

US EPA ARCHIVE DOCUMENT

1 FIFRA SCIENTIFIC ADVISORY PANEL  
2 OPEN MEETING

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5 REVIEW OF WORKER EXPOSURE  
6 ASSESSMENT METHODS

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9 U.S. ENVIRONMENTAL PROTECTION AGENCY  
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16 JANUARY 9, 2007

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## 1 FIFRA SCIENTIFIC ADVISORY PANEL (SAP)

2 January 9, 2007

3 Review of Worker Exposure Assessment Methods

4 Morning Session

5 DR. HEERINGA: Okay, good morning

6 everyone. Good morning everyone. Welcome to the first  
7 day of our scheduled four day meeting of the FIFRA  
8 Science Advisory Panel on the topic of a Review of  
9 Worker Exposure Assessment Methods.

10 My name is Steve Heeringa, I am the Chair of  
11 the FIFRA SAP and a statistician at the University of  
12 Michigan. I have very little specific expertise on the  
13 topic that we'll be discussing over the next four days  
14 and my job will be primarily to manage the meeting to  
15 see that we have a full and open discussion of the  
16 scientific material and a complete coverage in terms of  
17 the panel's responses to the charge questions.

18 We're very fortunate to have assembled a  
19 large panel of experts in areas relevant to the topic  
20 for the next four days and I'd like to have them  
21 introduce themselves and I'll begin with the Gator on  
22 my left, Doctor Ken Portier.

23 DR. PORTIER: I had to put my hat on. I'm  
24 Ken Portier, I'm Director of Statistics at the American  
25 Cancer Society, but more importantly I was 27 years at

1 the University of Florida. They waited for me to leave  
2 before they won the National Championship so I just  
3 have to say, go Gators.

4 My expertise is in statistics and statistical  
5 issues in risk assessment.

6 DR. HANDWERGER: I'm Stuart Handwerger,  
7 I'm a member of the permanent committee. I'm in the  
8 Departments of Pediatrics and Cell and Cancer Biology  
9 in the College of Medicine at the University of  
10 Cincinnati and I am a developmental and molecular  
11 endocrinologist.

12 DR. CHAMBERS: I'm Jan Chambers with the  
13 College of Veterinary Medicine at Mississippi State  
14 University. I'm a pesticide toxicologist, I'm a member  
15 or the permanent SAP and I'm also a member of the EPA's  
16 Human Studies Review Board.

17 DR. BUCHER: I'm John Bucher, I'm with the  
18 National Toxicology Program at the National Institute  
19 of Environmental Health Sciences. I'm a toxicologist  
20 by training and I have interest in cancer bioassays and  
21 general issues in toxicology.

22 DR. HINES: My name is Cynthia Hines, I'm  
23 a research industrial hygienist with the National  
24 Institute for Occupation Safety and Health and I do  
25 occupational exposure studies, mostly field based

1 research. And I extend all my condolences to my  
2 neighbors and friends who are diehard Buckeye fans.

3 DR. JOHNSON: My name is Dallas Johnson,  
4 I'm a retired statistician from Kansas State  
5 University. I worked there 30-some years and most of  
6 those years I did consulting in the agriculture  
7 experiment station and did some work with pesticide  
8 studies while I was there.

9 DR. APPLETON: I'm Hank Appleton with the  
10 U.S. Forest Service. I'm a pesticide toxicologist  
11 there and I've been working in the area of occupational  
12 exposure assessments for approximately 25 years with  
13 the EPA and as a consultant.

14 DR. KIM: My name is David Kim, I'm from  
15 the Department of Environmental Health at Harvard  
16 School of Public Health. My research experience is in  
17 exposure assessment, exposure dose relationships and  
18 using physiological models.

19 DR. BARR: I'm Dana Barr, I'm with the  
20 Centers for Disease Control and Prevention in Atlanta  
21 and I'm the Chief of the Pesticide Laboratory there.  
22 My area of expertise is in human bio-monitoring,  
23 exposure assessment and I've been working in that field  
24 for about 20 years.

25 DR. LU: Good morning, I'm Alex Lu from

1 the Rollins School of Public Health at Emory  
2 University. My interest is using biomarkers to assess  
3 pesticide exposures stethoscope and pharmacokinetic  
4 models to reconstruct the dose and for risk  
5 calculation.

6 DR. HUGHES: My name is Brian Hughes, I'm  
7 a toxicologist in the pesticide section of the Michigan  
8 Department of Agriculture. My interest is actually  
9 doing field research for occupational risk assessments  
10 in the agricultural setting. I'm working a lot with  
11 MSU or Michigan State University to conduct these  
12 studies.

13 DR. LANDERS: My name is Andrew Landers.  
14 I'm an agricultural engineer at Cornell University  
15 where my interests are looking at engineering methods  
16 to reduce operator contamination and environmental  
17 pollution..

18 DR. MACDONALD: My name is Peter  
19 MacDonald, I'm a professor of mathematics and  
20 statistics at McMaster University in Canada. I have  
21 general expertise in applied statistics and I think  
22 this is my 7th year on FIFRA panels.

23 DR. HAMEY: Good morning, I'm Paul Hamey,  
24 I'm from the U.K.'s Pesticide Safety Directorate which  
25 is our regulatory agency for pesticides and I'm

1 responsible for human exposure assessments there.

2 DR. ROBSON: Good morning, I'm Mark  
3 Robson, I'm the Director of the New Jersey Agricultural  
4 Experiment Station and professor of entymology at  
5 Rutgers University and initially was for many years the  
6 pesticide extension specialist, dealing with pesticide  
7 applicator training and impact assessment, and more  
8 recently research around pesticide exposures,  
9 particularly to children and farmers.

10 DR. POPENDORF: I'm Will Popendorf, an  
11 industrial hygienist with Utah State University and  
12 probably about 30 years of experience in pesticide  
13 exposure.

14 DR. CURWIN: I am Brian Curwin with the  
15 National Institute for Occupational Safety and Health.  
16 I'm a research industrial hygienist, conducting  
17 occupational exposure assessment studies with a  
18 particular interest in pesticide exposure assessment.

19 DR. HEERINGA: Thank you very much panel  
20 members. Before I turn the mike over to our designated  
21 federal official, Myrta Christian, I'd just like a  
22 procedural item that I failed to mention in our initial  
23 meeting, and that is for panel members, members of the  
24 EPA and also members of the public who will be  
25 participating in these sessions, when you come to the

1 microphone, since the sessions are being recorded and  
2 also it's important for everyone to know who's speaking  
3 in general, please state your name before you begin  
4 speaking and so that'll become part of the record.

5 At this point in time I'd like to introduce  
6 the designated federal official for today's meeting,  
7 Myrta Christian. Myrta.

8 MS. CHRISTIAN: Thank you, Doctor  
9 Heeringa, good morning. I am Myrta Christian and I  
10 will be serving as the designated federal official for  
11 the FIFRA Scientific Advisory Panel for this meeting.

12 I want to thank Doctor Heeringa for agreeing  
13 to serve as Chair of the FIFRA Scientific Advisory  
14 Panel for this meeting. I also want to thank both the  
15 members of the panel and the public for attending this  
16 meeting of the FIFRA SAP to consider the review of  
17 worker exposure assessment methods.

18 We appreciate the time and effort of the  
19 panel members in preparing for this meeting, taking  
20 into account their busy schedules.

21 The FIFRA SAP is a federal advisory committee  
22 that provides independent scientific peer review and  
23 advice to the Agency on pesticides and pesticides  
24 related issues regarding the impact of proposed  
25 regulatory actions on human health and environment.

1           The FIFRA SAP only provides advice and  
2 recommendations to EPA. Decision making and  
3 implementation authority remains with the Agency.

4           As the DFO for this meeting I serve as a  
5 liaison between the panel and the Agency. I am also  
6 responsible for ensuring provisions of the Federal  
7 Advisory Committee.

8           As the designated federal official for this  
9 meeting a critical responsibility is to work with  
10 appropriate Agency officials to ensure that all  
11 appropriate ethics regulations are satisfied. In that  
12 capacity panel members are briefed with provisions of  
13 Federal Conflict of Interest Laws. In addition, each  
14 participant has signed a standard government financial  
15 disclosure report. I, along with our deputy ethics  
16 officer and in consultation with the Office of General  
17 Counsel have reviewed these reports to ensure all  
18 ethics requirements are met.

19           For members of the public requesting time to  
20 make a public comment, please limit your comments to  
21 five minutes unless prior arrangements have been made.  
22 For those that have not preregistered, please notify  
23 either myself or another member of the SAP staff if  
24 you're interested in making a comment.

25           For presenters, panel members and public

1 commenters, please identify yourself and speak into the  
2 microphone provided since this meeting is being  
3 recorded.

4           There is a public docket for this meeting.  
5 All background materials, questions posed to the panel  
6 by the Agency and other documents related to this SAP  
7 meeting are available in the docket. Overheads will be  
8 available in a few days. The agenda lists content  
9 information for such documents.

10           At the conclusion of the meeting the SAP will  
11 prepare a report as it responds to questions posed by  
12 the Agency by materials, presentations and public  
13 comments. Excuse me. The reports serve as meeting  
14 minutes. We anticipate the meeting minutes will be  
15 completed in approximately eight weeks after the  
16 meeting.

17           Again, I wish to thank the panel for their  
18 participation and I'm looking forward to both a  
19 challenging and interesting discussion over the next  
20 few days.

21           DR. HEERINGA: Thank you, Myrta. Over the  
22 next few days we are going to hear a large number of  
23 presentations. This session involves the coverage of a  
24 substantial amount of material. The panel has received  
25 a very well organized and extensive amount of advance

1 material to prepare for these meetings.

2 Presentations will be given by members of the  
3 EPA Scientific Staff, Health Effects Division, also  
4 Health Canada and also representatives of several of  
5 the industry task forces.

6 Because there is such a volume of material,  
7 EPA has suggested that the sessions actually be broken  
8 up into presentations over three days, followed by  
9 specific charge questions that typically would be  
10 related to the subject matter of the presentations that  
11 preceded it. This is a little different from what we  
12 normally do where we have presentations and the charge  
13 questions are reserved for the end.

14 I think it'll work quite well, it will give  
15 us a chance to hear presentations of material followed  
16 by the charge questions. The advice that I've given to  
17 the panel and I think in general for the proceedings of  
18 this meeting, in that obviously if a presentation at a  
19 later date brings forth new information that would  
20 inform either a change or an extension to a response to  
21 a prior question, I will allow us to revisit that prior  
22 question or the panel member can state that I would  
23 like to go back and say that based on what I just  
24 heard, I'd like to amend or to augment my response to  
25 that prior question. I think that'll work quite well.

1           With regard to public comments, at this point  
2 I see that we only have three public commenters  
3 scheduled. And I think in large part that is due to  
4 the fact that we have substantial participation by  
5 industry task forces and representatives already  
6 present as part of the scheduled agenda for this  
7 meeting. If you are in the audience and do want to  
8 make a public comment I'll just reinforce Myrta's  
9 statement, see her to schedule a time. This is an open  
10 and public meeting, you have an opportunity as a member  
11 of the public to make a presentation or offer comments  
12 for a limited period of time.

13           So at this point in time I guess I'd like to  
14 actually begin our session and I'd like to do that by  
15 introducing Doctor Tina Levine, who is the Director of  
16 the Health Effects Division of the Office of Pesticide  
17 Programs at the EPA. Tina.

18           DR. LEVINE: Thank you very much. First  
19 let me take this opportunity to thank the staff of the  
20 SAP and Hammad Said and Laschonya Richardson and Andre  
21 Geisler for all the effort they put into making this  
22 meeting run smoothly. And I'd also like to thank the  
23 scientists in HED that have worked so tirelessly to put  
24 this, the scientific part of this session together.

25           I want to welcome the members of this

1 impressive SAP and thank you in advance for your  
2 consideration and advice on some very important issues  
3 regarding worker exposures that will be presented over  
4 the next four days.

5 I also want to offer my thanks to the staff  
6 of the Pest Management Regulatory Agency of Canada and  
7 the California Department of Pesticide Regulation for  
8 being here to take part in the presentation of these  
9 issues to the panel, as well as members of the industry  
10 task force that are presenting.

11 The Pesticide Authorities of EPA, Canada and  
12 California have been working very closely together for  
13 a number of years to determine data needs, study  
14 design, methods to measure exposure and the best way to  
15 regulate occupational risks from pesticides.

16 The three agencies have also worked very  
17 closely with industry experts who are members of the  
18 task forces developed to satisfy data needs in this  
19 area.

20 Since all four groups have been cooperating  
21 in this effort over the last decade or more, each group  
22 will be making presentations to the panel over the next  
23 four days. As you know EPA has recently completed a  
24 ten years effort, reevaluating pesticides residues on  
25 food and has in conjunction with this effort also

1 considered many of the risks form occupational  
2 exposures. The data and methods that were used have  
3 allowed us to complete these assessments in a timely  
4 manner and put in place measure, including the use of  
5 additional personal protective equipment, the use of  
6 clothes mixing loading systems and increasing the time  
7 interval before workers can enter treated fields, to  
8 further protect and ensure the safety of workers.

9 While the data and approaches that have been  
10 developed over the past years have served us well,  
11 there remain issues and questions on which we are  
12 seeking advice and recommendations to help improve how  
13 worker risk is estimated and regulated:

14 In order to ensure that the methods and  
15 designs that will be used to develop new data in the  
16 future incorporate the most recent scientific thinking,  
17 a number of issues and questions are being presented  
18 for the panel to consider. The advice and  
19 recommendations that are provided will be taken into  
20 consideration as new protocols are reviewed and new  
21 worker exposure guidelines are developed.

22 Many of the issues that will be presented  
23 have been discussed for a number of years while others  
24 are relatively new ones that have been recently rated  
25 by the Human Studies Review Board. For example, issues

1 regarding methods for measuring exposures to handlers  
2 have been raised in the past as have issues regarding  
3 passive dosimetry methods. More recently, since many  
4 of these studies conducted involved the intentional  
5 exposure to workers, questions regarding the need for  
6 the new data have been raised by the Human Studies  
7 Review Board.

8 As we update our current exposure database we  
9 want to ensure that the methods used and data generated  
10 are as scientifically rigorous as possible. We want  
11 worker exposure assessments that more accurately  
12 predict potential worker risks and that can better  
13 inform risk managers of when and what additional  
14 measures are needed. We look forward to a constructive  
15 dialog with the panel over the coming days on these  
16 important issues.

17 And I thank all again.

18 DR. HEERINGA: Thank you, Doctor Levine.  
19 And I also appreciate you recognizing the participation  
20 of the California Department of Pesticide Regulation  
21 too, I had omitted them in my earlier comment.

22 At this point I think we're ready to move on  
23 and we have an introductory and overview presentation  
24 by Jeff Evans of the Health Effects Division of the  
25 Office of Pesticide Programs. Good morning, Jeff.

1 MR. EVANS: Good morning and thank you.  
2 Again, my name is Jeff Evans of the Office of Pesticide  
3 Programs, Health Effects Division and I'd like to go  
4 over a few introductory items to help put these issues  
5 into perspective.

6 First I'd like to talk a little bit about how  
7 we conduct our handler exposure assessments and use the  
8 data that we've looked at in great detail for the  
9 presentations and for our discussions. Also to  
10 describe these existing database known as the pesticide  
11 handlers exposure database or PHED. I'll talk a little  
12 bit about the PHED limitations and also with thoughts  
13 towards the development of the new database and as Tina  
14 pointed I'll go over some of the items highlighted by  
15 the Human Studies Review Board when they reviewed  
16 protocols for studies that are meant to go into this  
17 new database. I'll briefly outline our goals and then  
18 introduce the presentations for the remainder of the  
19 program.

20 Just a few definitions, certainly these  
21 people performing these tasks are certainly workers but  
22 we have a definition of workers and handlers. Workers  
23 are people who perform reentry tasks while people who  
24 do the mixing, loading, transferring and applying of  
25 pesticides and handling open containers and person

1 guiding aerial aircraft for applications are referred  
2 to as handlers. And this worker protection standard  
3 that we have assigns interim clothing requirements and  
4 personal protective equipment for handlers based on the  
5 toxicity of the end use product.

6 And this just briefly outlines the types of  
7 PPE in clothing requirements based on the acute  
8 toxicity of the end use products. Next slide please.

9 What we do in our risk assessments is we go  
10 beyond the original acute toxicity profiles and we'll  
11 need to evaluate the clothing that's required on  
12 labeling based on the toxicity of the entire database  
13 for a given pesticide, which means comparing handler  
14 exposure as well as other exposures of course, to the  
15 appropriate toxicity studies from the entire toxicity  
16 database for a given pesticide active ingredient.

17 In many risk assessments we'll need to  
18 evaluate all the handler scenarios for a given  
19 pesticide and we do this by using scenario specific  
20 contact factors called unit exposures which are the  
21 focus of this SAP.

22 Now, the concept for unit exposure is this  
23 contact factor, is that handler exposure is dependent  
24 on physical processes of mixing, loading and applying  
25 pesticides rather than the actual physical chemical

1 properties of the pesticide, within limitations of  
2 course. A wettable powder formulation is an awful lot  
3 like flour for instance. And that's a very dusty  
4 product compared to say a laundry detergent that's  
5 formulated like a flowable concentrate, so the dust  
6 component just by virtue of the formulation itself is  
7 an important component in the potential for exposure.  
8 Likewise, pouring liquids is certainly a different  
9 component than handling a dust product. Applying  
10 pesticides with a tractor drawn ground boom application  
11 could perhaps give exposure to the lower part of the  
12 body and the hands while an air blast applicator  
13 driving through an orchard might result in more  
14 exposure to the head. So there's physical processes  
15 involved in this and I think that's an important  
16 component and sort of the backbone of the unit exposure  
17 concept.

18 We have a database, a PHED that has unit  
19 exposures representing a wide variety of handler  
20 activities with and without PPE and these unit  
21 exposures are then used with other factors such as  
22 application rates and area treated to determine handler  
23 exposure. Next slide please.

24 This is a very simple algorithm outlining the  
25 basic nuts and bolts of the day to day exposure

1 assessment process and you can see the end exposure is  
2 prominently, figures into the scenario. We will also  
3 use that to determine the exposure for each use on a  
4 pesticide label and will incorporate the, usually the  
5 maximum application rate and estimate of acres treated  
6 to get the sense of how much AI and individual may  
7 handle on a given day. We will factor in dermal  
8 absorption if that's required for the assessment.  
9 Sometimes we compare these exposures to studies  
10 performed dermally on laboratory animals. Also, other  
11 ways to look at the amount handled for a mixer, loader,  
12 applicator would be perhaps gallons mixed per day. And  
13 of course this is normalized by body weight and then  
14 compared to doses in animal studies for margins of  
15 exposure.

16 Now, again this simple algorithm assumes that  
17 exposure is proportional to the amount of AI handled,  
18 so if you handle 20 pounds you're going to have two  
19 times the exposure of somebody who only handled 10  
20 pounds for the same scenario. So the air blast  
21 applicator handling 20 pounds is going to have twice as  
22 much as an air blast applicator applying 10. Next  
23 slide please.

24 Now an advantage of the database is that it  
25 allows exposure assessments to also focus on the parts

1 of the body that have the greatest potential for  
2 exposure. So we can assign appropriate personal  
3 protective equipment. For example, chemical resistant  
4 gloves or chemical resistant headgear if it looks as  
5 though that's really where the exposure pattern is  
6 happening. And you can also impact, or look at the  
7 impact of other PPE such as coveralls and determine  
8 whether or not that's going to matter in a risk  
9 assessment. Forcing someone to wear more clothing than  
10 they need to if it doesn't offer much protection is  
11 also important for risk managers to know.

12 We have values for engineering controls if  
13 the PPE do not prove to be acceptable with respect to  
14 risks. And this framework also permits the evaluation  
15 of reducing pesticide application rates, provided that  
16 there's a cost/benefit analysis. And also we can  
17 consider things like limiting the formulations, as we  
18 talked about the dusty formulation of the wettable  
19 powder to perhaps more of a flowable concentrate or  
20 liquid pesticides, depending on how the risk assessment  
21 works out. Next slide please.

22 Just briefly the PHED has four databases.  
23 The mixer/loader component has a lot of the, as I've  
24 discussed, the wettable powders, the dry flowables, open  
25 mixing and loading of liquids, small component

1 flaggers, there aren't as many flaggers as their used  
2 to be with the advent of GPS, as within most cases  
3 limited the need for flagger exposure scenarios.  
4 Applicator scenarios, again that's the larger scale  
5 agricultural equipment, the air blast and ground boom  
6 applicators as I discussed and the mixer/loader  
7 applicator largely consists of the smaller handheld  
8 sprayers, backpack type sprayers and those sorts of  
9 things.

10 And this database has quite a number of  
11 monitored events from a variety of handler studies with  
12 and without the use of chemical resistant gloves and  
13 some engineering controls. Next slide please.

14 Here's just an example of what risk assessors  
15 would use. You can see the unit exposures for the  
16 various, we have two formulation mixing/loading  
17 activities up there and also for aerial applicators and  
18 air blast spreaders. And you'll notice, and I'm sure  
19 in the background document you're quite focused in on  
20 the different numbers of observations and measurements  
21 for a given unit exposure scenario. And I think we'll  
22 go to the next slide, but just keep in mind the air  
23 blast values, we'll get to them in a minute.

24 And again in the background document you  
25 probably also got the sense that for the six example

1 case studies that we have presented, there are  
2 competing study designs within a number of those  
3 scenarios. And over the years as time went on  
4 investigators conducting these studies determined that,  
5 in the beginning they focused on parts of the body that  
6 they felt had the most exposure and then over time and  
7 with the advent of our guidelines they began to measure  
8 all parts of the body that were appropriate for risk  
9 assessment purposes.

10 So consequently we'll have combinations of  
11 studies in the database consisting of measure values  
12 from individuals of limited body parts. And so you can  
13 see just by the representations on the screen that the  
14 individual on the left, there was hand exposure and the  
15 legs and then for another situation perhaps just the  
16 hands were monitored. That's probably what the  
17 investigator thought might have been important at the  
18 time. And then also someone might have incorporated a  
19 chest patch to also include in the estimates of  
20 exposure.

21 So all of those are combined for a given  
22 scenario. So air blast could have a range of studies  
23 having different study designs. And certainly some  
24 scenarios are more problematic in this way than others.  
25 Next slide please.

1           Just to briefly go over how unit exposures  
2 are calculated. It's a fairly simple process. Let's  
3 just imagine that the patch on the person that was on  
4 the right and that you would get an amount measured in  
5 milligrams per sample and that is extrapolated to the  
6 surface area and adult's chest and of course you  
7 compensate for the size of the patch in which it was  
8 measured and then those milligrams are simply divided  
9 by the pounds of AI, pesticide active ingredient that  
10 were applied in that scenario. Next slide please.

11           And thank goodness for computers, they  
12 calculate all those and as you can see the PHED  
13 provides summary statistics and sums all the unit  
14 exposures and also makes cuts on the distributions of  
15 those various body parts. And you can see again at the  
16 head fairly large amounts of exposure, this is for the  
17 air blast scenario you saw on the previous table and  
18 you can see that that might be something that an  
19 individual could use to focus on for risk mitigation  
20 purposes. Also you've got hands down at the bottom  
21 there also representing high exposure whereas other  
22 parts of the body aren't as critical. And so I think  
23 this is a nice advantage of a database of a lot of  
24 pesticide studies where you can look for trends and  
25 make more informed risk management decisions. Next

1 slide please.

2 The database has served the Agency very well  
3 over the years although I would have to say that the  
4 studies that went into it perhaps didn't, weren't  
5 designed with a database in mind and there are a number  
6 of limitations within this database and I think for  
7 many people the competing study designs is relatively  
8 important. In addition to having incomplete body part  
9 measurements there is also the issue of having patches  
10 represent certain parts of the body and then whole body  
11 dosimetry also being cut up and segmented in ways that  
12 can capture the measurement in that part of the body.

13 There's been a long term debate looking at  
14 the differences in performance of using cotton gloves  
15 or other absorptive materials to represent exposure to  
16 the hands compared to hand rinses, you know, using many  
17 different solvents. I think all of that helps to  
18 complicate the matters in our analyses of these data.

19 And you'll find that we have a fair amount of  
20 clustering because of those sorts of factors in  
21 addition to the fact that when these studies are  
22 performed they might find five, six, ten, fifteen  
23 individuals and in the past many of those people  
24 applied the same amount of material. So you kind of,  
25 when you start to look at these data in a more

1 expansive manner you will see that there are clustering  
2 because of perhaps individual study effects because of  
3 the way that the study was in fact structured.

4 Many of the studies were conducted for short  
5 durations and they handled small amounts of pesticides  
6 and consequently there are a fair number of non-  
7 detects. A lot of that also has to do that back in the  
8 late '70s, early '80s there might have been method  
9 performance issues that are not as precise as we can  
10 capture today. And so, you know, there's a lot of  
11 uncertainty. If a pesticide was applied for only a  
12 small amount of time and you had a very high detection  
13 limit you didn't capture anything. So those kinds of  
14 data gave us I think a fair amount of uncertainties.

15 Again many of the unit exposures are  
16 composites, varying numbers of body part measurements.  
17 And some of the studies, I think the people that put  
18 the database together went through a lot of sort of  
19 investigation to find out whether or not various field  
20 fortifications were conducted, what the laboratory  
21 performance was, in particular for the older studies  
22 and that some body parts were not measured because they  
23 simply couldn't verify how the quality control aspects  
24 of the study were conducted. Next slide please.

25 So what we have coming forward is a new task

1 force to develop a new database of pesticide exposure  
2 scenario unit exposures. And we think that they have  
3 incorporated many new study design aspects that should  
4 prove to be a better database, certainly longer study  
5 durations. Also an important factor for the hand rinse  
6 issue is limiting the time between exposure activity  
7 and hand rinse collection. The lag time between  
8 collecting those hand rinses seems to have an impact on  
9 what we think about the performance of those methods.

10 Also, more sensitive analytical methods and  
11 in general better surrogate compounds that the chemists  
12 have a very good handle on. We're going to have a  
13 wider range of AI handled per scenario: You might see  
14 in some of the examples from the case studies that  
15 there is either too few amounts of AI handled or the  
16 spread is very wide and wouldn't it be nice to have  
17 something in between to help explain the trends of the  
18 unit exposure concept?

19 And also we have a consistent study design  
20 where we have the entire body measurements being  
21 collected and each individual would then have their own  
22 individual unit exposure that we can I think express  
23 more plainly in distributional analyses.

24 And again this database is designed that I  
25 think we'll be able to look at the issue of whether or

1 not exposure is proportional to measures of AI contact  
2 a little bit better than the data that we have now.  
3 Next slide please.

4 Now, as Tina pointed out some of these  
5 studies have the protocols for components of the  
6 studies have gone to the Human Studies Review Board and  
7 these five field studies were meant to be conducted  
8 during the 2006 growing season and some of the results  
9 of the HSRB, I think on the positive note they  
10 certainly acknowledged that there are advantages to  
11 having a generic database, they recognized the cost of  
12 collecting these data. And also it's not an easy task  
13 to go out and logistically perform these studies,  
14 finding cooperators and getting all the field  
15 fortifications, collecting the measurements, getting  
16 them to the lab, there's a lot to it.

17 However the HSRB did determine that the  
18 protocols lacked some documentation supporting the need  
19 for the new data and this is something new for us.  
20 We're always delighted to get new data but we found  
21 ourselves in a situation where we do need to explain  
22 why we would have intentional exposures of individuals.  
23 And so I think this is a challenge that we're facing  
24 with this new task force. Next slide please.

25 They pointed out that of course that there is

1 not enough, that we didn't say enough in our protocol  
2 establishment about the existing database known as  
3 PHED. We were not clear on how the new data would be  
4 used or combined with old data. The need for  
5 additional information about the statistical approach  
6 for the database was not well described and I will have  
7 a full day and a half or so of discussion of sample  
8 size determinations.

9 And we also need to consider baseline  
10 biomedical or biological monitoring data and we thought  
11 it would be wise to look at the existing data that we  
12 have in some of the studies are in PHED and other  
13 studies submitted to various agencies and see how the  
14 two, passive dosimetry and biological monitoring  
15 methods compare. Next slide please.

16 They also raised the question regarding the  
17 proposed dermal exposure collection methods and the  
18 AGTF protocols and how they may systematically  
19 underestimate potential exposures. And this of course  
20 is the hand rinse method compared to suing cotton  
21 gloves for measuring hands.

22 The tash forces in many studies have also  
23 incorporated face neck wipes versus the hat patch or a  
24 shoulder patch that may have been used in the earlier  
25 studies. And also, really the relative differences

1 between a whole body dosimetry versus the relative  
2 patches. In some presentations later in the program  
3 you'll be looking at the differences between those two  
4 techniques, also with respect to biological monitoring.

5 And we should certainly point out as Tina  
6 mentioned, that EPA has previously identified some of  
7 these issues raised by the HSRB and intended to seek  
8 advice regarding hand rinse and passive dosimetry  
9 performance in the past as some of you know, and we  
10 certainly feel that these are very, very important with  
11 respect to our guideline requirements. Next slide  
12 please.

13 So our goals, one of them is to simply put it  
14 as plainly as we can, is that we certainly seek the  
15 panel's advice on the techniques that we're using for  
16 evaluating the existing handler exposure database and  
17 for making determinations if new handler data are  
18 needed. And more importantly, if the handler data are  
19 needed we want them to be collected in a manner that  
20 produces accurate information to the extent possible,  
21 without resulting in systematic underestimates of  
22 exposure.

23 And if handler data are needed, then how many  
24 samples should be collected? And we invite the panel  
25 to comment on the AG. Handlers Exposure Task Force's

1 proposal for determining sample size.

2           So our presentations are structured, one,  
3 just to get into the historical precedent for  
4 establishing generic bases. Our colleague from PRMA,  
5 John Worgan will present this. And then Jeff Dawson  
6 will go into the six scenarios in the case study and  
7 that way you'll really start to get into the nuts and  
8 bolts of the program and the data behind it. And then  
9 also we'll have presentations from two task forces  
10 generating new data, the Agricultural Handlers Exposure  
11 Task Force and we'll have Curt Lunchick, Doctor Richard  
12 Collier and Doctor Victor Canez for the AG. Handlers  
13 Exposure Task Force. And then Doctor Ryan Williams  
14 will also present some aspects of the Antimicrobial  
15 Exposure Assessment Task Force.

16           There are differences in the types of data  
17 that these two task forces are going to generate and  
18 Doctor Cassi Walls from our Antimicrobial Division will  
19 delineate those differences for the panel.

20           And we also have, really starting to get into  
21 the key issues, the presentations addressing whether  
22 passive dosimetry methods result in underestimates of  
23 exposure. And looking at the two really key methods of  
24 assessing occupational exposure, and that is the  
25 biological monitoring and passive dosimetry components.

1 Doctor Sheryl Beauvais of California EPA will make that  
2 presentation.

3 We're going to also look a little bit at what  
4 the literature and PHED data have on the comparisons of  
5 passive dosimetry and hand rinse methods. And the AG.  
6 Handlers Exposure Task Force is also going to present  
7 their view on the comparisons of biological monitoring  
8 and passive dosimetry, and we'll have Doctor John Ross,  
9 Doctor Graham Chester and Doug Baugher and other  
10 members from the AHETF also making those presentations.

11 And the statistical considerations, we have a  
12 number of presentations regarding those aspects and the  
13 proportionality between exposure and the amount of  
14 active ingredient handled, using the example case study  
15 scenarios that Jeff Dawson is going to be talking about  
16 this morning. This of course is the unit exposure  
17 concept, that proportionality, the relationship of  
18 exposure per amount of AI handled.

19 Also we'll have a statistical basis for the  
20 AHETF Data Development Program and also we're going to  
21 have a discussion about the data development plan from  
22 our perspective at EPA and then also the AHETF will  
23 finish up with their data development plan and  
24 considerations.

25 And with that I'll be happy to answer any

1 questions the panel may have.

2 DR. HEERINGA: Thank you very much Mr.  
3 Evans. Turning to the panel, are there any questions  
4 of clarification at this point for Jeff Evans? It's  
5 fairly straightforward. I think we're ready to move on  
6 in that case.

7 At this point we have another introductory or  
8 essentially an historical perspective on the worker  
9 assessment methods and welcome, John Worgan of Health  
10 Canada.

11 MR. WORGAN: Thank you and good morning.  
12 I work as the Director of the Reevaluation Management  
13 Division in the Pest Management Regulatory Agency  
14 within Health Canada. And the PMRA as we call it is  
15 the equivalent of the U.S. EPA Office of Pesticide  
16 Programs.

17 And if you want to find out more about the  
18 PMRA you can do an internet search, you can Google it,  
19 you can type in PMRA and ignore the first thing that  
20 comes up because it's probably going to be the  
21 Professional Motorcycle Racing Association. But if you  
22 look at the second item it'll be the PMRA website and  
23 if you want to find out more you can just look at that.

24 So as the Chair had indicated, the purpose of  
25 my presentation is basically to provide an historical

1 overview of worker exposure methods and this helps set  
2 the stage for some of the subsequent discussions and  
3 presentations that we're going to have here over the  
4 next few days.

5           And specifically I'm going to talk about all  
6 of the past and some of the current cooperative work  
7 that is being, or has been undertaken by partners that  
8 include not only the government regulatory agencies,  
9 but also the pesticide industry as well as academics  
10 and other researchers in government, to develop and to  
11 refine over time a number of things.

12           First of all, exposure data requirements and  
13 the secondly, occupational exposure study guidelines,  
14 because the data that are generated for regulatory  
15 purposes need to be done according to guidelines.

16           And then lastly to talk about the generic  
17 exposure databases with a particular focus on PHED.

18           And then also during my presentation I am  
19 going to highlight some of the advantages of  
20 cooperative work for all of the stakeholders. So, not  
21 only for the regulatory agencies but also for the  
22 industry, and as well ultimately for the user of  
23 pesticides because our mandate, our roles and  
24 responsibility are the protection of the health and  
25 safety of workers.

1           So firstly, on the worker exposure methods,  
2 the original impetus to conduct worker exposure  
3 assessments were triggered by concerns about  
4 agricultural workers who were exposed to acutely toxic  
5 compounds such as the OP's when they reentered treated  
6 fields. And the pioneering work by Durham and Wolfe  
7 who proposed using passive dosimetry to assess exposure  
8 was done in 1962. So prior to that time only  
9 occupational hazard assessments could be conducted  
10 because we really only had one half of the risk  
11 equation. We had the hazard part, we didn't really  
12 have a good handle on the exposure part.

13           And all of the agencies, so EPA, PMRA and  
14 California DPR do require and have required since  
15 sometime in the early 1980s, exposure data to  
16 demonstrate the safety of products. And the definition  
17 that's in the EPA FIFRA is that there be no  
18 unreasonable adverse effects. And within the Pest  
19 Control Products Act that we've got in Canada we've got  
20 a very similar definition. So just keep that slide  
21 there please.

22           So in order for studies to be done in a  
23 scientifically valid manner for regulatory purposes we  
24 do require guidelines and the guidelines also help to  
25 ensure international consistency which is important to

1 us within a NAFTA context. And it also helps to ensure  
2 the use of the best available science at the time. And  
3 these guidelines as I had mentioned are also the basis  
4 for the more detailed study protocols that industry  
5 needs to submit to the regulatory agencies before  
6 studies are conducted.

7 So as Doctor Levine had mentioned we've been  
8 cooperating among the regulatory agencies for, you  
9 know, nearly twenty years and this work has been partly  
10 to develop and to refine the guidance, documents to the  
11 guidelines that we provide to people that are  
12 conducting these studies.

13 And the first set of guidelines or protocols  
14 were developed by WHO, the World Health Organization.  
15 The first version was published in 1975 and was  
16 primarily dealing with exposure to the OP's and using  
17 the patch methodology that Mr. Evans talked about.

18 Then the next version was put out in 1982 and  
19 it was updated to address exposure to all classes of  
20 pesticides and did include the whole body dosimetry  
21 technique in addition to the patch technique. And I  
22 believe, you know, during the, as Jeff had mentioned,  
23 that during the next few days we'll be talking about  
24 whole body dosimetry versus passive or patch techniques  
25 as well for estimating dermal exposure. Okay, that's

1 correct.

2           So much of the seminal research on exposure  
3 monitoring was conducted between 1974 and 1984 and EPA  
4 then took that research that had been developed and  
5 analyzed it and prepared some pesticide assessment  
6 guidelines. Initially in 1984 it was called  
7 Subdivision K, Reentry Exposure Assessment and this was  
8 to standardize the conduct of studies to estimate  
9 exposure to workers who would be reentering treated  
10 fields as the original concerns around this issue were  
11 related to the reentry. And that guideline was then  
12 followed a couple of years later in 1986 by a  
13 Subdivision U Guideline that was to provide guidance on  
14 how mixer/loader applicator studies were to be  
15 conducted. And it did have some improvements over how  
16 previous studies were done. As Jeff had mentioned that  
17 some of the initial studies were done just with patches  
18 on certain body parts. The Subdivision U guidance  
19 requested that all of the body parts be represented in  
20 the studies.

21           So wanting to some advice from scientists,  
22 EPA went to a scientific advisory panel on the  
23 Subdivision U Guidance Document or guidelines in 1986  
24 and some of the outcomes of that were that it was  
25 recommended that EPA should encourage the use of

1 concurrent passive dosimetry and biological monitoring.  
2 They also agree that either the hand wash or the cotton  
3 glove could be used, but that certain chemicals might  
4 require special consideration, in particular those that  
5 are rapidly absorbed or are persistent on skin. And  
6 then they also agree with EPA's intention to develop a  
7 generic database, and we'll be talking a little bit  
8 more about that, but that there were certain chemical  
9 properties related to, that might affect  
10 bioavailability that should be taken into account, so  
11 that would be things like dermal absorption. Yeah,  
12 that's correct.

13 So as more exposure studies were conducted  
14 and submitted to the regulatory agencies, EPA in 1993  
15 conducted a pesticide, what they called a pesticide  
16 rejection rate analysis to look at the factors that  
17 resulted in studies not being acceptable for regulatory  
18 purposes. And on the basis of this analysis they  
19 determined that many of the studies were rejected due  
20 to QAQC kinds of considerations, method validation  
21 issues and the like. Also found that not all  
22 pesticides are easily analyzed with respect to passive  
23 dosimetry media and I guess an example here might be,  
24 you know, fumigants, the highly volatile ones that, you  
25 know, for the dermal exposure, a patch technique would

1 obviously not be the best.

2           And then they also found that, you know, many  
3 of the examples in the earlier version of the PHED  
4 generic database, you know, had some issues around  
5 method validation and that impacted on the available  
6 data to generate exposure estimates. And then as a  
7 result of that analysis I think there was increased  
8 interest on the part of the regulatory agencies as well  
9 as industry in a more cooperative effort in data  
10 collection to ensure that better quality data would be  
11 available for databases.

12           So then the other thing too is that in 1993  
13 there was an OECD workshop on methods of pesticide  
14 exposure assessment that was held in Ottawa and the  
15 purpose of that workshop was to review the issues  
16 around sampling for exposure assessment for the  
17 mixer/loader/applicator scenario. And we also  
18 discussed a draft protocol that, or guideline or  
19 guidance document that had been put together. And  
20 because it was an international workshop we had  
21 representatives from a large number OECD countries, and  
22 they represented not only the regulatory agencies, but  
23 also researchers in the area as well as industry.

24           And there were a number of things that, you  
25 know, came from that workshop that I think helped

1 advance the area and helped provide some further  
2 guidance on how studies should be done. And one of the  
3 main areas I think that was extensively discussed was  
4 the duration of the exposure monitoring periods. Many  
5 of the earlier studies were done over very short  
6 periods of time. It was recommended after extensive  
7 discussion and debate, that the exposure monitoring  
8 period be something along the lines of a full typical  
9 workday or a fairly substantial portion of a full  
10 typical workday.

11 Then in 1994 EPA held a workshop on the  
12 revision to the guidelines for post-application  
13 exposure assessment. And again, just to indicate that  
14 there was extensive EPA, PMRA and DPR collaboration  
15 back then, we did attend and California DPR did also  
16 attend that workshop.

17 Then in 1997 there was another EPA, PMRA,  
18 OECD workshop on the post-application exposure  
19 guidelines and I think one of the outcomes from that  
20 workshop was the, related to the use or the potential  
21 use for generic transfer coefficients for the post-  
22 application scenario. So again we did discuss the  
23 methodologies and I think helped further advance the  
24 field.

25 Then in 1997 as a result of the Ottawa

1 workshop that I'd mentioned had taken place in 1993, an  
2 expert group had been established and had discussed  
3 the, an appropriate guidance document for the conduct  
4 of occupational exposure assessment during application.  
5 This was then approved by OECD and there are a number  
6 of things that came out of this. I think, you know, it  
7 helped advance the field, it helped standardize some of  
8 the approaches that we take, it recommended a longer  
9 duration of sampling than had been done in the past,  
10 and then it also, you know, did discuss the possibility  
11 of using concurrent passive dosimetry and biomonitoring  
12 in an individual study. Next slide.

13           Then in 1998 post-application guidelines, the  
14 Series A75 as they're called now, were taken to a  
15 scientific advisory panel not unlike this one here and  
16 the focus was primarily on the residential component of  
17 that guideline because it was prepared partly in  
18 response to the new FQPA requirements, but the panel  
19 did not identify any substantial deficiencies in the  
20 agricultural requirements for post-application exposure  
21 guidelines.

22           So in conclusion there's been, for the  
23 guideline component there's been, you know, very  
24 considerable international involvement and  
25 harmonization since the 1980s among all of the

1 regulatory agencies and, you know, we've been working  
2 hard I think, you know, since the early 1980s to  
3 improve our understanding of how these studies should  
4 be done and that I believe is reflected in the guidance  
5 documents that we currently use. Next, that's right.

6 So just turning your attention just to  
7 discuss very briefly the NAFTA harmonization activities  
8 that have been taking place since about 1995, EPA, PMRA  
9 and California Department of Pesticide Regulation have  
10 been working under the umbrella of the NAFTA technical  
11 working group on pesticides to develop, improve and  
12 harmonize exposure assessment approaches and tools.

13 And then in, and there's an error in the  
14 slides, it's not 1998, it's 2000, after a few years of  
15 rather extensive discussion among the agencies we did  
16 finalize harmonization work on a variety of different  
17 issues, including things such as clothing protection  
18 factors, duration of sampling periods for studies,  
19 dermal absorption as well as guidelines for using and  
20 reporting of PHED. Next slide.

21 So now I'm going to turn our attention to the  
22 generic exposure database development. And then, first  
23 of all, in the early years, in the 1980s when we  
24 started to require these assessments to be done, EPA  
25 and Health Canada used individual studies that were

1 either in the published literature or were conducted  
2 specifically for regulatory purposes, to conduct  
3 preliminary mixer/loader/applicator assessments. And  
4 this was based on the concept that Jeff had mentioned  
5 in his presentation, that handler exposure is primarily  
6 a function of the physical process of the  
7 mixing/loading and applying of pesticides and the  
8 formulation type, rather than the chemical properties  
9 of the pesticide itself. It was felt that a generic  
10 approach might be suitable for assessing exposure.

11 Then in a paper that was presented to the  
12 American Chemical Society in 1985 by Hackerthorn and  
13 Eberhart, they reviewed the literature and found that  
14 in the open literature there were really insufficient  
15 data that could be used to support the concept or the  
16 hypothesis that had been advanced about the physical  
17 process of the mixing, loading and applying, the  
18 formulation type as being the most important variables  
19 determining exposure. But they did identify as well  
20 that there were substantial studies available in the  
21 databases of individual companies that, you know, could  
22 help support that hypothesis.

23 So they had recommended the development of a  
24 generic exposure database back in the mid-80s, using  
25 available data. So not just what's in the published

1 literature but also what's out there in the databases  
2 of individual companies. Next slide.

3 So after fairly extensive discussion the  
4 pesticide handler exposure database or PHED Task Force  
5 was formed. The companies that were members of this  
6 waived their proprietary rights for those studies that  
7 were to be entered into the database and PHED, which is  
8 basically just a software tool was developed  
9 cooperatively by EPA, Health Canada, California DPR and  
10 the industry side, NACA. It, as has already been  
11 mentioned is just basically a compilation of inhalation  
12 and passive dosimetry data for a variety of different  
13 scenarios. Its use assumes that the exposure data is  
14 independent of the active ingredient. And one of the  
15 advantages of that is that it's felt that it generates  
16 more widely representative and robust estimates of  
17 exposure than could be derived from an individual  
18 study.

19 So the data in the PHED are graded by  
20 analytical quality controls, so things such as  
21 laboratory and field recovery are used to assign a  
22 grade to the data rather than on study design. So  
23 study design considerations could be things such as the  
24 duration of the exposure monitoring event. So as I had  
25 mentioned earlier, over time as we got more knowledge

1 and experience it was realized that duration of the  
2 exposure monitoring event was a very important factor  
3 and that it is now like one of the, you know, is a key  
4 factor in the design of the new study. And the  
5 advantage is, is that it helps minimize non-detects and  
6 it also, you know, gives greater confidence in studies  
7 in particular where you might expect low rates of  
8 exposure such as closed mixing/loading.

9 And because it is, if it is done over a  
10 longer period of time it would result in a larger  
11 number, range of activities that would be monitored  
12 during a day.

13 So PHEDs was publicly released with Version 1  
14 in 1992 with about 50 studies using only patch  
15 methodologies. Then we did an analysis in 1992 that  
16 indicated that additional data would increase the  
17 utility of PHEDs and we also did some other analysis  
18 looking at the impact of variables on exposure.

19 Then Version 1.1 was released in 1995 which  
20 was an incremental improvement because it went from 50  
21 to 100 studies that represented more than 1,700  
22 monitoring events. And it also included some studies  
23 with the whole body dosimetry technique.

24 So, and then some of the studies were also  
25 conducted with both patches and whole body dosimeters

1 so that does allow for some comparisons.

2 So, because there is a strong desire among  
3 regulatory agencies for using data, in particular in  
4 this case here, exposure data in a consistent manner  
5 and then also to ensure consistent sub-setting and  
6 application of PHED, the regulatory agencies did  
7 develop some standardized tables for a variety of  
8 different scenarios for use in exposure and risk  
9 assessments. So we have the Canadian tables and the  
10 U.S. tables which are very similar.

11 The other advantage is that this does allow  
12 us to streamline evaluations so that we don't have to  
13 run PHED for each and every single assessment.

14 So generic databases, now I'll just talk a  
15 little bit about the international, beyond the North  
16 America but, you know, generic databases were accepted  
17 as part of a tiered approach to exposure and risk  
18 assessment for workers. And this is included in the  
19 OECD guidance documents that we've worked on. And  
20 generic databases have also been developed and used by  
21 other regulatory agencies and I've mentioned one here  
22 on the slide, which is the more recent POEM or EUROPOEM  
23 which is used in Europe. But there are some earlier  
24 databases that were also developed along the same time  
25 frames as when we developed the first version of PHED.

1           And then also on a smaller scale there are  
2 some other databases that, you know, we do use  
3 generically. There's the ORETF database which is the  
4 Outdoor Residential Exposure Task Force database which  
5 does have some mixer/loader data that we can use  
6 generically. And then we also have a Canadian  
7 Antisapstain Exposure Study which is done to cover off  
8 about, a large number of active ingredients for about  
9 ten to twelve registrants that we've got for  
10 antisapstain products.

11           So, how do these generic data fit into a  
12 testing scheme for workers? It's really quite simple.  
13 We use a tiered approach, tier 1 where a PHED  
14 assessment and default dermal absorption would be used  
15 to estimate exposure and ultimately risk. If need be a  
16 refinement would then be done at tier 2 where you would  
17 actually use compound specific dermal absorption data  
18 and consideration of protective measures. And then the  
19 last tier is if you need to move to this level, would  
20 be to do an exposure field study, some dermal  
21 absorption data or a biological monitoring study, or  
22 both.

23           So the advantage of this approach is that it  
24 does put the resources where the need is in terms of  
25 the data generation and also where the risks are. So,

1 you know, it is cost effective for everybody involved.

2 Then with respect to the advantages of PHED  
3 and the generic databases, we've already heard about,  
4 you know, some of the limitations of PHED and I just  
5 wanted to run through quickly the advantages. It is a  
6 critical tool for the agencies to conduct safety  
7 determinations as mandated under FIFRA and PCPAA. It  
8 does maximize the use of resources, it reduces costs to  
9 regulatory agencies and registrants because, you know,  
10 as we all know the studies are expensive.

11 The past rejection rate analysis assessment  
12 that had been done by regulatory agencies indicated  
13 that there are benefits to working together  
14 cooperatively to generate exposure databases which  
15 would contain higher quality data and higher confidence  
16 data. And it also allows to, it allow everybody  
17 involved to conduct assessments with a greater degree  
18 of certainty where you have a larger number of  
19 observations than you have from a single individual  
20 study.

21 It also does improve the consistency in  
22 developing exposure estimates because industry and the  
23 agencies will use the same data sets. And in order to  
24 achieve this goal of consistency as well, the EPA, PMRA  
25 and California did develop in '95, guidelines on the

1 use of PHED and I'd mentioned, similar surrogate  
2 exposure tables.

3 And it does also enhance our ability in the  
4 regulatory agencies and the regulatory community and  
5 also with researchers, to identify and address the  
6 significant data gaps, because when you put all of the  
7 data together I think it becomes much more evident as  
8 to where the data needs are and it allows us to target  
9 our resources to those areas that require better data.

10 Then in the NAFTA area, just to provide a  
11 little bit of background on the guidelines for using a  
12 reporting PHED, these do include criteria for  
13 acceptable PHED surrogate data in terms of things such  
14 as data quality, quantity and degree of specificity.  
15 Recommend for example that you don't extrapolate more  
16 than one order of magnitude with respect to the  
17 kilograms active handled per day because it just means  
18 you're extrapolating quite a bit. That it does also  
19 provide a methodology for interpreting PHED exposure  
20 estimates in terms of the appropriate statistical  
21 measures and it also provides for a consistent  
22 reporting format for PHED exposure calculations.

23 And my last slide is that, you know, it's  
24 just to recap that, you know, we have been working for  
25 well over twenty years, probably about twenty-five

1 years internationally on harmonization activities to  
2 develop the best exposure methodologies in terms of  
3 guidelines and databases. But that this is an ongoing  
4 activity for us under NAFTA to refine exposure  
5 assessments that we do. We currently have a project  
6 underway on dermal absorption. We have as well been  
7 participating since 1994 in the development of some of  
8 these new harmonized exposure databases such as the  
9 ARTF, the Agricultural Reentry Task Force database,  
10 AHETF which is on for discussion today and the next few  
11 days and the antimicrobial database as well.

12 And all of the agencies that are involved in  
13 this particular activity have been represented on the  
14 joint regulatory technical committees advising these  
15 task forces and we also do, you know, review all of the  
16 study protocols before those studies are actually  
17 generated and put into the database, to ensure that  
18 they meet the highest standard.

19 And overall, you know, the harmonization or  
20 all of this work that we're doing on exposure  
21 assessment does contribute to ongoing work sharing and  
22 joint reviews among the agencies. But probably more  
23 importantly it does provide us with, you know, better  
24 tools to assess exposure and risk and ultimately  
25 fulfill our mandate which is the protection of the

1 health and safety of, you know, workers.

2 So I think with that I think my next slide is  
3 just I'm willing to entertain any questions if there's  
4 time.

5 DR. HEERINGA: Thank you very much, Mr.  
6 Worgan. At this point in time do we any questions on  
7 the history and development including standards and  
8 data sets for worker exposure assessment? Doctor  
9 Portier?

10 DR. PORTIER: I lost some of the acronyms,  
11 I got most of them--

12 DR. HEERINGA: Okay, sorry.

13 DR. PORTIER: -- but I lost it at the end.  
14 The AR, ARTF.

15 MR. WORGAN: The ARTF is the Agricultural  
16 Reentry Task Force so they are generating, and have  
17 been generating since about 1994 a generic database to  
18 assess reentry exposure to workers.

19 DR. PORTIER: And the ORETF?

20 MR. WORGAN: That is the Outdoor  
21 Residential Exposure Task Force and they have generated  
22 data to assess post-application exposure to turf  
23 chemicals and have also generated data to assess  
24 exposure to people who are mixing, loading and applying  
25 those turf chemicals.

1 DR. HEERINGA: And all of these task  
2 forces are combined industry/government task forces?

3 MR. WORGAN: That is correct. And we do  
4 have that, as I mentioned a joint regulatory committee  
5 that is advising all of those task forces to make sure  
6 that it does meet our requirements.

7 DR. HEERINGA: Any other questions of  
8 clarification at this point? Okay, I want to thank the  
9 presenters for their initial introductions and then the  
10 historical overview that we have just heard as well.

11 We're a little bit ahead of the agenda which  
12 is a good thing because we have plenty of opportunity  
13 to get behind on the agenda in this session.

14 So let's start out by taking a twenty minute  
15 break. I have 10 of 10:00 on my watch so let's say 10  
16 after 10:00 we'll reconvene.

17 (WHEREUPON, there was a recess).

18 DR. HEERINGA: Okay, let's get underway.  
19 Welcome back everyone. Okay, let's get underway  
20 please. Welcome back everybody to the second half of  
21 our first morning session of the FIFRA SAP meeting on  
22 the Review of Worker Exposure Assessment Methods.

23 At this point in the morning program we've  
24 heard an introduction to the four day session and also  
25 a history of some of the developments of data sets and

1 methodology for worker exposure assessment.

2 And now we're going to move on to a  
3 presentation by Jeff Dawson of the Health Effects  
4 Division, Office of Pesticide Programs on a series of  
5 case studies or a case study. Jeff, good to see you.

6 MR. DAWSON: Thank you Doctor Heeringa.  
7 Before I start I'd like to clarify one issue that was  
8 raised this morning and that's about the relationship  
9 of the task forces with the regulatory agencies. I  
10 wanted to make it clear that the various task forces  
11 that we discuss this morning are essentially industry  
12 driven efforts with industry funding and such and that  
13 essentially we provide oversight form a technical  
14 review perspective for them and guidance on, you know,  
15 their methods and how they should analyze their data  
16 and such. But essentially they're their own entity and  
17 there's not really a formal relationship kind of as was  
18 implied this morning.

19 DR. HEERINGA: Thank you for that  
20 clarification.

21 MR. DAWSON: So what I'd like to do in  
22 this presentation is to delve into some of the issues  
23 that were raised this morning a little bit deeper and  
24 to kind of outline the data that were made available  
25 for our analyses in the form of a case study. So some

1 of the information that you're going to hear about is  
2 repetitive and I'll apologize for that up front and  
3 just kind of quickly go over it. And I'm sure you'll  
4 all have some clarifying questions at the end because  
5 what I'd like to do is talk about the six scenarios and  
6 delve into one in some explicit detail to illustrate  
7 some of the data and how we've use it and such.

8           So, this is the basic overview of my talk so  
9 a little bit about the goals. A little bit, and this  
10 is where the redundancies are going to come in about  
11 the basis and general concepts and then we'll talk in  
12 detail about the six case study scenarios and then  
13 begin to introduce some of the issues and limitations  
14 associated with this data that really form the bulk of  
15 the remainder of this SAP meeting over the next few  
16 days.

17           So our goals here as I indicated are to  
18 provide a common data set for the analyses associated  
19 with the various charge questions. For example,  
20 related to proportionality or the evaluation of hand  
21 monitoring methods or the performance of whole body  
22 dosimetry, some of the issues that we've raised in the  
23 charge questions.

24           We also want to illustrate in this discussion  
25 in a little bit more detail how the passive dosimetry

1 methods are used and more importantly, how we've  
2 handled the data and begin to show, examine some of the  
3 limitations associated with the currently available  
4 data.

5           So just to reiterate, Jeff Evans showed this  
6 slide this morning. Our real focus here is on the  
7 generation of the unit exposure estimates which in this  
8 equation, so again we calculate dose by taking these  
9 unit exposure estimates which are a rate, an exposure  
10 rate based on the amount that impinges on the skin  
11 compared to, and the way we've done it at this point  
12 is normalized by the amount of active ingredient  
13 handled for handlers, multiply that by application rate  
14 and the acres treated per day for various types of  
15 application equipment and adjusting by dermal  
16 absorption if we need to and adjust by body weight to  
17 calculate our risks which are generated, the term we  
18 use to represent risk is the MOE or margin of exposure.

19           And we have a table or a database if you will  
20 of different unit exposures for each type of job that  
21 we look at related to agricultural production and the  
22 use of pesticide chemicals. And the various task  
23 forces which will be offering presentations later, for  
24 example the AHETF and the AEATF, their basic product is  
25 to develop a database of these unit exposure estimates.

1           And again we covered a little bit about this  
2 this morning, the PHED or the pesticide handlers  
3 exposure database, and I'll quickly go through this,  
4 based on the concept by Hackerthorn and Eberhart, the  
5 first version was 1992 and we upgraded it in 1995, it's  
6 a joint effort. We didn't really hear too much about  
7 this this morning. There's, in the current database as  
8 we use it today there's approximately 100 different  
9 passive dosimetry studies which represents  
10 approximately 1,700 different monitoring events. And  
11 what it does it combines these studies in various ways  
12 that we use to develop our exposure estimates.

13           And what's useful for the purposes of the  
14 analyses that we're going to be talking about,  
15 especially tomorrow, is that some of the studies also  
16 contain concurrent biological monitoring data which is,  
17 they serve as the basis for some of the discussion  
18 tomorrow.

19           And it should be pointed out for PHED, going  
20 back to John Worgan's talk, that this is the tool that  
21 forms the basis for most of our current occupational  
22 handler exposure analyses and our risk assessments.

23           Again the output is the unit exposure value  
24 and we have the four basic categories of types of  
25 exposures, the mixers and loaders, the applicators, the

1 flaggers and then we have some data that actually  
2 monitor people doing combined tasks. And when you  
3 break these four basic categories up we identified 37  
4 major job tasks within agriculture that we have data  
5 for that are addressed in the database. For example,  
6 it might be a pilot flying a plane, it might be  
7 somebody, you know, mixing a tank of liquid spray, it  
8 could be someone driving an air blast sprayer through a  
9 field and so on.

10 And within each of these tasks we have varied  
11 exposure estimates. Of course that's dependent upon  
12 the amount of data available for those cells for  
13 different levels of personal protective clothing and  
14 equipment. So we might have data for somebody wearing  
15 normal work clothing which is something like I have on  
16 right now, long pants and long sleeved shirt or there  
17 might be additional data where they're wearing a  
18 coverall or a pair of protective gloves or so on. And  
19 we would have different estimates to represent those  
20 different levels of protective equipment. Again,  
21 depending on the amount of data available.

22 And Jeff Evans showed this slide earlier this  
23 morning, it's just the distribution of the different  
24 basic databases and PHED and we have the most data for  
25 applicators and then the next is the highest populated

1 databases for mixer/loaders. And that's where we  
2 believe those two categories really account for the,  
3 you know, the vast majority of pesticide handling  
4 practices in agriculture.

5 Now the database includes in it, different  
6 varieties of exposure monitoring information. We  
7 talked a little bit about these, the different methods  
8 this morning. For dermal monitoring we have the patch  
9 method which I'll show some actual slides,  
10 illustrations of it in a minute and also whole body  
11 dosimetry which essentially is donning a garment that's  
12 worn underneath the work clothing that acts as the  
13 sampler. And then there are various hand monitoring  
14 techniques. In the database itself we actually have  
15 various washing techniques and they are different types  
16 of aqueous soap solutions, various alcohols, methanol,  
17 ethanol, isopropanol and they also incorporate in them,  
18 depending upon the investigators that did them, a  
19 variety of washing techniques. For example, in some  
20 studies they would put their individual hands in a bag  
21 and kind of shake it, in other studies they would take  
22 their hands together and rub it vigorously like you  
23 would wash your hands at the sink, those kind of  
24 things. So there's quite an array of ways that those  
25 data were collected.

1           And also along with the washing techniques,  
2           in some cases they wore, investigators had the  
3           individuals wear cotton gloves or in one study we even  
4           had people wearing tie back gloves that were collected  
5           and analyzed for the residues on the hands.

6           This slide just illustrates kind of the  
7           latest thinking on how we would employ a patch method  
8           study and as Jeff and John spoke of this morning, this  
9           process evolved basically from looking at what  
10          investigators thought was a few key points of exposure  
11          to really trying to encompass sampling across all the  
12          regions of the body. And so if someone were to conduct  
13          a patch study today you would see samples from, you  
14          know, the shoulders or the upper arms and so on and the  
15          x's and o's basically represent, in some studies they  
16          collected patches on the outside representing bare  
17          skin, excuse me, and in other cases they would have the  
18          patches under, actually underneath like a shirt like  
19          this and worn on a t-shirt or something. So you would  
20          be capturing residues as it passed through the outer  
21          garment and measuring the actual breakthrough of the  
22          residues onto the patch underneath that garment. So  
23          you would be in effect evaluating the performance of  
24          the garment as far as protecting the individual.

25                 And you may all recognize this person sitting

1 to my right here, that's him in the picture. But this  
2 is an illustration of the patch method and how it has  
3 been historically employed. For this method it has  
4 some drawbacks. For example, let's say if you've got a  
5 large splash up here on the shirt where, you know,  
6 there's no patch you would miss that exposure event.

7 In other cases investigators would take these  
8 patches and cover them. Let's say if you wanted to  
9 evaluate the efficacy of a rain suit for example you  
10 would cover the patch and what was done would be you  
11 would cover the patch in a rubberized material similar  
12 to a rain suit, and at the time the thinking was that  
13 was a good way to do it but it doesn't account for, for  
14 example, the seams on the clothing and the buttonholes  
15 and things like that that people who develop protective  
16 clothing standards care about. So there are some,  
17 there's some uncertainty around how that method would  
18 be employed.

19 And essentially what you get from a study  
20 like this is let's say on this chest patch right here  
21 you would measure that, measure the total residues that  
22 impinge on that patch and you would present that and  
23 you know the surface area of that patch, so typically  
24 the way the data are presented would be on a microgram  
25 loading per surface area amount. So typically it's

1 microgram per centimeter squared of patch surface area  
2 would be how that would be presented.

3           And then what you do to analyze the overall  
4 results of these kinds of studies is, as Jeff Evans  
5 indicated earlier, you would, we have a information  
6 about the kind of standardized surface areas of a, you  
7 know, a 50th percentile human or a 90th percentile  
8 human, whatever it is and you would take the residue  
9 loading information from your patch and extrapolate it  
10 to the different body regions based on that and add  
11 them all together to calculate your dermal exposure.

12           And this slide just illustrates those surface  
13 areas that are used in the calculations and we'll talk  
14 a little bit more about the detailed outputs and such  
15 from PHED and these are the numbers that are actually  
16 hardwired into the PHED system. And these were  
17 accepted in the literature and taken from the,  
18 basically the EPA, the Agency wide exposure factors  
19 handbook for standard surface areas. They've changed a  
20 little bit since then but we haven't, not significantly  
21 so we really haven't modified these estimates at this  
22 point. But we will be considering that issue as we,  
23 you know, move forward with new data development if we  
24 need to use this kind of information.

25           And as Jeff said earlier, you know, the way

1 we do it is the regional surface area times the patch  
2 residue loading and that's how we do the calculations.

3           And this is just an illustration of the whole  
4 body dosimetry, they're typically cotton blend garments  
5 that are collected and analyzed, you know, via GC or  
6 something to get the total amount of residue impinging  
7 upon the person. And this would typically be worn  
8 under a layer of outer work clothing kind of like what  
9 I have on or maybe two layers if you had a coverall or  
10 something like that. In some cases investigators would  
11 also segment the garment, so you might segment the  
12 upper and lower legs or the forearms or something to  
13 have some concept of how deposition was occurring on  
14 different body regions of the individual.

15           And this just is an illustration of that  
16 process so here you can see that they're segmenting off  
17 the lower legs and, you know, continuing on so, but at  
18 the end what you would do is add all those residues  
19 together to represent a total dermal exposure for that  
20 individual for the analysis. But it still gives you  
21 the benefit of being able to look at the segmentation  
22 process and the deposition process.

23           And then as was indicated earlier we  
24 basically have two methodologies for evaluating hand  
25 exposures. One, basically what we called a trapping

1 method in the background document is the use of some  
2 sort of glove material where the residues impinge on  
3 that and are collected and the sample is analyzed and  
4 the amount of residue on that filter media or whatever  
5 you want to call it is equivalent to the exposure to  
6 the hands. And in some cases, and I'll illustrate this  
7 in a little bit of detail later, depending upon what  
8 the, how the investigators did it, the samples were  
9 kept separate in some cases and in some cases the  
10 samples were added together. It just depended upon how  
11 they did it. And that was part of the challenge for us  
12 when we began to develop this database, was looking at  
13 all the possible iterations of how these studies were  
14 done and adding them together. And it's something  
15 useful for our generic database approach.

16 And in other cases, you know, individuals,  
17 the hand on the right would be analogous to somebody  
18 working with their bare hands because there's no  
19 barrier to prevent, you know, total exposure to the  
20 hand as they went about their activities. And in other  
21 cases, you know, individuals would wear some sort of  
22 protective glove which would give you a, you know, a  
23 layer of protection that prevents the residues from  
24 impinging on the hands. And gloves are very cheap and  
25 an easily implementable approach to reducing exposures.

1           And then the other method is various hand  
2 washing methods and you can see here, this is an  
3 individual who, they're actually using some sort of  
4 mechanical agitation in a solution to remove residues  
5 from their skin. And then that wash solution would be  
6 collected and analyzed. In other cases like I said  
7 there would be different methods for doing this where  
8 an individual would just put their hands in a bag or  
9 something and shake it and the materials were kept  
10 separate so you would have information on the left and  
11 right hands for example without the mechanical  
12 agitation part.

13           And then in other cases, you know, we do get  
14 biomonitoring data, some of the data that are in PHED  
15 as I said also have concurrent biomonitoring. Most of  
16 the information that we get from biomonitoring studies  
17 where we calculate some sort of absorbed dose for  
18 example or a body burden are based on urinary outputs.  
19 In some cases we've used, you know, blood levels to do  
20 the same thing but most, the vast majority is urine  
21 based with, and I know there's some pharmacokineticists  
22 on the panel, you know, and the challenge there is to  
23 have the appropriate pharmacokinetics with the  
24 excretion profiles and such that allow you to develop  
25 appropriate dose estimates. So we look at that very

1 carefully when we evaluate biomonitoring.

2 So as I said earlier, and when I first talked  
3 about PHED and the 37 different job tasks that we have  
4 data for within agriculture that are in the database  
5 itself, we can delineate exposure levels in each of  
6 those scenarios based on different levels of clothing  
7 and protective equipment that are used. And again this  
8 is very proportional to the amount of data that we have  
9 available and you'll see this. There's one glaring  
10 example of this in the case study which I'll present in  
11 a little bit. But typically these are the levels that  
12 we look at in our risk assessment process, it's the use  
13 of normal work clothing which is long pants and a long  
14 sleeved shirt like I have on. And that's essentially  
15 the genesis of that scenario is from the worker  
16 protection standards that Jeff Evans introduced in his  
17 talk earlier.

18 And then what we do we tend to add protective  
19 equipment and such in a tiered way and this slide  
20 represents our tier. And it's, the first think we do  
21 is add protective gloves, it's a cheap and easy way to  
22 reduce exposures. And then also add possibly like  
23 require the use of a coverall and such. And then we  
24 can also look at engineering controls as well, for  
25 example, clothes loading systems where you can take a,

1 let's say a standard, a bottle with some sort of  
2 fitting and put it on a pump and it transfers the  
3 material right into a mixing tank or something like  
4 that. Or requiring an applicator for example to let's  
5 say make an air blast application in a closed cab  
6 tractor as opposed to a tractor without a cab where,  
7 you know, we believe that that cab, the physical nature  
8 of that cab will reduce the exposure to the individual  
9 inside.

10 So this slide is, it's very easy to read I  
11 know, but basically when we, as we talked about earlier  
12 we began to compile the data into a database. We went  
13 through a very systematic approach of attempting to  
14 codify the different parameters in these studies. And  
15 I believe in the background materials we tried to  
16 illustrate this a little bit with, A, if you looked at  
17 the actual data set you can see there is a series of  
18 columns with different codes and such and that's, this  
19 information here is just kind of a snippet of how to  
20 decode that information. For example you might see a  
21 column in the database where it says, action of  
22 pesticide and if you see like a number 1 you knew it  
23 was a fungicide of some type or if you were looking at  
24 what kind of liquid was it, code 1 would be an  
25 emulsifiable concentrate and code 3 would be a

1 microencapsulite which are very different although  
2 they're liquids, they're both liquids, and so on. For  
3 example, mixing procedures, open mixing and then like  
4 codes 2 and 3 here would be the use of some kind of  
5 closed system.

6 Sorry. So this slide represents actual data  
7 from PHED and just, we can walk through this example a  
8 little bit to show how the coding is implemented and  
9 the kinds of information that we collected. For  
10 example on the applicator data collection form I think  
11 there is 140 or so fields of data that we collected or  
12 we tried to collect for each different study. The  
13 monitoring event, a lot of times the data weren't  
14 available, the investigators didn't collect it or so on  
15 and, you know, we just acknowledge that or tried to,  
16 tried our best to obtain that information, but in some  
17 cases it just wasn't available.

18 So the first thing we did, we can walk  
19 through this column by column, would be each of the 100  
20 studies was assigned a code. So in this particular  
21 example this shows data from two different studies,  
22 Study 460 and Study 523. And then, and for those of  
23 you we're on 460 and 523, and then what we did within  
24 each study was assign a code to each individual that  
25 participated. So there's an interesting thing in this

1 slide right here, you can see that five different  
2 subjects participated but there was eight monitoring  
3 events. And the reason for that is in Study 460,  
4 Subject D participated four different times, so four  
5 different sets of monitoring samples were collected  
6 from that individual. It may have been over different  
7 days, it could have been, you know, an a.m. and a p.m.  
8 on two different days, I'm not quite sure off the top  
9 of my head. But we could provide that information if  
10 someone was so interested. And then for 523, four  
11 different individuals did the activity. So here you  
12 get the total of five people.

13 And then you move to the next column and  
14 that's the amount of active ingredient that was applied  
15 during the monitoring events. And Jeff Evans spoke, or  
16 maybe John spoke this morning about the clustering  
17 issue related to exposure data, this column really  
18 represents that because you can see in let's say 523  
19 here where the four individuals basically used the same  
20 amount of active ingredient during their monitoring  
21 events, 5.38 pounds of active ingredient. And then  
22 basically in Study 460 that one individual used, except  
23 for one case right here, 6.75 pounds of active  
24 ingredient. And we'll have a lot of discussion over  
25 the next couple of days related to developing data

1 where there's a range of such information so you can  
2 begin to understand how, you know, handling different  
3 parts, different amounts of active ingredient and such  
4 may impact the exposure predictions.

5 And then the same is true for the, you see  
6 the same phenomena in the acres treated, this next  
7 column is the amount of acres treated that these  
8 individuals did. In Study 523 they treated 12 acres  
9 each. In Study 460 that one individual treated between  
10 30 and 37 acres, and it's kind of down here as well.

11 And the same with the amount of spray  
12 solution applied, you know, from 1,350 to about 2,000  
13 gallons of dilute spray that they would have applied  
14 during their application event.

15 So these are kind of the, this is, these  
16 columns here basically represent, you know, the design  
17 and structure of the study, you know, how many people  
18 and the repeat measurements and these columns here are  
19 examples of the various exposure factors data that we  
20 collected which help us to characterize the kinds of  
21 exposures that occur. And then these columns here  
22 represent the actual exposure monitoring results for  
23 those individuals.

24 Now you can see in this column, this is B  
25 hands in which means, as I said earlier there were

1 different ways of collecting hand monitoring  
2 information. In Study 460 what they did if they  
3 collected hand monitoring at all they kept the hand  
4 data separate. So what this column represents is in  
5 523 here the studies, in that particular study they  
6 washed their hands together and collected it as one  
7 sample. In Study 460 probably what happened is, again  
8 as I said earlier they keep the information separate.  
9 But for our purposes when we calculate total exposure  
10 we would add those together anyway. It's just how the  
11 data came to us but we used it in the same way just by  
12 adding it together to get the total dermal exposure.

13 Now as far, basically PHED was, at the time  
14 it was developed the vast majority of the data were  
15 based on the patch methodology and so it was really the  
16 arrays and such in the system were really configured  
17 around housing patch methodology based data. So some  
18 of the codes and such in the data that are there really  
19 reflect that methodology and it wasn't-- we housed also  
20 whole body dosimetry data in there but it's, we kind of  
21 had to make some adjustments for how we did it. But  
22 the codes really reflect the patch methodology. So  
23 there are various codes and for example these two  
24 columns here represent data that would have been  
25 collected on the forearms underneath, when you see the

1 word, in, in our coding system, that's underneath some  
2 level of personal clothing so it would be like  
3 underneath my shirt for example. And this is the right  
4 for forearm, this is the left forearm. And our coding  
5 system, if you see a -1 that means there were no  
6 detectable residues in that sample. So you can see in  
7 Study 460 whatever, whatever they did, 7 of the 8  
8 samples had non-detectable residue so these three and  
9 these four. These three over here and these four. And  
10 then we did, on this one sample we found, or the  
11 investigators quantified a residue of .018 micrograms  
12 per centimeter squared on that forearm patch.

13 Now in Study 523 it's a little bit different,  
14 you see a different code here which is -2. And what  
15 that means is, if you go back to that picture, in this  
16 study they probably had two patches on their chest and  
17 those two patches at the end of their monitoring event  
18 were combined and analyzed as one sample. So when you  
19 see the -2 code that means in that particular study  
20 you've got one sample for the chest that represents,  
21 you know, both patches that were on their chest.

22 And when you took the average residue loading  
23 for those two patches it ranged from let's say .051 to  
24 .019, or I'm sorry, .04 is the high end of that range,  
25 micrograms per centimeter squared. And again I've

1 tried to hit these on the highlights down here so is  
2 you want to you can refer back to them and kind of get  
3 the general concept of what I was talking about.

4 Along with the monitoring information itself  
5 in the database, the vast majority of these studies  
6 also had inherent in them a fairly extensive level of  
7 analytical quality control and I forget who it was but  
8 somebody this morning had discussed the grading  
9 criteria for the different data and this slide  
10 basically represents how we graded the data based on  
11 the analytical information in various studies.

12 So we should probably, let me introduce kind  
13 of what the things mean. So a laboratory recovery for  
14 example would be a sample that would be intended to  
15 ensure the performance of your analytical method in the  
16 lab. So once you have a sample in the lab it  
17 guarantees, you can see how the performance of that  
18 analytical method, how that analytical method, excuse  
19 me, is performing in the laboratory to ensure that can  
20 actually measure residues that are sitting in a sample  
21 in the lab.

22 And then we also, so what we determined would  
23 be grade A quality data would be that you have a highly  
24 functional lab method where you get essentially  
25 quantitative recovery between 90% and 110%, and that's

1 what we call grade A data for lab recovery. But it  
2 also had to have a little variability associated with  
3 the methodology, so we wanted a CV, a coefficient of  
4 variation associated with that kind of data of 15 or  
5 less. And so then you can see how as you progress  
6 through different grades of data, grade B and C and  
7 such, how we would allow for, you know, less  
8 quantitative recovery and a little bit more variation  
9 with the method.

10 This column here represents what we call  
11 field recovery samples. So essentially in our studies  
12 what we do is we build in a positive control under  
13 field conditions to evaluate if there's actual losses  
14 under field conditions of residues during the  
15 performance of the monitoring of that.

16 Unlike a lot of the I would say more standard  
17 industrial hygiene methods where there's information  
18 around the ruggedness and performance of methods, a lot  
19 of times, you know, it might be one study on a  
20 particular chemical so we dealt with how the methods  
21 perform as far as residue loss and such by doing these  
22 positive controls under field conditions. And so if,  
23 for example 20% of the material would volatilize off or  
24 was lost for whatever reason, you know, it would, you  
25 would have a field recovery of 80% and it would fall in

1 the grade A category, given that you had an adequate  
2 lab method as well. And then you can see how, you  
3 know, we opened up the range of field performance data  
4 there. And in some cases there were studies where they  
5 didn't have it so you automatically got pushed down to  
6 what we call grade C and you would look at storage  
7 stability over here to, and storage stability would be  
8 if you collect a field sample and it's placed let's say  
9 under cold storage or frozen until analysis so we also  
10 want to look at the lifetime of that sample between  
11 collection and analysis to make sure there wasn't  
12 residue lost just due to storage.

13 And you can see over here the preferred  
14 methods. What we'd do, we would use this information  
15 in some kind of combined way. It depends upon again  
16 the design of the study and the data we had available  
17 to correct measured residues, to account for losses and  
18 such of the residues before they were entered into the  
19 database. So this leads to the generic nature of the  
20 database where we're essentially trying to eliminate  
21 the chemical specific nature of the volatilization and  
22 the losses and such from the dosimeters by correcting  
23 for this method performance information. And so it's  
24 important to understand that all the raw, all what you  
25 see is data and the database you've had, that

1 information that you've had to work with is being  
2 already corrected for this kind of results. And  
3 essentially if you dug into the database in sufficient  
4 detail, for each monitoring event record there would be  
5 a piece of information like this that would indicate  
6 how the data were corrected.

7           So again, we've already touched on this a  
8 little bit but the challenge here was, you know, based  
9 on the rejection rate analysis and some of the  
10 historical events that John pointed out, the challenge  
11 for us was to develop a tool that gave us a little more  
12 oomph as far as how we did our exposure assessments for  
13 regulatory purposes. So the thought was to combine  
14 these various studies that we had available into the  
15 generic database, and of course the difficulty in that  
16 approach is compositing studies of various designs and  
17 they will be a lot of discussion about this over the  
18 next couple of days. And for example, one of the  
19 things that, because of the composite approach it makes  
20 it difficult for us to do, you know, straight  
21 distributional analyses because you have different  
22 parts of the body regions have different numbers of  
23 samples associated with them and so on.

24           So this is just what an actual output, this  
25 is an earlier version of the PHED than what Jeff Evans

1 had showed this morning and there's a lot of  
2 information up here but what I wanted to hit in this  
3 part of the discussion was just kind of the key factors  
4 that we would consider in developing a result based on  
5 PHED. So the first thing we would do is we have this  
6 database of 1,700 records or so, but let's say we  
7 wanted to look at mixing/loading as an activity. So  
8 the first thing we would do would be to segment out our  
9 entire database based on only mixing and loading so we  
10 would throw away, not throw away, but we would only  
11 utilize that information for mixing and loading. And  
12 then we had, and you can kind of look at the, follow  
13 the coding here as I go through it, so you can see  
14 mixing/loading right there.

15           And then the next thing we want to do is  
16 let's say we wanted to do an assessment for the dry  
17 flowable type of formulation which is a little granular  
18 material that you would typically mix in some water and  
19 spray it as a dilute spray solution. So you would  
20 again take your mixing/loading data and segment it  
21 based on the fact that it's a dry flowable. And in the  
22 one slide with all the codes on it you would just  
23 select that code. And then you would say, well I want  
24 to look at open mixing and loading so you would do that  
25 as well. And then we want to see within that available

1 data, what do the analytical grades look like  
2 associated with that data? So in this case we had a  
3 lot of data so we were able to only use, you know, the  
4 higher quality A, B grade data if you refer back to  
5 those criteria. So what that, after we did all that  
6 segmentation of the data, essentially it gives you 26  
7 different monitoring events that we could look at for  
8 the purposes of this analysis.

9           Within that analysis as well is, the other  
10 segmentation part would be based on the particular  
11 clothing that the people were wearing. So those 26  
12 records represent somebody wearing long pants and a  
13 long sleeved shirt, but not something like a coverall  
14 as well, or not using an engineering control.

15           So what it does then is, we talked a little  
16 bit about the data in the arrays, it uses the data in  
17 the different arrays to calculate for different body  
18 regions and here's the standard body regions that it  
19 calculates dermal exposures for. You know, the head,  
20 the neck, the upper arms, the chest and so on. It  
21 takes the data from the various disparate kind of study  
22 designs and populates each of these arrays. And so you  
23 can see here that there were 26 total records but you  
24 can see over here that for example head monitoring was  
25 only done on 19 of those records, or neck monitoring

1 was only done on 16 of those records and so on. In  
2 some cases, you know, there are 26 records for the  
3 thighs and the lower legs so that meant in every one of  
4 those monitoring events, you know, patches or some kind  
5 of dosimeter was worn on the thighs and the lower in  
6 every one.

7 And so the key kind of criteria for just  
8 establishing how we do the analyses based on PHED or,  
9 you know, our segmentation criteria and then you  
10 identify the number of records and you look at the  
11 various levels of clothing and protective equipment and  
12 how the populations for the different sampling  
13 locations are populated. The other thing it does is  
14 it, and this is one of the difficulties of combining  
15 data from different studies, it populates an array of  
16 data for each of these locations and it determines the  
17 distribution type for the data within each of these  
18 arrays and it uses Carl, McGarrel, Smirnoff as the test  
19 for doing that. And then when you calculate like a  
20 composite dermal exposure for this particular activity  
21 it picks the most representative central tendency value  
22 and adds them together. For example, for here you'd  
23 see the head, it's lognormally distributed. It would  
24 take the geometric mean and that would be the component  
25 that would be added together to get your composite

1 dermal exposure for the head. And in most cases most  
2 of these data tend to be lognormally distributed. If  
3 it's other it uses the median value. And if it's  
4 normally distributed it uses the mean.

5           So the PHED output I just showed represents  
6 one of the analyses that lead to this document which I  
7 believe Jeff and John already talked about a little  
8 bit. But this is actually a page from our, what we call  
9 our surrogate exposure table that we use for our tier 1  
10 or our standard kind of occupational exposure  
11 assessment. So we would have our 37 different job  
12 tasks that we look at. This is scenario 1 out of 37  
13 and this is dry, and the nomenclature, sorry, speaking  
14 of dry-- the nomenclature here would be, you know, dry  
15 flowable open mixing and loading. And then we have  
16 dermal exposures with different levels of protective  
17 equipment or clothing. And you can see here in this  
18 middle row it would be somebody wearing normal work  
19 clothing with bare hands and this bottom row would be  
20 representative of somebody wearing normal work clothing  
21 with protective gloves on.

22           And then what I just showed you would be,  
23 it's an analysis for the single layer of clothing and  
24 for the head and neck and the remainder of the dermal  
25 exposures outside of the hands. Now the hands are done

1 differently because they're graded separately so we had  
2 to go back and do the separate type of analysis, a  
3 similar analysis for the hands and just separate them  
4 out if we wanted to use the same kind of grades and  
5 such.

6 And then we add them together to get the  
7 total dermal exposure estimate which goes into the MOE  
8 calculation which I showed earlier.

9 And you can see, based on the table, the  
10 previous PHED output when you saw the number of samples  
11 within each of the data arrays, depending upon the  
12 array they range from 16 to 26 and they were all A, B  
13 grade data. So in this scenario we're using pretty  
14 good quality data. And I'll show you as we delve into  
15 the case study information that this really varies  
16 depending upon how the database was populated in each  
17 of the different cells that we created.

18 So we might as well start getting into the  
19 more detailed case study analyses and the purpose of  
20 these case study analyses was really to form kind of  
21 the foundation for the analyses that you will all be  
22 considering over the next few days.

23 And so what we did was pick six different  
24 representative ones and they range in how the  
25 information was populated, so some of them are very

1 heavily populated scenarios, others are not. Some have  
2 good quality grading criteria quality associated with  
3 them and some are more marginal. So what we did, we  
4 picked, and these, if you go back and look through our  
5 surrogate exposure table, these are just the  
6 corresponding numbers to the various scenarios that we  
7 used out of the 37. So we looked at different mixing  
8 and loading scenarios, for example q dry flowables or a  
9 granular material and a granular material might be a  
10 dry material that would be, you know, put in the ground  
11 at the same time as you would plant corn or something,  
12 so there's no spray solution associated with it, it's  
13 loaded and applied as a dry material. And then  
14 liquids, so mixing a liquid to put into some kind of  
15 diluted spray solution and then spray.

16 And then for application we used for this  
17 example, this case study we looked at air blast  
18 applications with both open and closed cab tractors and  
19 we looked at the application of solid materials through  
20 what we call solid broadcast spreaders.

21 DR. HEERINGA: Jeff, before you proceed,  
22 Doctor Portier had one question of clarification which  
23 he thought might be good to ask.

24 MR. DAWSON: Sure.

25 DR. PORTIER: Yeah, before you get too far

1 I just wanted to clarify a few things. When you, back  
2 on slide 12 you have the biometrics for the person.

3 I'm assuming that's all male measurements, right?

4 Chest size--

5 MR. DAWSON: It's actually representative  
6 of the general population.

7 DR. PORTIER: Okay, is this in Haines'  
8 data?

9 MR. DAWSON: I believe it may have been,  
10 it was the, it may have been in Haines but I have to  
11 kind of clarify that.

12 DR. PORTIER: Yeah, because you didn't  
13 have a reference on that.

14 MR. DAWSON: Yeah.

15 DR. PORTIER: And then on slide 19--

16 MR. DAWSON: It was the, it was definitely  
17 the data in the original version of the exposure  
18 factors handbook, whatever the source of that was at  
19 the time.

20 DR. PORTIER: It was something like the  
21 1980, in Haines 1.

22 MR. DAWSON: Right, right.

23 DR. PORTIER: If anything--

24 MR. DAWSON: Right.

25 DR. PORTIER:-- the '79 data.

1 MR. DAWSON: I think that is correct.

2 DR. PORTIER: On slide 19 you were talking  
3 about, that's dose sample, so for example you would  
4 have a patch, you'd dose the patch, then you put it on  
5 the person and then it--

6 MR. DAWSON: No--

7 DR. PORTIER:-- stays there?

8 MR. DAWSON:-- no, no, they would, these  
9 would be the actual exposure measurements. So we would  
10 put the sample on the person, they were going to go out  
11 and do whatever they did and then we would collect it  
12 at the end of whatever they did and we would--

13 DR. PORTIER: Oh, that's fine.

14 MR. DAWSON:-- we would analyze that to  
15 see how much exposure they would get to the skin.

16 DR. PORTIER: Oh, I'm sorry, then it's the  
17 next slide then.

18 MR. DAWSON: Okay.

19 DR. PORTIER: I was talking about the--

20 MR. DAWSON: Yeah, yes--

21 DR. PORTIER:-- the recovery, the field  
22 recovery stuff, I wasn't quite clear what--

23 MR. DAWSON: Right.

24 DR. PORTIER:-- that really meant.

25 MR. DAWSON: Field recovery specifically?

1 DR. PORTIER: Yeah.

2 MR. DAWSON: So field recovery  
3 specifically is intended to quantify the residue losses  
4 from the dosimeters that you're using under actual  
5 field monitoring conditions. So it would be  
6 essentially a set of positive controls set aside under  
7 field monitoring conditions so it would be essentially  
8 a set of positive controls set aside under field  
9 monitoring conditions so let's say to evaluate if the  
10 humidity or the temperature or the sunlight of those  
11 conditions caused the residues to degrade or be lost or  
12 whatever from the samples.

13 DR. PORTIER: So they're just sitting on  
14 the side.

15 MR. DAWSON: Right.

16 DR. PORTIER: And then they go in with the  
17 batch as a control process.

18 MR. DAWSON: And there are various, some  
19 people would have it where people would walk around  
20 with, you know, positively spiked samples or something  
21 on them. It just, it varied depending upon the, on how  
22 the actual individual investigators would design their  
23 studies.

24 MR. PRESENT: And then one more. On slide  
25 22, how were non-detects handled in this? When you

1 have an observation number is that numbers of detected  
2 or the numbers of--

3 MR. DAWSON: It's just that there was a  
4 sample.

5 DR. PORTIER: Okay.

6 MR. DAWSON: And so if you go back to the  
7 slide with the data, I forget the number-- click back a  
8 couple.

9 DR. PORTIER: 19?

10 MR. DAWSON: Yes, that one, that one. So  
11 here you can see these were listed as a non-detect so  
12 basically for the purposes of this database we used  
13 half the detection limit.

14 DR. PORTIER: Right.

15 MR. DAWSON: And we understand clearly  
16 that, you know, the use of censored data is an issue  
17 and that's one of the issues we want to try to address  
18 in the future to do a better job with that.

19 DR. HEERINGA: Thank you very much, Jeff.  
20 I guess we have one more question. Doctor Johnson  
21 please.

22 DR. JOHNSON: Thank you. I didn't quite  
23 understand the -2. I thought you were going to say  
24 that the -2 represented two samples and non-detects in  
25 both, but you never mentioned non-detects in both.

1 MR. DAWSON: No, the -2 would just be that  
2 there would be two patches, one on the chest and the  
3 investigators at the end of the monitoring event would  
4 take both those patches and combine them. So you would  
5 just, this was just so we could track that both  
6 locations on the chest were monitored but you end up  
7 with only one result. And if there was a non-detect in  
8 one of those patches we would have, when we entered the  
9 data, taken half the detection limit kind of by hand  
10 and combine that with the measured residue and put it  
11 in.

12 And if they were both non-detects I think we  
13 would have given it a -1 code.

14 DR. LEVINE: There's a -1 in the first  
15 column up there.

16 MR. DAWSON: Right, but he's talking about  
17 these where it's -2's and how we--

18 DR. LEVINE: When you were talking about  
19 the -1 were you talking about the -1 in the first  
20 column as opposed to the second column?

21 DR. HEERINGA: Doctor Levine you have to  
22 turn your microphone on please.

23 DR. LEVINE: Does the -1 above the -2  
24 indicate that there was only one sample for those?  
25 It's a different kind of descriptor? I think that's

1 what was confusing me too.

2 MR. DAWSON: It's a different descriptor,  
3 so each row is an individual and the data associated  
4 with an individual. So in this particular case let's  
5 say this individual there were two patches worn. The  
6 patch on the left forearm was non-detected but the  
7 patch on the right forearm had a measurable residue in  
8 it.

9 DR. LEVINE: It's very confusing.

10 DR. JOHNSON: And that could go down to  
11 the next individual?

12 MR. DAWSON: Right, and that's where I'm  
13 headed next. On this individual they had two patches  
14 that they wore on their chest. And so the -2, and at  
15 the end of the monitoring event those two patches were  
16 combined and analyzed as one sample instead of  
17 individually.

18 DR. JOHNSON: Okay, so that's on the left  
19 arm, right?

20 MR. DAWSON: It's just, it's just recorded  
21 that way. So when the database would calculate it, it  
22 would see this code in it and say, oh, I have it  
23 combined so I have to extrapolate that to the whole  
24 body surface area for that region of the body. So that  
25 was the purpose of the coding.

1 DR. JOHNSON: So it doesn't have anything  
2 to do with the amount that was there?

3 MR. DAWSON: Well, and then the -2 has  
4 nothing to do with the amount that's there. And then  
5 here, when those two samples are added together and  
6 analyzed, the amount of residue that impinged on them  
7 was .0023 micrograms per centimeter.

8 DR. JOHNSON: Right. I think some of the  
9 confusion is though, the one column is labeled as the  
10 right arm and the other column is labeled as the left  
11 arm.

12 MR. DAWSON: I understand, it's just these  
13 are taken directly from the database.

14 DR. JOHNSON: So would there be two right  
15 arm columns?

16 MR. DAWSON: No. Just one. It's just--

17 DR. JOHNSON: So what if the left arm then  
18 had something that was detected on two patches? What  
19 would be recorded?

20 MR. DAWSON: But you would have a patch on  
21 the left and the right arm. Or if, we typically didn't  
22 see where they would have two patches on the right arm.  
23 It would be one patch to monitor the right arm.

24 DR. HEERINGA: This is a pooled measure of  
25 both arms and they just use the data convention to

1 record it in the column for the left arm, even though  
2 it is a pool across left and right arms, is that  
3 correct?

4 MR. DAWSON: Correct.

5 DR. JOHNSON: Okay.

6 MR. DAWSON: Okay.

7 DR. HEERINGA: So there are a number of  
8 data conventions in this database that you have to  
9 understand. You can't just go into these columns and  
10 analyze them.

11 MR. DAWSON: And the reason we wanted to  
12 point this out for you all is that trying to go through  
13 this kind of cold is very difficult.

14 DR. HEERINGA: Okay.

15 DR. JOHNSON: Right.

16 DR. HEERINGA: Well this has been very  
17 useful.

18 DR. JOHNSON: I've got one more question.

19 DR. HEERINGA: Okay.

20 DR. JOHNSON: Dallas Johnson again. On  
21 the coefficient of variation on slide 22, was that  
22 calculated in terms of the raw units or was that  
23 calculated in terms of the log units?

24 MR. DAWSON: That's a good question.

25 DR. JOHNSON: It might correspond to the

1 geometric mean.

2 MR. DAWSON: I don't believe it  
3 corresponds to the geometric mean but I'll have to  
4 figure that out and let you know later. I don't know  
5 that answer off the top of my head.

6 DR. JOHNSON: Okay, thank you.

7 MR. DAWSON: It is raw data, I'm hearing  
8 from the gallery.

9 DR. JOHNSON: Thank you.

10 DR. HEERINGA: I have a few more  
11 questions, I want to make sure we let--

12 MR. DAWSON: Absolutely.

13 DR. HEERINGA:-- Mr. Dawson get on with  
14 his presentation but Doctor Landers and then Doctor  
15 Pependorf.

16 DR. LANDERS: Can you tell me, do you have  
17 a way of ensuring that the workers in the case studies  
18 are actually licensed sprayer operators or are they  
19 sometimes research workers who may have a different  
20 technique as opposed to a full time employee?

21 MR. DAWSON: In the database there are,  
22 there is actually a coding criteria where we try to  
23 ascertain the level of experience associated with the  
24 different workers. Some in fact were licensed PCOs. I  
25 would say the vast majority of those who were monitored

1 were let's say a grower who's treating their own farm.  
2 And we tried to evaluate let's say if they were, you  
3 know, we tried to identify their level of experience  
4 and, you know, who their employer was and those kind of  
5 things to make that known. And there's a series of  
6 comment fields in there as well but you could go  
7 through and try to look at it.

8 DR. HEERINGA: Doctor Popendorf.

9 DR. POPENDORF: Yeah, I was noticing in  
10 the last slide, number 23, the glove for the hand data,  
11 with and without gloves, and perhaps you will be  
12 commenting on this later, but I thought it was maybe in  
13 the context of limitations, the fact is that you're  
14 showing, or the data shows more exposure with a glove  
15 slightly than without a glove. And is that important?

16 MR. DAWSON: As you know there's a lot of  
17 variability associated with this and so what you're  
18 seeing is that variability inherent in these results.  
19 So I would suspect if you increase the sampling  
20 intervals that you would, you know, you would probably  
21 see a better delineation between the use of gloves and  
22 not. It's just, it's reflective of the data we had to  
23 fill this scenario.

24 And one of the other issues that we're going  
25 to talk about is that censored data in this particular

1 data set becomes important because you can see there's  
2 a note here that in one, in a couple of these studies  
3 that they had relatively high limits of quantification  
4 for the glove hands unfortunately, and that appears to  
5 be skewing this result a little bit. So censored data  
6 for this particular analysis is important to consider.

7 DR. HEERINGA: Doctor Bucher.

8 DR. BUCHER: I was just wondering, when  
9 this data set was put together were you relying solely  
10 on interpreting reports that were submitted to you or  
11 was the database in some way, was there an effort to go  
12 back and try to fill in missing information?

13 MR. DAWSON: Absolutely, we went through a  
14 rigorous process with the varying agencies and the data  
15 generators. So we would, the way it worked would be,  
16 first of all we would review the report and try to  
17 populate the database fields as much as we could to the  
18 extent we felt reasonable. And then we would go  
19 through as a joint effort and identify the missing data  
20 fields and actually issue letters and call backs to the  
21 individual investigators and try to populate this  
22 database as extensively as we could.

23 But like I said, and this took five, seven,  
24 eight years to do this and even with all that level of  
25 effort there were still some data fields that we could

1 not, you know, fill.

2 DR. HEERINGA: Thank you very much. I  
3 think we've gotten our feet wet or our hands dirty so  
4 to speak and there will be plenty more questions of  
5 this nature I'm sure.

6 So if you would proceed Jeff with the  
7 discussion of the six scenarios.

8 MR. DAWSON: Okay.

9 DR. HEERINGA: We'll return to questions  
10 after that.

11 MR. DAWSON: I daresay you got some  
12 exposure.

13 So the case, the specific case studies that  
14 we selected, we looked at these 6 different scenarios,  
15 and again they are 6 of the 37 that we have in our  
16 surrogate guide.

17 And what I tried to illustrate on this slide  
18 is that the, how the data are, how or what data are  
19 available for each of those specific scenarios. So you  
20 can see here for scenario 1, and we'll talk about  
21 scenario 1 in more detail to kind of illustrate a  
22 little bit more about the kind of data questions that  
23 we've just talked about. But there were 6 different  
24 studies and 28 different monitored subjects, but there  
25 were 50 monitoring events so that means that a lot of

1 subjects, for a lot of subjects there were repeat  
2 measurements.

3 And then for the granular loading there were  
4 8 studies, 48 subjects and 96 monitoring events.

5 For liquids and mixing/loading, 43 studies  
6 and this is probably our heaviest populated scenario  
7 that we have, 146 different subjects but 271 monitoring  
8 events.

9 And you can kind of follow this as we go down  
10 here where you can see 14 studies for air blasts with  
11 open cab, 39 subjects but 91 events. And you can see a  
12 lot of disparity here with number 14, 2 studies, 2  
13 subjects, 5 events.

14 So in this particular there was 1 subject  
15 that was monitored once and 1 that was monitored 4  
16 times.

17 And these data, the data for the case study  
18 really represent about 25% of the total database that  
19 we have to work with.

20 And the next few slides just kind of  
21 illustrate in a physical sense for those of you that  
22 don't have background in this area, what we mean by the  
23 nomenclature, so this slide represents, you know, open  
24 mixing and loading of some kind of granular or solid  
25 material so you can see this powder flying around up

1 there. And basically what we mean by open loading is,  
2 you know, there's no barrier between the material  
3 itself and the individual as they are doing this  
4 process. So it would be like you opening a bag of  
5 flour and dumping it into a tank.

6 And I mean we could call it closed loading if  
7 there was some kind of, you know, closed container with  
8 a valve or something. You could slap on a coupling or  
9 something and open it and it would go in. So you would  
10 eliminate, you would, I'm sorry, you would put a  
11 barrier between yourself and the chemical at that  
12 point.

13 And then this slide just represents what we  
14 call air blast application, you know, some kind of  
15 orchard tree here, an apple or something, and this is  
16 an open cab tractor clearly and an air blast sprayer.  
17 And so you have a tank of spray solution and some kind  
18 of engine and in the back here there is an array of  
19 nozzles and there's a large fan like essentially an  
20 airplane propeller kind of thing that sucks air into  
21 the back of this machine and then it blows it out at  
22 100 or so miles an hour across the nozzle banks that  
23 forces the spray into the canopy of the trees.

24 And then this slide just represents what we  
25 call a solid broadcast spreader. So here you'd be

1 putting a granular material in this hopper along with  
2 your seed and fertilizer and you'd be, you know,  
3 creating furrows as you drug the implement across the  
4 field and that's how you'd apply the pesticide. And in  
5 this particular scenario, I apologize we didn't have a  
6 good picture for that open cab which we're doing in the  
7 case study but this would be like a closed cab solid  
8 broadcast spreader scenario. That's what's represented  
9 by this picture.

10 So now the next couple of slides really  
11 illustrate some of the various specifics of the data  
12 from the case study. And as I said earlier, scenario 1  
13 has six different studies, 1, 2, 3, 4; 5, 6. The way  
14 we've coded them for example is this is Study 460 and  
15 this is Study 502 and so on. And what each of these  
16 pictures represents is the sampling regimen that was  
17 employed in that particular study. So you can see  
18 here, these are the actual, these are representations  
19 of the actual data that we're using to collect, that we  
20 have, I'm sorry, that we have available for us for  
21 assessing open mixing and loading exposure to dry  
22 flowables.

23 So we had our 6 studies and if you go back to  
24 that initial table with the monitoring events, there  
25 are 50 monitoring events for this scenario, so in this

1 one there were 16 people, 16 monitoring events, I'm  
2 sorry, that were, where the samples were collected in  
3 this way and I'll get to what, how the sampling  
4 regimens meet in a second. And then there were 10  
5 people that were monitored in this regimen, 8 people  
6 that were monitored with this one and so on.

7 And then the little dots here represent the  
8 use of the patch method and if the dots are red that  
9 means they were kept separate for the purposes of  
10 integrating them into the, they were kept separate for  
11 the purposes of the analysis. And so what the  
12 investigators did at the end of the monitoring period  
13 they would say collect this chest patch and analyze  
14 that individual chest patch separately. So that would  
15 be the information that we'd integrate into the  
16 database.

17 And in this particular, let's say Study 460  
18 there was 1 chest patch and then there was-- I'm sorry,  
19 I'm not reading this correctly-- yeah, there was 1  
20 chest patch and then there was a patch on the upper and  
21 the lower arms and so on. So you can see they were on  
22 the thighs and on the lower legs and one on the head.

23 And then if it's H, that means the method for  
24 hand sampling was some kind of washing method and you  
25 can see that all of-- I'm making sure I'm reading my

1 codes right-- that all these different studies were  
2 collecting hand exposures with some kind of wash  
3 methods. And then the P here or the B here represents  
4 whether or not they wore some kind of protective gloves  
5 over their hands. So in 5 of the 6 studies here they  
6 wore some kind of protective glove over their hands.  
7 In this one study they had, they were working with bare  
8 hands.

9 And WBD represents the use of whole body  
10 dosimetry. So in this particular study they wore like  
11 a long sleeved t-shirt under their clothing which was  
12 collected and analyzed as a whole sample along with  
13 pants. In this particular study I would suspect what  
14 they did was have like a total body suit or something  
15 that was collected and analyzed.

16 In this particular study here, 10002 and  
17 1,000 as well, there was some kind of amalgam of the  
18 two methods where you had like a whole dosimeter which  
19 was a, the way they did it here was a short sleeved t-  
20 shirt with, you know, here they used a wiping method on  
21 the forearm. So there's various, the point here is  
22 that, just to illustrate there's various ways that  
23 investigators chose to collect this kind of information  
24 and this slide illustrates that diversity.

25 And so, and if you go up here you can see

1 that there are different, a little bit more description  
2 around the different methods. For example here in 460  
3 they used gauze patches with an ethanol handwash. In  
4 0502 they used gauze patches with a methanol handwash.  
5 And here they used a combination of wiping, whole body  
6 dosimeters, gauze patches and a soap solution for their  
7 handwash.

8 But they way we use the, the way we created  
9 the database is we've added all these data points  
10 together and essentially treated them similarly.

11 So if we go into the next, and I'm sure  
12 you'll all have some questions around this but just  
13 basically, the same kind of illustrations for a couple  
14 more of these and this is open loading granules. Here  
15 there were 8 studies and within these 8 studies there  
16 were 96 different monitoring events and here closed cab  
17 air blast applications. There were 4 studies with 32  
18 monitoring events.

19 And I have to, can we slip back to slide 26  
20 for just a minute? I forgot to mention this earlier.  
21 There is an error on, for scenario 12 the numbers here  
22 are incorrect, they're duplicated from number 1 so  
23 basically it's 4 here and 19 here and 32 here for slide  
24 12. I apologize for the error and not mentioning it  
25 earlier.

1           So again it's 4, 19 and 32 and what made me  
2 think of it was getting to that descriptor of the  
3 graphics. So that was slide 26 and it's scenario 12  
4 and it's 4, 19 and 32.

5           And then no need to beat a dead horse, I mean  
6 you can see for open mixing and loading there were 43  
7 different studies so you can imagine what the  
8 combination of various techniques must look like for  
9 this. And air blast open cab, 14 studies, a little  
10 more palatable. And for the granular open cab there  
11 were only 2 studies but only 5 monitoring events so  
12 it's simpler to deal with there. But of course you  
13 don't have as much data to work with clearly.

14           Along with, so getting to the raw data and  
15 the kinds of data that we collected in general for  
16 these studies, it's kind of general information which  
17 is the quality and number of workers et cetera that  
18 we've already talked about, various exposure factors,  
19 information, for example how much chemical they  
20 handled, the weather conditions that were present  
21 under, during the monitoring events, the various  
22 sampling parameters. And then the monitoring data  
23 themselves, you know, dermal exposures for different  
24 regions, air levels and so on.

25           So just, and if you go through and do this

1 for any of the scenarios that we have but we'll just  
2 take one which is the dry flowable mixing and loading  
3 at this point. So again there were 6 different  
4 studies, 28 subjects and 50 different events. But when  
5 you look at how many subjects were involved in multiple  
6 monitoring events, what I found that there were 9  
7 different subjects that were involved, monitored  
8 multiple times and the range for those subjects was  
9 from 2 to 5 monitoring events per person. And then  
10 when you, how we used the data, we had a lot of data  
11 for this particular scenario so we culled it or we  
12 segmented it based on the grading criteria and the  
13 results that were available from the studies.

14 And so, I don't know if you remember or not  
15 but I'll show this again in a second, you know, we had  
16 grade A and B dermal data with 26 different monitoring  
17 records. And for the hand data, and this we'll just  
18 focus on the use of protective gloves at this point,  
19 for grade A and B data we ended up with 21 different  
20 records that we used for that analysis.

21 And these data were collected between the  
22 years 1985 and 1991 in six different states, Canada and  
23 Australia. And again you could do this kind of, pull  
24 out this information for any of these analyses.

25 And as I showed earlier on this slide the

1 monitoring regimens were quite varied. You know,  
2 patches in different combinations of whole body  
3 dosimeters, et cetera.

4 Just a few illustrations of the kinds of  
5 information you can get. So for example the products  
6 handled in these monitoring events, again there were  
7 50, they range from 25% to 85% weight/weight  
8 concentration and just that simple mean was, you know,  
9 55%. In some cases they handled between 1 and 9 tank  
10 loads but the mean was around 4 tank loads for each  
11 monitoring event. Sorry. For the total amount applied  
12 it ranged from 2.3 to 440 pounds of active ingredient  
13 and the mean was around 56 pounds. And again this is a  
14 key criteria for us because this is what we used to  
15 develop our normalized unit exposure estimates, the  
16 pounds handled.

17 Just a little bit on the sampling conditions.  
18 The weather was quite varied depending upon the nature  
19 of the application, from low to high humidity, you  
20 know, low, relatively low to high temperature  
21 conditions, you know, and typical wind speeds and such.  
22 And the, another key component that we look at quite a  
23 bit is exposure duration from, the mean was about 3  
24 hours or so for all those data up to about 8.1 hours is  
25 the maximum. The screening levels, we talked a little

1 bit about censored data. The mean screening level for  
2 the limited detection was .013 micrograms per  
3 centimeter squared, keeping in mind what a microgram is  
4 which is like .00, whatever to a pound so it's like 10  
5 to -9 pounds to give you some perspective about those  
6 screening limits.

7 And then the hands, the mean LOD was 23  
8 micrograms per sample and two of these studies had very  
9 high limits of detection. And if you recall, somebody  
10 asked about the, why there were differences between the  
11 gloved and, or why the gloved and the non-gloved hands  
12 looked pretty similar, and this is one of the reasons  
13 why because of the censored data.

14 Just kind of a little bit about the exposure  
15 monitoring data, we showed the, what the individual  
16 records look like a little bit. For the, let's say  
17 bare head patches we had, of the 32 monitoring events  
18 of the 50 they actually measured samples on the head, 3  
19 of those were non-detects and the residues ranged up to  
20 25.7 micrograms per centimeter squared. Bare hands,  
21 there were no non-detects as you might expect when  
22 you're mixing and loading a concentrated product and  
23 the range were, the measured residues ranged from 58 to  
24 930 and so on.

25 And the just more of the same where we pulled

1 out data from different arrays. The thing to take away  
2 from this slide is that on a lot of these studies there  
3 were whole body dosimeters so if you actually went in  
4 and looked at the data you'll see this number. Well a  
5 lot of the numbers look similar and that's basically  
6 how we, they would be the same let's say for if you  
7 wore a whole body dosimeter on your legs you would see  
8 the data from the thighs and the ankles where it would  
9 basically calculate an estimate, an average estimate  
10 over that whole body surface area and that's how we  
11 integrated it into the database. So people had  
12 questions about that. That's why it looks that way.

13 And then just a little bit about, you know,  
14 we talked about all these kind of generic field of  
15 information that are available in the PHED outputs and  
16 this is just the specifics for this example of how we  
17 calculated the exposures. As I said it creates a data  
18 array for each of the body regions and we're picking  
19 the best estimate of central tendency and adding them  
20 together and this slide just illustrates the mechanics  
21 of that process. So, you know, our 11.9921 comes from  
22 here, it's the geometric mean, it's lognormal and all  
23 these geometric means, add them together and this is  
24 the amount of the unit exposure estimate for the head  
25 and neck component of the dermal exposure.

1           And for here, for the rest of the dermal  
2 exposure it would add the geometric means and then take  
3 the median for the back estimates. And add them  
4 together and you can see .0186 and .0382 and if you  
5 flip the slide-- and these translate into our surrogate  
6 table that we use for assessments. The .0186 and the  
7 .0382, and that's under, you know, one layer of  
8 clothing.

9           And then I just put this slide in to kind of  
10 illustrate-- you could go crazy and create all  
11 different kinds of graphical analysis with the  
12 different data, I'm just downloading it in the database  
13 and so I, this is just one illustration of a possible  
14 way that you could, you know, present the data. And so  
15 this is exposure in micrograms on the hands and this is  
16 with protective gloves for that scenario. So you can  
17 see, you know, micrograms per both hands added together  
18 and then this is the amount of active ingredient mixed.

19           And we're going to have a lot of discussion  
20 over the next couple of days about linearity and  
21 extrapolation of the data and those kinds of things and  
22 this is to just kind of introduce that topic.

23           And so just kind of wrapping up here, issues  
24 and limitations, you know, the key issues we kind of  
25 want to address over the next few days are related to

1 PHED and the use of these data in general are, you  
2 know, how do the sampling methods perform? Is there a  
3 systematic bias for example associated with the  
4 sampling method? Particularly on the hands. That's  
5 become a, it's become a, it's a controversial topic for  
6 us. And, or are there breakthrough and losses under  
7 field conditions for the various dosimeter regimens  
8 that we use? And another factor is you can see how  
9 various scenarios where the population of the data  
10 varied quite a bit for the various scenarios. So we  
11 want to, as we move forward in trying to develop, you  
12 know, new information that's going to carry us for the  
13 next, you know, several years, we want to make sure  
14 that we get adequate sample sizes to go with that and  
15 we need to define and develop a statistical sampling  
16 plan that we all can live with.

17 And some of the key limitations and hopefully  
18 some of these have been fairly evident based on the  
19 nature of the presentation, but you know, for example  
20 on the dry flowable one, you know, the data were 1985  
21 to 1990 or so, so they may be some modern practices  
22 that we haven't, we don't have information for, like  
23 for example the use of induction bowls or certain newer  
24 thoughts on the use of engineering controls and such.  
25 We also wanted to try to move away from the clustering

1 kind of concept that you see in the data. For example,  
2 that one table that I showed where everyone handled  
3 essentially the same amount of active ingredient and  
4 try to develop a broader range of information to  
5 represent the variety of situations you see in  
6 agriculture.

7           And then of course we wanted to look at this  
8 inter and intra-personal variability and that's kind of  
9 the reason why I showed that one example where there  
10 was, you know, one study where on individual was  
11 monitored four times but then in the same scenario  
12 there was a study where four different individuals were  
13 monitored.

14           And you know, the disparity of the sampling  
15 design kind of speaks for itself so we want to try to,  
16 we know that's a limitation, we want to, you know,  
17 address that. I guess our optimal thought would be to  
18 kind of really standardize the monitoring methodology  
19 but we want to make sure it performs appropriately.  
20 And then we want to ensure that our limits of  
21 quantification and such are consistent, A, with our,  
22 what we need, where we need to be from the hazard and  
23 risk assessment perspective but also to eliminate the  
24 concept of censored data as much as we can from this  
25 type of results.

1           And so in summary, you know, the six  
2 scenarios from PHED are really the cornerstone of the  
3 analysis that have been conducted in preparation for  
4 this meeting. Hopefully I've, in a short way,  
5 illustrated the passive dosimetry methods and kind of  
6 how we use the data, I'm sure you all have a lot of  
7 questions and try to begin to illustrate some of the  
8 limitations of these data.

9           DR. HEERINGA: Thank you very much Mr.  
10 Dawson. At this point we'll turn to the panel to see  
11 if there are any questions of clarification. Yes,  
12 Doctor Bucher.

13           DR. BUCHER: So all of these various  
14 design differences in these studies have been pointed  
15 out and have been presented primarily as limitations in  
16 putting together a combined database, but I was  
17 wondering whether in fact the Agency has looked at  
18 these design differences as potential advantages in  
19 that the particular physical chemical characteristics  
20 of say a chemical or a pesticide that is water soluble  
21 might, you know, a handwash with water might, or a  
22 soapy solution might in fact be appropriate whereas an  
23 alcohol solution might not. I mean has there been that  
24 level of thought given to these various reports in  
25 terms of combining data?

1 MR. DAWSON: We're certainly aware that's  
2 an issue and that's part of the controversy in the  
3 discussion that's developed over the last few years.  
4 And I think it's led us to this point. I think one of  
5 the actual charge questions for tomorrow or the next  
6 day is focused on this very issue where we've tried to  
7 summarize the kind of information that are available in  
8 the literature around this issue and kind of open it up  
9 to you all to, you know, consider.

10 For example, one of the possibilities we were  
11 thinking of was adjusting based on the log KOW of the  
12 particular active ingredient. At the same time looking  
13 at the reality of how the methods perform under the  
14 field conditions, which is another element of the hand  
15 assessment that we'll be talking about tomorrow.

16 DR. HEERINGA: Other questions from panel  
17 members at this point? Doctor Johnson.

18 DR. JOHNSON: Yes, on the summary  
19 statistics for like the head and neck and hand and so  
20 on, are those then, are the numbers shown like in slide  
21 40, adjusted for the area of that particular part of  
22 the body?

23 MR. DAWSON: Yes. So for example if you  
24 look at let's the head and the geometric mean of 12  
25 basically, when the data are created in that array they

1 are created in such a manner where it represents the  
2 residue loading over that entire body region, so it's  
3 already be calculated and adjusted for from the patch  
4 and the standard surface area to populate that array,  
5 to get that total per region.

6 DR. JOHNSON: Thank you.

7 DR. HEERINGA: Yes, Doctor Lu.

8 DR. LU: You showed slides in terms of how  
9 the whole body dosimetry are being processed are sample  
10 collection.

11 MR. DAWSON: Correct.

12 DR. LU: Segmentation and so on and so  
13 forth. Since this is going to be used exclusively in  
14 the task force proposed studies, is there a standard  
15 operating procedure in terms of how the whole body  
16 dosimetry are being, will be processed?

17 MR. DAWSON: Yes. I'm sure that that  
18 could be provided if you wanted to look at it, right.

19 DR. LU: Okay.

20 DR. HEERINGA: Doctor Kim.

21 DR. KIM: Slide 30, in some of the  
22 placement of the patches is the front and back  
23 distinction made? Like are there any placed on the  
24 back as well as the front?

25 MR. DAWSON: Yes, in some studies they

1 would place them on the back as well. And you'd be  
2 interested in that, for example, you know, the picture  
3 of the air blast applicator you're really interested in  
4 the back and the neck and the head because of the way  
5 that that application method is, you know, putting a  
6 lot of spray right up in the air right behind you with  
7 an open cab. So we definitely, those kinds of studies  
8 they would have definitely done that as a monitoring  
9 event.

10 DR. HEERINGA: Yes, Doctor Chambers.

11 DR. CHAMBERS: Are you weighting the data  
12 for the quality or are you just rejecting the poor  
13 quality data?

14 MR. DAWSON: When we created the surrogate  
15 table we tried to segment the data based on data  
16 quality and we opted to, you know, prefer to use the  
17 grade A and B quality data when we did it. But if you  
18 go and look through the surrogate table which I think  
19 was provided as background information, you can clearly  
20 see that for some situations like the one where there's  
21 5 monitoring events, you know, that's clearly not as  
22 good a quality data as what we could have, but it was  
23 the only available data for that particular scenario so  
24 that's why, you know, we ended up using it.

25 So we tried to, as we do the risk

1 assessments, try to provide that as a characterization  
2 piece that travels along to the risk managers to let  
3 them know, look hey, you may have an issue here. If  
4 your risks are kind of marginal or something we may  
5 need additional data to help us clarify this or  
6 whatever it might be. And that ties into the tiered  
7 approach that John was talking about earlier.

8 DR. HEERINGA: Yes, Doctor Barr.

9 DR. BARR: This is kind of a followup on  
10 Jan's question and that's, were similar methodologies  
11 used for most of the analytic values that were  
12 presented? I mean I know that you gave whether or not  
13 surrogate, or whether or not the recoveries were within  
14 an established range and whether or not the CVs were  
15 within an established range. But were the methods  
16 similar enough so that those CVs and recoveries could  
17 actually be comparable?

18 MR. DAWSON: No, and that's one of the  
19 drawbacks of this, of these data where essentially, you  
20 know, it could be HBLC, it could be GC, it could be all  
21 different varieties depending upon the nature of the  
22 active ingredient and the nature of trying to extract  
23 residues from the sampling media. And they're actually  
24 more difficult than you might think because of sizing  
25 agents and such and you're screening at such low

1 levels.

2 DR. BARR: Was that taken into  
3 consideration when you were grading the data as well?

4 MR. DAWSON: Just based on the-- yes, and  
5 in the guidelines we have criteria for what we'd like  
6 to see as far as the minimum amount of the various  
7 aspects of the quality control. So we want so many  
8 method validation samples at different levels so we get  
9 a range of performance across, for each media and so  
10 on. And then we want, it's the same way with the  
11 analytical, I mean, I'm sorry, the lab recoveries, we  
12 want a range of sampling on the spiking levels so we  
13 can evaluate the performance of the method over a range  
14 of loading rates and such.

15 DR. HEERINGA: Jeff, I have a question  
16 which I'm sure will come up but I wanted to ask it in  
17 this context because it relates I think to how these  
18 scenarios are used in the regulation process.

19 Are there warnings or some sort of indication  
20 to the recipients of these analytic outputs on the  
21 numbers of observations that fell below the limit of  
22 detection? There's an issue of potential mixtures of  
23 distributions as opposed to a continuity of  
24 distributions and I think that I don't-- you may be  
25 aware of it but the SAP has gone through a lot of these

1     distributional issues, I know Peter and Ken have been  
2     party to that with the OPP's pesticides on food residue  
3     database--

4                     MR. DAWSON: Right.

5                     DR. HEERINGA:-- there's a lot of  
6     commonalities in some of the, at least the data issues  
7     here. With regard to that limit of detection, is there  
8     any sort of flag or do people typically proceed with  
9     these averages using 50% LOD on the non-observed or low  
10    limit?

11                    MR. DAWSON: Essentially how we built the  
12    database was, I mean, and keeping in mind it was built  
13    in 1990 or something--

14                    DR. HEERINGA: Sure.

15                    MR. DAWSON:-- it was half the LOD if we  
16    could obtain and half the LOQ, it just depended upon  
17    the nature of the results that were reported. And as  
18    far as flagging individual samples, for example what we  
19    tried to show, and if you recall in that one example  
20    with dry flowables, and I forget the slide, you could  
21    really see how the higher levels of detection were  
22    skewing, possibly skewing that result--

23                    DR. HEERINGA: Uh-huh.

24                    MR. DAWSON:-- which I think was Will  
25    Pependorf's question about why were the gloved and the

1 un-gloved hands so similar? And it could be, it could  
2 be it was inherent in the variability but it also could  
3 be the fact that the results for the gloved hand was  
4 being driven by the limit of detection--

5 DR. HEERINGA: Uh-huh.

6 MR. DAWSON:-- because they're relatively  
7 high compared to the other sampling media.

8 As far as conducting a specific analysis  
9 using this tool you could get down to the individual  
10 sample level but it would, it would just take some  
11 work--

12 DR. HEERINGA: Right.

13 MR. DAWSON:-- because of the tools. And  
14 you probably realized looking at the data set, it's  
15 fairly cryptic, the work was so, it could be done, it  
16 would just take a lot of effort.

17 DR. HEERINGA: The other question I have  
18 just relates to-- and again I think maybe it's, can  
19 defer for later, but if I look at the graph on page 42,  
20 the way I read that, it looks like glove failure to me  
21 in about three cases. And, but we just accept this  
22 data as sort of part of the distribution and it's  
23 modeled again sort of in the same straightforward  
24 fashion, right?

25 MR. DAWSON: Right, and our perspective

1 was, even though let's say that 1,200 value, could well  
2 indeed be glove failure.

3 DR. HEERINGA: Or somebody could have  
4 poured something inside?

5 MR. DAWSON: Right. But our, we didn't  
6 censor data based on that at all.

7 DR. HEERINGA: Sure, okay.

8 MR. DAWSON: It is, it just is what it is.

9 DR. HEERINGA: Yeah, that's fine.

10 MR. DAWSON: Right.

11 DR. HEERINGA: I appreciate that. Any  
12 other questions of clarification at this point? Yes,  
13 Doctor MacDonald.

14 DR. MACDONALD: Yeah, how well do these  
15 patches work over a long period of time? Do they  
16 saturate or shed or do they just continue to absorb the  
17 material?

18 MR. DAWSON: For the most part the amounts  
19 of actual volume that are deposited, when you see  
20 something like 25 or 40 microgram per centimeter  
21 squared, it actually represents a very low volume of  
22 the spray solution. So for the most part they remain  
23 intact pretty well. It's not like the individual is  
24 taking a shower in this stuff.

25 But there were studies, and I myself have

1 conducted several studies that are in this database  
2 where, under field conditions, extremely wet like hand  
3 methods in a greenhouse and such, where we saw patches  
4 actually beginning to disintegrate, they were so wet.  
5 So we would kind of stop the process and, you know,  
6 that would be it for that particular event.

7 So it really had to do with the direction of  
8 the individual field investigator to address how those  
9 samples were collected and they really had to watch  
10 that method. For example we used alpha cellulose and  
11 it would do that but for gauze patches, you know, you  
12 could have, you could have overloaded but for the most  
13 part you don't, you don't really see that in these  
14 results. You don't see it with the data.

15 DR. MACDONALD: Should we be interpreting  
16 the dry and the wet materials differently? Were there  
17 different problems with the sampling in those two  
18 cases?

19 MR. DAWSON: Well I, in effect I guess the  
20 answer is yes, because in effect that's how we've done  
21 it. We believe at this point that there are physical  
22 differences between the two processes so we've  
23 segmented the data in that way. But it could be that  
24 that's, you know, not in fact the case for whatever  
25 reason. But that's how we've done it at this point.

1 DR. HEERINGA: Yes.

2 DR. HINES: Just a clarification, when  
3 you're doing the gloved to no gloved comparison can it  
4 happen that you're actually talking about two different  
5 chemicals?

6 MR. DAWSON: Yes it's possible.

7 DR. HINES: So there could be another  
8 interface there with the glove composition as well.

9 MR. DAWSON: It could be, but again you  
10 could also kind of get to that issue by looking at the  
11 recovery data that goes with it and the grades.

12 DR. HEERINGA: That was Cynthia Hines, my  
13 apologies, I covered my cheat sheet here for a moment.  
14 Other questions? Yes, Doctor Curwin.

15 DR. CURWIN: Yeah, I just have one  
16 clarification. So you say that if the, you don't  
17 correct for any values where the recovery is greater  
18 than 90%, but do you do any correction if you're above  
19 100%? Is there any downward correction or any  
20 correction for background levels?

21 MR. DAWSON: We tended to include in there  
22 positive and negative controls. There may have been a  
23 few circumstances because of matrix interferences or  
24 something where we may have corrected. And I, off the  
25 top of my head I don't believe we downward corrected,

1 but there may be a few circumstances where that did  
2 occur but I don't believe as a general rule we did.  
3 Okay, we never did.

4 DR. HEERINGA: No, the report states that,  
5 one of the documents said there is no downward  
6 correction on that.

7 At this point, we'll have opportunity again  
8 to return to all of these issues but we have one  
9 additional presentation that is scheduled before the  
10 lunch break today and I'd like to welcome Doctor Cassi  
11 Walls who is going to talk about issues related to  
12 antimicrobial pesticides. Doctor Walls.

13 DR. WALLS: Thank you. Again, my name is  
14 Cassi Walls and I work in the antimicrobials division.

15 And this morning I am just going to present  
16 our perspective on the issues that you will be  
17 reviewing over the next several days.

18 But first I'd like to start off with going  
19 over AD's approach to risk assessment. AD's handler  
20 exposure and risk calculations are very similar to  
21 those calculated by HED. There were equations  
22 presented this morning by Jeff Evans and Jeff Dawson  
23 that went over the general algorithm for assessing  
24 exposure. And we actually use the exact same  
25 equations.

1           The input parameters might be a little bit  
2 different to accommodate antimicrobial input parameter  
3 or scenarios but the concept is identical.

4           We also use generic data to assess exposure.  
5 And the generic data again are the unit exposures.

6           The standard normalization procedures are  
7 generally used to express the unit exposures. In other  
8 words, that the units are in terms of milligrams per  
9 pounds of AI. However, AD might consider in the future  
10 using other parameters for normalization. Other  
11 parameters might include something like treatment  
12 solution concentrations or for a closed system  
13 equipment, we might consider the number of couplings  
14 that somebody is attaching or detaching throughout a  
15 day.

16           And again we use the margin of exposure  
17 approach to assess non-cancer risks. And again it's  
18 the exact same equation that I believe Jeff Evans  
19 presented this morning.

20           So we have a different few sources of data  
21 and models that we use to assess exposure within AD.  
22 We have two primary data sources for generic data. The  
23 first generic data, and when I'm talking about generic  
24 data, again this is the unit exposures. The first  
25 source of unit exposure data that we rely pretty

1 heavily on is the CMA data and that was conducted by,  
2 collected in 1992 by the Chemical Manufacturers'  
3 Association. It's important to note that this current  
4 data is fairly limited so any time that AD uses this  
5 data to support a registration or re-registration we  
6 are requiring the registrant to generate conformatory  
7 data to support these exposure estimates when we use  
8 the CMA data.

9           And the other source of data that we're using  
10 is the PHED data and as you all know this is the focus  
11 of this meeting. But there are several scenarios  
12 within the PHED database that can be applicable or  
13 relevant to AD uses, even though these are primarily  
14 conventional agricultural chemicals. The uses that are  
15 relevant to AD may be aerosol cans, airless sprayers,  
16 paint brush uses and lower pressure hand wand sprayer  
17 equipment.

18           In some cases the generic data just, they're  
19 just not quite adequate enough to assess exposure so  
20 then we rely on the models. When assessing inhalation  
21 exposure it's important to note that the existing  
22 generic data are limited to low vapor pressure  
23 chemicals. In several cases we assess volatile  
24 chemicals and when we assess volatile chemicals the  
25 generic data are just inappropriate to use to we have

1 to use models to estimate the air concentrations. And  
2 I've listed a few of the primary models that we rely on  
3 within AD.

4 The first model is the multi-chamber  
5 concentration exposure model or the MCCEM model and  
6 we'll use this to assess, or to estimate air  
7 concentrations resulting from uses of foggers. The  
8 wall paint exposure assessment model that, it's pretty  
9 self-explanatory for painting exposures. And the  
10 exposure assessment tool, we will use that to estimate  
11 air concentrations resulting from use of air  
12 deodorizers.

13 And again for some of the dermal exposure  
14 scenarios, again not all of the generic data can quite  
15 fit the mold so we have to use models for that too.  
16 And a prime example for that one is a machinist who is  
17 working with metal working fluid that has been  
18 preserved with an antimicrobial chemical. For that  
19 particular scenario we actually use a model based on  
20 the whole hand emersion method that's based on the  
21 ChemSTEER model.

22 So why is AD interested in the outcome of  
23 this SAP meeting? Well as I stated earlier our  
24 existing unit exposure data has quite a few limitations  
25 in addition the limitations that we're talking about

1 with, related to the PHED data. And so there is a need  
2 for us to collect additional data to augment and to  
3 maybe perhaps replace our existing data.

4 The exposure monitoring methodologies and  
5 protocols that are proposed by AD are actually the same  
6 as HED's. They're both based on the EPA Series 875  
7 guidelines. AD also uses the scenario based approach  
8 in our exposure assessments and some of these scenarios  
9 are in the PHED database, some of them are not, and so  
10 again there is a need for us to collect additional  
11 antimicrobial exposure data.

12 So even though the case studies presented  
13 during the series of days over this meeting are  
14 agricultural specific, the recommendations and the  
15 advice from you on the methodologies will be considered  
16 by AD.

17 So there are several similarities that I  
18 alluded to with AD and HED's monitoring protocols and  
19 I've listed some of them that will be discussed over  
20 the next several days. And these include the  
21 suitability of generic data for use in exposure  
22 assessments. The issues pertaining to hand exposure,  
23 whether gloves versus hand washes are more appropriate  
24 and if hand washes are determined to be more  
25 appropriate, what do you do about hand rinse

1 recoveries? Passive dosimetry issues and whole body  
2 dosimeters versus patches, what's more appropriate to  
3 evaluate? Proportionality of exposure to pounds of AI  
4 handled, again the normalization methods for the unit  
5 exposures. And intra and inter-individual variability,  
6 how do we capture this type of data and what do we do  
7 with it?

8           So even though there are quite a few  
9 similarities, there are also a lot of differences.  
10 First off, the Antimicrobial Exposure Assessment Task  
11 Force, the AEATF, is a separate task force that's  
12 formed for the collection of antimicrobial exposure  
13 data and they will be giving a presentation this  
14 afternoon on their overview of their task force.

15           Again as I mentioned the CMA, the current CMA  
16 database has some limitations very similar to the PHED  
17 data and in some cases there are several more  
18 limitations so there may be actually even a greater  
19 need for us to collect additional antimicrobial  
20 exposure data.

21           The antimicrobial chemicals are used in quite  
22 scenarios and different work functions. Antimicrobial  
23 chemicals can be used in daycares, in schools and  
24 hotels, restaurants and medical premises and the work  
25 functions are going to be very different. For example

1 we're going to be looking at mopping and wiping of  
2 these chemicals. Another example of a different type  
3 of scenario is that antimicrobials can be used as  
4 materials preservatives, a material preservative in  
5 metal working fluids or in chemicals used to treat  
6 pressure treated wood. Another big difference or major  
7 difference is that the population size of antimicrobial  
8 users is actually much greater than the conventional  
9 chemicals. Again, we're looking at people who are  
10 mopping and wiping and so there's a lot more people who  
11 are going to be out there that we want to try to be  
12 able to estimate exposure for them and that population  
13 size is actually much greater than conventional  
14 chemical users.

15 And in some cases the data that will be  
16 generated and will be used for occupational handler  
17 exposures, we might actually be using those to evaluate  
18 residential handler exposures as well. And a good  
19 example of those are the mopping and wiping and aerosol  
20 spray users.

21 Another difference between the AEATF and the  
22 ag handler studies is that the AEATF exposure studies  
23 will be simulated in a laboratory setting. And this  
24 can lead to clustering implications. And we haven't  
25 really gotten into the statistics behind determining

1 the appropriate number of samples to collect. And when  
2 I'm talking about clustering implications, that's what  
3 I'm referring to, not to the clustering issues that I  
4 believe Jeff Evans and Jeff Dawson talked about earlier  
5 this morning.

6 So the AEATF studies will be conducted in one  
7 site in a lab versus the agricultural chemical studies  
8 will be conducted in multiple field study locations.  
9 And again the antimicrobial chemicals studies will be,  
10 in some cases will occur via simulated activities  
11 whereas the agricultural is actually following people  
12 who are actually doing the application of the  
13 pesticide.

14 And again we will be doing some field studies  
15 but our fields are very different than in the  
16 agricultural arena. We'll be going into a machining  
17 facility where people are working with metal working  
18 fluids that are treated or preserved with  
19 antimicrobials and also going into a pressure treatment  
20 wood facility.

21 So in summary we are AD, we are very  
22 interested in the outcome of this meeting and we will  
23 be carefully listening to the panel's advice and  
24 recommendations throughout the next several days. I  
25 want to reiterate that AD's methodological approaches

1 are very similar to the ones that you'll be seeing by  
2 HED. For AD the methodology is more important than the  
3 specific examples and details provided in the case  
4 studies. And AD will consider adopting the SAP's  
5 recommendations and advice into the AEATF protocols for  
6 many of the issues that will be discussed over this  
7 meeting and I've listed a few of them. But it's not  
8 just limited to these. Some of these issues include  
9 hand exposures, again looking at the gloves versus  
10 handwashes, whole body dosimeters, sample sizes and the  
11 statistical methodologies used to determine the sample  
12 sizes, the proportionality and the normalization of the  
13 unit exposure in the inter and intra-individual  
14 variability.

15 Any questions?

16 DR. HEERINGA: Thank you very much, Doctor  
17 Walls. Are there any questions on the interests of the  
18 antimicrobial division? Doctor Johnson.

19 DR. JOHNSON: I'm sorry, but the acronym  
20 AD represents what?

21 DR. WALLS: It's Antimicrobial Division,  
22 I'm sorry for not clarifying that.

23 DR. HEERINGA: In the work that I do it  
24 represents Alzheimer's Disease so it hit me at first  
25 and I kind of had to ask to, but someone has AD-- so

1 obviously no implications here. Yes, Cynthia.

2 DR. HINES: What accounts for a greater  
3 reliance on simulated activities in your endeavors than  
4 say in the agricultural sector?

5 DR. WALLS: I'm sorry, can you repeat  
6 that, I didn't--

7 DR. HINES: What accounts for a greater  
8 reliance on simulated activities for the antimicrobials  
9 versus field studies?

10 DR. WALLS: Why are we doing simulated  
11 activities, is that --

12 DR. HINES: It seems to me there's a  
13 greater reliance in your--

14 DR. WALLS: Well not, there's not  
15 necessarily a greater reliance but it's for this,  
16 there's one study that I know of off hand that will be  
17 a mopping and wiping study that will be conducted in  
18 like a wedding hall type of scenario, or facility and  
19 the participants are basically going to go through and  
20 mop that particular area. It's just easier at this  
21 point to get participants to go into this environment  
22 and to monitor them. But we are also doing field  
23 studies as well. It's just because it's a mopping and  
24 wiping scenario, it's easy to go into this one area.  
25 There's not a huge reliance on this but that is the one

1 scenario that I can think of that's simulated. Not all  
2 of them will be simulated.

3 And again the people aren't going to be told,  
4 aren't going to be given a script on how to do it,  
5 they're going to do it their own way so there is going  
6 to be some inter and intra-variability on how they  
7 conduct the mopping and wiping scenarios.

8 DR. HINES: Actually that was my next  
9 thought, is you're going to have different subjects  
10 issues--

11 DR. WALLS: Yes.

12 DR. HINES: -- in the field.

13 DR. WALLS: Yes, and they're not, again  
14 they're not going to be told how to do it, they're just  
15 going to be using the same facility.

16 DR. HEERINGA: Yes, Doctor Appleton.

17 DR. APPLETON: Would you provide a little  
18 more information on, you say that the CMA study has  
19 data limitations, could you be a little more specific  
20 on that one?

21 DR. WALLS: Yes, and actually to help me  
22 answer that question a little bit more concisely I'd  
23 like to ask Tim Leighton to come to the table. He also  
24 is a colleague of mine at Antimicrobial Division.

25 DR. LEIGHTON: Yes, I'm Tim Leighton from

1 the Antimicrobial Divison, AD.

2 The limitations in the CMA study, a lot of  
3 them are based on the chemicals selected where we  
4 wouldn't have good recoveries and also there is a  
5 limited number of samples. Those are the two main  
6 ones.

7 DR. HEERINGA: Doctor MacDonald.

8 DR. MACDONALD: Are you also interested in  
9 antimicrobials that are intended for direct dermal  
10 applications like handwashes?

11 DR. WALLS: Yes.

12 DR. LEIGHTON: When we're, for the samples  
13 there's going to be from mopping and wiping there are  
14 going to be direct concentrations getting on the hand  
15 from the dilute solutions. We are going to look at the  
16 hand rinses right now and not glove samplings for the  
17 monitoring technique.

18 DR. MACDONALD: I was referring to  
19 products that are intended as hand rinses rather floor  
20 washes.

21 DR. WALLS: Those are not pesticides,  
22 those are--

23 DR. LEIGHTON: Oh, so you mean monitoring  
24 actually, so no, that's something that's under the  
25 FDA's perview.

1 DR. HEERINGA: One additional question  
2 that Doctor Portier had, I had the same thought, is  
3 that the SAP has actually heard and dealt with the  
4 whole issue of fumigants as well and those would be  
5 inhalation exposures primarily but I presume these need  
6 to be loaded into injectors or sprayers, and are those  
7 covered under some of the work that you're doing here?  
8 I don't want to complicate things but where would that  
9 fall Jeff, in the realm of things? I'm talking about  
10 agricultural fumigants primarily.

11 MR. DAWSON: Jeff Dawson, HED, at this  
12 point the intent of the industry task forces, and they  
13 may want to comment on this later, was to, they've  
14 limited their scope basically to typical agricultural  
15 chemicals.

16 For example in a fumigant risk assessment  
17 what we've done was there is actually a fairly  
18 extensive worker exposure monitoring set of data that  
19 we've used specific to the six or seven let's say soil  
20 fumigants that we're looking at now. For example,  
21 methyl bromide has around 40 studies, you know, one 3d  
22 has, you know, 8 or 10 or something. So we're  
23 actually, in comparison to the individual active  
24 ingredients that are more conventional pesticides, they  
25 tend to have more monitoring data.

1 DR. HEERINGA: Thank you, it helps very  
2 much to sort of know where that all stands in the  
3 larger picture. So, any other questions from panel  
4 members at this point?

5 Okay, we are just a little past the noon hour  
6 and I'd like to break for lunch. We're right on  
7 schedule, I appreciate the contributions certainly of  
8 all of the presenters for staying on schedule and we  
9 don't want to limit questions obviously, but it's nice  
10 with a four day meeting to at least start out in a  
11 timely fashion.

12 What I'd like to do is, I think this  
13 afternoon's agenda may be relative to tomorrow's and  
14 certainly the day after, I think has a little room in  
15 it. Since we have lunch options here, and I'm not  
16 going to go through those but most of them would  
17 require us to leave the building. I don't think you  
18 can get to 23rd Street and back in one hour. What I'd  
19 like to propose is that we take an hour and fifteen  
20 minutes for lunch, I think that's a little more  
21 reasonable, it gives people a little more time to get  
22 to their location and then get back here in time.

23 So let's say that we will reconvene at 1:20,  
24 twenty minutes after the hour of one o'clock with the  
25 meeting and we'll look forward to seeing everybody

1 there.

2 Just before we turn to our designated federal  
3 official, Myrta Christian, do you have anything to add,  
4 Myrta?

5 MS. CHRISTIAN: Yes. For the panel, if  
6 anyone wants to have lunch at the Hyatt they have a  
7 lunch buffet so it would be easier and faster and  
8 closer, it's across the building. Thank you.

9 DR. HEERINGA: Okay, we'll see everybody  
10 at 1:20.

11 (WHEREUPON, the morning session was adjourned for  
12 lunch.)

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## 1 FIFRA SCIENTIFIC ADVISORY PANEL (SAP)

2 January 9, 2007

3 Review of Worker Exposure Assessment Methods

4 Afternoon Session

5 DR. HEERINGA: Okay, thank you everybody,  
6 I hope you had an enjoyable lunch.

7 Welcome back to the afternoon session of the  
8 first day of our FIFRA Science Advisory Panel Meeting  
9 on the topic of the Review of Worker Exposure  
10 Assessment Methods.

11 This morning we heard introductory and  
12 overview remarks from Jeff Evans of the Health Effects  
13 Division of the EPA and a historical perspective on  
14 worker exposure assessment and data sets from John  
15 Worgan of Health Canada, the Pest Management Regulatory  
16 Agency. And then also Jeff Dawson of Health Effects  
17 presented a number of case studies that illustrated how  
18 the existing PHED data set is used and Doctor Cassi  
19 Walls provided us some insights on how another EPA  
20 division, the Antimicrobials Division would be drawing  
21 on the information and discussion in this session in  
22 planning their own applicator and worker assessment  
23 studies.

24 So we return this afternoon and on the  
25 agenda for this afternoon are two sessions to be

1 presented by members of the various task forces.

2 And the first task force who will be  
3 presenting is the AHETF, and I'm not going to attempt  
4 the acronym, I assume we'll be tested on this at the  
5 end of the four days but I'll let the representatives  
6 give us the full definition of the acronym. And I  
7 think the first speaker is Richard Collier.

8 DR. COLLIER: Thank you, Doctor Heeringa.  
9 My name is Richard Collier, I am Vice President for  
10 Regulatory Affairs of Landis International and in that  
11 role serve as the representative to the Agricultural  
12 Handlers Exposure Task Force for Mitsui Chemical. I  
13 also serve the task force as the Chair of the  
14 administrative committee, the governing body for this  
15 task force.

16 I'm very pleased to have this opportunity to  
17 speak to the Scientific Advisory Panel today and  
18 appreciate the opportunity to discuss with you the work  
19 of the AHETF and we'll get with that.

20 I never try to pronounce this acronym, I find  
21 it unpronounceable and would love to hear how it is  
22 pronounced by others.

23 This presentation has four parts, at least my  
24 portion of it does. I'll introduce the AG. Handlers  
25 Exposure Task Force and then in doing so, cover some of

1 the history and the activities of the task force.  
2 We'll discuss the regulatory need for additional  
3 handler exposure data from the point of view of the  
4 task force. In the process of doing that we'll talk  
5 about some of the limitations of the existing data and  
6 the pesticide handlers exposure database. In so doing  
7 I'll try to not be too duplicative of the presentations  
8 that you heard this morning. Some of the information  
9 on the slides certainly is, but I'll try to limit my  
10 comments to those areas where the task force would like  
11 to emphasize something perhaps beyond what was  
12 emphasized this morning or take a slightly different  
13 view from this morning's presenters.

14 This presentation also has two other parts so  
15 when my portion is completed Doctor Lunchick with our  
16 task force will discuss the selection process that  
17 we've used in the process of reviewing existing data  
18 for inclusion in the AHED, the Agricultural Handlers  
19 Exposure Database, the new database being developed by  
20 the AHETF. And Doctor Victor Canez will discuss with  
21 you the manner in which our field studies are  
22 performed. I will in my presentation though cover the  
23 scope of the work that we plan to do in the AHETF, give  
24 you a brief history as to where we are at this point in  
25 our work and give you a brief introduction to the

1 Agricultural Handlers Exposure Database.

2 My academic background is in the field of  
3 biochemistry and if in the process of my presentation I  
4 use terminology that has specific meaning in statistics  
5 or in other scientific disciplines, it's unlikely that  
6 I mean that term to be interpreted strictly in a very  
7 specific manner. So with that disclaimer we'll go on.

8 The regulation of pesticides in the United  
9 States has its basis in two safety determinations that  
10 the EPA is required to make before it can register a  
11 new pesticide or a new use of an already registered  
12 pesticide. The most general of these is the no  
13 adverse, no unreasonable adverse effect standard in  
14 FIFRA, the primary law, and this standard is applicable  
15 to all uses of all pesticides. It's a risk/benefit  
16 standard under which the adverse effects, if any, must  
17 be outweighed by benefits. The second standard is the  
18 reasonable certainty of no harm standard that applies  
19 to pesticides in foods and drinking water.

20 It's this first, no unreasonable adverse  
21 effects risk/benefit standard that applies to the  
22 regulation of pesticide exposure in occupational  
23 settings which is the subject of the efforts of the  
24 AHETF. This is a crucial point that I want to make,  
25 that reasonable estimates of risk are a necessary

1 component of the risk/benefits decision that EPA is  
2 required to make. Consequently in the arena of  
3 pesticide handler exposure assessments a tool is  
4 required that provides reasonably accurate exposure  
5 assessments, neither significantly overestimating nor  
6 underestimating exposure. I think this viewpoint is  
7 consistent with the desire for more accurate  
8 assessments that was expressed by Doctor Levine in her  
9 opening comments this morning.

10           During these proceedings we expect to show  
11 you that the data generation program used by the AHETF  
12 meets those requirements and while it may take us  
13 several presentations to get to that point, we will we  
14 think at the end of our presentations, not just today  
15 but over these next several days, that you'll agree.  
16 And we hope that at the end of the process we have your  
17 concurrence with that but we also look forward to your  
18 suggestions on how that program can be improved.

19           Let's look for a moment at how regulated  
20 industry satisfies the various data requirements that  
21 it receives from the regulatory agencies. These  
22 requirements are levied not in a very general sense,  
23 but levied against each individual applicant or holder  
24 of a registration, that is each individual registrant.  
25 Each registrant is free to develop the data to satisfy

1 those requirements on its own. However FIFRA Section  
2 3(c)2(b) allows registrants to collaborate by jointly  
3 developing data that's required by EPA. Under this  
4 provision registrants have over the last several  
5 decades formed chemical specific task forces to respond  
6 to data requirements for individual active ingredients  
7 and more recently have formed generic task forces in  
8 response to data requirements that affect a large  
9 number of active ingredients.

10 A task force can just be defined as a  
11 consortium of companies that work together on a common  
12 project but under FIFRA these task forces have varied  
13 quite substantially, some as small as two members and  
14 some as great as forty or more. They're working  
15 together to meet specific data requirements but have to  
16 deal with providing the resources for the technical,  
17 regulatory, legal, administrative and financial aspects  
18 of a consortium. This process is important to the  
19 companies because it does save the companies money and  
20 I'll be the first I think to admit that. But it also  
21 saves on the cost of generating duplicate data sets  
22 that minimizes the number of test animals that are  
23 utilized, the number of samples collected and in the  
24 case of exposure work, the number of workers that have  
25 to be monitored. It also reduces the number of studies

1 that have to be reviewed by the regulators.

2 The early task forces were organized to  
3 satisfy the requirements related to specific active  
4 ingredients. This started mainly in the 1980s but  
5 they're still evident today, many such task forces  
6 within the industry exist. 1990 was the first year for  
7 generic task forces and in this sense we mean generic  
8 in that a task force is fulfilling a regulatory  
9 requirement or a group of requirements that are  
10 applicable to many different kinds of pesticide  
11 products. It follows that membership in generic task  
12 forces tends to be much larger than membership in  
13 product specific task forces.

14 We turn our attention to the generic task  
15 forces in the worker exposure arena for conventional  
16 chemicals. Three such task forces have been formed  
17 over the years, most recently being the Agricultural  
18 Handlers Exposure Task Force which I represent today.  
19 This task force focuses on mixing, loading and applying  
20 pesticides in agricultural occupational settings. The  
21 Agricultural Reentry Task Force was formed in 1994-95.  
22 Its focus was on the reentry exposure, that is the  
23 exposure to a pesticide of a person who enters an area  
24 that's previously been treated with a pesticide or to  
25 which a pesticide has been applied. Those activities

1 covered by that task force are such things as weeding,  
2 thinning or hand harvesting of crops. The Outdoor  
3 Residential Exposure Task Force has developed data to  
4 address the potential exposure related to handling and  
5 to reentry activities in outdoor residential settings,  
6 lawns, around ornamental plantings and home gardens.

7 Collectively these task forces have funded  
8 the development and fully funded the development of  
9 some \$50 million of data in these three areas. I  
10 should mention that the industry members of these task  
11 forces are the sole source of funds for this work, no  
12 government funds from any source are utilized.

13 The remainder of my part of this presentation  
14 will focus on the arena, the Agricultural Handlers  
15 Exposure Task Force, that of handler exposure in  
16 agricultural occupational settings.

17 AHETF was formed in December of 2001, it  
18 currently has nineteen member companies, I won't read  
19 them off for you, they're there on the slide but I will  
20 comment that because this is a generic task force you  
21 may note that its membership is a broad representation  
22 of some very large companies and some much smaller  
23 companies, because the work of this task force is  
24 applicable to a very wide variety of agricultural  
25 pesticides.

1           The AHETF like other industry task forces was  
2 formed, not to conduct basic or applied research,  
3 that's not our goal, in fact it probably wouldn't even  
4 be allowed under the law, but in any case we were  
5 formed because we needed to respond to data  
6 requirements that were established by the EPA. In the  
7 case of AHETF those data requirements took several  
8 different forms. First the Health Effects Division,  
9 HED, of EPA's Office of Pesticide Programs indicated  
10 that the existing data in the PHED database were  
11 insufficient to meet some of its needs. The second  
12 aspect of the requirements we were seeing is that EPA  
13 began to develop scenario monographs that merged PHED  
14 data with other data that had been submitted by the  
15 registrants over the preceding time period. And even  
16 in addition to that EPA continued to required  
17 additional data, both for new and existing chemicals  
18 under the ongoing registration and re-registration  
19 processes.

20           The direction that the HED was taking did  
21 cause some concerns among the registrant community.  
22 Those concerns centered really on two issues. One was  
23 the limitations of the existing studies for generic use  
24 and I'll get into that in some detail here momentarily,  
25 and the apparent lack of recognition of data protection

1 rights when studies were used in handler scenario  
2 monographs, and I'll expand on that as well.

3 The successful work of the other generic task  
4 forces that had gone before, and our understanding of  
5 the limitations of the existing data led us to the  
6 conclusion that a new data set was needed. That was  
7 based upon studies that were designed for use in a  
8 generic database and it would result in a superior tool  
9 for handler exposure risk assessments.

10 That conclusion should not be viewed as being  
11 negative in regard to the quality of the existing  
12 studies for the purposes that those studies were  
13 originally generated for. When a study that's designed  
14 to meet a specific need for a particular product is  
15 attempted to be used another way, as in a generic  
16 database, one's going to run into limitations and  
17 sometimes those limitations are quite substantial.

18 The studies that are, that preceded our work  
19 were largely studies that were initiated to address a  
20 specific issue that EPA had required a registrant to  
21 address. Consequently those studies would be designed  
22 in a way that they would address that question. It  
23 does not necessarily mean that such a study is going to  
24 be very useful when it's attempted to be applied to  
25 support the registration of some other compound or

1 other uses even of the same compound. For example, the  
2 toxicological properties of a given product may require  
3 that workers wear more protective clothing when using  
4 that product than is the minimum standard for products  
5 across the board.

6           Doing a study with more protective clothing  
7 may be very appropriate to answer a specific question  
8 about a particular chemical but to be most effectively  
9 used in a generic agricultural exposure database we  
10 think that workers should wear the minimum protective  
11 equipment that's required and prescribed by the Worker  
12 Protection Standard.

13           If that's the case and data are generated in  
14 that way, then the resulting data could be most broadly  
15 applicable without having to apply clothing correction  
16 factors. Another example, and we've seen some  
17 circumstances this morning already in which there are  
18 substantial numbers of data points with values less  
19 than the limit of quantification.

20           When that happens typically one half the LOQ  
21 or in some case one half the limit of detection is used  
22 in calculating the potential exposure. And a study  
23 that produces such data may be quite appropriate for  
24 answering the specific question for which the study was  
25 done initially. But it may be not very useful to try

1 to address the exposure for a compound that's used at a  
2 much higher use rate or for a compound that has more  
3 inherent toxicity than the original product.

4 Coming back to the regulatory need for  
5 additional exposure data, let's look at the, at those  
6 needs as EPA expressed them to industry. The director  
7 of EPA's Health Effects Division in March of 2001  
8 expressed the limitation of the existing data in the  
9 PHED database as PHED being in need of a substantial  
10 overhaul, the data being outdated or scientifically  
11 inadequate by today's standards. Also noting that some  
12 of the use scenarios that were important at that point  
13 in time were either missing from the PHED database or  
14 were under represented, that is insufficient data to be  
15 very useful. Although PHED contained some of the best  
16 data that were available at the time it was put  
17 together it clearly was not meeting all of the Agency's  
18 needs. I think that's borne out by the information  
19 that we saw this morning in Jeff Dawson's presentation  
20 of the six case studies.

21 HED attempted to address those needs by  
22 developing handler exposure data monographs beginning  
23 with seed treatment in which that data that were  
24 represented in the PHED databases were merged with  
25 other data that the registrants had submitted over the

1 years or otherwise were available. Yet, the Agency  
2 didn't find this a sufficient source for it's risk  
3 assessment needs. It continued to require more new  
4 data through the registration process and through the  
5 re-registration process. We can go to the next slide.  
6 Yeah, that's good.

7           You might be asking yourself, why was all the  
8 existing data not in the PHED database? And to answer  
9 that question we need to look a little bit at PHED and  
10 how it came to be. I won't go through all the details  
11 here, John Worgan described those in quite some detail  
12 for you this morning. I will comment though that PHED  
13 is a generic database in that it is based on the  
14 supposition, and I think appropriate one that exposure  
15 in the mixing, loading and application regimes is  
16 primarily driven by the nature of the product  
17 formulation rather than the specific chemical  
18 properties of the active ingredient and by other  
19 general parameters such as the use rate and use  
20 frequency.

21           One of the key things about the PHED database  
22 though is that the data represented in it were those  
23 data that the contributing companies were willing to  
24 waive their data compensation rights. And that became  
25 a serous problem. Some 50 studies were added to the

1 initial version but there were many other studies that  
2 industry was not willing to contribute to that database  
3 and we'll get to why that is the case. On this slide I  
4 just want to point out that the generic approach is one  
5 that presumes that one compound can be used to  
6 represent exposures for another compound so long as  
7 it's used in a similar manner. The reason for that is  
8 that the exposures that are associated with mixing,  
9 loading and applying are primarily influenced by those  
10 physical aspects of the application process, the  
11 equipment used, application rates, type of formulation.

12 Mr. Worgan went through in some detail this  
13 morning the history of PHED. I want to call your  
14 attention to a couple of key items. The first version  
15 of PHED was released in June of 1992. Within a year of  
16 that point or approximately a year, in July of 1993,  
17 Doctor Penney Finner-Crisp wrote a letter to the  
18 National Agricultural Chemicals Association, now  
19 CropLife America, that expressed the Agency's concern  
20 that insufficient data were represented in PHED. Over  
21 the next year and a half an additional 50 studies were  
22 contributed but there were several things that were  
23 happening right at this point that made it very  
24 difficult for industry to contribute all of its studies  
25 to PHED. In the latter part of the 1980s the Good

1 Laboratory Practices Requirements were released, and  
2 those requirements added quite substantially to the  
3 cost of doing this sort of field research. Companies  
4 found it very difficult and I guess some would have  
5 said impossible, for them to decide to contribute those  
6 very expensive studies on their newer compounds and  
7 formulations to a database that their competitors could  
8 then use freely without having made any contributions  
9 at all.

10 This has never been about whether the data  
11 are publicly available. A person in the general public  
12 can have access to the results of any of these data  
13 because they are data that deal with the health effects  
14 of pesticides. But the issue here was fair  
15 competition, and because these studies are quite  
16 expensive it became a significant issue with industry  
17 and it was, it just became impossible for studies that  
18 themselves could easily exceed a half a million dollars  
19 for a single study, could be contributed and then allow  
20 the competition to use it without any compensation.

21 So in the latter part of the 1990s ACPA and  
22 EPA began to discuss possible solutions. A proposal  
23 from the industry trade association was produced to  
24 create a new task force and to do that in such a way  
25 that the data that were generated by that task force

1 would be available to populate a new database, but that  
2 the data compensation rights under FIFRA would not be  
3 waived, so that while the data could be utilized and  
4 cited by any registrant, the registrant who was not a  
5 member of the task force would have to agree to  
6 appropriately compensate the task force for having  
7 cited those data.

8 In summary then, PHED developed rather  
9 quickly a data dilemma. Industry ceased to contribute  
10 new studies to PHED. PHED was last updated in 1995.  
11 It has about 100 studies in it but there are at least  
12 that number of studies that have been submitted over  
13 the years that are not represented in PHED. Disparate  
14 study designs became a significant problem. Those were  
15 discussed with you to some degree this morning. I and  
16 my colleagues will be discussing various aspects of why  
17 those disparate designs severely limit the utility of  
18 that database going forward. And the bottom line was  
19 there was no incentive for industry to submit new  
20 studies for contribution or for inclusion in the PHED  
21 database.

22 PHED was viewed as having several different  
23 data related problems. The variability and quality of  
24 the data, most of which were not performed according to  
25 good laboratory practices, they were, most of these

1 were generated prior to the GLP requirements coming  
2 into play, many of the scenarios are not represented,  
3 poor representation for others. Consequently there was  
4 no incentive to upgrade the actual database system  
5 itself.

6 That led to rather severe software  
7 limitations. And then the questions of applicability  
8 of the data, given their age, came into play. The  
9 Worker Protection Standard which came into play in the  
10 latter 1980s provided for an education and training  
11 program for pesticide workers and consequently the  
12 impact of that program on the way pesticides are  
13 handled in the field is not represented in the PHED  
14 database. How great that impact is, we just don't know  
15 at this point because the database doesn't give us that  
16 information.

17 I mentioned that there were some software  
18 issues. The PHED database is a database that runs in  
19 the DOS operating system, predating Windows and in the  
20 Revelation Database Management System which has been  
21 unavailable commercially for several years now. So  
22 technical support for the PHED operating system is  
23 virtually nonexistent.

24 As we look to the future we do expect to  
25 learn from the past and there were some good things

1 that happened in the past and good aspects of PHED that  
2 we hope to utilize going forward. While PHED did  
3 represent an advance, a very significant one at the  
4 time that it was developed, it suffered from the use of  
5 data that were initially developed for purposes other  
6 than for inclusion in a generic database. It also  
7 suffered from the unwillingness of industry to  
8 relinquish its data compensation requirements for many  
9 of its more recent high quality studies for free use by  
10 its competitors.

11 We believe that the final product from AHETF  
12 will be quite superior to the products that we have  
13 available today because the studies that are  
14 represented in it are designed to meet strict  
15 requirements for utilization in a generic database.  
16 There's an old saying that a collection of facts  
17 doesn't make for good science any more than a pile of  
18 bricks makes for a good house. When one attempts to  
19 create a generic database from studies that are not  
20 designed from that purpose you're dealing with a pile  
21 of bricks. With AHETF's AHED, the Agricultural  
22 Handlers Exposure Database, we think we'll end up with  
23 a house.

24 The AHETF approach is going to allow the  
25 regulatory agencies to make much better use of their

1 resources, both by reducing the number of studies that  
2 they'll have to review and also the effort required to  
3 make a sense, make good sense out of a pile of bricks.

4 One of the ways in which the develop of PHED  
5 was right on target was its recognition of the benefits  
6 of a generic approach. Those were discussed as a part  
7 of the original PHED proposal back in 1983 and they're  
8 still applicable today. I won't read those, John  
9 Worgan included those in his presentation this morning,  
10 but we think they're still applicable.

11 That brings us to the formation of the AHETF.  
12 Our objective was to establish an industry task force  
13 for the purpose of sharing resources in the design,  
14 evaluation and development of an agricultural handler,  
15 that is mixer, loader and applicator exposure database.  
16 When the task force was formed we divided our  
17 activities and defined what we needed to do, first to  
18 define the scope of what it was that we were going to  
19 try to accomplish, set a budget and a time line,  
20 selection criteria for the studies and then to identify  
21 and review existing studies to determine whether any of  
22 those, and which if any, would meet the criteria for  
23 inclusion in a generic database, to develop the AHED  
24 database and then to generate data to populate it.

25 The first phase of our effort included the

1 drafting of the Joint Data Development Agreement that  
2 is the basis of AHETF. It is organized as a limited  
3 liability company in Delaware. We outlined the purpose  
4 and scope and anticipated costs and time frame of the  
5 work, engaged in enrollment of members to the task  
6 force and identified the administrative and technical  
7 needs that were required and then secured the support  
8 from the members for those.

9 In the second phase we developed data  
10 selection criteria. Those criteria are provided to you  
11 as Appendix A of the technical summary document that  
12 was provide to the SAP. Doctor Lunchick, after my  
13 comments are completed here, will discuss with you the  
14 development of those criteria and how they were applied  
15 to existing studies. We did then review all the  
16 available data against those selection criteria and  
17 developed, began to develop new database software that  
18 would be the, that would become AHED. And then to  
19 identify and prioritize data gaps and began phase three  
20 which was to acquire the existing proprietary data that  
21 did meet our selection criteria, and then to plan and  
22 execute new studies. After Doctor Lunchick is  
23 completed then Doctor Canez will discuss with you the  
24 process we used in generating those new studies.

25 We are currently in phase three, we have

1 acquired the existing data that have met our  
2 requirements and we're in the process of developing new  
3 data. In doing so we used the methods and study  
4 designs that conform to the existing guidelines. Some  
5 of those have been discussed with you this morning and  
6 I just wanted to comment that the passive dosimetry  
7 methods that are a part of the questions that this  
8 panel is asked to address have been, at least some  
9 aspects of them have been the subject of previous SAP  
10 reviews and I think you have those in the material that  
11 has been provided to you.

12 The nineteen members of the AHETF set about  
13 to determine its scope and concluded that we would  
14 develop data for more than 30 different handling  
15 scenarios involved in one aspect or another of aerial  
16 application, ground application, air blast equipment,  
17 application in greenhouses with handheld sprayers and  
18 in seed treatment.

19 The study designs that we use are always  
20 conducted in accordance with the guideline A75  
21 requirements. All of our study designs are reviewed  
22 and agreed upon by a joint regulatory committee with  
23 representation from EPA, Health Canada, California  
24 Department of Pesticide Regulation and USDA. It's that  
25 committee that was referred to several times this

1 morning as the means by which we as an independent task  
2 force coordinate with the regulatory body. All of the  
3 protocols of our studies are reviewed by an independent  
4 institutional review board and all of our data are  
5 designed specifically for use in the AG. Handlers  
6 Exposure Databases, AHED.

7 That is a contrast to the data that are  
8 represented in the PHED database which are not, were  
9 not designed specifically and lead to so many of the  
10 limitations that have been referred to.

11 The AHETF studies intentionally vary certain  
12 key parameters, particularly the amount of active  
13 ingredient handled since that is the basis of the  
14 normalization process that is a current part of the  
15 regulatory picture, that is one of the factors that  
16 choose to intentionally vary.

17 We also vary location because we understand  
18 that practices can differ from one part of the country  
19 to another and we also attempt to the degree possible  
20 to vary the types of equipment that are used within a  
21 given scenario. All of that is done to permit a better  
22 characterization of the exposure distributions, better  
23 than the typical active ingredient specific study would  
24 do that holds some of those key parameters relatively  
25 constant.

1 I'll touch just a moment on which chemicals  
2 we use in our studies within AHETF. We refer to those  
3 as our surrogate chemicals and we look for several  
4 different characteristics in choosing a surrogate or a  
5 group of surrogates.

6 First we look for products that are  
7 registered for use on a wide variety of crops. We do  
8 that so that the investment that we make in the  
9 analytical methodology to press the levels of  
10 quantification down to very low numbers can be utilized  
11 in many different studies for different scenarios. We  
12 require, we want to use products that require the  
13 minimum use of personal protective equipment and that  
14 implies that the formulations that we use are going to  
15 be low acute toxicity formulations.

16 We want to select chemicals that will allow  
17 us a very low limit of quantification so that we have  
18 very few data points in our database that are not real  
19 measured values. And across the group of surrogates we  
20 look for diversity in chemical and biological  
21 properties but we do for reasons that were discussed  
22 here earlier this morning, we do exclude highly  
23 volatile compounds, the fumigants. It's our view that  
24 those types of products are not as amenable to a  
25 generic database in a generic approach as low

1 volatility compounds are.

2           If we look at the characteristics of scenario  
3 data that we seek for our generic database, the first  
4 principle is that one person monitored, doing one set  
5 of tasks in one particular location, in one particular  
6 period of time, one particular set of environmental  
7 circumstances and one particular set of their behavior  
8 is the basic unit of our data set, what we call the  
9 monitoring unit.

10           Multiple locations are generally represented  
11 in each scenario in order to give some geographical  
12 diversity, a varied amount of active ingredient handled  
13 at each location. We'll go into some of the  
14 statistical reasons for some of these selections in the  
15 latter presentations that are made I think on Friday  
16 according to our agenda. Varied equipment and our  
17 attempt here is to collect data that are reflective of  
18 the range of current practice in the field in a given  
19 application scenario.

20           Logistics usually, or typically dictate that  
21 each location is going to be a separate GLP study. And  
22 that's not always the case but it most often is.

23           I'll try to give you a perspective of what  
24 the AHED database looks like in terms of the data that  
25 populate it. Its universe, the outer circle here is

1 composed of several different scenarios, I mentioned  
2 earlier that when we're done there should be more than  
3 30 of them.

4 The scenarios here are indicated in the light  
5 blue ovals. They usually divide themselves into areas  
6 of either mixer/loader types activities or applicator  
7 type activities. Within each scenario there are  
8 usually multiple studies, those are the sort of orange  
9 circles or ovals here. And within each study there are  
10 multiple monitoring units, individual people in a given  
11 set of circumstance monitored for their exposure.

12 Some studies may have within it monitoring  
13 units that fall in more than one scenario, the oval in  
14 the upper center of the figure here shows one  
15 particular study with some monitoring units that fall  
16 in ST1, a mixer/loader scenario and some monitoring  
17 units in the same study that fall in the applicator  
18 scenario. We do that, we design a study that way at  
19 times because it works well to monitor both the mixing  
20 and loading and then the applying of that loaded  
21 material in the same operation, the same location at  
22 the same time.

23 These studies that are represented in this  
24 figure may be new studies performed, generated data by  
25 the AHETF or they may be, they may represent studies

1 that have been acquired and included in the data base,  
2 so they may be both new or existing data.

3 A few of the milestones of the work of the  
4 task force thus far, the data selection criteria were  
5 identified in mid 2002. These are much more stringent  
6 than the criteria used for data that are represented in  
7 the PHED database. Our group of experts reviewed over  
8 200 existing studies that began in mid '02 and were  
9 completed in early '05 and the result of that review  
10 which was obtained with the concurrence of the Joint  
11 Regulatory Committee of the regulating agencies, was  
12 that we chose to purchase 105 monitoring units, that,  
13 those are the ones that were determined to be  
14 acceptable both from a technical and for their  
15 applicability for use in a generic database.

16 We began field studies in 2003 to address the  
17 data gaps that we could see in the database at that  
18 point in time. We began the development of the  
19 database management system. Its first version was  
20 available to our membership in April of '05 and  
21 contained the data from all of the existing studies  
22 that we had purchased and the data from the AHETF  
23 studies that had been done at that point. We'll go on  
24 to the next slide.

25 From this point on, as we look to the future,

1 we look toward supporting a regulatory transition, a  
2 transition from the use of the PHED database to the use  
3 of the AHED database as individual scenarios are  
4 populated in AHED and are considered to be the best  
5 available data to represent that particular scenario.  
6 As time goes on we expect then that we will complete  
7 this next generation generic database and in the  
8 process, cover nearly all agricultural handler  
9 scenarios.

10 With nineteen companies, perhaps more in the  
11 future, covering all of the scenarios that are  
12 important to those companies, we think that database  
13 will have a very broad utilization within the  
14 agricultural use regime.

15 New study data results are going to be  
16 broadly available but we do plan to retain the data  
17 compensation rights. What that means in practice is  
18 that a company who is not a member of the task force  
19 will have rights to cite those data to support their  
20 registrations, but in the process of citing the data  
21 they will be required as is required under FIFRA to  
22 provide compensation to the task force for their  
23 citation and dependence on those data.

24 Let's take a brief look at AHED and what it  
25 looks like. This is not intended to be a tutorial but

1 a very high level introduction and I won't spend a lot  
2 of time on this. The, this is however a stand alone  
3 application for viewing, querying and analyzing handler  
4 exposure data. The system is designed so that it can  
5 be extended by adding analytical tools as is needed and  
6 can be updated to new versions as they become  
7 available.

8 It's developed in a Microsoft Windows  
9 compatible environment. The software is going to be  
10 readily available upon release, this is not going to be  
11 some black box that we expect regulators to utilize.  
12 All of the algorithms within it and the manner in which  
13 computations are made will be readily available for all  
14 to see and will be supported for at least 15 years  
15 after the last submission of data represented in the  
16 database.

17 Users of AHED, if we can go to the next  
18 slide, may use the system to analyze individual studies  
19 or scenarios made up of multiple studies as we  
20 discussed previously, to explore relationships between  
21 exposure and the amount of active ingredient handled  
22 and other variables. We don't promise that exploring  
23 relationships with other variables is going to be a  
24 successful thing. As we get into the discussion of our  
25 statistical parameters for the development of this

1 system and in talks that come later in these  
2 proceedings, the promises we make if you will as to  
3 what the system will do will be described for you in  
4 some detail. You can use this system then to develop  
5 basic exposure assessments or to conduct refined  
6 assessments when those are necessary. The AHED  
7 database is being developed by the Agricultural  
8 Handlers Exposure Task Force in conjunction with the  
9 Antimicrobials Exposure Task Force and by the European  
10 Crop Protection Association and Occupational and  
11 Bystander Exposure Expert Group. All three of these  
12 organizations are contributing to the develop of the  
13 database management system. Each will have their own  
14 set of data represented within independent copies of  
15 this system. It is being programmed by  
16 infoscientific.com.

17 The database currently has within it 185  
18 monitoring units that represent 9 different scenarios,  
19 I won't read those out for you here, but they're listed  
20 on the slide. It contains information that's collected  
21 about each of the workers that are represented in a  
22 monitoring unit. Such things as their height, weight,  
23 age, years of experience. We capture application  
24 information, what was the height of the crop that was  
25 being, to which material it was being applied, what

1 kind of equipment was being used, ground speed, boom  
2 height, how the product was mixed, what kind of  
3 equipment was used for that, what are the capacities of  
4 the various pieces of equipment, information about the  
5 product itself that was used to generate that  
6 particular monitoring unit, what was the formulation,  
7 how was it packaged, what were the package weights, et  
8 cetera.

9 AHED itself, we'll take a brief look at what  
10 it looks like, the opening screen gives you choices of  
11 doing unit exposure analyses, looking at worker  
12 statistics and doing unit conversion so that you can  
13 establish units either in metric units or in any one of  
14 several other options. When you choose information to  
15 look at workers you can see how they are identified in  
16 the system, what kind of task was done, the age of  
17 workers.

18 There's a menu function to convert codes to  
19 English terms so that you don't have to memorize what a  
20 code means in this system. In doing analyses for unit  
21 exposure you can select from the database whichever of  
22 the monitoring units meet your particular needs by task  
23 and by formulation of product, by the kind of equipment  
24 that's used and you can choose to normalize that data  
25 or not normalize it. So you can produce an output that

1 it, that shows just the raw exposure numbers, you can  
2 normalize by the amount of active ingredient handled  
3 which would probably be by far the most common, or you  
4 could explore normalization by other factors that are  
5 represented in the database. Unit exposure outputs  
6 provide data in various different forms. I'm not going  
7 to try to go through the computations that are behind  
8 these.

9 That's beyond this high level introductory  
10 talk. But just to indicate that the reports, once they  
11 are generated by the system can either be viewed on the  
12 screen, printed, saved to a file or output in Excel for  
13 input into other analytical tools.

14 The system has online help to help the user  
15 understand how the system is best utilized and what  
16 the, it's limitations are. It has an update function  
17 so that new data can readily be put in that is menu  
18 driven, easily used, data that are entered into the  
19 system can be given a pending status so that it can be  
20 reviewed for quality assurance in the data entry  
21 process before the data get an active status and are  
22 available for utilization in any of the analyses done  
23 within the system.

24 When data are output one can input that data  
25 directly into many different types of secondary

1 analytical tools to produce a wide variety of analyses  
2 of the data output.

3 Our interactions with the regulatory agencies  
4 thus far indicate that AHED is acknowledged as a very  
5 significant improvement over PHED. And that it's our  
6 intention as individual AHED scenarios are completed,  
7 to begin to rely on AHED data. We believe AHED will  
8 become the preferred tool of analysis for the  
9 regulatory agencies.

10 In my part of the presentation here I've  
11 attempted to provide for you some of the history in the  
12 activities of this task force to date, our view on the  
13 regulatory need for additional handler data and the  
14 scope of our data development effort and a brief  
15 description of the database tool, AHED. The takeaway I  
16 hope you will gain from this part of the presentation  
17 is that our task force exists not to do basic or  
18 applied research, but to meet specific data  
19 requirements that have been established by the  
20 regulatory agencies. That is our goal in life.  
21 Existing handler data simply don't meet those needs.  
22 AHETF data is designed specifically for use in generic  
23 exposure databases to overcome the limitations of the  
24 kinds of data that have been utilized to date. And we  
25 believe that AHED then will become the next generation

1 tool for handler exposure assessment.

2 I'd be pleased to answer any questions you  
3 may have or simply go on to the next phase of this  
4 presentation.

5 DR. HEERINGA: Well thank you very much,  
6 Doctor Collier. I think let's take just a few moments  
7 for some quick questions. We can come back obviously  
8 but I look to the panel. Doctor Portier.

9 DR. PORTIER: You know, as our ag  
10 engineering will tell you, ag technology continues to  
11 move, right, and new application technologies are going  
12 to come out. How long do you view, how far into the  
13 future do you see creating and populating new scenarios  
14 in the database?

15 DR. COLLIER: A very interesting question.  
16 One of the reasons why there is a need right now is  
17 that current scenarios, current equipment, are not well  
18 represented in the database tools that are available  
19 today and we can certainly conceive that ten years from  
20 now, if additional advances are made, and we certainly  
21 that they will, that there will be a continuing need  
22 for additional data. I can't comment on whether this  
23 task force will be the group that ten years from now is  
24 ready to step forward and say, well, we're going to  
25 fill that data gap. But it's I think quite clear to me

1 personally that the industry will find itself in a  
2 position where it will need to fill that data gap.

3 So this is an effort I think that, while the  
4 task force has established a scope for what it can see  
5 today, that scope may have to be revisited over time  
6 and it wouldn't surprise me if it were expanded as time  
7 goes on.

8 DR. HEERINGA: Doctor Chambers, Jan.

9 DR. CHAMBERS: I have a couple of  
10 questions that might be answered by the subsequent  
11 presentations, so if so, just defer. You talked about  
12 low acute toxicity formulations that were going to be  
13 used. I assume that means that the chemical itself  
14 might not be low toxicity, is that correct?

15 DR. COLLIER: That is correct. The  
16 requirement for the minimum personal protective  
17 equipment that is prescribed in the Worker Protection  
18 Standard and on pesticide labels is driven by the acute  
19 toxicity properties of the particular formulation. So  
20 for example, a product that itself may be moderately  
21 toxic as a technical chemical, might have a 5% granular  
22 that has a very low acute toxicity. So the, that part  
23 of our selection is driven by the acute toxicity  
24 properties of the formulation, not necessarily of the  
25 active ingredient itself.

1 DR. CHAMBERS: You talked about  
2 diversity of chemical and biological properties. When  
3 you say biological, so you mean different modes of  
4 action in terms of its toxic mechanism or other

5 DR. COLLIER: Yes.

6 DR. CHAMBERS: things?

7 DR. COLLIER: And I was thinking of it  
8 even more broadly than that, of wanting the database to  
9 have within its group of surrogates, both  
10 representatives of the broad classes of pesticides,  
11 insecticides, fungicides, herbicides and not be limited  
12 to one of those classes.

13 DR. CHAMBERS: You also spoke about  
14 varying the amount of active ingredient handled at each  
15 location. Does that mean you're going to have  
16 different formulations of varying concentrations of  
17 different time of exposure of the workers?

18 DR. COLLIER: It would mean that there  
19 would be different amounts of most likely the same  
20 formulation handled by different workers. That will  
21 have some impact on the work period but we do have some  
22 limitations on the work period as well that Doctor  
23 Canez will cover I think in his presentation. So I'll  
24 defer the remainder of that answer to Doctor Canez.

25 DR. CHAMBERS: Sure. And then the last

1 question I have, and I think I'm sort of putting my  
2 HSRB hat on here for a moment, the worker information  
3 that you're generating, the workers are anonymous,  
4 they're not going to be identified afterwards, is that  
5 the idea or linking the data to individuals? By name,  
6 right, by --

7 DR. COLLIER: The names of the individuals  
8 are not represented in the database. They are of  
9 course kept in the task force records and in the raw  
10 data. That is really an issue as you said, with your  
11 HSRB hat on, that we are still working on and I don't  
12 think we have a final answer on how, how and what means  
13 that information will be protected or made available.  
14 It certainly will not be represented in the database.

15 DR. CHAMBERS: Okay, and then a slight  
16 follow up there, you're getting height, weight, so  
17 forth like that, are you analyzing on that or is it  
18 just accumulating it at this point?

19 DR. COLLIER: As a task force we do not  
20 expect to analyze on that basis. We however don't  
21 limit how the user of the AHED database utilizes the  
22 information. So a user may have some interest in  
23 selecting data on those bases and doing analyses on it.  
24 The system would allow them to do that sort of thing  
25 and to segregate data in that way. But that's not a

1 part of the routine analyses that the task force itself  
2 would expect to do.

3 DR. CHAMBERS: Thank you.

4 DR. HEERINGA: Yes, Cynthia.

5 DR. HINES: All right, just one quick  
6 question. You mentioned that one of the parameters  
7 that you'll be varying is the equipment used. And I  
8 was wondering for say for something like a ground boom  
9 application where you may have a farmer using a ground  
10 boom with a tractor and you also could have a  
11 commercial or custom applicator using their large  
12 vehicles, is that all included in this equipment  
13 variation or are you focused more on the private  
14 applicator?

15 DR. COLLIER: This is exactly in Doctor  
16 Canez' area of responsibility of the task force so I  
17 think I'll defer that answer to him.

18 DR. CANEZ: This is Victor Canez, do you  
19 want me to answer now or demonstrate that during my  
20 presentation?

21 DR. HINES: I can wait, that's fine.

22 DR. CANEZ: Okay.

23 DR. HEERINGA: Doctor Portier has another  
24 question.

25 DR. PORTIER: You mentioned that users who

1 are, I guess users who are not members of your task  
2 force or of your consortia, are going to have to pay to  
3 use. And I wondered if that, you mentioned, the way  
4 you said it was kind of interesting. You said they're  
5 going to pay to cite it in a report. Does that mean  
6 you could use it and if you decide it's not useful for  
7 your application and you went off and generated new  
8 data, you wouldn't have to pay for that peek?

9 DR. COLLIER: In some aspects FIFRA is a  
10 very strange law. A user of this data who is not a  
11 pesticide registrant would not have any fee to pay to  
12 utilize the data.

13 The requirement comes when a pesticide  
14 registrant chooses to utilize this data to support  
15 registration of their products. So a pesticide  
16 registrant may, is allowed under FIFRA to cite data  
17 that have already been submitted to the Agency, but in  
18 so doing, so long as those data are not within a period  
19 of exclusive use by the originator, or are not less  
20 than, or not more than 15 years since their initial  
21 submission, that registrant is required to pay  
22 compensation to the initial submitter of that data.

23 So that sort of a, that compensation aspect  
24 really refers only to the utilization of the data by a  
25 non-member company to support a pesticide registration.

1 DR. HEERINGA: Thank you very much. Yes,  
2 Doctor Landers and then Doctor Curwin.

3 DR. LANDERS: You mentioned earlier that  
4 part of AHED is the ECPA Occupational Bystander Group.  
5 How applicable are, how applicable is the data that  
6 could be generated in Europe to U.S. conditions?

7 DR. COLLIER: Certainly some data  
8 generated in the U.S. could be applicable to European  
9 utilization and vice versa. However, the data  
10 compensation issues and the manner in which data are  
11 protected in the U.S. differs quite substantially from  
12 the way data are protected in Europe and in other parts  
13 of the world.

14 Consequently we have not yet found a workable  
15 way to share the data and address those compensation  
16 issues. I'm always optimistic that such sharing may  
17 occur in the future, but for the present the  
18 collaborative effort on the part of ECPA and the Ag.  
19 Handlers Exposure Task Force is in the development of  
20 the database management system, not in the sharing of  
21 data from studies themselves.

22 DR. HEERINGA: Doctor Levine has a

23 DR. LEVINE: I just want to make a very  
24 minor subtle correction to what the impression that  
25 might be left here is. The EPA doesn't like monitor

1 the payment of data compensation. But when you submit  
2 an application for registration, if you cite data that  
3 is owned by someone else there is a requirement that  
4 you make an offer to pay and the Agency does make sure  
5 that you've made that offer. In terms of actually  
6 what's decided upon for payment, we're out of the  
7 picture.

8 DR. HEERINGA: But the task force has  
9 legal recourse under FIFRA to go after whoever it  
10 chooses to.

11 DR. COLLIER: Indeed we do but it is not  
12 as, as Doctor Levine says, it's not through the Agency

13  
14 DR. HEERINGA: Right.

15 DR. COLLIER: but through other means.

16 DR. HEERINGA: Right, independently, yeah.  
17 Doctor Curwin and then I'd like to move on to Curt  
18 Lunchick's presentation.

19 DR. CURWIN: I just have one little or a  
20 couple of clarifications. But I think this question  
21 was answered but I just want to be sure, but it sounds  
22 like the database will be, there will be some  
23 flexibility in it that you can add new studies in the  
24 future that aren't necessarily being considered right  
25 now, so down the road, maybe ten years down the road

1 there will be this flexibility to add new information  
2 as it comes about?

3 DR. COLLIER: We certainly expect that  
4 will occur.

5 DR. CURWIN: Okay. The other question is,  
6 you mentioned some of the information that's going to  
7 be collected such as application information, mix  
8 information and such, but I didn't notice that there  
9 was any information on environmental information such  
10 as temperatures and humidity and wind speeds. Is that  
11 going to be collected as well?

12 DR. COLLIER: A fairly broad variety of  
13 weather conditions and environmental conditions are  
14 captured, I just didn't highlight that in my  
15 presentation.

16 DR. HEERINGA: Okay, at this point in time  
17 I'd like to move on to the second component of the  
18 AHETF presentation and Mr. Curt Lunchick will be doing  
19 this segment. Doctor Lunchick.

20 DR. LUNCHICK: Thank you, Doctor Heeringa.  
21 Just as background I am with Bayer CropScience, I am  
22 responsible for the non-dietary exposure assessments  
23 there and I guess I date myself a little because in a  
24 prior life I was actually at the EPA involved in the  
25 development of both Subdivision U and the Pesticide

1 Handler Exposure Database, so this is like deja vu.

2 I wanted real quick to address one of the  
3 questions Doctor Chambers asked in regards to the  
4 surface area and the body weights. We actually, there  
5 are algorithms in the AHED database to use that in  
6 regards to calculating surface area for each individual  
7 worker because of obvious differences that could exist,  
8 so whe necessary.

9 I'm going to talk about one of the components  
10 of the development or the obtaining data for the AG.  
11 Handler Exposure Database. Doctor Canez is going to  
12 talk about the second which is going out into the field  
13 and monitoring workers to develop new data.

14 Before we did that the task force underwent a  
15 very extensive effort to evaluate whatever existing  
16 data we were able to look at to determine if it met our  
17 needs with the idea if we had sufficient existing data,  
18 that's preferable to going out and developing new data  
19 which would be repetitive. Our selection criteria as  
20 we started this process and what we had the benefit of  
21 that did not exist at the time that the Pesticide  
22 Handler Exposure Database was put together, was we had  
23 actually started to create AHED and could put in data  
24 as we were looking at it to make sure it was compatible  
25 with the way we were going to or we were thinking we

1 would intend to use it in the generic database.

2 As we started looking at the data, right off  
3 the bat we required that any study we looked at would  
4 be compatible with the EPA guidelines, the 875 Series,  
5 Subpart or Part A which is specific to applicators to  
6 handlers.

7 In addition as I said we were also looking to  
8 make sure it would be compatible with an exposure, use  
9 in a generic exposure database and I'm going to hone in  
10 on that because there are some important distinctions.  
11 It was previously mentioned both by Doctor Collier and  
12 by I think Jeff Evans and Jeff Dawson, at the time PHED  
13 was put together most of the studies that made up the  
14 database. make up the database today, were developed  
15 with the intention of addressing a specific active  
16 ingredient, and not to be used generically. Can we  
17 have the next slide.

18 That's an important distinction to keep in  
19 mind. With product specific study designs, although  
20 they too may meet the Agency guidelines, the OECD  
21 guidelines, et cetera, they are conducted by an  
22 individual company to address an issue or the exposure  
23 potential of that active ingredient. And what you  
24 generally see is when we're doing a risk assessment we  
25 want to look at the upper end of the potential exposure

1 for that specific AI, so we will conduct a study at the  
2 label maximum application rates. And that's great in  
3 that you get say 15 monitoring units if you meet the  
4 requirements of Subdivision U, but when you want to  
5 look at things statistically for the effect of say the  
6 differences in the amount of active ingredient handled  
7 on the exposure potential, you're kind of stymied when  
8 all the monitoring units handled essentially the same  
9 amount of active ingredient. Next slide.

10 And that's I think the big difference when  
11 you look at the generic database in and the study  
12 design, is we're more interested now in ranges to get a  
13 range of exposure potential rather than focusing in  
14 with multiple data points at a given amount of active  
15 ingredient.

16 And as Doctor Canez will go into detail with,  
17 the studies that we're actually taking out into the  
18 field, we focus on and we focus during the evaluation  
19 of existing studies, the amount of active ingredient  
20 handled and also making sure the equipment that was  
21 being used was representative of a scenario that the  
22 data were intended to address. We wanted to make sure  
23 we were getting different types of equipment that fit  
24 within that exposure scenario area.

25 With that in mind and the emphasis on that

1 difference we develop a three step process to look at  
2 the data and document the review process and the final  
3 selection decision making process.

4           The initial process was a primary review by  
5 the data owner, generally the members of the task  
6 force, though theoretically it could have been others  
7 that were interested in selling their data to the task  
8 force. If the studies met the criteria at that point  
9 the company or the study submitter would forward the  
10 data to the task force and the data then went,  
11 underwent a secondary review by contractors that we  
12 hired specifically to review the studies and make sure  
13 the data actually met the criteria that we have  
14 established, and I'll go over that shortly.

15           If the study data passed the primary and  
16 secondary review process, then a final review was done  
17 by the task force as a whole with consultation and  
18 concurrence from the U.S. EPA, the Pest Management  
19 Regulatory Agency, California's Department of Pesticide  
20 Regulation and the U.S. Department of Agriculture. We  
21 wanted to make sure that everybody was comfortable with  
22 the studies before the task force would write the check  
23 to the data holder.

24           The general study designs, I'll go through  
25 this quickly, you'll get more of this as Doctor Canez

1 goes through his talk. Again the key thing is the  
2 compatibility with the existing guidelines. We needed  
3 to make sure that we understood that all the pertinent  
4 information from the description of the worker to the  
5 equipment to the weather conditions, you name it, was  
6 well understood and documented in the study reports.  
7 We didn't want to get into a lot of guessing as to what  
8 may have gone on and things like that.

9 All the study participants, unlike the  
10 Pesticide Handler Exposure Database, our requirement  
11 was that they had to be normally employed in conducting  
12 the type of work that they were monitored for. No  
13 company employees or college students or anything like  
14 that. These had to be agricultural employees. The  
15 experience that they had could vary all over the place.  
16 We documented the experience but they could be new to  
17 the job or they could be on it for 30 years, that  
18 didn't matter. What was important was it was their  
19 job.

20 An important distinction was, and this was a  
21 pragmatic decision, was we wanted data under normal  
22 work attire consistent with a caution signal word  
23 label, that's the long sleeved shirt, long pants,  
24 chemical resistant gloves. This was basically again,  
25 if you start to get into the other types of protective

1 clothing, a second layer of coveralls, chemical  
2 resistant clothing, things like that, the permutations  
3 of combinations and the amount of data you need to  
4 collect begins to grow extensively, it becomes a very  
5 extensive, expensive process.

6 Time wise, Lord knows how long it would have  
7 taken us to do this. A very pragmatic decision, let's  
8 focus on the basics and then if you need to address  
9 additional layers of clothing, the mitigation, there  
10 are avenues available in the database from using  
11 harmonized assumptions on clothing protection values to  
12 actual data which actually a lot of it's coming out of  
13 the Pesticide Handler Exposure Database. So you do  
14 have avenues available and if necessary then a  
15 registrant would augment the database by conducting  
16 their own study to address questions from additional  
17 PPE if necessary.

18 And then the final issue was GLP. We wanted  
19 our studies to be conducted under the good laboratory  
20 practices, but on the other hand we didn't want to  
21 reject a study that had perfectly good data for some  
22 bureaucratic type of reason. For instance, whoever  
23 conducted the study didn't keep training records on  
24 some of the employees of the laboratory. It had  
25 nothing to do with the quality of the data, it just

1 didn't meet the various specifics of GLP, we would not  
2 reject a study because of that. But the documentation  
3 of quality assurance, analytical chemistry, those type  
4 of things obviously we made a requirement. Next slide.

5           For the field aspects, and again I think this  
6 had been beaten into the ground, but all the studies  
7 had to be consistent with the existing EPA guideline.  
8 To address the issue that you heard from Jeff Dawson  
9 with the variability and where dosimeters were and all  
10 the complications that arose from that, we required  
11 either whole body dosimetry that monitored the entire  
12 body areas plus the monitoring of the head and face and  
13 neck, or if there was patch dosimetry, that the key  
14 body areas were covered, that's a minimum of 10  
15 patches, again plus the hand, head and face monitoring.  
16 We actually did an analysis looking at the Pesticide  
17 Handler Exposure Databases data and other data as to  
18 whether we were seeing any real differences between  
19 patch data and whole body dosimetry data in predicting  
20 total dermal exposure, and the answer was it was  
21 marginal to none and therefore we saw no reason to  
22 prefer one methodology over the other.

23           And finally the issue of hand exposure which  
24 will be discussed extensively tomorrow, again we looked  
25 at using the Pesticide Handler Exposure Database.

1 Whether there was anything definitive in our minds or  
2 glove dosimeters versus the different handwash, rinse,  
3 wipe methodologies we did see, and there will be more  
4 discussion tomorrow, some differences between glove  
5 dosimeters and hand washes, hand rinses, but made the  
6 decision that we would accept any of those data, we did  
7 not see anything that indicated one method was better  
8 than the other.

9 In regards to duration we wanted to avoid  
10 this issue of the 20 minute ground boom replicate. We  
11 have all non-detects and you could say, oh, there was  
12 no exposure. We're requiring, or required that all the  
13 data we looked at and acquired had to be at least half  
14 a day, a typical workday or half of the acreage  
15 treated. That way if we were seeing non-detects we  
16 knew they were legitimate, we're not into massive  
17 extrapolation from 20 minute time durations to 8 hour  
18 days or anything like that. And finally all matrices,  
19 we had to have field fortification data. We needed to  
20 know what the loss potential of the active ingredient  
21 in that study was.

22 The non-detect criteria, you've heard  
23 multiple discussions on, and just quickly to reiterate,  
24 we were sensitive to the impact of a lot of non-detects  
25 on an exposure estimate. I think Jeff Dawson showed a

1 very good example with the questionable results of not  
2 wearing gloves actually giving lower exposure, being  
3 driven by detection limits and things like that. We  
4 made sure if we were accepting a study with a  
5 significant amount of non-detects, that it was because  
6 of the exposure potential. Our requirement for the  
7 limit of quantification was low, it had to be a low  
8 number. We actually went through an exercise that if  
9 an exposure potential was based on the LOQ the tox end  
10 point that would start to indicate a health risk of  
11 concern would be so low, in the neighborhood of say, I  
12 forget what the exact number was but NOL of 10  
13 micrograms per kilogram per day, that the likelihood of  
14 running into that situation with the use of AHED would  
15 be minimal.

16 Analytical criteria, I think everybody could  
17 read this but again we wanted to keep tight reins on  
18 making sure we had good recoveries, both in the  
19 laboratory and on the field matrices, that we were not  
20 dealing with studies where we were losing material  
21 during the monitoring period.

22 And again I'm just going to beat this into  
23 the ground because we think it is important, as we went  
24 through this process we saw a lot of very good studies  
25 and we decided not to acquire them. It was because of

1 their utility or what we felt was a lack of utility in  
2 a generic database, it had nothing to do with the  
3 study's quality in regards to addressing a single AI  
4 that it was designed to do. And I think a very clear  
5 and pragmatic example of this is, we saw studies with  
6 15 or more very good monitoring units, all at  
7 essentially the same amount of active ingredient  
8 handled which we could have acquired at a fairly  
9 substantial price, but frankly it would have been much  
10 more effective to spend that money to go out in the  
11 field and acquire that same number of monitoring units  
12 where we were varying the amount of active ingredient  
13 handled to give us better power in looking at this  
14 issue of the relationship between the exposure and the  
15 amount of active ingredient handled.

16 And that's the end of my presentation. If  
17 there are questions.

18 DR. HEERINGA: Well thank you very much,  
19 Doctor Lunchick. Steve Heeringa, I have one question  
20 which I'll insert first so I don't forget it.

21 On page 5 and Doctor Collier mentioned it  
22 earlier too, that you undergo IRB review for each of  
23 these individual studies, but in terms of the  
24 utilization of AHED in the registration and other  
25 processes with EPA, do you face, and maybe this isn't a

1 question for you, do you face a second review when that  
2 data is submitted in support of a registration by the  
3 EPA's own Human Subject Review Board? If so, would  
4 there be some benefit in getting preapproval from the  
5 EPA Human Subject Review Board? I'm thinking about  
6 process and making the process efficient. Maybe I'm  
7 and you don't have to answer this question but if

8 DR. LUNCHICK: Well, let me, I think, let  
9 me answer it as best I can.

10 DR. HEERINGA: From your perspective

11 DR. LUNCHICK: Right.

12 DR. HEERINGA: as a database developer.

13 DR. LUNCHICK: It's a two stage process in  
14 that all of the studies that we are going to conduct  
15 from this point forward are clearly going to undergo  
16 this two tier review process, both the protocol itself  
17 which will go through EPA review and the EPA will  
18 present it to the HSRB, then when the data are  
19 completed we evaluate the data and it'll probably be  
20 done actually on a scenario basis rather than  
21 individual studies, those data will go back again to  
22 the HSRB for the approval.

23 Now the existing studies that we've already  
24 acquired all predated the HSRB. And I think, and I'll  
25 defer to John Corley is I mangle this, but under the

1 rule, those data which are already in AHED are not  
2 required to go to the HSRB but the EPA has to do an  
3 ethics review and whether that was completed or not, I  
4 think most of those studies were reviewed by the Agency  
5 in one form or another for that issue. Is that  
6 correct? Okay.

7 DR. HEERINGA: Okay, it's just a point I  
8 think for some of us involved in this process of med  
9 schools and other things that it just seems like  
10 another hurdle that with some sort of coordination as  
11 we're seeing in the Davato Development and the protocol  
12 review it might save time and utilization. I assume  
13 the other thing you would want to keep in this data  
14 base are actual copies of these human subjects  
15 approvals when you have them and as they occur.

16 DR. LUNCHICK: The task force will  
17 definitely have and keep that. Whether it, that won't  
18 be in the actual AHED manipulations but, yes.

19 DR. HEERINGA: Okay. Other questions from  
20 members of the panel for Doctor Lunchick? Doctor Kim.

21 DR. KIM: I have a question about the  
22 passive dosimetry. Can you clarify whether the 10  
23 patch dosimeters are placed in a set location or are  
24 they varied?

25 DR. LUNCHICK: They have to cover the main

1 body areas. In other words the left and right lower  
2 leg, upper leg, chest, back, left and right upper arm  
3 and lower arms. And that's the 10 areas. Then there  
4 could be front and back in addition to it but that's  
5 the minimum that we set.

6 DR. KIM: This is independent of the work  
7 task or process?

8 DR. LUNCHICK: Correct.

9 DR. KIM: Okay.

10 DR. HEERINGA: Doctor Hamey.

11 DR. HAMEY: A follow on question related  
12 to the patch data. You commented that you saw only a  
13 marginal difference between the patch and the whole  
14 body dosimeters. Was that for outer data or for inner  
15 data or for both?

16 DR. LUNCHICK: To the extent my memory  
17 remembers it's clearly inner data. And again that was  
18 once the values say on a patch or the whole body  
19 dosimeter were all added together, extrapolated to, you  
20 know, the entire body, that particular body area. I do  
21 not believe that we looked at the outer potential  
22 exposure area because that's not an area we're focusing  
23 on.

24 DR. HEERINGA: Yes, Doctor Pependorf.

25 DR. POPENDORF: Yes. Curt, could you

1 refresh my memory? Earlier you were describing the  
2 database looking at minimal PPE and I think you  
3 mentioned the caution keyword. Does that include  
4 gloves or

5 DR. LUNCHICK: Yes.

6 DR. POPENDORF: so it does include  
7 gloves. There would be no, I was wondering, getting to  
8 a point of being able to discern the effect of gloves

9 DR. LUNCHICK: Right.

10 DR. POPENDORF: whether that's an  
11 option in the design?

12 DR. LUNCHICK: We, we are following the  
13 Worker Protection Standard which for mixing and loading  
14 is going to require the chemical resistant gloves. I  
15 cannot think of an exception with any of the products  
16 we're looking at. I mean if we got into a bio  
17 pesticide that's a possibility but we do not have one  
18 at this point that we're looking at.

19 When you get into application, especially  
20 with the engineering controls and then enclosed cabs,  
21 those individuals will not have gloves on. They would  
22 have to be available for any repairs or anything they  
23 do outside of the cab, but inside they would not have  
24 it on. So it's going to be consistent with the WPS and  
25 will not allow anybody to slip below the requirements

1 of the WPS.

2 DR. HEERINGA: Doctor Hughes.

3 DR. HUGHES: I'm assuming that you're  
4 using a typical workday as 8 hours. Are you looking at  
5 activity specific sorts of distributions of how often a  
6 worker works? And can you define what you mean by half  
7 the acreage?

8 DR. LUNCHICK: Yeah. I think Doctor Canez  
9 will get into more of that but it will vary by the type  
10 of equipment. When you're getting into the boom  
11 equipment for instance and field crops, I mean you're  
12 talking 8, 10, 12 hour days. I think some of our  
13 replicates have gone over 12 hours. Acreage, we talk  
14 to grower groups to get information as necessary. We  
15 actually have a subcommittee that interacts, so before  
16 we go out and design a study we're trying to learn as  
17 much as possible of what's typical. We also have the  
18 EPA defaults on acreage that we use as a guide. For  
19 instance, open cab ground boom, 80 acres, orchard  
20 crops, 40 acres are examples.

21 DR. HEERINGA: Doctor Hamey.

22 DR. HAMEY: A question about the PPE this  
23 time in the existing studies. Were there any issues in  
24 identifying the standards of the PPE in the existing  
25 studies to ensure that they matched the current, modern

1 standards?

2 DR. LUNCHICK: Let me just make sure I'm  
3 understanding exactly what you're trying to get at. In  
4 regards to long sleeved shirt and long pants I think  
5 that it was fairly standard. The gloves, they had to  
6 be either waterproof or chemical resistant. There are  
7 nuances depending on the formulation, but essentially,  
8 you know, you're talking not a cotton glove, you're not  
9 talking a leather glove, but some natural rubber or  
10 synthetic rubber type of glove. The condition of the  
11 glove

12 DR. HAMEY: Well I was thinking more that  
13 if we, certainly in studies in the U.K., if we look  
14 back at studies done sort of 15, 20 years ago,  
15 sometimes the protective gloves would not be the length  
16 that we required and cover enough of the cuff, that  
17 sort of thing.

18 DR. LUNCHICK: If I re I mean we were,  
19 I'm trying to remember whether there were any cases  
20 where we didn't have enough information. We were  
21 making sure that they were what we would consider  
22 protective, going up the fore you know, the wrist for  
23 example and not, you know, some, like a latex surgical  
24 glove. I think in every case we were pretty convinced,  
25 I mean because it is an important aspect that what we

1 were considering PPE was, that information was  
2 available in the studies we were looking at. And  
3 clearly in the studies we're doing that's an area we're  
4 spending a lot of time on.

5 DR. HEERINGA: Okay, at this point in time  
6 I think I'd like to go on to Dr. Canez' presentation  
7 and we'll again have time for questions after his talk.  
8 Doctor Canez.

9 DR. CANEZ: Okay, I'd like to thank you  
10 for the opportunity to make this presentation. My name  
11 is Victor Canez and I work for BASF Corporation as a  
12 risk assessment, in the risk assessment group. And my  
13 responsibilities are for occupational and residential  
14 risk assessments, but I'm here today at the Technical  
15 Chair of the AG. Handler Task Force. And in that role  
16 I'm responsible for making sure that data are generated  
17 the way we need it generated and we can fulfill those  
18 database requirements.

19 The objective of this presentation is to  
20 provide you with some background on the field  
21 procedures that AG. Handler Task Force specifically  
22 uses to generate their data. And also to provide some  
23 introduction to some of the topics that we'll be  
24 hearing in the next few days.

25 Specifically you've been hearing some of the

1 procedures used for exposure monitoring for PHED  
2 studies but I'll talk specifically about AG. Handler  
3 techniques.

4           How are those measurements collected, a  
5 little bit on what are the regulatory objectives of  
6 these data and specifically I'll give you an example of  
7 open cab ground boom scenario that we've collected  
8 data, show you some information on where we've  
9 collected these monitoring units, the range of pounds  
10 handled, the range of pounds handled per day and just  
11 where we've conducted these studies.

12           I'll also talk about how these field sample  
13 are collected, how the passive dosimetry techniques are  
14 used, what techniques we used and a little bit about  
15 data quality. There's been some talk about field  
16 fortifications and I'll explain exactly what that is.

17           First some definitions. You've heard the  
18 term, scenario study and monitoring unit. Scenario is  
19 a grouping of pesticide handling situations that can be  
20 logically combined. Now AG. Handler didn't go out and  
21 make these ourselves. We basically use pesticide  
22 handler database as a role model and we use the same  
23 scenarios that are typically found there and use those  
24 for ours. And pretty our scenarios match theirs for  
25 most cases.

1           These groupings are based on common  
2 properties of the exposure situation such as common  
3 application equipment, common formulation, common  
4 mixing and loading procedures. Examples of scenarios  
5 include open cab air blast applications, or open pour  
6 mixing/loading of liquids.

7           When I talk about studies I mean specifically  
8 a good laboratory practice study that's following these  
9 GLP guidelines. This is generally one study conducted  
10 with one test substance in one geographical area over a  
11 short period of time. Each study will have a final  
12 report. The final report will contain a field study  
13 report which will include all the aspects that, that  
14 summarizes all the aspects of the field activities. An  
15 analytical report will summarize the analytical  
16 results. And a summary section that will summarize the  
17 magnitude and distribution of the exposure to each  
18 worker monitored.

19           The monitoring unit, this is an individual  
20 that was monitored for potential dermal and inhalation  
21 exposure for a period of time that represents a typical  
22 workday. Historically this has been referred to as a  
23 replicate by EPA and AG. Handler, but since HSRB we've  
24 moved on from that term and now we're using the term,  
25 monitoring unit. So if over the next through days or

1 in answering questions I slip and say replicate, I tend  
2 to mean monitoring unit.

3 You've seen this graphic report, or this  
4 graphic before but what I'd like to do is expand on the  
5 little oval that's up there. Now even though we may go  
6 out and do a study that's specifically designed to  
7 address a particular mixing/loading scenario, once we  
8 mix and load that material that material needs to be  
9 sprayed somehow.

10 And if that volunteer agrees to be monitored  
11 then we'll monitor him and also if we need the data  
12 we'll monitor him, if we don't, that application would  
13 just go on like it normally would have and that crop  
14 will be treated like it normally would have, but we  
15 will not monitor that applicator. But in some cases we  
16 will have applicators and monitors in one study.

17 There's been a lot of talk about the  
18 measurements we take when we go into the field and this  
19 is by no means a comprehensive list of some of the  
20 measurements we take when we go out into the field and  
21 conduct a study. But this is, will give you some idea  
22 of some of the information we collect. And some of  
23 this information may or may not have an influence on  
24 the exposure but we collect it for various reasons that  
25 I'll get into.

1           Specifically this is an example of the data  
2 collected or calculated during the conduct of a study  
3 to assess the exposure during an application made using  
4 a ground boom, open cab ground boom application to  
5 field crops. The measurements may differ as a scenario  
6 differs but this will also give you an indication of  
7 what we're collecting for this, at least for this  
8 scenario. Information may include boom height, that  
9 would be the height from the crop or from the ground,  
10 the boom width, the position of the boom, whether it's  
11 in front or behind the tractor or the cab, the number  
12 of nozzles on that boom, the speed of the tractor as it  
13 moves through the field, the spray pressure from that  
14 tank, the spray concentration within that tank, the  
15 number of loads that that applicator will apply and AG.  
16 Handler Task Force does have a criteria of at least  
17 three loads. The period of exposure, once again AG.  
18 Handler does have a criteria of at least 4 hours, but  
19 generally these will approach 8 hours or more. The  
20 personal protection equipment that's used during the  
21 application and the amount of active ingredient  
22 handled.

23           As mentioned earlier we do try to get  
24 chemicals that have the minimum PPE which would be long  
25 sleeved shirts, long pants and at least for

1 applicators, may or may not require gloves.

2 In addition to the application equipment that  
3 is being collected there's information on the crop  
4 that's also collected. And that would be the crop  
5 treated, whether it's a broadcast crop, specifically  
6 what kind of crop it is, whether it's broadleaf, grass,  
7 what kind of crop it is, the stage of growth of that  
8 crop, the crop height at application and the crop  
9 culture, such as row spacing, furrow height and any  
10 other thing that may, whether it's been irrigated or  
11 any other background information. If you'll press the  
12 next slide.

13 Now, even though there's a great deal of  
14 information that's collected on these factors that may  
15 impact exposure, investigating the relationship to  
16 exposure would be very difficult and very costly. But  
17 what we do gather this information for is to assess the  
18 suitability of these exposure data to demonstrate that  
19 these data are representative of the normal  
20 agricultural practices that occur out in the field.

21 As with the applicator scenario previously  
22 discussed there is a variety of measurements collected  
23 for mixing and loading procedures. These may include  
24 the formulation being use, the height of the tank, the  
25 tank volume, the mixer/loader equipment, whether it's

1 an open pour mixing/loading into a tank or it's a semi-  
2 closed system such as an eductor system or fully closed  
3 system, the number of containers opened, the container  
4 size and packaging type, the number of mixing/loading  
5 events, and also we have a three vent minimum for this  
6 for the AG. Handler Task Force, the concentration of  
7 spray in the tank, the period of exposure, once again,  
8 at least 4 hours, the PPE and the amount of AI handled.  
9 As with the application scenario these measurements  
10 also serve to assess the suitability of the exposure  
11 data.

12 In addition to the measurements specific to a  
13 mixer/loader or an applicator procedure, additional  
14 information and measurements are collected that relate  
15 to any exposure scenario and these will include  
16 environmental data, things like temperature, relative  
17 humidity, wind direction and speed, cloud cover,  
18 precipitation, these will all be collected during the  
19 exposure period.

20 In addition, each worker is assigned an  
21 individual observer to monitor their work habits,  
22 describe their activities and record all actions and  
23 times associated with the handling tasks. These tasks  
24 include, but are not limited to the start and stop of  
25 the handling activity, any breaks in work for

1 biological or meal reasons and any activities that may  
2 affect exposure such as cleaning of maintenance of the  
3 equipment. All of these observations are recorded and  
4 included in the raw data.

5 All of the workers used in the studies are  
6 professionals that normally conduct the scenario task.  
7 It is important to realize that since these workers are  
8 experiencing conducting these tasks, that they are not  
9 instructed at all on how to perform these tasks. We do  
10 monitor to make sure that label requirements are  
11 followed but the workers will perform these tasks in  
12 the way they normally do them, and we will monitor how,  
13 and we will monitor and record how those tasks are  
14 conducted. Workers must be at least 18 years of age,  
15 in good health and that also includes not being  
16 pregnant or nursing, and they must speak English and/or  
17 Spanish.

18 These photographs illustrate the variability  
19 in some of the procedures within a scenario. The  
20 outlined procedures, the ones that are  
21 outlined in red, show workers performing an open pour  
22 mixing/loading procedure. As you can see there's a  
23 variety of tank heights, measuring procedures, tank  
24 volumes, all of which may impact exposure. The AG.  
25 Handler Task Force strives to capture this variability

1 in designing studies, by conducting studies in a  
2 variety of geographical areas, using a variety of  
3 crops, a variety of equipment and most important, a  
4 variety of workers.

5 As discussed before, during the conduct of  
6 the field portion in this study a great deal of  
7 information is collected. Many of these measurements  
8 are influenced by the equipment available to address  
9 the scenario, the crop, the time the study was  
10 conducted or by regulatory requirements or default  
11 values. This influence may limit the variability of  
12 some of these measurements collected within a scenario.  
13 For example, in addressing the exposure to open cab  
14 ground boom applicators, similarities in equipment  
15 within the scenario may limit the variability of  
16 certain measurements. Some of these similarities are  
17 generalized below in that open cab ground boom  
18 equipment are generally smaller than closed cab  
19 application tractors, generally associated with smaller  
20 farms, have smaller spray tank capacities and have  
21 smaller boom widths. These generalities about open cab  
22 ground boom equipment may result in a lower number of  
23 acres treated per day because the size and the speed of  
24 the tractor and may also result in more tank loads  
25 applied due to the tank size and boom width.

1           Therefore some of the measurements collected  
2 during the study may be limited by the scenario being  
3 addressed. In the case of open cab ground boom  
4 application exposure the range of measurements for  
5 things such as boom height, boom width, acres treated,  
6 tank capacity and other factors may be limited by that  
7 equipment and the similarities may be found across the  
8 country.

9           To address the question about variability in  
10 equipment, these are photographs that were, photographs  
11 of equipment that were used in addressing the open cab  
12 ground boom scenario conducted by the AG. Handler Task  
13 Force. These show equipment that are used to treat  
14 tall grass where the boom is approximately three feet  
15 high and quite wide, designed to cover a large area of  
16 grass. It can be compared to a banded application in  
17 an orchard. This equipment right here, a banded  
18 application in orchards where the boom was in front and  
19 the movement through the orchard was much slower than  
20 other application techniques. This bottom picture here  
21 illustrates a preplanned incorporation equipment that  
22 was used in an AG. Handler study.

23           So this pretty much illustrates the type of  
24 equipment that you would find in an open cab ground  
25 boom, in open cab ground booms that are used throughout

1 the country.

2 As with application equipment, the crop  
3 treated also influences the variability of the  
4 measurements collected during the study. Crops are  
5 generally grown in geographically similar areas. The  
6 geographical clustering results in crop stages that are  
7 similar during the conduct of the study.

8 As an example, soybeans grown in Illinois  
9 will be generally at the same stage of growth during  
10 August, you'll not find newly planted soybeans, you'll  
11 not find soybeans ready to harvest, they're all going  
12 to be about the same stage of growth, about the same  
13 height and so that limits the variability when you go  
14 out to do the study. In addition, many crops may limit  
15 the range of application rates since the product labels  
16 generally specify a narrow range of application rates  
17 also. So that also limits the variability in pounds of  
18 AI handled.

19 Finally, the seasonality of crops, of the  
20 crop growing seasons limit the time available to  
21 conduct these studies. AG. Handler feels that they  
22 conduct approximately MUs per year but this, these  
23 studies need to be squeezed into the growing season.

24 As discussed, many of the aspects of  
25 conducting field studies are influenced by the

1 constraints in the crop being treated, the surrogate  
2 being used in the study and the equipment being used to  
3 treat the crop or to address a scenario. Major factors  
4 that influence the exposure are handler activities  
5 associated with a scenario and the personal habits of  
6 that individual worker. AG. Handler Task Force uses  
7 professional handlers that are experienced in these  
8 tasks being conducted to address a scenario and does  
9 not instruct these workers on how to perform these  
10 tasks. During the design and conduct of these studies,  
11 AG. Handler Task Force will adjust the amount of AI  
12 handled per day over a broad range of AI from the  
13 scenario being addressed. The justification and  
14 statistical analysis for using amount of AI handled per  
15 day as a normalization factor will be discussed in a  
16 subsequent presentation by Doctor Larry Holden.

17 This graphic represents that the exposure to  
18 a single monitoring unit is really a combination of  
19 many factors that are present during that exposure  
20 period. Some factors may have more of an influence on  
21 the exposure than others. The amount of AI handled and  
22 the worker's activities during the handling process may  
23 have a great deal of influence while crop height and  
24 tractor speed may have smaller influences. Regardless  
25 of the influence of the individual factors, the

1 exposure to the MU is a combination of all of these  
2 factors. Therefore each MU is a single sample of the  
3 potential exposure for the possible universe of MUs  
4 that represent that particular scenario.

5 Even though a great deal of information is  
6 collected on factors that may influence exposure to  
7 that particular MU, the objective of the AG. Handler  
8 Task Force is to populate a database that can be used  
9 by regulatory authorities for estimated exposure to  
10 handlers. Therefore the normalization factor used  
11 needs to have regulatory applicability. Historically  
12 this normalization factor has been the amount of AI  
13 handled per day by the handler. And once again Doctor  
14 Larry Holden will later discuss this normalization  
15 factor.

16 What I'd like to do now is give you a little  
17 bit of information on how we geographically spread  
18 these monitoring units out. In an attempt to capture  
19 the variability among crops, equipment, workers and  
20 other factors that may influence exposure, AG. Handler  
21 conducts studies across a number of geographical areas.  
22 In the following slides I'll demonstrate the location  
23 of the open cab ground boom studies, I'll demonstrate  
24 the location where the open cab ground boom studies  
25 were conducted. There was a total of 34 MUs were

1 monitored and the range of AI handled per day ranged  
2 from 5 to 500 pounds. Next slide.

3 The first study or first data collected was  
4 on peanuts and there was 2 MUs and they handled 5 and  
5 50 pounds of Chlorothalinol per day. The next location  
6 was in the Pacific Northwest on grass seed. That was 2  
7 monitoring units, they handled 128 and 300 pounds  
8 active ingredient. Next location was peanuts, there  
9 was a single MU, and that was, and that MU handled 10  
10 pounds of active ingredient. These first three are  
11 examples of studies that were designed to handle  
12 mixing/loading scenarios but the opportunity to collect  
13 an application monitoring unit was available and we  
14 needed the data and we took those.

15 Next set. These were studies that were  
16 designed to monitor open cab ground boom applications  
17 and so this study was done, it was an orchard trellis  
18 application using the banded application technique with  
19 Simazine, there was 5 monitoring units and they ranged  
20 from 25 to 91 pounds handled per day. The next was to  
21 bare ground orchard floor, once again using Simazine,  
22 this was 5 monitoring units, the range of pounds AI  
23 handled per day was 98 to 195 pounds. We did 6  
24 monitoring units on applications on cabbage and turf  
25 using Chlorothalinol, the range was from 38 to 420

1 pounds. We did 5 monitoring units using a pre-plant  
2 incorporation to corn seed and those are 5 monitoring  
3 units with Diazinon as a surrogate and the monitoring  
4 units exposure ranged from 48 to 150 pounds. And a  
5 final set was to peanuts, soybeans and turf using  
6 Chlorothalinol, there's 8 monitoring units and the  
7 pounds of AI handled ranged from 80 to 500 pounds.

8 In summary, this testing was over a 16 month  
9 period. There was 8 studies conducted in 8 different  
10 locations, 34 different monitoring units, each of them  
11 were individual separate applicators, 3 difference  
12 surrogate chemicals, one fungicide, one herbicide, one  
13 insecticide, 4 different open cab ground boom  
14 applications types, we had 5 monitoring units using  
15 banded application in orchards, 19 monitoring units  
16 broadcast application to field crops, 5 monitoring  
17 units broadcast application to the orchard floor and 5  
18 monitoring units conducting soil incorporation. We had  
19 10 different crop from plum fruit, berries, cabbage,  
20 all the way to soybeans and turf. And once again the  
21 pounds AI handled ranged from 5 to 500 pounds for each  
22 of these individuals, for each of these 34 individuals.

23 In the next few slides what I'd like to do is  
24 demonstrate now I've shown you how these vary  
25 geographically. What I'll do is show you how these

1 studies filled in a graph of the range of active  
2 ingredient handled. In the first slide these are the  
3 first 5 monitoring units that we collected, these were  
4 the studies that, the studies were designed to collect  
5 mixing/loading but we were there and we collected  
6 monitoring units for open cab ground boom. These for  
7 grass, for seed and peanut ranged from 5 to 300 pounds.  
8 Next slide.

9 The ones in yellow are the new ones as  
10 they'll be in subsequent slides. These were orchard  
11 and trellis crops, these were banded application  
12 because they move through the fields a little bit  
13 slower. These, the range was toward the lower end but  
14 there is some overlap in these and those wee from 25 to  
15 91 pounds. Orchard bare ground, they move a little bit  
16 faster through the field.

17 The row spacing in the orchards that were  
18 done in California were a little bit wider than they  
19 were in the previous study, but those ranged from 98 to  
20 195 pounds. Cabbage and turf studies ranged from 90 to  
21 400 pounds.

22 Pre-plant incorporation, you can see these  
23 were toward the lower ends but there were some toward  
24 the middle range and you might expect this because when  
25 you're pulling equipment through the field that is

1 incorporating this material, that tractor is going to  
2 be slowed down as it's moving through the field. And  
3 that ranged from 48 to 140 pounds. And the final last  
4 MUs were on soybeans and turf and those ranged from 80  
5 to 500 pounds.

6 So in summary, for open cab ground boom  
7 applications we had 100 fold range of pounds of AI  
8 handled per day, from 5 to 500 pounds, conducted the  
9 studies in 8 locations and we had 34 monitoring units.  
10 And that also demonstrates that there was some overlap  
11 in all of these studies that we had conducted.

12 In summary of this study design portion  
13 there's a vast amount of information that we collect.  
14 The range of this information is limited for many  
15 parameters and the range is influenced by the location,  
16 the scenario and many other factors. The diversity in  
17 workers and equipment is stressed by AG. Handler Task  
18 Force. Each monitoring unit is a sample of that  
19 scenario universe and the range of active ingredient  
20 handled is the primary objective in designing these  
21 studies. And also we're designing these studies for  
22 regulatory applicability.

23 In this next section I'd like to discuss the  
24 passive dosimetry that is used by AG. Handler Task  
25 Force. These are noninvasive techniques that measure

1 pesticide exposure to humans. We use established  
2 techniques and specifically AG. Handler studies use  
3 whole body dosimeters for dermal residues, hand washes  
4 for hand residues and face and neck wipes for face and  
5 neck areas and absorbent tubes placed in the breathing  
6 zone. The validity of these methods and their ability  
7 to reliably estimate worker exposure will be discussed  
8 in a presentation by Doctor John Ross later.

9 AG. Handler Task Force uses whole body  
10 dosimeters, we don't use the segment one, these are all  
11 one piece, what you may call union suits made out of  
12 100% cotton. They're divided up into 6 sections, front  
13 torso, rear torso, upper and lower arm and upper and  
14 lower leg. We divide these whole body dosimeters into  
15 sections to provide information on the distribution of  
16 the exposure. This information may be beneficial to  
17 regulatory authorities when applying mitigation factors  
18 to protect workers.

19 Hand washes are collected after the outer  
20 clothing and the PPE have been removed by the workers.  
21 This is specified in the AG. Handler, in the  
22 appropriate AG. Handler SOP, or Standard Operating  
23 Procedure. Hand washes are completed before the face  
24 and neck wipes are collected. And during hand washes  
25 the worker immerses their hands in 400 mils of wash

1 solution are placed in a collection bowl or were poured  
2 over their hands while they scrubbed their hands for a  
3 minimum of 30 seconds. The worker will lift his hands  
4 out of the wash solution and while holding the hands  
5 over the bowl the remaining 100 mils will be used as a  
6 rinse solution. The worker's hands will drain for  
7 approximately 5 seconds and then that liquid remaining  
8 is the analytical sample. These methods are a little  
9 more rigorous than some of the previously, methods that  
10 were previously discussed by EPA.

11 Hand washes are collected at the end of each  
12 workday but if bio breaks or meals are required,  
13 additional hand washes are collected. Residues from  
14 these hand washes are combined to estimate the total  
15 exposure during that workday. Combining hand washes  
16 may provide a conservative estimate of the total  
17 deposition on the hands.

18 Face and neck wipes are conducted by  
19 moistening gauze pads with approximately 4 mils of  
20 aerosol OT solution and these moistened gauze pads are  
21 used to wipe the worker's face and neck, front and back  
22 and a total of 2 wipes are conducted per sample.

23 Inhalation exposure is monitored by using an  
24 OVS tube or an OSHA Versatile Sampler Tube that is  
25 linked, or that is hooked up to a sampling pump that is

1 calibrated at approximately 2 liters per minute. Pumps  
2 are generally turned on as the worker approaches the  
3 site where exposure will first occur and then the pump  
4 is turned off when the dosimeters are ready to be  
5 removed. So basically in our studies the exposure time  
6 is equal to the pump time because that's the exposure  
7 period.

8           We talked a little bit about quality control  
9 and field fortification samples. And field  
10 fortification samples are used to determine the  
11 stability of residues during the exposure period,  
12 during the storage period and during the extraction and  
13 analysis. The way these are conducted is that they'll  
14 spread these matrices out on table and treat the matrix  
15 with a known amount of test substance and allow them to  
16 weather if they're required for the exposure period.  
17 Now, the ones that are allowed to weather are the inner  
18 dosimeters and the air sampling tubes.

19           Those are treated with a known amount of  
20 chemical and they're left out in the environment for  
21 the exposure period, or time equivalent to the exposure  
22 period. The hand washes and the face and neck wipes,  
23 those are collected and immediately put into storage so  
24 there's no weathering on those samples because there's  
25 no weathering as the samples are collected. Workers

1 exposure residue values are adjusted for field  
2 fortification values. As discussed earlier there's  
3 always upward adjustment, but no downward adjustment.

4 In addition, all studies are conducted  
5 following Good Laboratory Practice Guidelines. A  
6 representative of the AG. Handler Task Force Quality  
7 Assurance Unit is present at each test site. This is  
8 an independent contractor that's contracted by the AG.  
9 Handler Task Force. In addition to his presence it  
10 also includes an audit of all data collected during the  
11 study. He ensures that we have standardized procedures  
12 for collection of data and we have independent  
13 oversight of our study.

14 Once the field and analytical portions are  
15 completed, analytical reports and field reports are  
16 written and those are combined into a study summary  
17 report. Once that data is reviewed and deemed to be  
18 acceptable, that data is then put into AHED.  
19 Subsequent scenario analyses can be conducted by  
20 anybody who has access to the database. And that could  
21 be a regulatory authority, it could be individual  
22 member companies or anybody who wants to analyze the  
23 data in different ways.

24 And each of these different arrows indicates  
25 a different type of analysis or scenario analysis that

1 could be conducted.

2 In summary of the past few presentations,  
3 Doctor Collier talked about the history of the AG.  
4 Handler Task Force, the regulatory need for the AG.  
5 Handler Exposure Data, the scope of the AG. Handler  
6 Data Development Program and introduction to AHED.  
7 Doctor Curt Lunchick talked about the selection  
8 criteria for putting purchased reports or acquiring  
9 previously conducted studies and incorporating that  
10 data into AHED. And I've discussed a little bit about  
11 our study designs and the data collection procedures.

12 DR. HEERINGA: Thank you very much, Doctor  
13 Canez. And we're at a little past 3:15 and we're going  
14 to need to take a break. For the balance of the agenda  
15 we have another presentation. I want to have a little  
16 time for questions here and also get the public  
17 comments in so people who were scheduled and expected  
18 to be this afternoon will have the time to present.

19 But for the moment here, are there questions  
20 for Doctor Canez. Yes, Doctor Barr.

21 DR. BARR: Thank you. On slide 7 I  
22 believe you said that the workers were allowed to do  
23 their tasks as they normally do but you did ensure that  
24 they followed label instructions. So what did you do  
25 in the instances where workers were not following the

1 label instructions? Were they just not included in the  
2 study?

3 DR. CANEZ: If we find a situation where a  
4 worker is not following the labels he will not be  
5 monitored.

6 DR. BARR: Okay.

7 DR. HEERINGA: Doctor Landers.

8 DR. LANDERS: Have you taken into  
9 consideration the length of time the sprayer, if it's a  
10 self-propelled sprayer or if it's a tractor drawn  
11 sprayer, the length of time that tractor has been in  
12 use in the spraying activity? The reason I ask this is  
13 as you know, modern tractors have very nice seats and  
14 these are great absorbent pads for pesticide residue  
15 from clothing and there may be some cross  
16 contamination. What are your thoughts on that?

17 DR. CANEZ: Pretty much whenever we go out  
18 to the field the workers will basically use the  
19 equipment they're familiar with. This is the equipment  
20 they've always used, they have, and so whatever has  
21 been used before, you know, if there's background  
22 information it's drowned out by the values we get and  
23 we really don't take that into consideration.

24 DR. HEERINGA: Doctor Popendorf.

25 DR. POPENDORF: You mentioned the hand

1 washing that you do when they take breaks. Is there  
2 any kind of limit on how frequently they need to take  
3 breaks? I know we've had some discussion, you know,  
4 about the affect of residue time on the skin and I mean  
5 some of these guys may go a long time without a break.  
6 I don't know, is there, how did that interface?

7 DR. CANEZ: It's pretty much with them, I  
8 mean some of them want to get done with this stuff  
9 because they want to go home or they want to go on to  
10 something else. Others say, hey, it's time for me to  
11 get a drink of water or take a break or go to the  
12 bathroom. It's up to them. And really it varies.  
13 Some it may be up to 6 hours because they want to  
14 finish. Others it could be every 2 hours.

15 DR. HEERINGA: Doctor Chambers.

16 DR. CHAMBERS: I gather from the  
17 pictures that you showed that these workers are using  
18 their own clothes then and they're not supplied  
19 particular clothes?

20 DR. CANEZ: In some cases if we find that  
21 their clothing is not WPS compliant which may have  
22 buttons missing, holes in the clothing, we will provide  
23 new clothing for them, but most of the time it's their  
24 clothes. We will ask them to make sure that it's been  
25 washed before they come onto the field.

1 DR. CHAMBERS: You want a range of  
2 active ingredients, so are you predetermining for each  
3 of the workers how much they're to apply and you stop  
4 their monitoring at that point or

5 DR. CANEZ: Yeah, in, yeah, in some cases  
6 we will. Or there's different ways to adjust the  
7 amount of AI handled. I mean each label has a range of  
8 pounds, has a range of treatment rates and also a range  
9 of spray volumes. So you can adjust those so you can  
10 have somebody going out and spraying the same amount  
11 but he's taking 8 ho9urs to do it, or you can have him  
12 do it in a more concentrated solution and he may do it  
13 quicker. So you can do some adjustments.

14 In some cases we'll say, after 150 pounds  
15 we're going to pull you off the tractor or when you  
16 finish that spray tank that'll be it and we'll stop  
17 your monitoring and then he'll go out and do the rest  
18 of his load or whatever he's going to do the rest of  
19 the day.

20 DR. CHAMBERS: Okay, so he finishes out  
21 his workday then?

22 DR. CANEZ: Yes, yes.

23 DR. CHAMBERS: Okay. Perhaps I should  
24 know what this is, but what's an OT solution, is that a  
25 detergent?

1 DR. CANEZ: It's, yes, it's, yeah, aerosol  
2 OT is a, it's a surfactant, it is, aerosol OT solution  
3 is 10% weight by weight, this is a concentrated  
4 solution of ionic surfactant dioctyl sodium  
5 sulfosuccinate

6 DR. CHAMBERS: Okay.

7 DR. CANEZ: also known as AOT.

8 DR. CHAMBERS: Okay, thanks. You said  
9 two face wipes per sample, is that like one followed  
10 immediately by

11 DR. CANEZ: Yes.

12 DR. CHAMBERS: the next?

13 DR. CANEZ: I mean what they'll do is  
14 they'll moisten the pads, they'll wipe the person down  
15 and they may moisten two pads at the same time but  
16 they'll wipe them down and put that in a plastic bag as  
17 a sample. They'll do that procedure again and put that  
18 in the same sample.

19 DR. CHAMBERS: So it's the whole  
20 monitoring period

21 DR. CANEZ: Yes.

22 DR. CHAMBERS: sampled twice at the  
23 same time.

24 DR. CANEZ: Yeah, because face and neck  
25 wipes are done at the end of the exposure period. Hand

1 wiper, you may have many of them.

2 DR. CHAMBERS: I have a question about  
3 how you picked the surrogate chemical. Is that  
4 something that's going to be addressed by one of the  
5 other speakers later?

6 DR. CANEZ: Not specifically. We talked  
7 about, you know, wanting to have chemicals that are,  
8 have low PPE requirements, or minimum PPE requirements.  
9 And to address your question, you know, even though we  
10 want low, or minimum PPE requirements, that compound  
11 may be packaged in a water soluble bag, that may only  
12 require minimum PPE. And that is one of the scenarios  
13 that will be addressed. If it's wettable powder and it  
14 requires additional PPE then we may not use that one.

15 DR. CHAMBERS: I'm putting on my HSRB  
16 hat again. You'll recall from our discussions in June  
17 there was some concern about whether this was really  
18 the chemical those workers were going to be exposed  
19 anyway or if this is an entirely different compound.  
20 And have you thought about that?

21 DR. CANEZ: Generally we, I mean basically  
22 the compound is labeled for the crops they're going to  
23 be spraying on and generally these folks are going to  
24 be spraying it anyway. It may not be one, it may not  
25 be this one specifically but it may be another

1 fungicide or it may be another herbicide that they're  
2 going to be using and so they may use this one instead.

3 DR. CHAMBERS: Okay.

4 DR. CANEZ: You know.

5 DR. CHAMBERS: Again, that will be a  
6 question from HSRB

7 DR. CANEZ: Okay.

8 DR. CHAMBERS: I'm quite sure.

9 DR. LUNCHICK: Yeah, let me just also,  
10 what we've done in the past and what we're going to do  
11 in the future may vary to address this issue of what's  
12 an observational versus a partly scripted. We haven't  
13 finalized our recruitment process to see if we can  
14 minimize this scripting issue versus moving toward  
15 truly observational, at least in some cases. So when  
16 we go to the HSRB we're going to have that clearly  
17 delineated with however it will be at that point.

18 DR. CANEZ: And to add to that, in some  
19 scenarios it may be easier to find some observational  
20 studies and some it will just be more difficult and  
21 we'll have to search harder.

22 DR. CHAMBERS: Sure. And then my last  
23 question is with respect to the whole body monitors,  
24 the union suits and everything. That again is  
25 something that came up with the HSRB. The concern

1 there if you will recall is that adding that extra  
2 layer of fabric, especially in the hotter scenario  
3 zones, you know, in the south in the summer and that  
4 sort of thing, that that could potentially cause some  
5 heatstroke or distress to the people. Have you thought  
6 about that one?

7 DR. CANEZ: Yes, and that was brought up  
8 in the HSRB review and what we've done is contracted  
9 somebody to help AG. Handler Task Force to devise a  
10 heat stress monitoring plan. And we'll have an  
11 industrial hygienist to help us develop that and when  
12 we go to the HSRB we'll have a plan worked out for you.

13 DR. HEERINGA: Doctor Curwin has a  
14 question and then maybe one or two others, and then  
15 Doctor Johnson.

16 DR. CURWIN: So you're trying to capture  
17 many scenarios and I anticipate there's going to be  
18 some scenarios where you're going to have a person who  
19 does the mixing, loading and applying all at the same  
20 time, particularly in some of the smaller type  
21 applications. How are you going to tease out the  
22 mixer/loader portion from the applicator portion? So  
23 if you're, if they're wearing these whole body  
24 dosimeters presumably they're not going to load their,  
25 say it's a backpack sprayer, load their backpack

1 sprayer which might take a couple of minutes, change  
2 them out of their dosimeter and then have them go  
3 apply, change them out of their dosimeter, so how do  
4 you plan to address that issue?

5 DR. CANEZ: I think it's going to vary by  
6 scenario, but in some cases like the agricultural  
7 scenario where somebody may be mixing and loading  
8 several tractors and a separate person going and  
9 applying, you can't separate those out. And we'll add  
10 those together when they're, when somebody is  
11 evaluating a mixer/loader/applicator scenario. In  
12 designing studies for these scenarios what we do is we  
13 discuss these application techniques and how these  
14 tasks are normally done throughout the country. The  
15 example you're using is nursery applicators that are  
16 using backpack application or rights of way that are  
17 doing those. We'll discuss with experts in those  
18 fields how those are actually done and if somebody  
19 normally does their own mixing, loading and applying  
20 we'll have scenarios that'll address those. And we  
21 won't try to tease those out because we feel in those  
22 scenarios that's what normally happens and that will  
23 reflect the exposure.

24 DR. HEERINGA: Doctor Johnson.

25 DR. JOHNSON: Yes, this is probably only a

1 question that a weird statistician would ask. But  
2 Doctor Lunchick provided some analytical criteria for  
3 current studies to be included and I'm just wondering  
4 if the new studies meet that analytical criterion?

5 MR. LUNCHICK: Either one of us.

6 DR. CANEZ: Short answer, yes. But I  
7 think some of these statistical criteria on how we're  
8 assessing that the data are adequate will be discussed  
9 in subsequent presentations in the next few days.

10 DR. HEERINGA: Okay, at this point in time  
11 I'd like to call for a 15 minute break. And when we  
12 return we're going to hear a presentation by Ryan  
13 Williams from the AEATF with regard to antimicrobials.

14 Public presenters, after Doctor Williams  
15 presentation we will have your public presentations. I  
16 anticipate that they would probably begin around 4:15  
17 or 4:20 and we hope to get them all in before 5:00 or  
18 5:15 when we will adjourn.

19 If you are in the audience and wish to make a  
20 public presentation and you have not yet registered  
21 with the FIFRA staff, if you would please Myrta  
22 Christian during the break.

23 Thank you very much and I'll see everybody  
24 back here at 3:45.

25 (WHEREUPON, there was a recess).

1 DR. HEERINGA: Okay, let's get back  
2 underway. Welcome back everyone to the second part of  
3 our afternoon session of the FIFRA SAP Meeting on a  
4 Review of Worker Exposure Assessment Methods.

5 I was joking with somebody in the hall, I  
6 need a little Terrier or a Border Collie or something  
7 like that with a bite that could just kind of but I  
8 appreciate everybody reassembling.

9 At this point in the afternoon agenda we are  
10 going to hear a presentation from Ryan Williams, Doctor  
11 Ryan Williams on the AEATF's overview and approach to  
12 the issue of worker exposure assessments. Doctor  
13 Williams.

14 DR. WILLIAMS: Thanks very much. Thanks  
15 for the opportunity to address the panel this afternoon  
16 and hopefully I'm going to expand and reinforce some of  
17 the comments that you heard earlier from Doctor Walls  
18 presentation. Real briefly I'm going to give you an  
19 overview of our program, give you a little bit more of  
20 the purpose, the background and scope of the  
21 Antimicrobial Exposure Assessment Task Force.

22 I'd just like to start out by saying that,  
23 you know, we are a separate task force to address  
24 exposure issues related primarily to biocides, but the  
25 scientific issues that we'll be discussing over the

1 next few days, we're principally aligned with them. We  
2 do look forward to interpretations or recommendations  
3 around the current data, limitations of the PHED  
4 database and also what we expect from data generation  
5 of today's scientific standards. The passive dosimetry  
6 issues, normalization and proportionality and data  
7 interpretation, along with a number of the statistical  
8 considerations that we'll get into, primarily sample  
9 size, inter and intra-individual variability. We  
10 really look forward to the panel's recommendations in  
11 those areas. Go to the first slide.

12 Real briefly, you know, we're addressing  
13 exposure assessments for antimicrobial pesticides and  
14 for the purposes here I've broken those down into two  
15 main areas and those are the products that disinfect,  
16 sanitize, reduce or mitigate growth or development of  
17 microorganisms on inanimate objects. So these are  
18 hospital disinfectants, things that are used in  
19 residences, institutionally and industrially. Also,  
20 antimicrobials are used as material preservatives so  
21 these are things that are incorporated into textiles,  
22 woods, floors and counter tops, clothing, things of  
23 that nature to prevent deterioration from microbial  
24 organisms. Next slide.

25 Here's some pictographs that outline some of

1 those uses, paint preservatives, metal working fluid,  
2 oil drilling preservatives, wood preservation, pulp and  
3 paper applications, disinfectant, sanitizers that are  
4 used in industrial, institutional and residential  
5 settings, textile preservatives, petroleum  
6 preservatives and cooling tower preservatives.

7           So real briefly, the purpose of our task  
8 force is to conduct exposure studies in order to  
9 develop accurate exposure assessments for biocide risk  
10 assessment and the associated and subsequent regulatory  
11 decision making process. And our intention is to  
12 address specific mixer/loader/applicator and reentry  
13 scenarios that are relevant to the antimicrobial  
14 chemical usage in industrial, institutional and  
15 residential settings.

16           We've been coordinating this effort  
17 extensively with the appropriate regulatory  
18 authorities. Our data is initially intended to be used  
19 for North American regulatory decisions. We have been  
20 coordinating with the European regulatory authorities  
21 as well. But currently we've been evaluating the  
22 existing data, developing study designs, protocols of  
23 the appropriate technical infrastructure to run a task  
24 force. We'll speak to that in a little bit more detail  
25 in some subsequent slides. And also ultimately data

1 analysis and the application of that data.

2 So similarly to the AG. Handlers group, we  
3 are also going to be constructing a database that  
4 allows the interpretation and generation of predictive  
5 exposure assessments. I'll speak to it a little bit  
6 more in detail but real similarly there's a, you know,  
7 a data collection period which we're about to embark on  
8 and then the ultimate database and useable piece that  
9 we will deliver at the end of the program.

10 So a brief history of the exposure data  
11 that's specific to the antimicrobials. In 1986 there  
12 was a data call in for biocides. The Chemical  
13 Manufacturers Associations assembled 20 companies that  
14 embarked on an effort to generate biocide specific  
15 data. This data is currently being used by the Agency  
16 to supplement the PHED data and supports the current  
17 registration and re-registration of a number of  
18 antimicrobial products. This data did support the unit  
19 exposure approach to exposure assessment and the  
20 generic data does serve as the foundation for the  
21 mixer, loader and applicator exposure assessments that  
22 have been conducted for current products.

23 Some of the limitations is, you know, as  
24 this, as we've evolved scientifically in the analytical  
25 realm and the exposure assessment arena, the original

1 biocide specific data set does have relatively high  
2 detection limits. Our program looks to generate data  
3 that has the dosimeter equivalent of 3 nanograms per  
4 centimeter squared. The previous data did have a  
5 number of scenarios that had extremely low numbers of  
6 monitoring units and not all antimicrobial scenarios  
7 were effectively captured or cited specifically the  
8 number extrapolated from analogous use applications.

9           So our program to date was initiated in early  
10 2003, driven by the additional registration needs of  
11 the upcoming registration and re-registration process.  
12 We had initial discussions with the EPA in June of  
13 2003, initiated a scoping process to figure out the  
14 feasibility of conducting a task force effort. We've  
15 placed parameters around the types of studies that we  
16 would conduct and/or accept, I'll get into those in a  
17 little more detail later, and developed an initial  
18 budget for our work. In mid-2004 the task force was  
19 officially launched with 37 member companies and we  
20 began to prioritize and create study teams that conduct  
21 the work. As I had mentioned earlier we are  
22 coordinating with the European task force and the EA  
23 regulatory authorities, this effort.

24           In early 2005 we developed our technical  
25 infrastructure, I'll discuss that in some upcoming

1 slides. We've conducted regular meetings with both  
2 U.S. EPA, the Canadian PMRA and the California  
3 Department of Pesticide Regulation. We initiated a  
4 search for some contractors for our initial work in the  
5 summer of 2005 and continued our ongoing coordination  
6 with the European authorities. To date we've developed  
7 data review and acceptance criteria for existing  
8 studies, we'll discuss that in a little more detail and  
9 initiated data review of member company studies and  
10 applications or refinements that would make some PHED  
11 scenarios useable for our data sets as they currently  
12 might not be useable today.

13 Again, to date our task force has 43 member  
14 companies, our scope includes 19 exposure scenarios for  
15 mixer/loader/applicators, bystanders and post-  
16 application activities and this is across all 16 use  
17 sites for biocides. Our initial schedule was projected  
18 to be in the field and conducting studies by the end of  
19 2005 and we anticipated at that time a 5 year program  
20 that would deliver a comprehensive data set for the  
21 Agency's use by 2009. Next slide.

22 This is out of our scoping document that was  
23 submitted to the panel and as you can see we projected  
24 to do 19 studies across 16 different use sites.  
25 There's more studies than use sites just to address

1 some scenario specific issues.

2 I would like to take the opportunity here to  
3 address a comment that was made earlier in the day and  
4 briefly referenced earlier around simulation studies.  
5 And as we're building this comprehensive program or  
6 task force has taken the approach where we're going to  
7 discretize tasks and where we have the opportunity to  
8 go in and monitor someone that's conducting a biocide  
9 activity or task in an institutional setting, we want  
10 to break down those tasks so we can use them in a  
11 discrete fashion.

12 So if someone was to go in and mix a solution  
13 and then pour that into a bucket and then mop a floor,  
14 you know, we see that as three separate different  
15 tasks. So to capture that we may need to simulate just  
16 the mopping section where we have someone come in and  
17 conduct an extended mopping period that would represent  
18 the number of mopping that they would conduct during an  
19 entire workday just to ensure that we're capturing the  
20 exposure that's relative to that specific application  
21 method.

22 A second consideration is with the amount of  
23 material that's handled for certain biocide application  
24 is much lower, you know, and you hear the agricultural  
25 group speak of pounds AI handled, there's a number of

1 times where we're handling milliliters or milligrams of  
2 material. An example of that would be a residential  
3 use of a disinfecting counter top product, you know,  
4 someone's going to squeeze a trigger on that and apply  
5 one gram of total formulation to a counter top and then  
6 proceed with wiping that. So we may need to increase  
7 the duration of that task in order to accurately  
8 characterize that exposure. Next slide.

9 As I mentioned we have a fairly complete  
10 technical infrastructure to our task force at this  
11 time. We've been developing and implementing existing  
12 study review criteria, I'll talk about those in some  
13 upcoming slides. We have purchased the rights to the  
14 AHED database and we're modifying that to the  
15 appropriate scenarios that are representative of  
16 biocides. That'll, if you're here for the rest of the  
17 week that's the BHED. So now we've got PHED, AHED and  
18 prospectively BHED. We've established analytical  
19 methods for a few antimicrobial compounds that we could  
20 utilize across a number of application methods. We've  
21 conducted GLP training for our study and protocol  
22 teams. We've contracted a quality assurance unit and  
23 we have a number of SOPs in place, we've developed some  
24 preliminary protocols. We're preparing for study  
25 audits and the appropriate archiving for the task force

1 effort. We've also developed a central website for  
2 document control. Currently that's available to our  
3 task force members but prospectively we will have a  
4 public site at some point once data generation begins.

5 This is our first slide on our review and  
6 acceptance criteria. This again was submitted to the  
7 panel and it's, you know, similar criteria to what we  
8 discussed earlier in the day.

9 We do have a rigorous review process that  
10 initiates with the data submitter. And the task force  
11 will conduct a review and ultimately will have a  
12 regulatory authority review of the data. We evaluate  
13 the comprehensive programs so we're looking at the  
14 characterization of the participant activity,  
15 supporting information that's relevant, site  
16 descriptions, raw data availability and the appropriate  
17 protocols and informed consents that you'd expect.

18 The field aspects are also, go through a  
19 rigorous review and including a number of the points  
20 that were touched on earlier today such as the field  
21 recoveries, the dosimetry extraction efficiencies and  
22 the appropriate sampling schemes, the number of  
23 replicates. The analytical aspects also go through an  
24 independent review, including the method validation,  
25 field fortifications, the appropriate stabilities, the

1 spike and recovery data. For our task force, again,  
2 bio-monitoring is acceptable as long as it's done under  
3 appropriate conditions with the appropriate informed  
4 consent and we do have the ability to extrapolate bio-  
5 monitoring results back to a generic database. That  
6 would be an appropriate dermal absorption factor and  
7 any of the absorption distribution data that would be  
8 needed to interpret that bio-monitoring result  
9 generically.

10 Additional areas that we're looking at are  
11 data that would, data or refinements that would be  
12 appropriate to make, existing data sets, useable or add  
13 utility to them for the biocide application methods.  
14 And a number of task forces are looking at this but one  
15 area would be penetration of dosimetry breakthrough  
16 data. This would be instances where we would maybe  
17 have outer dosimetry but non-detects on an inner  
18 dosimeter, taking into account the appropriate  
19 penetration resulting in potential dermal exposure, it  
20 could be useable in a number of biocide scenarios. For  
21 this again we're not just limited to occupational  
22 exposures, so in the instance that you did have someone  
23 making a residential biocide application it's very  
24 feasible that that application could occur under  
25 circumstances where the person was just wearing short

1 sleeved shirts and shorts. So gloves, the Worker  
2 Protection Standard doesn't necessarily apply across  
3 all of the biocide application methods. The next  
4 slide.

5           So again just to reemphasize the conditions  
6 that our studies will be conducted under, they'll be  
7 under the appropriate GLP methods, comply with the  
8 Harmonized 875 Series Guidelines. Again we do have  
9 some key study design considerations. The diverse use  
10 patterns that I've mentioned, scenarios that often  
11 involve indoor environments, handling small amounts of  
12 material which may necessitate simulated use  
13 environments and we also need to use potentially more  
14 sensitive analytical methods to minimize the number of  
15 non-detects.

16           Again these are specific considerations, we  
17 feel that the scientific issues that are at hand and  
18 the recommendations of the panel really do align very  
19 squarely on the charge questions that we'll be  
20 discussing throughout this week.

21           Again these are a lot of the methods that  
22 have been outlined previously today but again, in  
23 monitoring dermal exposure we'll be using inner and  
24 outer whole body dosimeters, we'll be utilizing hand  
25 washes, face and neck wipes, we will monitor inhalation

1 exposure for all of our study participants. We intend  
2 to videotape all of our studies for archiving purposes  
3 to address any outliers that we have and to bring  
4 people that are using this data for regulatory  
5 purposes, the opportunity to go back and observe  
6 precisely what happened during the collection interval.  
7 Our studies will be submitted to the Agency for use as  
8 completed along with input into a comprehensive  
9 database that we intend to deliver at the end of the  
10 program. And just again, our materials and samples  
11 will be archived as appropriate.

12 I think that was my last slide. The managing  
13 director of our task force is Doctor Has Shaw and we  
14 are organized under the auspices of the American  
15 Chemistry Council.

16 DR. HEERINGA: Thank you very much, Doctor  
17 Williams. Are there any questions from members of the  
18 panel regarding the plans for exposure assessment  
19 databases from the Antimicrobial Exposure Assessment  
20 Task Force, AEATF.

21 Ken, Doctor Portier.

22 DR. PORTIER: Can you give us a hint as  
23 what kind of percentage of non-detects you're shooting  
24 for? I mean it sounds like you're dealing with very  
25 low doses which are going to translate into even lower

1 exposure levels and, I mean I can visualize a large  
2 amount of NDL data, right?

3 DR. WILLIAMS: Yeah, I get, we don't  
4 have a number that we anticipate and our goal would be  
5 to have none so we can accurately interpret the results  
6 of the studies but I'm not sure that that's feasible.

7 DR. HEERINGA: Questions from any other  
8 members of the panel? Yes, Doctor Curwin.

9 DR. CURWIN: I may have this wrong but on  
10 slide 11 you list a bunch of scenarios and you have  
11 studies down and it looks it's just one study with  
12 about 15 replicates for the most part for each of these  
13 scenarios.

14 So my understanding is that's essentially the  
15 minimum for the guidelines. So is this database then  
16 going to be when you do our assessment and you'd come  
17 up with your generic estimate you're only going to have  
18 15 monitoring units per scenario? And if that's the  
19 case it seems to me that this having a generic database  
20 doesn't make it any more robust than an individual  
21 study which is considered one of the advantages of  
22 having a generic database.

23 DR. WILLIAMS: Well I think the generic  
24 piece is that you can extrapolate exposure to multiple  
25 chemicals based on their physicochemical properties, in

1 this case assuming that the application method is what  
2 drives the exposure and not the attributes of the  
3 active ingredient. So I would say that there would be  
4 utility in having a generic base with 15 replicates.

5 DR. CURWIN: Yeah, this is Doctor Curwin  
6 again. I understand that, I guess one of the, I think  
7 in one of the previous presentations this afternoon one  
8 of the advantages of the generic database is more  
9 confidence in the exposure assessment. And I assume  
10 that's because there's more monitoring units for a  
11 given scenario than you might do in one individual  
12 study, but that doesn't seem to be the case here.

13 DR. WILLIAMS: Yeah, and again it's just,  
14 you know, we believe that the application method drives  
15 the potential exposure, so in that case, you know, you  
16 would have the utility to extrapolate the exposure  
17 assessment to other active ingredients.

18 DR. HEERINGA: Any additional questions  
19 for Doctor Williams on his presentation or the plans?  
20 Okay, with that I'd like to thank you very much for  
21 this presentation and I think we'll again return to  
22 this area throughout the next three days, along with  
23 the agricultural worker exposure assessment.

24 At this point in the afternoon agenda, and I  
25 think we're reasonably on track, we have reached the

1 point where we're going to introduce public comments.  
2 And again this is a public meeting and we have had  
3 requests from five individuals to make short public  
4 comments and I would encourage each of these  
5 individuals to limit their public comments to the  
6 agreed upon five minutes.

7 There are prepared statements submitted by  
8 many of the public commenters. The panel has copies of  
9 those, they've been distributed during the break.  
10 These prepared comments will be placed in the docket  
11 for this particular meeting and should be available in  
12 one to two days.

13 MS. CHRISTIAN: In two days.

14 DR. HEERINGA: Two days Myrta says on the  
15 website if you don't have a copy of them but I'm sure  
16 maybe the authors would be willing to share one as well  
17 if you're interested.

18 Okay, at this point in time in terms of  
19 public commenters, I'm going too invite first Ms.  
20 Rebeckah Adcock, representing the Pesticide Policy  
21 Coalition. And Rebeckah, if you would use the  
22 microphone over here to my left.

23 Please introduce yourself again and state  
24 your affiliation.

25 MS. ADCOCK: Thank you members of the

1 panel. Thank you for the opportunity to comment today  
2 to the FIFRA SAP. My name is Rebeckah Adcock and I am  
3 the elected chair of the Pesticide Policy Coalition.

4 For those of you who aren't as familiar with  
5 PPC, we are the I guess outgrowth of a previous  
6 organization, a voluntary member organization that has  
7 been around for a long time trying to ensure the  
8 availability of safe, effective and affordable pest  
9 management tools. Our mission and of the membership is  
10 to work for and support transparent fair and science  
11 based regulation of pest management issues and we  
12 represent food, agricultural, pest management and  
13 related organizations.

14 PPC is very pleased to see this FIFRA  
15 Scientific Advisory Panel comprised of so many world  
16 class experts in occupational health exposure  
17 assessment, toxicology and statistics. And we  
18 especially appreciate Doctor Chambers willingness to  
19 serve on both the Human Studies Review Board and the  
20 SAP.

21 Despite the unexpected challenges raised for  
22 all of us by the HSRB in its June 2006 Exposure  
23 Assessment Protocol Reviews, we acknowledge that EPA  
24 has made great efforts to try to quickly address these  
25 challenges and concerns. PPC is grateful for the AG.

1 Handlers Exposure Task Force's tireless work over the  
2 holiday to modernize the Worker Exposure Monitoring  
3 Program and make it available for the panel's review.  
4 This exposure monitoring program will provide state of  
5 the art exposure data for the new Agriculture Handlers  
6 Exposure Database.

7 PPC believes that these data are an essential  
8 international resource needed to ensure the highest  
9 level of agricultural worker protection. The HSRB has  
10 questioned the need for the exposure assessment studies  
11 and suggested that, if not essential, these studies  
12 would be unethical. To address the HSRB's concern, PPC  
13 urges this panel of experts to make very clear that its  
14 recommendations, to make very clear in its  
15 recommendations to EPA, that exposure assessment  
16 studies carried out during normal work activities are  
17 essential for risk assessment and thus making them  
18 essential to the protection of agricultural workers.

19 We look forward to observing the work of this  
20 panel over the next few days and once again the PPC  
21 appreciates both your expertise and willingness to help  
22 EPA in its review of worker exposure assessment  
23 methods, essential to the safe review and use of pest  
24 management tools.

25 Our members thank you.

1 DR. HEERINGA: Thank you for your  
2 comments. The next public speaker, or commenter that  
3 I'd to invite up is Doctor Larry Olsen who is a  
4 professor at Michigan State University but is here  
5 representing himself. Doctor Olsen.

6 DR. OLSEN: Thank you, Mr. Chairperson and  
7 Panel for allowing me to make these comments. Most of  
8 my comments will be repeats from what you have already  
9 heard throughout the day today. And I am speaking on  
10 behalf of myself. Michigan State University has many  
11 different opinions on this topic and I'll just express  
12 my own.

13 I'm Larry Olsen, Professor of Entomology,  
14 also the North Central Region USDA CSREES IPM Center,  
15 Co-Director and I'm the State Agriculture Extension  
16 Project Leader.

17 My interest in being here is basically in  
18 three different areas. First, I was the former  
19 Pesticide Education Coordinator at Michigan State where  
20 I was responsible for pesticide applicator training and  
21 developing training materials on pesticide regulations.  
22 Second, I'm a charter member, I was on the board of  
23 directors and a former Treasurer of the American  
24 Association of Pesticide Safety Educators, acronym,  
25 AAPSE, just another acronym for today. And lastly, as

1 a research team member conducting worker exposure  
2 studies in Michigan.

3 I'd like to make comments relative to two fo  
4 the charge questions being considered by the SAP Review  
5 Panel.

6 The number one charge question, data needs.  
7 To more fully evaluate agriculture handler worker  
8 safety there needs to be an emphasis on improving the  
9 comprehensive database of exposure data that exists in  
10 the Pesticide Handlers Exposure Database to meet the  
11 most if not all pesticide handlers for eventual risk  
12 use in risk assessment. And many of the studies now in  
13 PHED do not meet current GLP requirements.

14 Studies will need to be conducted where  
15 exposures measured using modern application equipment,  
16 for example, over the row sprayer, air curtain  
17 sprayers, new pesticide formulations, you might  
18 consider some of the new seed treatment formulations  
19 with the polymer coatings that essentially eliminate  
20 dust and other exposure scenarios or application  
21 techniques where you might think of a lock and load for  
22 a granular applicator where there is absolutely no  
23 exposure to the product itself. Just some examples of  
24 the new studies that could be conducted.

25 It is important for the data to be high

1 quality, peer reviewed and applicable to all pesticide  
2 handlers. The generic task force approach is one that  
3 has the best chance of developing a comprehensive and  
4 quality database in the short term. Other studies will  
5 be needed in the long term.

6 Similarly, to generate more refined  
7 agriculture reentry worker risk assessment, eventually  
8 there will need to be a more comprehensive database to  
9 estimate worker exposure for more worker activities  
10 involving a greater number of workers and conducted in  
11 multiple locations.

12 For both the ag. handlers and ag. reentry  
13 workers, protocols for both body exposure estimates and  
14 bio-monitoring need to be developed and standardized so  
15 all who conduct studies will be available to provide  
16 high quality data the EPA can use in probabilistic risk  
17 assessments. Better pesticide use data is needed on  
18 all crops to more accurately estimate exposure.

19 Also the current descriptions of worker and  
20 handler activities needs to be reassessed from the  
21 current approximately 1,200 activities to more fully  
22 reflect the actual exposure scenarios.

23 All this will take time and resources but  
24 will result in greater safety to pesticide users and  
25 those who work in pesticide treated fields.

1           The second charge question, passive dosimetry  
2 performance. The passive dosimetry methodology  
3 provides the body part source of exposure data  
4 necessary for identifying mitigation for personal  
5 protective equipment using inner and outer dosimeter,  
6 skin contact can be estimated for exposure assessment.  
7 Inner dosimeter data plus skin exposure component for  
8 face and neck wipes and hand washes provide nearly  
9 total exposure estimates. For a few worker activities  
10 an additional component of inhalation exposure may need  
11 to be considered. Bio-monitoring can or might  
12 complement the dosimetry data exposure to refine the  
13 risk assessments.

14           An example of the body part data that was  
15 generated in the last two years was hand harvesting  
16 blueberries. For 16 workers, hand harvesting  
17 blueberries for 4 hours each, 47% of the mean total  
18 exposure was on the hands. The margin of exposure for  
19 full exposure was 2,675 for a Fosmet which is the  
20 standard insecticide used by the growers, but 24,635  
21 for Imidacloprid, known as Provado, the reduced risk  
22 pesticide.

23           If the resulting exposure and risk had been a  
24 concern, an MOE greater than 100, then mitigation  
25 measures could have been developed to reduce the

1 workers', or the harvesters' exposure to reduce the  
2 risk to acceptable levels.

3 This type of whole body dosimeter, neck and  
4 face wipes and handwash data is critical to refine  
5 mitigation measures necessary to protect the workers.

6 A couple of general comments. I applaud the  
7 EPA for assembling this review panel and asking these  
8 important questions on scientific methodology that have  
9 a bearing pesticide safety. I can attest to the fact  
10 that growers likewise are concerned about their own and  
11 their workers' safety. As we conduct these exposure  
12 studies growers are nervous about what we might find.  
13 But they do want to know that the mitigation practices  
14 in place are protective.

15 Growers explain to us that if we find an  
16 exposure and a risk that is high, they want us to  
17 conduct more research to mitigate that risk. They also  
18 want the data that is representative of their  
19 situation. In blueberries right now we use table grape  
20 harvesting in California as the standard test and that  
21 is not applicable in the long to estimate risk to hand  
22 harvesting blueberries in Michigan. We eventually need  
23 more data that is truly representative of the local  
24 conditions and local crop.

25 Finally I'd like to go back to my association

1 with AAPSE, namely the extension and state lead agency  
2 organization and discuss another issue that's not one  
3 of the charge questions. I strongly urge EPA office  
4 and I naively assume there is an office that's in  
5 charge of coordinating the risk assessments and  
6 mitigation, that whoever makes that final decision on  
7 pesticide risk mitigation measures, to remember AAPSE  
8 as an organization. I suggest that EPA office,  
9 wherever it might be, to develop a list serve for  
10 outreach to share the results of the decisions with our  
11 Land Grant University partners and State Department of  
12 Agriculture Partners in pesticide education. Simply by  
13 including us in the distribution of that information  
14 will tremendously aid in the awareness of your  
15 decisions and provide applicators the information they  
16 need to comply with the label changes through  
17 attendance at extension pesticide applicator training  
18 sessions. USDA data shows that we've reached over a  
19 half million applicators per year in every application  
20 category and we would look forward to sharing your  
21 label changes and mitigation measures with pesticide  
22 users if we were made aware and knew what those changes  
23 were.

24 Not one of the charge questions but a  
25 challenge that I would hope you would recommend to EPA.

1 I just want to thank you for listening to my  
2 comments and hope you consider them in your  
3 deliberations and in your recommendations to EPA.  
4 Thank you.

5 DR. HEERINGA: Thank you very much Doctor  
6 Olsen. Our next public speaker is Mr. Andrew Moore who  
7 is representing the National Agricultural Aviation  
8 Association. Mr. Moore.

9 MR. MOORE: Good afternoon members of the  
10 SAP. My name, as you mentioned, Andrew Moore, with the  
11 National Agricultural Aviation Association, also known  
12 as NAAA. NAAA represents more than 1,400 members in 46  
13 states and the association members are operator pilots,  
14 licensed as commercial applicators that use aircraft to  
15 enhance food and fiber production, protect forestry and  
16 control health threatening pests. It's estimated that  
17 aerial application accounts for almost 25% of  
18 commercial crop protection applications and nearly 100%  
19 of forest protection applications in the United States.

20 Two major focuses of the NAAA are to ensure  
21 the safety of our industry's workers and to strengthen  
22 our industry's economic viability and today I'd like to  
23 acknowledge the work conducted by the Agricultural  
24 Handlers Exposure Task Force in providing updated work  
25 exposure assessments that will help our industry on

1 both of these accounts.

2           Since exposure data are used to establish  
3 regulatory occupational risk assessments and these  
4 assessments are required to obtain and maintain product  
5 registrations, it is important that a state of the art  
6 generic exposure database is available to both  
7 registrants and regulators. Where these exposure data  
8 do not exist, regulatory agencies must extrapolate from  
9 other data or make assumptions that are generally  
10 conservative and may place some valuable crop  
11 protection product registrations available to our  
12 industry in jeopardy.

13           Today regulators such as EPA estimate  
14 exposure during large acreage aerial application by  
15 extrapolating from exposure data developed from studies  
16 where the acreage was small. As an example, the EPA  
17 takes the amount of exposure measured when 120 acres  
18 are treated, then multiplies that exposure number by 10  
19 to arrive at the exposure number for an aerial  
20 application to 1,200 acres. Both the industry and the  
21 regulators recognize that this kind of extrapolation  
22 probably overestimates chemical exposure to pilots and  
23 loaders who make applications on large acreages.  
24 Because there is little data supporting the belief that  
25 actual exposure is much lower, using extrapolated

1 exposure numbers puts some crop protection products  
2 registrations at risk for our industry. The AG.  
3 Handlers Exposure Task Force is an important consortium  
4 in that it is developing a new generic database that  
5 can be used to better assess potential chemical  
6 exposure of workers who mix, load and apply crop  
7 protection products. This is vitally important to the  
8 aerial application industry because recent changes in  
9 application equipment, mixing/loading techniques,  
10 pesticide formulations and packaging and personal  
11 protective equipment must be reflected in the current  
12 database that are not covered in the Pesticide Handlers  
13 Exposure Database, an older database that you all know  
14 about that EPA, Canadian regulatory authorities, the  
15 California Department of Pesticide Regulation all use  
16 to estimate agricultural handlers exposure.

17 And one such new study that was submitted to  
18 the AG. Handlers Exposure Task Force new database was  
19 accomplished in October 2004 in Garden City, Texas  
20 where several members of the custom aerial application  
21 community participated in a large scale exposure  
22 monitoring study done in conjunction with the U.S.  
23 Department of Agriculture. 16 pilots and 16 loaders  
24 working with the USDA apthous bo weevil eradication  
25 program in the High Plains of Texas were selected for

1 the 10 day exposure study. This particular group was  
2 selected because it represented professional workers  
3 who handle and apply the greatest amount of chemical on  
4 a daily basis. The exposure data generated in this  
5 study verified that actual exposure from large acreage  
6 applications is less than what would be determined by  
7 extrapolation. The AG. Handlers Exposure Task Force  
8 study and resulting data provided high quality exposure  
9 data that are representative of actual acreage use and  
10 this is important as it removes the uncertainty that  
11 comes with extrapolating exposure from smaller  
12 acreages. Thanks to the data from this study assessors  
13 can more accurately determine potential risks involved  
14 in the handling of a given chemical.

15 NAAA supports the AG. Handlers Exposure Task  
16 Force Database because it will provide real, not  
17 extrapolated data. This will provide actual safety  
18 risks from exposure and will be instrumental in  
19 registering new products and maintaining the  
20 registrations on existing products aerially applied.  
21 And this is important to the U.S. agriculture and  
22 forestry industry as a whole because of their reliance  
23 on aerial application services. Aerial application is  
24 often the safest, fastest and most economical way to  
25 treat crops and forests. Aircraft help in treating wet

1 fields and spraying when crop canopies are too thick  
2 for ground rigs. When pests or disease threaten a  
3 crop, time is critical, an airplane or helicopter can  
4 accomplish more in an hour than any other form of  
5 application can perform in a day. This is important  
6 when facing a pest infestation. In addition, aircraft  
7 are necessary to low or medium tillage farming systems  
8 which can reduce soil erosion by as much as 90%.

9 That concludes my remarks today. Again,  
10 thank you to the SAP for this opportunity to provide  
11 the National Agricultural Aviation Association's  
12 comments on worker exposure assessment methods.

13 DR. HEERINGA: Thank you very much, Mr.  
14 Moore. We appreciate those comments.

15 At this point in time I'd like invite up to  
16 the microphone, our next public commenter which is  
17 Doctor Pamela Rowel who is appearing on behalf of Farm  
18 Worker Justice, Incorporated.

19 DR. ROWEL: Thank you very much for this  
20 opportunity to speak to everyone. I'd like to first  
21 start by introducing my colleague, this is Shelley  
22 Davis, she's the Deputy Director of Farm Worker Justice  
23 where I also work. And Farm Worker Justice is a  
24 national nonprofit advocacy group dedicated to  
25 improving the health and safety of migrant and seasonal

1 farm workers throughout the U.S.

2 We're here to express some of our concerns  
3 about the scientific issues raised in the study  
4 protocols for the new Agricultural Handler Exposure  
5 Database. We feel that there is a lot of value in  
6 retaining of the existing database. It should continue  
7 to be used and integrated into any future studies.

8 I will go into some, a little detail on why  
9 we feel it should be retained and also what our  
10 concerns are about the new studies. While the EPA  
11 argues that there are limitations on the existing PHED,  
12 or P-H-E-D or however we're pronouncing it, it should  
13 continue to be used for, it has provided a lot of  
14 information over the years based on the existing  
15 system, the study designs.

16 And some of the issues that were brought up  
17 are ones that we feel don't necessarily need change at  
18 this time. For example, the new application techniques  
19 are not included in the PHED, however in the real world  
20 many of those handling tasks do continue to be  
21 performed with the techniques that were used in the  
22 original studies.

23 Not all growers have switched over to newer  
24 techniques, technologies and equipment and it would be  
25 useful to know how many are actually using them before

1 making a complete changeover.

2 The use of the maximum label rates as  
3 included in the studies in the PHED are preferable to  
4 the new protocol that is going to be based on whatever  
5 application rate the grower is using. Since the  
6 maximum label rate is always legal and the possibility  
7 of using that rate would provide a better estimate of  
8 possible exposure and would be the preferred approach.

9 The PHED includes 1,700 monitoring units as  
10 they are now being called, replicates as they were  
11 being called, whereas the new database when completed  
12 will contain only about a third as many points. So  
13 there are a lot of data points in there that should be,  
14 that would contribute to the overall knowledge of this  
15 issue. And finally the PHED data are not proprietary  
16 (sic), proprietary and therefore are available to be  
17 inspected by the general public.

18 Now, with respect to the proposed database,  
19 in addition to its smaller size it incorporates a  
20 number of problematic assumptions and procedures from a  
21 scientific perspective. Now, the task force does  
22 acknowledge that its design does not address intra-  
23 individual variability but this problem puts the  
24 reliability of the data into question given the  
25 variations in the day to day fluctuations and

1 variations in individual's metabolisms and worker  
2 activities, a whole range of things that become part of  
3 making those assessments. So in order to know that you  
4 have real, reliable data, you need to have some measure  
5 for inter, intra-worker variability. This is  
6 particularly important because the EPA is using these  
7 data to set absolute values for exposure doses based on  
8 the particular scenario. So the, using just one single  
9 data point from a worker may misrepresent the  
10 situation.

11 Let's see, the small number of events per  
12 scenario are going to provide insufficient statistical  
13 power for any kind of generalization, excuse me. And  
14 they, excuse me, and they won't adequately represent  
15 the full range of the distribution. This greatly  
16 limits the database's ability to describe inter-worker  
17 variation as well as its generalizeability to the  
18 larger handler population which does consist of  
19 hundreds of thousands of workers nationwide.

20 The next point is that we've discussed quite  
21 a bit today already, the issue of the hand wipes and  
22 rinses and washes, the various techniques for capturing  
23 residues on hands. I have provided a couple of studies  
24 that have been conducted that address this issue.

25 First off, researchers have found that some

1 pesticide's residues are quickly absorbed in through  
2 the skin and therefore any delay in collecting the  
3 rinses or wipes increases the possibility of  
4 underestimating the exposure. And in addition there  
5 was another study conducted by these researchers that  
6 indicated that hand wipes produced a tenfold  
7 underestimate of the actual exposure when compared to  
8 the controlled situation that they had set up. So it,  
9 there is considerable issues still with the validity  
10 and reliability of the hand wipe data.

11 Let's see, the, if you're following along  
12 here I'm sort of trying to summarize here so I'm just  
13 going to skip a couple of these. Scripting of the  
14 handler scenarios which has also been discussed here  
15 today in order to meet certain study requirements means  
16 that they will not necessarily directly represent  
17 actual work situations. For example, the protocol  
18 calls for the use of all pesticides at a Category 3  
19 level, even though some of those pesticides that are  
20 going to be included, for example, Chlorophyrophos, are  
21 typically used at a concentration that would put them  
22 into a Tox 2 category. So when you combine all these  
23 various issues, the data collected under these  
24 conditions are not going to adequately represent,  
25 reflect the worker's exposure in the real world and in

1 their real world work situations.

2 And finally the Human Subjects Review Board  
3 in the June meeting raised significant questions about  
4 the protocols and expressed concerns about some aspects  
5 of its study design and we would like to bring that,  
6 the final report back into your consideration.

7 So in conclusion we request that the task  
8 force not jeopardize the health and well being of  
9 handlers by replacing the existing database, unless and  
10 until it is able to invest the resources and the time  
11 needed to develop a database that is based on  
12 scientifically valid and reliable studies. Thank you.

13 DR. HEERINGA: Thank you very much Doctor  
14 Rowel, for your comments.

15 At this point in time we have one additional  
16 public speaker scheduled and they have opted out so I  
17 think we've reached the end of the formal comments.

18 But I want to open it up to members of the  
19 panel, hopefully individuals who are on, who were  
20 public speakers here would be able to come back to the  
21 mike if there are questions. But are there any  
22 questions at all of clarification for any of the public  
23 commenters? Doctor MacDonald.

24 DR. MACDONALD: Yes, I have a question for  
25 Pamela Rowel. You were critical of the samples sizes

1 being proposed and we are discussing that later in the  
2 week so I would be interested to know if your  
3 organization has an opinion on what the sample size  
4 should be or what rationale should be used to arrive at  
5 it?

6 DR. HEERINGA: Doctor Rowel, would you be  
7 able to work, there's going to be one other question I  
8 think from Doctor Pependorf, can you come back to the  
9 microphone please? Sorry for the inconvenience, I  
10 should have just had you stay there. Okay. Thank you  
11 very much. Peter, would you like to repeat your  
12 question please?

13 DR. MACDONALD: Yes, you were critical of  
14 the sample size recommendation, and as we are going to  
15 be discussing that later in the week I was wondering if  
16 your organization has an opinion on what the sample  
17 size should be or what rationale should be used to  
18 arrive at that number?

19 DR. ROWEL: I'm going to let my colleague  
20 here, the Deputy Director of Farm Worker Justice go  
21 ahead and handle that.

22 DR. HEERINGA: Ms. Shelley Davis.

23 MS. DAVIS: In preparation for these  
24 comments we did consult with some experts and it was  
25 the opinion of the experts that it would take at least

1 sample size of 30 to generate data that could be used  
2 in a probabilistic assessment. Now I really, I don't  
3 pretend to have the statistical expertise on this issue  
4 but that's the information that we were given.

5 DR. HEERINGA: Okay, thank you very much.  
6 Again this will be a topic I think of much discussion  
7 at a later point in this meeting so we appreciate those  
8 comments and Peter's question.

9 Doctor Popendorf also had a question but it  
10 turns out I think it's for Mr. Moore. So thank you  
11 very much Ms. Davis and Doctor Rowel.

12 DR. POPENDORF: Is Mr. Moore still here?  
13 Andrew Moore?

14 DR. HEERINGA: Andrew Moore is still here  
15 or did he run for the plane? He's stepped out, okay.  
16 Okay. Any other questions from members of the panel?

17 Okay, I'm not seeing any. Are there any  
18 other members of the audience who, after hearing this  
19 discussion would like to make a public comment? And  
20 again you'd be limited to five minutes. Going once,  
21 going twice, okay, sold.

22 Please step to the microphone and introduce  
23 yourself please.

24 MR. DRIVER: Jeffrey Driver, also  
25 representing the Antimicrobial Exposure Assessment Task

1 Force.

2 I just wanted to add to a comment that was  
3 made earlier regarding the minimum number of 15  
4 replicates per scenario.

5 Several points that might help inform that  
6 question. One of them is the number of monitoring  
7 units proposed for many of the scenarios represent,  
8 currently proposed, represent the only monitoring units  
9 that are, would be available. So, you know, in, and  
10 actually for some of the other scenarios the proposed  
11 monitoring units, excuse me, would represent a  
12 supplement to the existing replicates that may only be  
13 two or three currently. So in that context what we're  
14 trying to do is certainly create a minimum data set  
15 that would represent the best available data.

16 Secondly or thirdly, the monitoring units  
17 that are being proposed are being designed as was  
18 indicated by Curt Lunchick, for purposes of a generic  
19 database so they would have the benefit of the study  
20 design for that purpose.

21 And I think finally it's sort of a balancing  
22 act in the sense of trying to provide, as I say, a  
23 minimum number of replicates that are of regulatory  
24 interest, or for the scenarios rather, that have  
25 regulatory interest for the EPA, so at least we have a

1 minimum data set for statistical analysis. Thank you.

2 DR. HEERINGA: Thank you very much. At  
3 this point if there are no additional persons  
4 interested in making a public comment, I'd like to  
5 bring today's session to a close. But before I do that  
6 I'd like to turn the mike over to our Designated  
7 Federal Official for any last minute instruction here.

8 MS. CHRISTIAN: I thank you, Doctor  
9 Heeringa. No instruction but just please remember to  
10 join us tomorrow at 8:30. Thank you.

11 DR. HEERINGA: Thank you everyone. And we  
12 made a lot of progress today, I want to compliment  
13 everybody on the organization of their presentations.  
14 There's a tremendous amount of information we're going  
15 to be going through over the next three or four days  
16 and I think we're off to a good start.

17 So we'll plan to see everybody tomorrow  
18 morning at 8:30.

19 Members of the panel, could we convene in the  
20 breakout room just briefly?

21 (WHEREUPON, the meeting was adjourned for the day at  
22 4:38 p.m.)

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19 financially, directly or indirectly, in this action.  
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25 SUBMITTED ON JANUARY 9, 2007

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