough in the back part of the sampler, that  
9 whole sample should be tossed away because you can see  
10 that it's an invalidated measurement because you don't  
11 know how much actually got out of the tube and is not  
12 being absorbed.

13 So in the case of whole body dosimetry, first  
14 of all we don't know whether there's a breakthrough or  
15 not. If there's a breakthrough then we have to throw  
16 the sample away. And you can see that we're only  
17 generating one dosimetry sample per subject. That's a  
18 very valuable sample. If you throw it away then you've  
19 got nothing. So that's a significant limitation.  
20 Breakthrough usually results from excessive exposures  
21 and then you just throw away a very high value of the  
22 number. Again that's something that you can never  
23 justify, you can never compensate it.

24 A lot of issues in terms of correction of the  
25 efficiency of handwash, the compensating absorption,

1 once we modify the skin integrity or based on the  
2 observation and a good guess, but we don't know how to  
3 compensate that because again it's very complicated.  
4 EPA actually is asking multi million questions. It can  
5 be resolved but how much money are you going to put,  
6 set aside to answer those questions? So again, those  
7 are just the discussions.

8 I think throughout the exercise of using the  
9 PHED data by EPA again we, you know, we can see that a  
10 lot of points that we try to study in terms of the  
11 agreement and so on and so forth is just not there.  
12 The reason it's not there is partly because of the  
13 quality of the data, but also it's because the nature  
14 of studying dermal exposures. Did I make sense?

15 DR. PORTIER: At this time we'll open it  
16 up too the panel. Any comments? Doctor Handwerger.

17 DR. HANDWERGER: It's just an obvious  
18 comment that the skin is more than just a filter. I  
19 mean it's not just a place where things go from the  
20 exterior of the body into the circulation. The skin  
21 certainly acts on a number of substances to change them  
22 biochemically and certainly things can have affects  
23 locally at the skin level. I think we're all aware of  
24 the role of sunlight for example on the metabolism of  
25 vitamin D and things like that. So I wouldn't just

1 think of skin as just a filter that doesn't modify  
2 things along the way. It may, certainly it may have a  
3 role in the metabolism of these things in addition to  
4 just how rapidly they get into the circulation.

5 DR. PORTIER: Doctor Pependorf.

6 DR. POPENDORF: Yes, I'd like to comment  
7 and sort of explore a couple of small modifications to  
8 what's been said.

9 I mean I think the first point is the issue  
10 of the bias and the statements have been made that  
11 there is no bias. And I think there's other evidence  
12 from other studies that weren't presented that suggest  
13 there could be a bias and I guess just the nuance here  
14 is that we're not able to detect a bias would probably  
15 be a better statement. There's just a lot of noise in  
16 the data and if it exists, clearly it's much smaller  
17 than all the effects of other variables that aren't  
18 being controlled.

19 The second point in terms of the compensating  
20 for absorption residues, I think a better word might be  
21 adsorption because I think it's really adsorption going  
22 on in the skin in terms of trying to do a wash to  
23 recover it, not so much whether it's absorbed and goes  
24 through the rest of the body, but it's retained by the  
25 skin, presumably eventually either to be as point out

1 by the skin model, it'll retain for maybe a long time,  
2 eventually some of it will be sloughed off, some of it  
3 will perhaps be washed off, some of it will be  
4 absorbed. But it, from a passive dosimetry perspective  
5 adsorption would keep it from being recovered in a  
6 wash.

7 And I think there's some good evidence again  
8 that suggests that it happens perhaps. Of course it  
9 varies with the chemicals, those that have been studied  
10 may be a factor of 2, 50% reduction, time dependent. I  
11 was playing with some of the data that's presented in  
12 the review and it, and you've got two points, you know,  
13 the immediate recovery and the 1 hour recovery. And if  
14 you assume an exponential retention model you get a,  
15 you know, of course you can draw a line through two  
16 points, any line, it turns out that the lines are  
17 characteristic of the KOW of the two chemicals. So I  
18 think it suggests that a model could be developed  
19 certainly that fits those two. The data that's  
20 available, now that's one dose, you know, immediate  
21 recovery and 1 hour later if you tried to apply that to  
22 real world scenarios you'd have to make some assumption  
23 of the time history of whatever you recover. And if  
24 for instance if you assume a uniform exposure over  
25 whatever that exposure period is, 1 hour, 3, 4, 6 hours

1 you're going to see two things.

2 One, you're going to see a lot more  
3 retention of that early dose so you'll need to do the  
4 integration basically of that formula. And I think if  
5 you work that out the way the numbers are going to come  
6 out, what you'll also see, people have commented that  
7 there's an equilibrium being reached, and I think again  
8 a better term there would be a steady state in terms of  
9 the dosing rate over a period of time, assume it's a  
10 constant dosing rate, retention's going on at a period  
11 of time and eventually you'll reach a point where  
12 you're only going to get off a certain, a fraction, a  
13 constant fraction of what's been deposited over time.  
14 That's the way the math would work out on that.

15 Let's see, I think a couple of other points  
16 here, one, we also looked a bit at, there was data on  
17 the wipes and I'm sure if wipes are being proposed as  
18 part of that new protocol but I think we really haven't  
19 commented on wipes per se, but I think there is a much  
20 stronger bias from a wipe than either the wash of a  
21 passive dosimetry and I don't think we would recommend  
22 wipes which kind of complicates a bit the face and neck  
23 assessments. But I think it would certainly be my  
24 recommendation and maybe we can look for some consensus  
25 whether that might be taken as one category that there

1 probably is a significant order of magnitude bias  
2 because not only are you having retention but you're  
3 not getting good mechanical recovery.

4           The last point I'd like to make is going back  
5 to the figures that I have up there. Looking at the  
6 issue of whole body dosimetry versus patches, I've  
7 been, I've used patches in several situations beginning  
8 with harvester data and I think one of the key aspects  
9 there is you can assume very uniform exposures. In  
10 applicators I don't think you can make that assumption  
11 and I think there are some limitations with patches.

12           Let's see, if we go on to the next, let's go  
13 with two more slides. I'll use this as an example.  
14 What I'm going to talk about under the next question  
15 has to do with biomonitoring versus excretion. But if  
16 you were to look at the issue of patches just as an  
17 issue of bias or performance, part of the broad  
18 question, is you look at this magnitude of the probable  
19 error, looking at the coefficient of variation in terms  
20 of coefficient of variation for patches would be the  
21 variability in the exposure on a given location, a  
22 given body part. If it isn't uniform, how variable is  
23 it? And you could put a value to that. The  
24 denominator instead of percent excretion is shown  
25 there, I'm sorry, I thought I had the intermediate one,

1 it's going to look exactly like this however, the  
2 denominator would be the ratio of the body area to the  
3 patch area. It's again it's a scaling factor much like  
4 excretion would be if you're modeling up from what's  
5 excreted to what the dose was or the same basic concept  
6 was applied to the denominator was recovery for the,  
7 for question 1. But in this case the scaling factor is  
8 a ratio for the body area for a given patch, to the  
9 patch area itself. And depending on the kinds of  
10 patches that are used you're looking at a 25 to 4% of  
11 that part of the body being covered by the patch. The  
12 reciprocal of that means you've got a scaling factor  
13 somewhere in the neighborhood of 25 to 50.

14 Now, if you have a scaling factor of, well,  
15 this is set up, the x axis here is basically the  
16 percent of the area covered, so if you're looking at 2%  
17 to 4% you can see where that is on the log scale on the  
18 x axis and even small amounts of variability in the  
19 dose is going to give you rather large variations in  
20 the measured dose. So I think the conclusion here if  
21 you hadn't already come to it is that patch monitoring  
22 for spotty exposures that might occur during  
23 application is probably not recommended. Or if you're  
24 going it you're going to see a large amount of  
25 variability in that data.



1 DR. PORTIER: Other comments? Doctor  
2 Popendorf.

3 DR. POPENDORF: I'm just looking at my  
4 notes. There were some other data also that I suppose  
5 could be an exception to what I just said. If for  
6 instance you're looking at a protected area where the  
7 exposure, once it goes through the barrier, for  
8 instance gloves or perhaps an enclosed cab where you're  
9 not getting spotty exposures you can make a much better  
10 assumption of uniformity which might get around this  
11 problem.

12 So there may be a few exceptions where  
13 patches would work, but in general what I said earlier  
14 is that I wouldn't recommend them here.

15 DR. PORTIER: I have a question of Doctor  
16 Barr or Cynthia. In looking at this, thinking about  
17 the breakthrough residues, so this is residue that goes  
18 through your clothes, through the whole body dosimeter,  
19 into the skin, right? So the concentrations are going  
20 to likely be very small? Do we have a probability of  
21 even being able to measure that? So the uncertainty in  
22 that value measured is going to be quite high anyway,  
23 right?

24 DR. BARR: Right, if you, the smaller,  
25 obviously the smaller the number the more uncertainty

1 in the measurement of the value. So I mean it's, I  
2 mean I think that what we've all talked about and  
3 discussed is that there may be some breakthrough that  
4 may or may not be significant. There may be some  
5 amount of residue that's not able to be dislodged from  
6 the skin, but overall it doesn't seem like it's going  
7 to be a significant enough amount to put the cost and  
8 effort into correcting for it. Unless there's some  
9 simple solution that's fairly easy and not very costly.

10 DR. PORTIER: Okay, that's what I thought  
11 I was hearing but I wanted something nice and  
12 straightforward like that so I could understand.

13 DR. HINES: This is a case where you'd  
14 like all your breakthroughs to come back non-detect,  
15 this is when it's good.

16 DR. PORTIER: And then I, and I guess it's  
17 a similar kind of thing for the AHED protocols that use  
18 the gloves. You really don't expect a lot of the hands  
19 so you're going to have low detection levels, a lot of  
20 non-detects and a lot of uncertainty and maybe not a  
21 lot of contribution to the overall dose.

22 DR. BARR: Correct. It's certainly not  
23 worth the effort and cost if you're not going to have a  
24 big contribution.

25 DR. PORTIER: Additional questions,

1 comments? Cynthia.

2 DR. HINES: I would like to reinforce what  
3 Brian said about you may want to look at a reentry  
4 situation, reentry workers differently because of the  
5 lack of gloves.

6 DR. PORTIER: Jeff Evans.

7 MR. EVANS: Again we thank you for that  
8 and we appreciate the distinction in the types of  
9 scenarios. We didn't expect that there would be as  
10 much of an issue with this handler database. But for  
11 reentry and residential where we don't assume the use  
12 of gloves I think that's important for us to continue  
13 to think about and I look forward to any additional  
14 thoughts you have as you take these, today's events  
15 into further consideration this evening. So thank you  
16 very much for that.

17 DR. PORTIER: I've made a note that  
18 Cynthia has the right to

19 MR. EVANS: Yeah.

20 DR. PORTIER: come back tomorrow and  
21 revisit this.

22 MR. EVANS: That's been promised.

23 DR. PORTIER: It's really important to  
24 the discussion so we're not quite closing this issue  
25 but I think we've had a very

1 MR. EVANS: We appreciate that.

2 DR. PORTIER: good discussion on it. I  
3 think at this point we'll move on to the third charge  
4 question on passive dosimetry and biomonitoring. That  
5 should be a lot of fun.

6 MR. DAWSON: EPA believes that a  
7 comparison of exposure estimates derived from data  
8 collected through biomonitoring with data collected  
9 through passive dosimetry is the most appropriate way  
10 to assess the predictive nature of a passive dosimetry  
11 based approach for estimating worker exposure.

12 Please comment on the strengths and  
13 limitations of this kind of comparison for judging the  
14 potential utility of passive dosimetry data in  
15 conducting exposure assessments.

16 EPA has conducted such a comparison using  
17 available data and believes that the comparison shows  
18 sufficient concordance of estimates based on  
19 biomonitoring data and passive dosimetry data, to  
20 support the conclusion that a passive dosimetry based  
21 approach can generate data that can be used to develop  
22 relatively predictive estimates of worker exposure for  
23 a wide variety of scenarios and activities.

24 Please comment on the adequacy of the  
25 analysis to support EPA's conclusion.

1 DR. PORTIER: Doctor Pependorf.

2 DR. POPENDORF: Well I think overall there  
3 is, what I've been sort of setting the stage for here  
4 in looking at some of these issues of variabilities is  
5 that there are limitations to both methods. There are  
6 variable factors that cause both methods to have, to be  
7 variable in terms of the number that's being derived as  
8 an indicator of the final result that you're trying to  
9 achieve.

10 I think maybe a good way to view this might  
11 be the third slide on that overhead, looking at the 5  
12 figure version, there you go. What I've tried to do  
13 with this figure is to give you a got back up two  
14 to give you a few scenarios here, looking at what we're  
15 really talking about in a pictorial sense. And on the  
16 left we're talking about the way a patch dosimeter  
17 might work and I've sort of alluded to in the previous  
18 question, the outcome of that.

19 What I've tried to present here is three  
20 options if you will of how to, three methods may be a  
21 good way to view it. The patch dosimeter is on the  
22 left, the whole body dosimeter is in the middle and no  
23 dosimeters basically relying on a skin wash as a  
24 passive dosimetry type method. At the bottom you'll  
25 see urinary excretion as a biomonitoring. You can do

1 that, potentially do that in any of these options but  
2 of course you'll end up with some errors under certain  
3 scenarios.

4 So let's go through that first one. The idea  
5 of a patch dosimeter, the first arrow is the total  
6 deposition onto the skin, so 100% of whatever it is.  
7 Okay, if you have patch dosimeters as I mentioned they  
8 only cover in general a small fraction, less than 5% of  
9 the skin, except for the hands where it usually would  
10 be a whole, a whole coverage. But you could use a  
11 patch dosimeter without really changing what goes to  
12 the skin. The downside of the patch dosimeter is the  
13 fact that you're estimating a dose by taking those  
14 patches, analyzing them and scaling back up to what  
15 that dose was. And that's where you get into that  
16 scaling error. And any uncertainty or variability in  
17 deposition causes that value to be quite large.

18 One of the questions that came is part of  
19 question 3 having to do with the concurrency if you  
20 will of dermal, or passive dosimetry in biomonitoring.  
21 If you were to use patch dosimetry that works pretty  
22 well. As you can see, the dose that reaches the skin  
23 is not changed very much, reduced only a small fraction  
24 by the portion of the body that was covered by the  
25 dosimeters which, with the exception of the hands and

1 how important that particular dose, is a small  
2 fraction. So it goes onto the skin, retains air, is  
3 absorbed, passes through whatever the target organs  
4 are. Some of that is going to be excreted. And I've  
5 sort of tried to indicate in that diagram that you're  
6 going to get only a fraction of the dose being absorbed  
7 through the skin so that arrow is smaller. If you  
8 tried to do something from let's blood or tissue you're  
9 going to have a scaling effect and by the time you get  
10 down to excretion you're having even a smaller  
11 fraction, trying to use biomonitoring you'll only have  
12 a small fraction analyze so you're going to have a  
13 problem of scaling back up.

14 The second scenario is the whole body  
15 dosimeter. There you're essentially covering most all  
16 of the body except generally the head and neck with a  
17 dosimeter which is going to get you a much more reduced  
18 dose going to the skin. Again, the same reduction,  
19 whatever that was, being absorbed in a further  
20 reduction to excretion. But if you're talking about  
21 using whole body dosimetry and concurrent  
22 biomonitoring, which is one of the recommendations on I  
23 think page 61 or so in the review, you really are, or  
24 you can't effectively do that without making some big  
25 assumptions in terms of what fraction of the whole, the

1 breakthrough if the dosimeter is up against the skin or  
2 if the dosimeter is not against the skin, perhaps some  
3 sort of penetration or whatever name you want to put on  
4 the amount of chemical that would go through that  
5 dosimeter which would cause the dosimeter to be  
6 slightly inaccurate, but would provide some amount of  
7 dose going to the skin, some amount coming out the, you  
8 know, with the urine. But you're looking at some  
9 interactions there that makes whole body dosimetry and  
10 biomonitoring in conflict with each other. And we  
11 wouldn't make a recommendation to try to do both.

12           And then the third scenario was basically the  
13 wash as a passive dosimetry type of approach. And  
14 there we talked about that earlier of how the, you  
15 don't have a dosimeter so whatever is happening at  
16 least this would apply to the hands or potentially to  
17 the face and neck. The chemical would go to the skin.  
18 At some point you'd try to wash that off but you're  
19 only going to get a fraction of that off. So there  
20 you're introducing again some errors in what you're  
21 getting off. Some is going to be retained, eventually  
22 going through. A lot of errors introduced with that  
23 method. So I think the idea of concurrent  
24 biomonitoring and passive dosimetry is not, I certainly  
25 would not recommend doing both of those. It's an



1 either/or sort of approach.

2 The previous question, I answered the issue,  
3 or tried to answer the issue of the variability of  
4 patches and what happens there. What I've presented on  
5 the next slide basically is the plot that was looking  
6 at the urinary metabolites. Now, if you just go back  
7 one we'll come up to that last one. Again, looking at  
8 no, number 4 there you are, okay.

9 The issue of trying to get, back calculate to  
10 dose if that's in fact the point of the database, is  
11 all going to be based on, particularly dermal dose or  
12 whatever might that be is, whatever contribution and  
13 the respiratory dose might be, back calculate on the  
14 basis of urinary excretion and what fraction of the  
15 original dermal dose gets excreted. And that's going  
16 to be the product of what's absorbed through the skin  
17 and what fraction comes out in the urine.

18 And those numbers by themselves are going to,  
19 most of the values that were presented in the slides  
20 earlier this morning are small fractions on the order  
21 of a percent or less than a percent of, two, maybe  
22 three-tenths of a percent. So I just took this scale  
23 down to 1, if you're actually, in some of the examples  
24 that were presented those numbers are actually less  
25 than 1% of the dose on the skin is coming back in terms

1 of the excretion. Well, how comfortable are you, how  
2 variable is that absorption and metabolism and  
3 excretion? I think it's probably more variable but I  
4 just kept these original 15%, 25%, 33% numbers that we  
5 had for the dosimetry.

6 Those were your three grades, A, B and C  
7 grades, recovery type values. And I think metabolism  
8 may be even, okay, I don't know, I'm not expert  
9 toxicologist, but I don't think you'd get down to 15%,  
10 25%, 33% are probably more realistic numbers. And if  
11 you're looking any sort of variability in absorption  
12 and metabolism, when you're trying to back calculate a  
13 dose from an excretion in the 1% range you're looking  
14 at some very large uncertainty figures, which I think  
15 is one of the contributors to that variability in  
16 looking at the correlations that we saw earlier between  
17 biomonitoring and dosimetry.

18 And dosimetry has its own uncertainties but  
19 that's a major problem that I think needs to be again  
20 incorporated as part of that grading kind of concept.  
21 I think it's very realistic to put, you know, grading  
22 to metabolism studies as well as passive dosimetry.

23 Just as a, so it doesn't look too  
24 discouraging we'll touch on the issue of sample size,  
25 but the next slide, you know, you've got all these

1 numbers up here, very large individual variabilities,  
2 but if you put 16 people on, the standard error, the  
3 mean goes down with the square root of m, so I just  
4 threw on the black line there. There standard error  
5 the mean, you know, you're looking at still a few  
6 factors, less than an order of magnitude but that's why  
7 your sample size is very important. And that's taking  
8 the 25% individual variability down to the result of  
9 looking at 16 people and you reduce your uncertainty by  
10 a large magnitude. So when we talk about sample size  
11 you'll see how important that is.

12 I think I mentioned the issue of  
13 biomonitoring, the concurrent biomonitoring that was on  
14 page 61, that we don't recommend for a large number of  
15 reasons, including that up here. And then my only  
16 other point is the, on the issue of creatinine and  
17 correcting biomonitoring, probably not terribly  
18 important if you're fairly sure that you're getting 24  
19 hour samples being collected. The only times it would  
20 be important is if you're going a grab sample and you  
21 don't know what the time base is. Creatinine is a good  
22 indicator of the duration that that person's been  
23 storing up and if you're trying to do 24 hour, or  
24 continuous monitoring and you want to have some quality  
25 assurance that you're getting all the urine being

1 produced, that is a quality assurance parameter that  
2 would add quality to the data.

3 DR. PORTIER: Doctor Barr, do you concur?

4 DR. BARR: Actually I have just a few  
5 concise comments. I think that because there's no gold  
6 standard method for assessing exposure, that the, using  
7 both methods and trying to compare both methods was the  
8 best way of ensuring that passive dosimetry does indeed  
9 meet the requirements for your exposure assessment. I  
10 think the agreement that you saw and you both  
11 demonstrated, both the task force and EPA has  
12 demonstrated is astonishing. And so either they're  
13 both right, in which case you're in a good situation or  
14 they're both wrong in which case I wouldn't know what  
15 to do.

16 DR. PORTIER: Brian Curwin.

17 DR. CURWIN: Just to maybe address the  
18 charge question a bit more specifically, there was a  
19 question about the strengths and limitations of this  
20 approach. And I think one of the strengths of this  
21 approach is if you consider the exposure dose response  
22 paradigm, biological monitoring is closer to the  
23 response and of that paradigm. And so intuitively you  
24 would think you have exposure so the chemical would get  
25 on clothing, a certain amount of that would penetrate

1 clothing and get on the skin, a certain amount of that  
2 penetrates into the body and you have an absorbed dose  
3 and that goes to the tissues and you have your affect.

4 And so if you think of that paradigm then the  
5 biomonitoring is certainly closer to that end that  
6 we're interested in which is the affect and which lends  
7 a bit a strength to it and you intuitively would think  
8 that the biomonitoring would be, would predict the  
9 passive dosimetry.

10 One of the limitations though is just the  
11 inherent variability in this type of work, whether it's  
12 passive dosimetry or biological monitoring, there's  
13 generally a large inter and intra-person variability.  
14 And in some cases, for example, especially where the  
15 intra-person variability is substantially larger than  
16 the inter-person variability, what you're going to have  
17 is an attenuation of the association that you're trying  
18 to see and you generally may not be able to find these  
19 sorts of associations unless you have a very good power  
20 for your studies.

21 In the case of what we saw here today then  
22 we've got these very good concordance, some good  
23 correlations that were significant. So if that's the  
24 case, despite this variability we're seeing, we're able  
25 to see these correlations and that, you know, as Dana

1 mentioned, I think that's astonishing.

2 In the literature generally you don't get a  
3 very good comparison between some sort of dermal  
4 exposure versus a urinary output. Usually these  
5 studies are comparing a dermal deposition value such as  
6 micrograms per centimeter squared compared to just a  
7 straight urinary concentration such as micrograms per  
8 liter or micrograms per gram.

9 It is possible that in the way that it was  
10 looked at by the Agency and by the task force, that by  
11 comparing calculated doses maybe we're better able to  
12 look at these, at the predictive nature of the passive  
13 dosimetry. Or it could be that the oversimplification  
14 of what we're doing here, which is, you know, is  
15 necessary in order to do these sorts of things is maybe  
16 leading to what we see.

17 I also am curious about some of the data. It  
18 seems that it's a bit limited. I don't have the exact  
19 numbers of what, or the data points in the task force  
20 analysis. There was 14 studies, I don't know how many  
21 data points in each study so I'm not sure of the power,  
22 but I'm curious about how the impact of some of this  
23 data may impact on what we saw. There's, if there's  
24 some repeated samples in these studies there are  
25 certainly going to be some auto-correlation and that

1 may impact on some of this and again the variability in  
2 the data.

3 DR. PORTIER: I think we're looking at one  
4 of the graphics, you can get a feeling for at least how  
5 many individual MUs that were involved in the 14  
6 studies, just counting all the dots and it's a lot. So  
7 I have a feeling the statistical power for this was  
8 probably pretty good.

9 I have some other issues I'll bring up after  
10 we do the panel.

11 Doctor Lu.

12 DR. LU: I actually, I'm not surprised to  
13 see the data between passive dosimetry and  
14 biomonitoring agreeing with each other based on the  
15 presentations from the EPA and the task force group,  
16 because after all, these two methods are designed to  
17 assess exposure. From time to time there are scenario  
18 cases that this agreement will exist. And it's  
19 probably mainly because the insufficiency of passive  
20 dosimetry data.

21 For example, if a worker wears whole body  
22 dosimeters and there was an accidental spill on the  
23 cotton shirt, what happens is that the amount of the  
24 breakthrough deposited on the skin will not be picked  
25 up by the dosimeter. But the biomonitoring data will

1 reflect such addition and that's where the disagreement  
2 exists.

3           However according to the data presented by  
4 both groups, this discrepancy is not common so that's  
5 the good news. And therefore the predictive ability of  
6 dosimetry data for occupational pesticide exposure is  
7 recognized here. But we should stop here, we should  
8 not further use the data in terms of risk assessment  
9 and risk management. According to Doctor Baugher, I  
10 think the last presenter, he basically suggests that  
11 dosimetry data can be used much better than other data  
12 in terms of risk assessment and risk management, which  
13 I totally disagree because the way that both the Agency  
14 and the task group people calculate a dose is totally  
15 not biologically relevant.

16           Because the only thing that you're taking  
17 into account is the absorption on the face, there is no  
18 consideration of the distribution of the pesticide in  
19 the human body, there is no consideration of the  
20 metabolism and excretions. And there's no  
21 consideration of the time. Those are very important in  
22 terms of the pharmacokinetics, how to describe the  
23 behavior of the pesticide in human bodies.

24           So the solution actually is right here in  
25 front of everybody. I remember in 2005 there was an



1 SAP that discussed how to interpret the cumulative risk  
2 assessment using some sort of pharmacokinetic approach.  
3 And I think the Office of Research Development actually  
4 presented their accomplishments on using  
5 pharmacokinetics to calculate a dose. And what  
6 happened is that this is, to me this is a validated  
7 approach, that you have a dose estimate based on dermal  
8 exposures and you have a bunch of urine data that you  
9 collect on the same workers, what happens is you should  
10 calculate, you should use those urinary metabolite data  
11 and use the simplified PK model to calculate the drug  
12 dose and see whether this dose would match to this one.  
13 If yes, then this question will be answered in a way  
14 that, yes, that's the case.

15 But you are not using the same approach so  
16 you avoid a big grave box which you justify that  
17 there's no knowledge, there is no tool. Well, in the  
18 case for chlorpyrifos that's not true because the ORD  
19 model actually used substantial chlorpyrifos data to  
20 come out with the simplified PK model. And I think  
21 that EPA and the task force people should go back and  
22 use the data and use the model and pick the data that  
23 you think is most reasonable for this practice and see  
24 how much easier it is using the model versus using this  
25 simple calculation to reach the conclusion.

1 I think it's too, I think it's premature to  
2 reach the conclusion that these two things are the same  
3 thing. It may be the same thing for exposure  
4 assessment purposes but not for the risk assessment.

5 DR. PORTIER: Doctor Robson.

6 DR. ROBSON: It's terrible to be last so I  
7 just want to reinforce a couple things. Unlike my  
8 colleague, Doctor Lu, I actually was surprised to see  
9 the concordance and I think as Doctor Barr mentioned,  
10 many of us, before we got the packet and to be candid,  
11 most of us, until we saw Doctor Ross' presentation,  
12 because it was in the packet, but when it was up on the  
13 screen it was fairly remarkable but I think it's our  
14 feeling that it would be helpful to see the other 20  
15 chemicals added in.

16 As it was brought out today there were 14  
17 presented but there were 20 that were selected not to  
18 be in.. It would be good to see those in to look at the  
19 correlation with the benefit of the additional data  
20 points. As several people have already said and Doctor  
21 Fenske said in his comment, his written comments, a  
22 chemical by chemical analysis of concordance would  
23 really be informative for us.

24 One of the things that also was mentioned a  
25 couple of times is the concern, there's still a concern

1 about under representing the estimate of exposure.

2 And finally I was thinking about as we were  
3 listening to the presentation today, Jeff's  
4 presentation from Tuesday morning when you had the open  
5 mixing of the dry flowable and those three data points  
6 that were off the line and I think we have to be very  
7 mindful that whichever approach we take there are still  
8 going to be, as I think you mentioned, Doctor Portier,  
9 that could either have been glove failure or just three  
10 very unique events. But for all of us who have done  
11 this, whichever method we take we still have to be  
12 mindful that there are going to be those kinds of  
13 events. Cynthia has mentioned, you know, the example  
14 with gloves I think that we can't overlook the fact  
15 that whichever path we take or if we take parallel  
16 paths that the real field activities are going to drive  
17 this in the end.

18 So I don't have anything profound to add,  
19 everybody has beaten me to it. But it's okay.

20 DR. PORTIER: I doubt if you're going to  
21 be the last commenter on this because I want to comment  
22 on something Doctor Lu said. I was thinking back to  
23 that 2005 discussion on the back calculating through  
24 the PK model and I think the conclusion we came up with  
25 was that it's feasible but the uncertainties as you go

1 back through these nonlinear models just, they add up  
2 so quickly that the value you get has hardly any real,  
3 the particular measurement for applied dose, whatever  
4 you called it, is, there's so much uncertainty with it  
5 that it's almost a useful, a useless number unless you  
6 really, really know the pharmacokinetics cold, and  
7 you've been able to measure what's going on with enough  
8 frequency to be able to understand what the clearance,  
9 you know, what the clearance kinetics or if I remember  
10 correctly.

11 So I have some real problems with working  
12 back that way but, and before you challenge me on this,  
13 I want to say, you know, statisticians; when they see  
14 someone say, we had 36 studies and we only analyzed 14  
15 and here they are and isn't it beautiful? The hair on  
16 the back of our head goes up, you know, because we  
17 really want to see all of the data. And so I too have  
18 some concerns that the beauty of the relationship is  
19 the beauty of the selection. You know, and I  
20 understand that the selection was done from a quality,  
21 a quality of data point of view, but that may only have  
22 enhanced the relationship. As was mentioned, you know,  
23 if you did a good study we would expect them to relate  
24 so it may be that these are the good studies and they  
25 relate. But in reality they may never really relate as

1 good as that.

2 DR. LU: Well I do not mean to challenge  
3 you but I guess I remember this because I am personally  
4 involved in this work right now.

5 Yes, there are a lot of uncertainties,  
6 especially you don't have that much information in the  
7 front end of the model. So that's why, if you started  
8 from the back end and the front end is empty then you  
9 kind of run into trouble. And that's why the EPA, they  
10 use chlorpyrifos as a model compound because comparing  
11 to other pesticides that are being used right now,  
12 chlorpyrifos has the most abundant data, both exposure  
13 data, human data and animal data.

14 In that SAP they were dealing with  
15 residential exposures so they don't really know what  
16 was the original dose was. And all they have is the  
17 biomarker data so that's how they do the backward  
18 calculaton.

19 As I mentioned earlier this afternoon, the  
20 occupational setting is the perfect, is the ideal work  
21 to study bio to use the biomonitoring data because we  
22 can use the estimate, the dermal estimated number as  
23 the input dose and set that as some sort of a  
24 comparison number and use this backward calculation to  
25 see what is the, a model output would be comparing to

1 this number. Again, you have to accept the fact that  
2 by doing this calculation, the number that we have can  
3 be considered as a gold standard because it takes into  
4 account biological and pharmacokinetic considerations.  
5 But that's kind of how I reach to my comment. No  
6 challenge.

7 DR. PORTIER: And I'm just thinking, you  
8 know, you have the dosimeter dose, right, measured dose  
9 and you're going to back calculate and the numbers  
10 themselves may be close but the uncertainty is going to  
11 be so big you could drive a truck through it. And so  
12 what will the, what will that really tell us? I'm not  
13 sure that's going to be there. But I think Dallas was  
14 next.

15 DR. JOHNSON: Yeah, I, everybody has been  
16 commenting about that figure so I guess I want to  
17 comment about it too.

18 I wasn't so surprised that the correlation  
19 was as high as it appeared to be in that figure, what I  
20 was surprised about was the slope was equal to 1, which  
21 does say that they're both, I can see why they might be  
22 correlated but the back transformations that were done  
23 were remarkable to make the slope come out to be equal  
24 to 1 which it apparently did.

25 The second comment has to do with, it seems

1 to me that, let me get away from any comments with  
2 respect to reality so that I don't embarrass anybody or  
3 make anybody mad. But suppose that we have a variable  
4 x and it's highly correlated with z and we have a  
5 variable y and it's also highly correlated with z, well  
6 then obviously x and y are going to be highly  
7 correlated with one another. And so it seems to me  
8 that in what we're looking in this case, z is some of  
9 risk that we actually haven't even measured yet. But  
10 we believe that these amounts of residue that get  
11 inside the body have some affect on risk. And so what,  
12 how they correlate with risk probably doesn't matter  
13 too much with how we measure it, whether we measure it  
14 through dosimetry or we measure it through bio  
15 measuring urine. And so either one of those would be  
16 correlated well and from a statistician's point of view  
17 I'm completely happy to use either one.

18 DR. PORTIER: Doctor Chambers.

19 DR. CHAMBERS: I think I'm going to  
20 argue with my friend Alex Lu also. In a lot of the  
21 points that have been brought up about the physiology  
22 are very important to consider and it actually kind of  
23 came up at lunch a little bit too, is that people vary  
24 a whole lot in their size, their physiology, the  
25 metabolism is going to vary with sex, age, what have

1 you, you know, physical condition, body fat and storage  
2 of lipophilic compounds and all.

3 So it really seems to me in thinking about  
4 this that when you get down to the biomonitoring and  
5 what's coming out in the urine, that's going to be  
6 driven an awful lot by the individual that you happen  
7 to choose to monitor at that particular point.

8 And conceptually if I understand what this  
9 whole process is about it's about developing a generic  
10 database that can be used across a variety of different  
11 occupational settings and a variety of different  
12 compounds that would be widely applicable.

13 And Alex, all the stuff he was talking about  
14 is very well taken I think if you're talking about a  
15 particular compound. And if you wanted to do an  
16 assessment on chlorpyrifos in particular, back  
17 calculating that from the well known pharmacokinetics  
18 would be useful. But in trying to develop a generic  
19 database here it seems like what is going to be the  
20 most accurate thing is what is deposited on the body,  
21 the passive dosimeters that can be used generically  
22 across again all the different occupational scenarios  
23 and across all the different compounds. And it's not  
24 going to be driven by the efficiency of one compound  
25 being metabolized very, very effectively compared to



1 another that is not.

2 So I would, my opinion in all of this is that  
3 the efforts are best spent in trying to develop the  
4 very best passive dosimeters possible that would be  
5 most applicable to the generic database and to de-  
6 emphasize the biomonitoring that is going be biased or  
7 influenced maybe not biased but influenced so much by  
8 the individual compound and the individual's  
9 physiology.

10 DR. PORTIER: Doctor Handwerger.

11 DR. HANDWERGER: Excuse me, I'd like to  
12 certainly support those comments because I've been  
13 looking at urine values for diagnostic purposes for 40  
14 years and I can tell you I really believe them, because  
15 yes, you may stand there and monitor people in the  
16 field and you may make sure they go to the bathroom and  
17 you've got the sample, but they are not spending 24  
18 hours under your observation. And it's very hard to  
19 get 24 hour reliable urines. I can't even get it done  
20 in a hospital or being supervised on a clinical  
21 research unit unless I have special nurses who  
22 understand that you begin the 24 hour collection on an  
23 empty bladder and you end it by urinating at a specific  
24 time so you get a true 24.

25 It sounds very simple but I can tell you it's

1 very hard to do and I think you're going to  
2 underestimate the reality of the situation because  
3 you're not going to get 24 hour urines.

4 Secondly, if you take anyone in this room and  
5 have them collect their urine every day for 24 hours  
6 and do it absolutely perfect, there will be a very  
7 striking differences in the creatinines over that  
8 period of a week. It won't be 1,000 plus or minus 53,  
9 it'll be 1,000 plus or minus 400. There is wide  
10 variation in daily creatinine.

11 So I don't, I can't look at a creatinine and  
12 say, aw, this is really representative of what is a 24  
13 hour urine for that person. I can't do that, I can  
14 tell you whether it's really a 2 hour collection but I  
15 can't tell you that it's a 24 hour collection. So I'm  
16 very suspicious when it comes to evaluating urinary  
17 data unless I know how it's being done and who is  
18 collecting it.

19 I review these papers for endocrine journals,  
20 collecting 24 hour urines as part of a study and boy,  
21 we really want to know exactly the experimental  
22 conditions under which it was obtained. And I think  
23 you'll underestimate your values and I think rather  
24 than trying to deal with almost an impossible situation  
25 to get really reliable numbers, I think your exposure

1 data is going to be a lot simpler and much more  
2 efficient in doing that.

3 DR. PORTIER: Doctor Curwin.

4 DR. CURWIN: Just to echo Doctor Chambers  
5 and Doctor Johnson, I think the ultimate goal here for  
6 the Agency is to do a reliable risk assessment on these  
7 chemicals. And so if we have a very accurate passive  
8 dosimetry method and then can compare that to toxicity  
9 studies that are dermal exposure as well I think we're  
10 going to have a better estimate of a risk in that  
11 sense.

12 And if we can compare what's deposited on the  
13 skin in the workers versus what's deposited on the skin  
14 in our health effects studies, I think that's going to  
15 be certainly more reliable and that's what I think  
16 Doctor Johnson was getting at, that we're not really,  
17 that we haven't really put this in the context of the  
18 health effects and the risk assessment.

19 DR. PORTIER: Doctor Lu.

20 DR. LU: I may sound like I'm running some  
21 office but I'm not. Let me, the limitation about  
22 biomonitoring or urinary metabolite is well taken. And  
23 actually things are changing right now in the field.  
24 For example the simplified PK model, the minimum  
25 criteria for the data to be able to use in the

1 simplified PK model is two consecutive urine voids.  
2 That's because that we need to know the time of the  
3 void and use the volume to back calculate. A 24 hour  
4 total void sample would be ideal and perfect but it's  
5 not going to be the case for everybody. And that's  
6 why, or to actually test the two consecutive urine  
7 model and they use this to compare to the data that  
8 comes with the 24 hour total void. And they found that  
9 it's really not that much different. They also test a  
10 different scenario but it's, most of it is not related  
11 to occupational settings so I don't want to bring this  
12 up.

13 In terms of individual variation and between  
14 a person's variation, yes, there are definitely the  
15 case, but if you look at, I don't want to say well  
16 designed studies, but if you at studies that's designed  
17 specifically to answer those questions and if you look  
18 at the variation that's coming from the biological data  
19 versus the variation coming from say for example, food  
20 consumption, they are approximately in the same  
21 ballpark number, the range.

22 So I mean you talk about one thing or the  
23 other you have to think about, if you think the  
24 variation associated with the biological data is too  
25 large to be acceptable, then you have to think about

1 what is the counterpart and what is the variation. In  
2 this case I will argue that if you look at the hand,  
3 the dermal exposure, the handwash or the skin wipe,  
4 they are as variable as biological data. There is no  
5 perfect solution for this.

6 DR. PORTIER: Doctor Chambers.

7 DR. CHAMBERS: But I think part of the  
8 variability in the urine is going to result from the  
9 differences in the physiology of people. The  
10 variability in the hand washes and everything is kind  
11 of inherent I believe in the technique itself. So it  
12 seems like if you're going down, you've got variability  
13 in the occupational exposures but what people do and  
14 how much they get deposited on themselves, if you go to  
15 the level of biomonitoring you've introduced even more  
16 variability. And it just seems like from the  
17 standpoint of a generic, to me, from the standpoint of  
18 a generic database for exposure that keeping it up at  
19 the level of what the occupation is creating is going  
20 to give better data that will be more generally  
21 applicable.

22 DR. PORTIER: Doctor Kim and then Doctor  
23 Handwerger.

24 DR. KIM: Yeah, just a comment about  
25 variability. It's my understanding that variability

1 and uncertainty have to be really well distinguished.  
2 Variability is a good thing for risk assessment. You  
3 want to capture that variability and you want to  
4 incorporate that, those sources of variability in any  
5 risk assessment because you want to capture as much of  
6 the population as possible.

7 The other thing is, there is a direction  
8 toward more refined risk assessment by looking at  
9 tissue dosimetry, understanding what the target tissue  
10 dose is and linking that with the toxicological data,  
11 adverse health effect, et cetera. And the only way I  
12 see that that can be done is to use a pharmacokinetic  
13 model. And in order to develop a pharmacokinetic model  
14 it takes a lot of time, you need, you start with an  
15 animal study, you can do a controlled human exposure  
16 study but you definitely also want to go out into the  
17 field and validate that model against human exposure  
18 data. And much of it comes from urine, urine  
19 biomonitoring data or blood biomonitoring data.

20  
21 DR. PORTIER: Doctor Handweger.

22 DR. HANDWERGER: Just a very minor point  
23 to Doctor Lu's comment about collecting a sequential  
24 couple of urines. Of course things are not released  
25 into the urine at a linear rate. A compound like a

1 pesticide metabolite may be very rapidly excreted so  
2 that 90% of it is urinated in the first hour or two  
3 after the initial exposure to the material. So I don't  
4 think that if you're going to do it you're going to  
5 have to do it looking at a long time interval so that  
6 you'll be sure that you're getting all of it. And I  
7 don't think that just collecting a couple of spot  
8 urines will necessarily provide you with the  
9 information for all compounds.

10 DR. PORTIER: Dallas.

11 DR. JOHNSON: A comment, a lot of the  
12 studies at Kansas State that involved animals where  
13 they want to look at, and they're going to measure  
14 urine because they can put their cows and calves or  
15 whatever sheep in cages, they often would not give them  
16 water for 24 hours prior to starting to collect data  
17 and then give the chemical or injection and then let  
18 them have water so that you sort of, you sort of put  
19 everybody on a similar standard beforehand. But I  
20 think you can take your workers and keep them from  
21 having water for 24 hours prior to collecting data.

22 DR. PORTIER: I'm sure that wouldn't go  
23 over well with the Human Studies Review Board. Doctor  
24 Appleton.

25 DR. APPLETON: Yeah, the Forest Service

1 can only offer one more data set. But about five or  
2 six years ago we commissioned a dermal exposure  
3 biomonitoring study for 24D which has a lot of good  
4 things going for it, it's been beaten to death with  
5 study for three generations and it's amenable to  
6 biomonitoring.

7 Our contractor in Syracuse who, Jeff Evans I  
8 think mentioned his name this morning, Pat Durken,  
9 massage the data in the literature from industry in  
10 support of the re-registration and compared that with  
11 our biomonitoring data and developed actually a PBPK  
12 model from it. And I'll tell you the data matched like  
13 that. It was really, really close. It could be an  
14 exception but this is one more vote for the  
15 biomonitoring people over here.

16 DR. PORTIER: I think we've, oh, one more  
17 comment, Doctor Barr.

18 DR. BARR: I have to have the last word on  
19 biomonitoring. I think it is going to be compound  
20 specific. I mean some pesticides are metabolized to  
21 multiple metabolites. The metabolism is very variable  
22 among people. Some pesticides are very consistently,  
23 like 24D, very consistently excreted as 24D. Those are  
24 much easier to deal with and so I think that you're  
25 going to find a wide degree of variability among



1 pesticides. And so if you're trying to, sorry Alex, is  
2 you're trying to make a generalizable or a general  
3 database I think that using biomonitoring data would  
4 not be the best place to start.

5 DR. PORTIER: Alex.

6 DR. LU: Yeah, well in the

7 DR. BARR: You won't let me have the last  
8 word.

9 DR. LU: I need to have the vote.

10 DR. PORTIER: I have the last word.

11 DR. LU: Well again I emphasize that one  
12 of the components in using the pharmacokinetic model or  
13 in all those estimate calculations, is that you need to  
14 know the time. I'm not saying you can just go out and  
15 take any consecutive urine sample and then forget about  
16 the rest of the information. No, that's not the case.  
17 I remember I said so. You need to know the time of the  
18 void. The reason that you need to know the time of the  
19 void is because, up, here is a hypothetical question.  
20 You spray chlorpyrifos and the application ends at  
21 1:00 p.m.

22 You have two consecutive urine samples, one  
23 at 7:00 p.m., one at 9:30 p.m., okay? You put those  
24 information into a simplified PK model. The billion  
25 other reasons would know that between the void, the

1 concentration of the chlorpyrifos in the urine within  
2 the absorption phase, the first decay phase or the  
3 second decay phase, assuming there's a two compartment  
4 distribution.

5 And from there the model will calculate the  
6 rest of the stuff that you want. If you don't input  
7 the time the model will not move on to the next window.  
8 So that's the key for set up, you have to know time.  
9 And my criticism, if that's truly a criticism to the  
10 Agency and the task force is that when you do the  
11 absorbed dose you ignore the time. And that's very  
12 critical. Even though you take an average it doesn't  
13 really mean anything.

14 DR. PORTIER: Doctor Popendorf. I'm  
15 getting the feeling that when you write up this report  
16 you're going to have a minority, a little bit of a  
17 minority opinion that's going to need to be represented  
18 in here.

19 DR. POPENDORF: It sounds like it to me as  
20 well. I've heard a couple of, you know, there are  
21 certainly a couple of argue approaches that are being  
22 proposed to this and I think to just kind of remind  
23 you, the issue that I'm talking about and a couple  
24 other people and several people have mentioned,  
25 sensitivity analysis. And I think, you know, to the

1 Agency that is certainly something that you guys can  
2 also pursue in terms of look using some sensitivity  
3 analyses on what you do, the issue of how variable the  
4 model is, you know, you, again you might get exactly  
5 the same result, but if you look at the uncertainties  
6 that go into the calculation, the confidence that, it's  
7 called propagation of errors, another kind of theory to  
8 that, and the uncertainty in the range of the results  
9 could very well be comparable to some of the analyses  
10 that I have generated here for the dosimetry side.

11 They're relatively easy to do because there's  
12 fewer parameters but the same approach could be taken  
13 to the model to generalize in terms of; well, how  
14 certain do those parameters need to be? And I think  
15 that could give you guys a lot of, you know, you've got  
16 the accuracy and the precision issues. And they  
17 sometimes interact but they are different and if you're  
18 looking for confidence or trying to interpret these  
19 other questions that are going to come up in terms of  
20 like linearity, can you really discern linearity from  
21 issues of variability in the data because of modeling  
22 or passive dosimetry or the biomonitoring or whatever  
23 approach that you're using? They all have variability  
24 built in. You just need to keep that in mind and try  
25 to quantify it. I think it gives you a real sense of

1 reality.

2 DR. PORTIER: I think we've pretty much  
3 discussed this. It's going to be interesting to see  
4 what comes out on the report on this one.

5 We actually may revisit this again tomorrow  
6 because tomorrow's discussion is going to center around  
7 variability and uncertainty and relationships in terms  
8 of the proportional stuff. So we may come back to some  
9 of this.

10 But I think we're ready to kind of draw a  
11 close to this discussion unless I see a dissenting  
12 remark. I don't see any.

13 Does this look like you got the, a feel for  
14 how the panel is going to fall out on this?

15 MR. EVANS: We do indeed, we sense a  
16 building momentum of additional thoughts in this  
17 matter, especially as we get into some of the other  
18 presentations we'll see in the next two days. And  
19 again we thank the panel for a very thoughtful  
20 discussion.

21 DR. PORTIER: Good. At this time I think  
22 we're going to call the meeting to a close for today.  
23 Because of the way we've structured the discussions and  
24 the questions for this particular SAP, there's not a  
25 big opportunity for us to move ahead very quick with

1 the program. For example we really don't want to go on  
2 to the question 4 until we've had the discussion  
3 tomorrow morning.

4 So I think at this point we're going to stop.  
5 The panel is going to meet again at 8:30 tomorrow  
6 morning, same time, same place.

7 Myrta, do you have any closing comments?

8 MS. CHRISTIAN: None at the moment, no.

9 DR. PORTIER: No. So I think we'll call  
10 it closed at this time. Thank you.

11 (WHEREUPON, the meeting was adjourned at 4:21  
12 p.m.)  
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25 SUBMITTED ON JANUARY 10, 2007

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