

US EPA ARCHIVE DOCUMENT

U.S. ENVIRONMENTAL PROTECTION AGENCY

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FEDERAL INSECTICIDE, FUNGICIDE AND  
RODENTICIDE ACT SCIENTIFIC ADVISORY PANEL  
(FIFRA SAP)

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OPEN MEETING TO CONSIDER AND REVIEW DRAFT  
FRAMEWORK AND CASE STUDIES ON ATRAZINE,  
HUMAN INCIDENTS, AND THE AGRICULTURAL HEALTH  
STUDY: INCORPORATION OF EPIDEMIOLOGY AND  
HUMAN INCIDENT DATA INTO HUMAN  
HEALTH RISK ASSESSMENT

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DOCKET NO.: EPA-HQ-OPP-2009-0851

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THURSDAY,  
FEBRUARY 4, 2010

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The Panel convened at 8:30 a.m. in  
the Lobby Level Conference Center of the U.S.  
Environmental Protection Agency, located at  
One Potomac Yard, 2777 Crystal Drive,  
Arlington, Virginia, Steven G. Heeringa,  
Ph.D., Chair, presiding.

FIFRA SAP CHAIR PRESENT:

STEVEN G. HEERINGA, Ph.D.

DESIGNATED FEDERAL OFFICIAL PRESENT:

MYRTA R. CHRISTIAN, M.S.

FIFRA SAP MEMBERS PRESENT:

JOHN R. BUCHER, Ph.D., DABT  
JANICE E. CHAMBERS, Ph.D., DABT,  
A.T.S.

GERALD A. LeBLANC, Ph.D.  
CAREY N. POPE, Ph.D.  
KENNETH M. PORTIER, Ph.D.

FQPA SCIENCE REVIEW BOARD MEMBERS PRESENT:

JOHN C. BAILAR, III, M.D., Ph.D.

FRANK J. BOVE, Sc.D.

RICHARD GREENWOOD, Ph.D.

ELLEN B. GOLD, Ph.D.

SHELLEY A. HARRIS, Ph.D.

WILLIAM L. HAYTON, Ph.D.

CHENSHENG LU, Ph.D.

BETTE MEEK, Ph.D.

NU-MAY RUBY REED, Ph.D., DABT

JOHN S. REIF, D.V.M., M.Sc.

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Adjourn

1 P-R-O-C-E-E-D-I-N-G-S

2 8:37 a.m.

3 MS. CHRISTIAN: Good morning. I  
4 am Myrta Christian, the Designated Federal  
5 Official for this EPA meeting.

6 I would like to welcome everyone  
7 and to thank you for participating in the last  
8 day of this meeting to review the Draft  
9 Framework and Case Studies on Atrazine, Human  
10 Incidents and the Agricultural Health Study:  
11 Incorporation of Epidemiology and Human  
12 Incident Data Into Human Health Risk  
13 Assessment.

14 Without further delay, I would  
15 like to introduce Dr. Steve Heeringa, Chair of  
16 the FIFRA SAP.

17 CHAIR HEERINGA: Good morning  
18 everybody and welcome back to what will be the  
19 final day of our three-day meeting of the  
20 FIFRA Science Advisory Panel on the topic of  
21 a Draft Framework and Case Studies on  
22 Atrazine, Human Incidents and the Agricultural

1 Health Study: Incorporation of Epidemiology  
2 and Human Incident Data Into Human Health Risk  
3 Assessment.

4 At this point, we would normally  
5 do introductions and I think we'll do that  
6 quickly this morning just to make sure we get  
7 this covered.

8 I'm Steve Heeringa of the  
9 University of Michigan. I'm a member of the  
10 permanent FIFRA Science Advisory Panel.

11 MEMBER PORTIER: Good morning.  
12 I'm Ken Portier, Director of Statistics at the  
13 American Cancer Society. I'm a  
14 biostatistician and a member of the permanent  
15 panel.

16 MEMBER CHAMBERS: I'm Jan  
17 Chambers, a Professor in the College of  
18 Veterinary Medicine at Mississippi State  
19 University. I'm a pesticide toxicologist and  
20 a member of the permanent panel.

21 MEMBER BUCHER: John Bucher,  
22 Associate Director, National Toxicology

1 Program, NIEHS.

2 MEMBER POPE: I'm Carey Pope,  
3 Professor of Toxicology, Oklahoma State  
4 University.

5 MEMBER MEEK: And I'm Bette Meek,  
6 Associate Director of Chemical Risk Assessment  
7 at the University of Ottawa, McLaughlin  
8 Center, on interchange from Health Canada.

9 MEMBER GREENWOOD: I'm Richard  
10 Greenwood. I'm a Professor of Environmental  
11 Science at the University of Portsmouth in the  
12 United Kingdom.

13 MEMBER HARRIS: Hi, I'm Shelley  
14 Harris. I'm Associate Professor at University  
15 of Toronto and a Scientist at Cancer Care  
16 Ontario.

17 MEMBER BOVE: Frank Bove, Senior  
18 Epidemiologist, Agency for Toxic Substances  
19 and Disease Registry. It's part of CDC.

20 MEMBER LU: Good morning, Alex Lu  
21 from Harvard School of Public Health. I do  
22 pesticide exploration and research.

1                   MEMBER GOLD: Hello. I'm Ellen  
2 Gold, Professor and Chair of the Department of  
3 Public Health Sciences at UC Davis and Chief  
4 of the Division of Epidemiology.

5                   DR. HAYTON: I'm William Hayton,  
6 Professor of Pharmacy, Ohio State University.

7                   MEMBER REED: Nu-may Ruby Reed,  
8 Toxicologist, California Environmental  
9 Protection Agency.

10                  MEMBER REIF: John Reif, Professor  
11 of Epidemiology, Department of Environmental  
12 and Radiological Health Sciences, Colorado  
13 State University.

14                  MEMBER LeBLANC: Gerry LeBlanc,  
15 Professor and Head of Department of  
16 Environmental and Molecular Toxicology, North  
17 Carolina State University.

18                  CHAIR HEERINGA: Thank you very  
19 much, members of the panel. And I think Dr.  
20 Bailar will probably join us. Here he is.

21                  Before we turn to the continuation  
22 of our discussion of the charge questions,



1 I'll just turn to Dr. Lowit to see if there is  
2 any follow up from the proceedings from  
3 yesterday.

4 DR. LOWIT: No, there's not.

5 CHAIR HEERINGA: Okay.

6 DR. LOWIT: But we really enjoyed  
7 yesterday's conversation and we look forward  
8 to the next couple of hours.

9 CHAIR HEERINGA: Thank you, thank  
10 you.

11 Okay. Without further ado, then,  
12 let's read -- we've completed our initial  
13 discussion of charge questions one through  
14 three. And again, for panel members, before  
15 we conclude the session this morning, we'll  
16 give everybody a chance to sort of go back and  
17 any last thoughts that you might like to add  
18 into the process in the public record, we'll  
19 do that.

20 But let's turn now to Charge  
21 Question No. 4. Shalu, if you would read  
22 Charge Question 4.1.

1 MS. SHELAT: Good morning.

2 Question 4.1., The Agency believes  
3 prospective epidemiology studies with robust  
4 exposure assessment, like the AHS, have the  
5 greatest potential for use in risk assessment  
6 especially for enhancing problem formulation  
7 and risk characterization. Please comment on  
8 appropriate ways to use these types of  
9 epidemiology studies in risk assessment.

10 CHAIR HEERINGA: Dr. Harris is our  
11 lead discussant on this one.

12 Shelley?

13 MEMBER HARRIS: Well, good  
14 morning, everyone. And excuse my coughing and  
15 my cold. I've been fighting this all week.  
16 So I'll try to keep that down.

17 I thought that I would -- you  
18 know, you have the luxury of having two days  
19 of conversations and discussions and then we  
20 get the final question today. It's a luxury  
21 and sometimes a little bit of a curse.

22 But I thought that what I might do

1 is answer this question in two parts. And  
2 first look a little bit -- talk a little bit  
3 about study design issues and attempt to  
4 summarize briefly what has been discussed over  
5 the past two days and bring it into context of  
6 prospective cohort studies. And a little bit  
7 about some of my thoughts on the different  
8 uses of prospective cohort studies in the risk  
9 assessment process.

10 So first of all, over the last  
11 couple days, we've discussed different design  
12 features of the epidemiologic studies and  
13 methods to qualitatively and semi-  
14 quantitatively evaluate them and also discuss  
15 some of their potential limitations and how we  
16 would make most efficient use of this kind of  
17 information in the risk assessment process.  
18 And for also risk management and risk  
19 mitigation.

20 And when we, as epidemiologists,  
21 when we teach epidemiology, we often describe  
22 studies from their weakest to strongest. And

1 that's sort of the approach we've taken in  
2 these sessions I think. We would say the  
3 weakest studies may be case reports or  
4 incident reports followed by clusters. This  
5 is nothing new to most epi people in the room.

6 We would then talk about cross-  
7 sectional studies or ecologic studies, looking  
8 at grouped data with grouped exposure  
9 measurements, retrospective studies, case-  
10 control studies, retrospective cohorts. And  
11 then finally leading up to the prospective  
12 cohort designs that we are addressing today  
13 assuming that those are the strongest designs  
14 to answer these types of questions.

15 But I would say that's not always  
16 the case. It really depends on the question  
17 being asked.

18 And I think that the EPA has taken  
19 a similar approach in grouping these studies  
20 into three main categories: the ecologic  
21 studies, retrospective studies, and the  
22 prospective studies. And I think that's --

1 from what I've heard over the last two days,  
2 it is very difficult to generalize strengths  
3 and weaknesses and limitations of these types  
4 of studies.

5           And, again, it depends on the  
6 questions being asked and what kind of data  
7 you need to obtain. So a cross-sectional  
8 study might be absolutely perfect to  
9 biomonitoring or to look at some kind of  
10 absorbed dose estimate that you may need for  
11 the risk assessment.

12           One thing that I think we all  
13 discovered is that we need some additional  
14 clarification in that document, the framework  
15 document, about exactly what a retrospective  
16 study is or we need to be very clear on that  
17 terminology.

18           So from our perspective, a  
19 retrospective study is something you hear --  
20 epidemiologists would say a retrospective  
21 study is a case-control study, something where  
22 you define the health outcome and you look

1 back and assess exposures whereas a  
2 prospective study is something where you  
3 define a group of individuals or cohort and  
4 follow them ahead in time and look at the  
5 health outcomes.

6           And so it is prospective in  
7 design. But we may -- where it gets confusing  
8 is we may have a historical cohort, that might  
9 be a better term to use, where you identify a  
10 group of individuals or a cohort in the past  
11 and measure their exposures over time. So  
12 that still has a prospective component.

13           And so I think it is important to  
14 make that distinction because a retrospective  
15 cohort can be very cost effective and  
16 efficient and answer your questions quickly if  
17 that's what you need done.

18           So having said and with all those  
19 disclaimers, I think ultimately we think of  
20 the prospective cohort as the best study  
21 design to answer some of our research  
22 questions associated with pesticide exposure

1 and health effects. And I think that's, in  
2 part, because we have the opportunity to  
3 collect the best exposure measurement or the  
4 best exposure data.

5           That doesn't necessarily mean we  
6 do collect the best exposure data. It's just  
7 we have the opportunity to do so. And the  
8 agriculture health study is an example of a  
9 study that really sets the bar pretty high for  
10 future studies and future cohorts on how best  
11 to go about collecting exposure information in  
12 a cost-effective way and then having it be  
13 very useful for industry, for the farmers,  
14 occupation, and also for risk assessments. So  
15 there are many, many more uses other than just  
16 risk assessment.

17           What I will say is as  
18 epidemiologists, and we have a really good  
19 handle on ascertaining cases and health  
20 outcomes and bias and that type of thing, but  
21 what we're never really good at or weakness in  
22 all studies, not just prospective studies, is

1 exposure measurement. And I think that's  
2 particularly relevant when it comes to  
3 pesticides. So if you want a particular  
4 epidemiologic study of any design, the first  
5 thing we will look at is how exposure was  
6 measured or not measured or what proxies were  
7 used and how much measurement error was  
8 associated with that.

9           And so I think that really needs  
10 to be our focus when we're looking at these  
11 studies and evaluating how -- qualitatively  
12 and quantitatively how good they are and how  
13 they should be weighted for risk assessment  
14 purposes.

15           And so which is great because  
16 that's our focus of the next question today,  
17 how do we go about using these great  
18 epidemiologic studies for risk assessment.

19           So I'm move on just a little bit  
20 just to the second part of the question. So  
21 I think that, you know, the prospective design  
22 is a great design is it is carried out and



1 conducted efficiently.

2           Some the advantages of using -- or  
3 having prospective cohorts such as this and  
4 others that are underway is that you can  
5 collect -- you can look at exposures and  
6 absorbed dose in the relationships between  
7 these things for single exposures and multiple  
8 exposures. And that allows us to look at  
9 these exposures over time and potential  
10 interactions and effects of mixtures, which I  
11 know everyone is interested in.

12           And it also helps to find what are  
13 the expected concentrations or doses that we  
14 would see in humans to feed back into the tox  
15 testing and the animal testing. So that's  
16 very helpful in an of itself.

17           We can look at changes in exposure  
18 over time so we're not interested in just  
19 daily estimates. We're interested in  
20 estimates of exposure over season and over a  
21 lifetime, how those vary, peaks and min/max  
22 values. And that's all very important

1 information to obtain.

2           So of that we can capture a bit on  
3 questionnaires but typically we can capture  
4 that with great biological monitoring studies  
5 or validation studies that are incorporated  
6 into those cohorts.

7           So I think this will come up quite  
8 a few times -- this will come up in the next  
9 few questions but I think that we really need  
10 to concentrate more effort on conducting  
11 validation studies within our cohorts and with  
12 biological markers that are well defined,  
13 biological makers of exposure and also lead  
14 into -- so I think we need to do these types  
15 of validation studies, looking at  
16 relationships between questionnaire data,  
17 absorbed dose estimates, and also exposure  
18 data and predicted exposures. And that's  
19 where that PHED database and those kinds of  
20 databases come in.

21           I think another advantage of the  
22 cohort studies -- prospective cohort studies

1 is that not only do we have the ability to  
2 look at the biological markers of exposure but  
3 the markers' susceptibility and effect. And  
4 that helps us to understand more about mode of  
5 action and mechanism. And so that's a real  
6 advantage to cohorts when well designed.

7           Let's see what else I have. I  
8 will, again, I have a lot of disclaimers. You  
9 know I talk about these advantages of the  
10 prospective cohort and that we can calculate  
11 absorbed dose. Well we might do that  
12 effectively for one day in a lifetime for one  
13 individual in the cohort. I mean it is  
14 impossible to calculate or measure absorbed  
15 dose of individuals over time. It's too  
16 expensive. We all know the issues with that.

17           So when we're talking about  
18 validation studies, you know, we say  
19 biological monitors is the gold standard but  
20 it's, you know, it's an alloyed standard in  
21 some ways. You've got to realize that this is  
22 not the true measure that we're looking at.

1 So that needs to be taken into consideration  
2 and good validation studies designed with  
3 repeated measurements and looking at  
4 variations within and between individuals over  
5 time I think is going to get at some of these  
6 issues.

7 And I think I'll leave it at that  
8 and let my colleagues jump in.

9 CHAIR HEERINGA: Thank you, Dr.  
10 Harris.

11 Dr. Greenwood?

12 MEMBER GREENWOOD: I think that if  
13 these studies are going to be useful, it is  
14 exceedingly important to get the stakeholders  
15 involved at a very early stage because you are  
16 going to need a lot of cooperation from these  
17 people in order to get the relevant exposure  
18 data and make sure that you can validated the  
19 exposure because that's pretty crucial when  
20 you are going to start comparing different  
21 methods of assessing exposure. You really  
22 need to have some gold standard you can

1 compare with.

2           And I think it's just going to be  
3 important to accept very large confidence  
4 intervals, very wide, because with the best in  
5 the world, there is a lot of variability  
6 between individuals in the ability to  
7 metabolize, for instance, and which  
8 metabolites are present.

9           One of the pitfalls I think I've  
10 seen in some of these papers is that people  
11 look at the correlation coefficient R and they  
12 get .4 and they seem pretty please with that.  
13 Well, actually r-squared is 0.16, that means  
14 only 16 percent of the variation is shared,  
15 which means that 84 percent isn't.

16           So, you know, but on the other  
17 hand, that's the nature of exposure data,  
18 pharmacokinetic data. And I think you're  
19 going to have to be able to work within that  
20 variability. And one of the problems that you  
21 face is just the expense of these studies,  
22 these biomonitoring studies and the difficulty

1 of getting people involved.

2 And I think it means that you're  
3 looking at something with a great deal of  
4 variability. And you're having the worst of  
5 all situations, a small sample size to try to  
6 get a fix on it. So I think you really need  
7 probably to work within the confidence  
8 intervals rather than the small sample going  
9 for measure of location.

10 Now having said that, I think that  
11 this is probably going to be very important if  
12 you're going to be comparing two data sets.  
13 It's one way that you can have common  
14 measurements. You've got something you can  
15 tie it down with.

16 Thank you.

17 CHAIR HEERINGA: Thank you, Dr.  
18 Greenwood.

19 Dr. Chambers?

20 MEMBER CHAMBERS: I had three  
21 thoughts while I was considering this  
22 question. One is that if the diaries on

1 current usage, I think are probably quite  
2 accurate in terms of services exposure. But  
3 if anybody is going to be asked about things  
4 that they were exposed to historically a large  
5 number of years ago, I think the accuracy of  
6 that is probably not as high. And I think you  
7 need to make sure you take that into account.

8           Certainly the Ag Health Study is  
9 very impressive in its size and its dimensions  
10 and that sort of thing. However the long-term  
11 outcomes of that are probably going to be  
12 quite a while in the future. And whether or  
13 not -- just how useful that will be for  
14 today's risk assessment is a little hard to  
15 say. But it will take a while to get the  
16 information.

17           The last thought I wanted to  
18 mention is that there are some more current  
19 exposure databases that will be forthcoming  
20 very soon as you well know. I sit on the  
21 Human Studies Review Board for EPA and we are  
22 in the process of -- or over the last couple

1 of years have been in the process of  
2 evaluating and making recommendations about  
3 the protocols for the Agricultural Handlers  
4 Exposure Task Force studies on what -- 25  
5 scenarios, I think, of different agricultural  
6 activities. And this is designed to give more  
7 current exposure data to replace the very old  
8 PHED data that is probably not so accurate for  
9 today's agricultural practices.

10 So as that data is forthcoming,  
11 that should really displace any of the PHED  
12 data if it really reflects more accurate  
13 studies. So that will be better exposure  
14 data.

15 CHAIR HEERINGA: Thank you, Dr.  
16 Chambers.

17 Dr. Portier?

18 MEMBER PORTIER: I don't have a  
19 whole lot to add. I think the real benefit of  
20 these prospective cohort epidemiology studies,  
21 beyond their ability to follow individuals  
22 over time, is the ability to gather



1 information to support modeling of a lot of  
2 the lifestyle factors, work environments, and  
3 how these things change over time, over a  
4 lifetime for an individual.

5           And I think this is the kind of  
6 information that is going to really help  
7 complement EPA's scenario approach because one  
8 of the things that you miss in the scenario  
9 approach is knowing how often and when the  
10 individuals view these scenarios.

11           So when you start trying to put  
12 them together to try to come up with the  
13 lifetime exposure, cumulative exposure  
14 statistic, you are going to be kind of  
15 modeling that. And you are going to need a  
16 lot of information to model it.

17           And that information is going to  
18 come from these prospective studies. Again,  
19 as Dr. Chambers said, retrospective studies  
20 have the problem of recall bias that -- and  
21 once you put that into modeling, it just kind  
22 of cumulates that issue.

1                   Also thought about how prospective  
2 epidemiology studies can help in hazard  
3 identification. And I think it provides the  
4 kind of health effect differences for the  
5 different cultural, behavioral, dietary,  
6 health factors, information on co-morbidities,  
7 a lot of that information you are going to  
8 need and just identifying the population you  
9 are looking at. For exposure assessment, it  
10 does the same thing for exposure for a lot of  
11 all of these factors.

12                   And then the last thing, I think,  
13 is the dose response relationship. Depending  
14 on the underlying structure of the targeted  
15 population, whether that's a very focused  
16 population like the Ag Health Study or more  
17 broader cohort studies, if they -- assuming  
18 they have validated measures of true exposure,  
19 the data from the prospective studies should  
20 provide useful information on human responses  
21 to varying levels of exposure.

22                   And has been stated here a number

1 of times, that's a large need to do a really  
2 good risk assessment that links animal data to  
3 human data without using a lot of uncertainty  
4 factors and all these other things. So I  
5 think that's the real benefit.

6           Something Dr. Chambers said got me  
7 thinking about what one of the -- no, it was  
8 actually something Dr. Greenwood said about  
9 engaging stakeholders. The American Cancer  
10 Society, as many of you know, has a large  
11 cohort study that we've done for years. And  
12 one of the benefits of being in a not-for-  
13 profit is we can engage these people who are  
14 involved in this cohort study and may become  
15 part of our family, right? We continue to  
16 communicate them and we keep them on our side  
17 and they want to give us information.

18           The problem with EPA is you are a  
19 regulator and it is hard for you to engage  
20 them in that kind of relationship. But you  
21 may want to look at how you utilize other  
22 partners who have those kinds of relationships

1 to get the kind of cohort -- prospective  
2 cohort data that you need.

3 I was sitting there thinking we're  
4 -- the American Cancer Society is in the  
5 process right now of recruiting for a  
6 prospective cohort study of a million people.  
7 I think there are going to be a few farmers in  
8 that and pesticide handlers in that database.  
9 I'm going to have to go back and see if we've  
10 got any right now. We only have 60,000 in the  
11 cohort right now but -- and that kind of  
12 cohort, they're collecting blood samples at  
13 recruitment so we'll have the early-day kind  
14 of information.

15 And I don't think we're alone in  
16 this kind of endeavor. There are a bunch of  
17 those kinds of cohorts going on where you  
18 might be able to extract that kind of  
19 information.

20 I think that's all I have.

21 CHAIR HEERINGA: Dr. Reif?

22 MEMBER REIF: Three comments just

1 to follow up. Dr. Harris did a good job  
2 outlining the general strengths of this  
3 prospective approach. And we would all -- I  
4 think epidemiologists certainly support that,  
5 recognizing that these studies are still  
6 uncommon because they are so large and so  
7 difficult and expensive to undertake.

8           So one of the -- I think one of  
9 the advantages or one of the opportunities of  
10 these kinds of studies is to collect  
11 quantitative exposure data as well as evaluate  
12 biomarkers that may be intermediate steps on  
13 the pathway to disease.

14           And initially when you think about  
15 this, it's daunting with respect to the  
16 logistics and the expense. But the way that  
17 I think the Agricultural Health Study has  
18 considered this is to do subsets. It isn't  
19 necessary to collect blood or analyze urine  
20 for pesticide metabolites from every single  
21 person in a cohort if a reliable and well-  
22 thought-out study design for the subset

1 sampling can be developed.

2           And I know that the Agricultural  
3 Health Study has thought about this  
4 extensively since the initiation of their  
5 study but has, in some instances, I think been  
6 hampered by lack of resources to do as much as  
7 they would have liked to do.

8           Again, Dr. Alvanja, of course,  
9 would be the best person to comment on that  
10 but I think there are opportunities and there  
11 have been efforts made to do some evaluation  
12 of exposure using biological monitoring. And  
13 I think that should be clarified because I  
14 think that's really the key to the next kinds  
15 of steps that the Agency would like to  
16 undertake, which is to use data like this in  
17 risk characterization, not just in hazard  
18 identification.

19           Your problem formulations don't  
20 really need a study like this. It helps but  
21 other studies can lead one through the initial  
22 steps.

1                   It's the risk characterization  
2 phase of this that's the trick, of course.  
3 And I know, of course, the Agency's  
4 deliberations collaboratively to work with NCI  
5 and other partners to try to figure out how to  
6 model these exposures is commendable because  
7 at the end of the day, it's developing  
8 accurate exposure measurements and  
9 measurements of intermediates that can, in  
10 fact, I believe lead to risk characterization  
11 information that can then be put into the risk  
12 assessment framework and compared side by side  
13 with animal data. And that, I think, is the  
14 ultimate goal of the use of epidemiology in  
15 risk assessment.

16                   And it is challenging and  
17 daunting. But you are correct, that I think  
18 this kind of study gives you the maximal  
19 opportunity to do that.

20                   I think there are some examples  
21 out there. There has been some discussion in  
22 the meeting about other attempts, perhaps with

1 TCE, also the arsenic literature I think is a  
2 useful place to look. EPA, of course, has  
3 been involved in standard setting or in  
4 development of MCLs from arsenic epidemiology  
5 data and much of that collected by Allan Smith  
6 and others might be relevant.

7           And actually there are at least  
8 one paper that I remember that Allan Smith and  
9 Berkeley wrote which actually describes the  
10 incorporation of the arsenic data into a risk  
11 assessment model. It's an older paper now.  
12 It's in the '90s, I believe. But there may be  
13 some information in that that can be useful as  
14 a model for how, in the arsenic case, one  
15 could approach risk characterizations.

16           So I think the risk  
17 characterization, that's the Holy Grail of  
18 this whole exercise with respect to the  
19 incorporation of epidemiology data. And Dr.  
20 Portier mentioned dose response relationships  
21 and I alluded to it yesterday to help  
22 understand for whatever outcome, the shape of



1 these dose response relationships in humans,  
2 that would be a very important goal, I think,  
3 of this exercise.

4           The last comment is that some  
5 endpoints lend themselves better to risk  
6 characterization in a cohort study like this  
7 than others. And I go back to the idea that  
8 for reproductive outcomes, given the finite  
9 and relatively short period of interest,  
10 perhaps a year from the initial exposure to  
11 the endpoint, this makes risk characterization  
12 in the Agricultural Health Study really more  
13 feasible.

14           If the exposure data are collected  
15 at the appropriate points in time and if they  
16 have been collected at appropriate points in  
17 time for women who become pregnant, then there  
18 is an opportunity to look at these subsets  
19 again in a very careful way. And that's why  
20 I asked the question the other day --  
21 yesterday -- about linkage with birth records  
22 because I do believe that there are

1 opportunities to explore reproductive  
2 endpoints beyond what's been already done in  
3 the Agricultural Health Study for any  
4 chemical. And in this case, the interest is  
5 in atrazine. So this, I think, is an  
6 opportunity that should be explored in depth.  
7 And with, of course, the assistance of NCI, I  
8 think that perhaps some progress can be made  
9 in that area.

10 The resolution of the exposure  
11 assessment between the EPA methods and --  
12 which, I guess, is the next question -- so  
13 I'll stop here.

14 CHAIR HEERINGA: Thank you, Dr.  
15 Reif.

16 Comments from other members of the  
17 panel?

18 Dr. Lu?

19 MEMBER LU: I'm Alex Lu. In my  
20 opinion, I think the Agricultural Health Study  
21 probably is the best that we can get in terms  
22 of using the data for the purpose of a future

1 risk assessment. I'm pleased that the  
2 Agricultural Health Study is still ongoing,  
3 you know, Phase II, Phase III studies.

4 But I do disagree that their  
5 exposure assessment method is robust just  
6 because they dichonomize so many exposure  
7 categories, you know, zero, three, nine, and  
8 so on and so forth. It's really easy to  
9 either magnify or, you know, significantly  
10 reduce exposure if you add those things up  
11 together.

12 However, I do see a great  
13 opportunity that EPA can work with the  
14 Agricultural Health Study by introducing your  
15 unique exposure concepts because this is an  
16 occupational database. It may take a while.  
17 It may require some effort. But if you were  
18 able to look at their exposure intensity  
19 information and convert it to your unit  
20 exposures metrics and see whether you can come  
21 to the same result, the outcome in terms of  
22 disease association and so on and so forth.

1                   And as I recall, Dr. Alavanja  
2 yesterday mentioned that in Phase II, Phase  
3 III, they're going to come out with chemical-  
4 specific exposure intensity. That's even  
5 better because you can actually go in and look  
6 at not just the chemical-specific exposure  
7 data, you can actually create a matrix that  
8 nobody in the world has in terms of the same  
9 person sprayed different pesticides, what  
10 would be the health outcomes.

11                   So I think my comment is just, you  
12 know, treat that as a data gold mine. And use  
13 your expertise. Unique exposure has been  
14 reviewed many times and the new data will come  
15 out. I think it is prudent to just limit  
16 these two datasets together.

17                   CHAIR HEERINGA: Thank you, Dr.  
18 Lu.

19                   Dr. Bailar?

20                   MEMBER BAILAR: I understand that  
21 the -- from the comment the other day that the  
22 Agricultural Health Study is not recruiting

1 any new members. The current subjects are  
2 getting older. They will eventually diminish  
3 substantially in number. That might make room  
4 for a new kind of study.

5 The question that I would have is  
6 not whether the data we have now on exposure  
7 are perfect, they're not. But can we do any  
8 better if we were to take this on again? And  
9 I'm not sure about the answer to that. It  
10 looks to me like the present study is doing  
11 pretty close to the optimum as of our current  
12 knowledge. But it would be worth some thought  
13 about whether there is going to be space for  
14 another -- a similar study with a younger  
15 cohort, a new cohort. And if so, how that  
16 might be attacked.

17 CHAIR HEERINGA: Thank you, Dr.  
18 Bailar.

19 That's a key issue in any  
20 longitudinal study program.

21 MEMBER HARRIS: Yes, oh, sorry.

22 CHAIR HEERINGA: Oh, Dr. Harris,

1 please?

2 MEMBER HARRIS: Oh, can I?

3 CHAIR HEERINGA: You can say it.

4 MEMBER HARRIS: Oh, I think, you  
5 know, given sufficient funds, we can do just  
6 about anything in a cohort study and they all  
7 could be much better. So I think -- so are  
8 you asking, you know, how would we improve on  
9 this?

10 CHAIR HEERINGA: I'm not asking  
11 about what's possible but what's feasible.

12 MEMBER HARRIS: What's feasible.

13 CHAIR HEERINGA: You know within  
14 foreseeable budgets and limits of trained  
15 personnel and so forth, number of subjects.

16 MEMBER HARRIS: Well, I think if I  
17 was to initiate another cohort study such as  
18 this in an agricultural setting or an  
19 occupational setting, I would certainly try to  
20 supplement it with biological samples that  
21 were collected within individuals over time.  
22 But that's a very expensive endeavor as we

1 know. And so whether that's feasible or not,  
2 is another question.

3 CHAIR HEERINGA: Dr. Portier?

4 MEMBER PORTIER: That reminded me  
5 of something I was thinking of which was the  
6 idea of recruiting the younger cohort. If the  
7 Ag Health Study is anything like a lot of the  
8 cohorts I've seen, you know, the average age  
9 is in the mid to late '50s. And so you're  
10 having to do retrospectively back to when they  
11 started forming.

12 You know most of them left college  
13 and starting forming the family forum when  
14 they were in their mid-20s. So you've got 30  
15 years of exposure before you get them in a  
16 prospective study, which is okay for cancer  
17 outcomes but maybe not great for reproductive  
18 outcomes.

19 So I think there is room not just  
20 in biomarkers and collecting blood samples but  
21 actually actively recruiting younger growers  
22 into this kind of program so you get that

1 lifetime. I know it's more expensive because  
2 now you've got to follow them for 60 years  
3 instead of 30 years but we'd get a lot more  
4 information on them.

5 Thanks, John.

6 CHAIR HEERINGA: Dr. Gold?

7 MEMBER GOLD: I was intrigued  
8 actually when Dr. Alavanja was talking about  
9 the challenges of dealing with the offspring,  
10 that they actually might think about the  
11 Framingham model which generated an offspring  
12 cohort in relationship to the original cohort.

13 And if they have a good  
14 relationship with this cohort, you know, given  
15 resources, et cetera, then you could enroll  
16 that cohort, the offspring cohort, and try and  
17 do, you know, an even better job of exposure  
18 assessment. That will be out of date in 10,  
19 20 years also but it would be relevant to  
20 looking, perhaps, at the reproductive outcomes  
21 in that part of the cohort.

22 CHAIR HEERINGA: Steve Heeringa.



1 The only difference I would see between  
2 Framingham and this study is in this study,  
3 enrollment was conditional on a behavior or a  
4 practice as of recruitment date, which was  
5 that you were a pesticide applicator.

6 I think Framingham as a general  
7 population study so the dynamic recruitment of  
8 individuals is sort of conditioned on a pre-  
9 existing status and that is your father or  
10 your mother was a pesticide applicator. So if  
11 we had a lot of -- clearly, you know, the  
12 offspring of pesticide applicators or  
13 pesticide-licensed purchasers are potentially  
14 farmers and pesticide purchasers but there is  
15 a whole set of other people coming in whose  
16 parents weren't in that category. That would  
17 be the difference.

18 Dr. Gold?

19 MEMBER GOLD: Yes, I agree that  
20 that's a difference but it actually could be  
21 a plus. I mean there's sort of different  
22 approaches here. I mean the initial approach

1 was to look at people with a high likelihood  
2 of high exposures, mainly applicators. And  
3 that has a great utility.

4 But there's also utility at  
5 looking at a broader spectrum of the  
6 population in terms of, you know, possible  
7 effects of exposure. And I would expect in  
8 the offspring you'll have some who are still  
9 applicators and farmers and some who aren't.  
10 But may still be exposed.

11 So, you know, I think -- I'm sure  
12 they're doing this -- but they could be  
13 looking at the relative merits of such an  
14 approach.

15 MEMBER BOVE: Thank you. It could  
16 family exposures, right? I mean children are  
17 playing around the house and the farm and  
18 getting that kind of an exposure. And that's  
19 the only way you'd be able to evaluate that.

20 CHAIR HEERINGA: Other comments in  
21 response to Question 4.1? This is your chance  
22 to come back.

1 Dr. Lu?

2 MEMBER LU: I want to add this  
3 disclaimer in terms of what I just said. I  
4 think EPA should see these as occupational  
5 datasets. They should not interpret them  
6 further other than outside of the workplace  
7 because sometimes it can get easy to kind of  
8 go over bounds because there are significant  
9 exposure pattern differences between exposures  
10 and non-exposures. And I don't think these  
11 things kind of -- they overlap significantly.

12 And also I would like to ask the  
13 panel the question, because I didn't get the  
14 chance to ask the Agricultural Health Study  
15 folks, is what do you think about a healthy  
16 worker factor in the Agricultural Health  
17 Study? Would that bias the outcome?

18 CHAIR HEERINGA: Good question.

19 Dr. Bove?

20 MEMBER BOVE: Not if you do an  
21 internal analysis. If you compare  
22 agricultural workers to the general

1 population, sure. But if you're doing an  
2 internal analysis, it shouldn't.

3 The problem would be in these  
4 studies, the major problem is loss of follow  
5 up. When you have a long prospective study,  
6 you lose people at the selection bias. I  
7 would be more concerned about that.

8 If you are comparing the  
9 agricultural workers to the general  
10 population, you really shouldn't be doing  
11 that. You know, there's no need to.

12 CHAIR HEERINGA: So, Dr. Bove,  
13 your point about internal is essentially  
14 conditioning on the characteristics of these  
15 individuals when they were enrolled, the  
16 exposure response relationships?

17 MEMBER BOVE: Hearing high and  
18 low, there might be some selectivity and loss  
19 to follow up on the health of the individual.  
20 But that's a loss to follow up problem, not a  
21 recruitment problem.

22 Loss to follow up is another

1 issue. I mean I was talking about healthy  
2 worker. Loss to follow up is a big problem,  
3 okay, and that has to be evaluated in any  
4 prospective study. And it could be related to  
5 exposure status for sure. And that's a  
6 problem.

7 We were just talking about healthy  
8 worker effects and there are several types of  
9 healthy worker effects, okay, and it includes  
10 not only loss to follow up but within the  
11 cohort you could have people who are exposed,  
12 highly exposed dropping out of farming, for  
13 example, because they are sensitized. I mean  
14 there are those kinds of issues. So I guess  
15 they are tied -- you can tie them together,  
16 sure.

17 MEMBER LU: I think my -- the  
18 issue that I can foresee here is that the  
19 healthy worker effects start at the  
20 recruitment stage. They are the only healthy  
21 workers that they see still working in the  
22 field in the farm industry for another 20, 30

1 years they participate. Whereas people who  
2 already have some health problems, they don't  
3 do the hard work. And they are not part of  
4 the Agricultural Health Study. Would that  
5 bias the outcome? It's not the process  
6 itself. It's at the recruiting stage, would  
7 the healthy worker effect come into play that,  
8 you know, make the study --

9 MEMBER BOVE: Ideally, you'd want  
10 to get people as soon as they enroll -- become  
11 farmers, right, to avoid that. I mean, you  
12 know, you are just starting work at a plant,  
13 right? If you don't get people that way, then  
14 yes.

15 he people who are sensitized quit  
16 and you lose those people. That also happens  
17 as time goes on, too. And, again, that's part  
18 of why you have loss to follow up is because  
19 people are leaving and you can't locate them.  
20 And they are leaving because they're  
21 sensitized, yes.

22 So there are all these -- we

1 haven't -- I mean there's a whole lot of  
2 healthy worker effect biases. It's a whole --  
3 you know, and so -- and this is one of them.

4 CHAIR HEERINGA: Dr. Reif?

5 MEMBER REIF: I just want to  
6 support what Dr. Bove is saying. If you were  
7 comparing this cohort to the general  
8 population, of course, farmers, as you point  
9 out, are generally healthy. They have to --  
10 they have a very physical lifestyle and job.

11 And also their behavioral  
12 characteristics differ from the general  
13 population in that they tend to smoke less.  
14 And that was noted in many case-control  
15 studies where they -- and also in original  
16 descriptive studies where they -- for example  
17 in mortality studies, the death rates of  
18 farmers from lung cancer and laryngeal cancer  
19 and other smoking-associated cancers are lower  
20 than the general population.

21 So that's where the healthy worker  
22 effect manifests itself. And it's well

1 recognized in earlier studies of farmers that  
2 they, in fact, have lower rates of cancer for  
3 some outcomes, especially the smoking-  
4 associated ones, and some higher -- some  
5 interesting higher rates of cancer for other  
6 outcomes like prostate cancer, which has been  
7 described in a number of studies.

8           So yes, that's where the healthy  
9 worker -- that comes in. But with respect to  
10 the hypothesis, that agricultural activities  
11 are related to cancer risks, goes at that  
12 stage, the healthy worker effect, I don't  
13 believe is an issue.

14           MEMBER BOVE: I think it is a lot  
15 more complex than that now that I'm starting  
16 to think about it, waking up, that, you know,  
17 first of all, of course there is the obvious  
18 healthy worker effect when you compare a  
19 worker population to the general population.

20           And then there are healthy worker  
21 effects that occur in a cohort like the one  
22 you are alluding to is even at the start, if



1 you haven't gotten people -- if you haven't  
2 gotten people at the start of their farming  
3 experience, some of those people may have  
4 tried it, been sensitized, and left. So  
5 you're missing those people.

6           Then over time, people who get  
7 sensitized and leave, they have a lower  
8 exposure, right? I mean they have a lower  
9 cumulative exposure and yet they may have the  
10 health effect because they're more sensitive  
11 to it and they're also the people you might  
12 lose. So there are a whole lot of things  
13 going on here that I'm sure the Agricultural  
14 Health Study is thinking about.

15           But these are part of the problem  
16 with -- see there are limitations to  
17 prospective study. I mean we talk about the  
18 length of time you have to wait for results.  
19 Now for results that occur quickly, if you're  
20 looking at reproductive topics, cancers,  
21 things like that, that's one thing. But if  
22 you're looking at chronic diseases, it's much

1 different thing. We have problems with loss  
2 to follow-up, you have problems with all of  
3 these issues that have been raised.

4           So that's why, you know, it is one  
5 of the better study designs but it has  
6 limitations just like other types of study  
7 designs whether you use case-control sampling,  
8 whether you use a retrospective cohort design,  
9 whatever terminology you want to use here, all  
10 these studies have pluses and minuses. And  
11 there's not one that is going to be terrific  
12 for risk characterization, okay.

13           If you wanted to do a risk  
14 characterization today, a prospective study is  
15 not what you'd want to do. You'd want to hope  
16 that a retrospective cohort study was done at  
17 least if you wanted to do something today.

18           If you want to do something in 30  
19 years, that's a different story. And I think  
20 that, you know, you'd plan this -- you can  
21 plan this out. Obviously the Agricultural  
22 Health Study was planned out with that notion

1 in mind, that we'd want to have that  
2 information 30, 40 years down the pike.

3 So similarly with Framingham, we'd  
4 want to have that information. You don't  
5 think it is going to give you information  
6 today, right. So anyway, that goes all over  
7 the place. Sorry.

8 CHAIR HEERINGA: Okay. Dr.  
9 Bailar, one last comment on this?

10 MEMBER BAILAR: How do you deal  
11 with these issues has to depend on the  
12 objectives of your study. With the  
13 Agricultural Health Study, there are multiple  
14 objectives and it would be hard to sort them  
15 out and focus the design on a specific issue.  
16 This might be even more true of a new  
17 Agricultural Health Study.

18 But if your interest, for example,  
19 is in hazard identification, you might want to  
20 focus on workers in the initial enrollment who  
21 have been in the profession for say three  
22 years, five years, because they are likely to

1 stay there.

2           Throwing out the short exposures,  
3 you might get rid of some of the ones are  
4 highly sensitive but at the same time, you'd  
5 get rid of a lot of people who are not going  
6 to contribute much in terms of lifetime  
7 exposure or long-term exposure. So this is  
8 going to have to be given a fair amount of  
9 thought.

10           CHAIR HEERINGA: Thank you, Dr.  
11 Bailar.

12           At this point, I think I'd like to  
13 move on. I'll turn, first of all, to Dr.  
14 Lowit. I mean I think there has been a good  
15 discussion of the properties, generally the  
16 prospective designs in the context of the  
17 Agricultural Health Survey.

18           I understand that there are over  
19 100 papers. And I suspect that many of these  
20 methodological issues have been addressed  
21 there and that you are looking at that, too.

22           But I think going back to Dr.

1 Harris's point, I think it really gets down to  
2 exposure assessment. And then  
3 characterization of risk.

4 DR. LOWIT: That's a good segue  
5 for the next question.

6 CHAIR HEERINGA: Very good. Would  
7 you like to read the next question into the  
8 record please, Shalu Shelat?

9 MS. SHELAT: Question 4.2, The  
10 Agency uses a predictive, scenario-based  
11 approach to calculate risks associated with  
12 the registered use patterns of pesticides.  
13 Estimates of risk based on varying levels of  
14 protective equipment, application methods, and  
15 use conditions are presented. The results of  
16 these assessments are used to specify label  
17 conditions that are required to support the  
18 new registration or continued registration of  
19 pesticides.

20 In contrast, the goal of  
21 epidemiologic exposure assessment within the  
22 AHS is to develop a relative exposure ranking

1 of individuals who are actual pesticide users  
2 within a cohort. It is not feasible to  
3 directly measure actual exposure in  
4 observational analyses such as the AHS.

5           The AHS exposure information is  
6 ascertained from questionnaires completed by  
7 individual cohort members. Because the AHS  
8 and the Agency have different purposes for  
9 evaluating pesticide applicator exposure,  
10 there are inherent differences in the  
11 occupational handler exposure methodologies  
12 between the AHS and Agency.

13           How to reconcile these differences  
14 in order to make optimal use of the AHS in  
15 developing regulatory policy is under  
16 investigation by a collaborative effort  
17 between EPA's OPP and investigators involved  
18 with the AHS. Case study B details a three  
19 step analysis plan for accomplishing this  
20 goal.

21           Please comment on the proposed  
22 plan for comparing the exposure assessment

1 approaches between the Agency and the AHS.  
2 Please include in your comments the scientific  
3 value of this comparison along with additional  
4 and/or alternative analyses which could be  
5 conducted.

6 CHAIR HEERINGA: And Dr. Reed is  
7 our lead discussant on this. Ruby?

8 MEMBER REED: So we're, in a  
9 sense, switching mode a little bit. We're  
10 adding another component of purpose or desire,  
11 looking at the AHS study.

12 It appears that the method of  
13 comparison is illustrated with the Agency's  
14 presentation between the groundboom and  
15 airblast applications is a reasonable first  
16 step. And I was sitting here and also as I  
17 was reviewing the Agency document, I was  
18 really curious about what is the expected  
19 outcome in this comparison.

20 And then, as you heard, you know,  
21 I was sort of drilling down to the difference  
22 between 3.7 and 7 in terms of what contributes

1 to the similarities. But, you know, we talked  
2 a little bit about that already. I think  
3 there is some common grounds in the database  
4 that are used between the two approaches that  
5 you could expect some similarities.

6 But then, you know, you will be  
7 doing a lot more comparisons than you could  
8 expect to see, you know, in some scenarios.  
9 There's wide differences. So I come away with  
10 just sort of philosophical within the first  
11 step, as you go down on the comparison list,  
12 there are scenarios. It is very important to  
13 discuss the uncertainties and variabilities in  
14 the database themselves.

15 And also that, in thinking ahead,  
16 that if the comparison really gives you a wide  
17 variety of differences, you know, as you do  
18 these ratios, it might be necessary for you to  
19 break out individual parameters in the AHS and  
20 to, you know, see if you can find some rhymes  
21 and reasons to it.

22 In terms of Step 2, that's



1 actually more exciting because now you are  
2 looking at biomonitoring data instead of  
3 these, you know, category-oriented parameters.  
4 And I guess, you know, in that sense you can  
5 be more focused in discovering factors that  
6 could contribute to the differences between  
7 the two exposure estimation methods.

8           But I really think that if I were  
9 to sort of think ahead, I really think that it  
10 would be more productive in this comparison  
11 for short-term exposure scenarios than going  
12 all the way back to the lifetime in all the  
13 equations with the lifetime factoring or, you  
14 know, long-term kind of scenarios.

15           Going into Step 3, it's really,  
16 really mind boggling with you think of, okay,  
17 so now, you know, if Step 1 and Step 2, you  
18 know, giving us enough encouragement for us to  
19 go on, it's really complex and especially for  
20 longer time scenarios.

21           And so I totally agree that the  
22 feasibility would have to be assessed at this

1 point in terms of how far to go. Really  
2 overall what I'm seeing is that, you know, the  
3 initial try is okay, making comparison is  
4 okay. But I think prioritization is very  
5 important because you have two goals and two  
6 very good goals.

7           One is just to look at chemical-  
8 specific issue in terms of exposure and health  
9 effects and plug that into risk assessment or,  
10 you know, make use of that in risk assessment.  
11 But the other goal is to see what we can gain  
12 from this and back to the Agency's default  
13 method of estimating exposure using current  
14 PHED or new PHED or, you know, something  
15 similar to that.

16           And so when I think of  
17 prioritization, I'm thinking if you get bogged  
18 down by these, you know, running the two goals  
19 together, I think it is reasonable to narrow  
20 it down to, you know, with the priority for  
21 one then the other.

22           And so if chemical-specific

1 information for atrazine or, you know, any  
2 other cases within the AHS, isn't priority,  
3 then put the PHED aside as added value and  
4 especially because PHED is probably going to  
5 receive new information in the future, and so  
6 that's sort of my take about the plan, the  
7 three-step plan. It's all very futuristic so  
8 we would have to see what happens.

9 CHAIR HEERINGA: Thank you, Dr.  
10 Reed.

11 Dr. Hayton?

12 DR. HAYTON: I had similar  
13 comments on the plan. I thought it was a  
14 rational way forward. The first step to do an  
15 evaluation of the exposure determinants, that  
16 made a lot of sense to me, trying to find  
17 similarities and differences in the various  
18 elements of the exposure metrics.

19 I think it is really clear that  
20 the two metrics have to be picked apart. And  
21 this is exactly what you're intending to do is  
22 to look at the various elements and see where

1 you can find commonality there.

2           The second step also made sense to  
3 use a biomonitoring dataset. And, as I  
4 understand it, to apply both metrics, you  
5 know, to the same exposure population.

6           And I don't know about the third  
7 step. I just can't comment on that with  
8 expertise. But it made sense to me but it is  
9 a little outside my expertise.

10           As far as scientific value, we  
11 were asked to comment on that. And I think  
12 obviously trying to find some commonalities  
13 between the two metrics would be useful if  
14 they can be found. The Agency metric connects  
15 laboratory studies, connects with laboratory  
16 studies. This conceptually allows results of  
17 laboratory tox studies to be used to regulate  
18 exposure limits, as I understand it.

19           And that there could be some  
20 linkage between the Agency and the AHS metric,  
21 then that latter metric likewise could inform  
22 regulation of exposures. So there is

1 certainly value if that can be done.

2 I didn't have any ideas about  
3 additional alternative analyses. One comment  
4 in the case study text on page 21, there's the  
5 statement that the AHS intensity level score  
6 differs from the Agency's exposure algorithm  
7 in that it does not attempt to quantify  
8 exposure or dose in absolute terms.

9 And then I looked back a couple of  
10 pages and I see that exposure -- I mean there  
11 is an explanation of exposure differing from  
12 dose in that dose refers to the amount of  
13 chemical to which individuals are exposed that  
14 crosses the external boundary.

15 And then I thought about my  
16 comment from, I think, yesterday, that even if  
17 we know what crosses the boundary, there is a  
18 lot of person-to-person variability in what  
19 the exposure of target sites is. So all of  
20 this led me to think that in a sense, the  
21 Agency's metric, even though it says  
22 milligrams per day -- it has some units

1 attached to it -- it's related to internal  
2 exposure but I think there are intervening  
3 steps that we can link between external  
4 exposure and internal exposure. And so it's  
5 not a particularly absolute measure of  
6 internal exposure by any means.

7           So also, you know, the other part  
8 of this, the Agency's exposure algorithm is  
9 not chemical specific but incorporates what is  
10 known generically about external exposure,  
11 physical state of product, equipment used in  
12 the application, protective measures used by  
13 the applicator, so sorry to be long-winded  
14 about this but this seems similar to me to  
15 what goes into the calculation of the AHS  
16 metric, too.

17           So you end up with a number from  
18 each metric. And I guess the trick is going  
19 to be what, you know, how can -- where is the  
20 Rosetta Stone? How can you link one number to  
21 the other?

22           But I think it's plausible that a

1 way can be found to make these metrics talk to  
2 each other. I think that's true.

3 CHAIR HEERINGA: Thank you very  
4 much, Dr. Hayton.

5 Dr. Harris? Shelley?

6 MEMBER HARRIS: Well, I don't have  
7 a whole lot to add. I had a little difficulty  
8 getting through the document. I'm a little  
9 bit confused -- had a hard time following it.

10 I think -- I probably have more  
11 questions than I have comments on some of the  
12 statements. I'm not sure if this is -- should  
13 we wait until after or --

14 CHAIR HEERINGA: Why don't you go  
15 ahead?

16 MEMBER HARRIS: Go ahead? So I  
17 think I have a fairly good grasp on the AHS  
18 and the intensity score and how that is  
19 derived and what they plan to do with that for  
20 coming up with some sort of ordinal ranking of  
21 exposures based on different categories and  
22 classifications. So I'm fairly clear on that.

1           Now the Agency's methods of  
2 assessing exposure, I've got down here -- I've  
3 got milligram per day measure. Is that  
4 something that is assumed to be an absorbed  
5 dose? Is that the way you are doing that?

6           CHAIR HEERINGA: Jeff Dawson?

7           MR. DAWSON: I'm Jeff Dawson. We  
8 would predict exposures -- it would be the  
9 amount to the skin. And then depending upon  
10 the nature of the endpoint, we would be using  
11 for risk assessment -- for example if we were  
12 comparing to a dermal administration toxicity  
13 study, we would just use that value.

14           If there was, for example, an oral  
15 administration study, we would apply some  
16 factor to account for dermal absorption to get  
17 to the absorbed dose. So when we talk about  
18 exposure, we're talking to the skin or --

19           MEMBER HARRIS: So you have a  
20 milligrams active ingredient per day? So that  
21 would be a dermal dose? And then you could  
22 apply some percent absorption and calculate an



1 absorbed dose with that? So that's --

2 MR. DAWSON: Correct.

3 MEMBER HARRIS: -- so you use the  
4 PHED and other databases to come up with those  
5 estimates on a daily basis? And then you  
6 multiply those by duration and things like  
7 that? I think lifetime exposures to come up  
8 with that? Is that --

9 MR. DAWSON: Correct.

10 MEMBER HARRIS: Correct, okay.

11 MR. DAWSON: So PHED provides an  
12 amount to the skin, for example, per pound  
13 that you apply. And then we use the knowledge  
14 about the cultural practice to represent each  
15 of the different scenarios for equipment type  
16 and the crop that's being treated to get to  
17 that daily dose estimate which, in effect,  
18 accounts for duration.

19 MEMBER HARRIS: Okay. Because a  
20 lot of my question is really how do we connect  
21 these two different exposure measurement  
22 techniques and I think the assumptions that go

1 into yours and the assumptions that go into  
2 the AHS are extremely important in doing that.

3 I also had another question about  
4 this unit exposure measure that the Agency --  
5 and I wasn't quite sure I understood that  
6 because in a couple places in the text, you  
7 talk about equivalency between chemicals so  
8 assuming the same kind of active ingredient  
9 apply.

10 But then -- and I understand that  
11 -- but there was another statement about  
12 looking within a chemical if you would double  
13 the application or double the amount applied,  
14 did you assume a double dose. And that was  
15 like a linear relationship. And that's  
16 something that I would probably dispute. But  
17 I'm wondering if that's an assumption.

18 MR. DAWSON: That is the  
19 assumption. And actually over the last couple  
20 years -- and I know for example Dr. Chambers  
21 has heard a lot about this because we've  
22 presented a lot of this issue to the HSRB with

1 our new study designs and also we talked about  
2 this some in the 2008 SAP, I think, where we  
3 talked about handler risk assessment methods,  
4 so we assume that linearity -- and there is  
5 some variability around that assumption -- and  
6 so with the data, we're attempting to evaluate  
7 that linearity as much as feasible with the  
8 new data.

9           So -- and what we see so far when  
10 we look at that is when people get higher and  
11 higher exposures, there's some kind of  
12 asymptotic relationship so we believe that  
13 assumption of linearity is actually somewhat  
14 conservative for the higher exposure folks.

15           MEMBER HARRIS: It's interesting  
16 in some of the occupational work we've done in  
17 different cohorts that we're finding -- in  
18 pesticide applicator cohorts, finding very  
19 little relationship between the amount of  
20 pesticide used or applied and the absorbed  
21 dose estimates, sort of on the level of, you  
22 know, 0.2 -- an r-squared of 0.2 or so. It's

1 quite, quite low.

2           We're finding that the other  
3 factors, the protective equipment factors are  
4 modifying that relationship between the amount  
5 used and the absorbed dose quite  
6 significantly. But I think that the pharma  
7 cohorts are a little bit different. I think  
8 it is probably more linear.

9           MR. DAWSON: Oh, and we would  
10 definitely agree that the use of protective  
11 equipment would significantly modify the  
12 exposures. And that's reflected in the  
13 measurements that we have, for sure.

14           MEMBER HARRIS: And so -- and also  
15 how much -- I know that some validation  
16 studies have been done with the PHED data or  
17 using biological monitoring. I'm wondering  
18 how much?

19           MR. DAWSON: That was actually one  
20 of the topics that we brought to this panel in  
21 2008.

22           MEMBER HARRIS: Okay. So I'm

1 probably asking some of the questions from a  
2 few years ago. Okay, okay.

3           So I ask that because I looked at  
4 the Agricultural Health Study and I looked at  
5 what kind of biomonitoring they have done in  
6 relation to trying to validate their measures.  
7 And I think that that's the natural connect --  
8 that they use the biomonitoring from the two  
9 different approaches and seeing how those  
10 relate to the exposure estimates. And then  
11 you can come up with some estimates of error  
12 and try to connect the two.

13           MR. DAWSON: I think that's  
14 definitely one of the issues that we will be  
15 looking at in the second phase of our  
16 approach.

17           MEMBER HARRIS: Okay.

18           MR. DAWSON: And just so everyone  
19 is clear, the unit exposures, we basically  
20 treat those generically because we believe if  
21 you use the same equipment, go apply the same  
22 field, whether you have, you know, Chemical A

1 or B in the tank, if you apply the same  
2 amount, that the exposure rate you are going  
3 to get is the same. And it's driven by the  
4 kind of the engineering aspects of how you  
5 make the application. And it's just to the  
6 skin. We evaluate it based on that.

7 MEMBER HARRIS: And so the only  
8 other thing I would add is that I think there  
9 is an opportunity in the Agricultural Health  
10 Study and I know the cohorts aging is not only  
11 just to go and do some validation but to go  
12 and do some predictive modeling of absorbed  
13 dose. And by taking samples within the cohort  
14 and using either the existing questionnaire or  
15 newly-obtained questionnaire information on  
16 their spraying practices and hygiene and  
17 behavioral characteristics and that type of  
18 thing. And trying to predict models of  
19 absorbed dose that you can use with the other  
20 applicators.

21 So it may be based on existing --  
22 if you want to apply it to the entire cohort,

1 it would be based on existing data that's  
2 collected, yes. Thanks.

3 MR. DAWSON: I would say we  
4 definitely agree with that. And those are the  
5 kinds of things we're thinking about for the  
6 Phase 2 and then when it got into the more  
7 chemical-specific aspects of Phase 3 based on  
8 what we learn.

9 MEMBER HARRIS: Thanks.

10 CHAIR HEERINGA: Thank you, Dr.  
11 Harris.

12 Dr. Bailar?

13 MEMBER BAILAR: I have very little  
14 to add. I think this has been a good  
15 discussion.

16 There is one thing, though, that  
17 concerns me. Like Dr. Harris, I had a lot of  
18 trouble understanding this. I had to read  
19 parts of it three times. So I recommend that  
20 the whole thing be rewritten for clarity. And  
21 that you add an abstract that's written for  
22 maximum clarity for people who are not on the

1 inside, who don't know the subject, think, you  
2 know, of the Congressional staffer who is not  
3 very far out of college with a degree in  
4 sociology. Would they be able to understand  
5 this? Not a chance.

6 MR. DAWSON: We appreciate your  
7 candor. And that's definitely something that  
8 we struggle with on a daily basis, absolutely.

9 CHAIR HEERINGA: We went through  
10 the SAP on the ag handlers exposure. And  
11 you've got to go back to high school chemistry  
12 and remember your method of units or you can't  
13 keep track of anything. So very good.

14 Dr. Greenwood?

15 MEMBER GREENWOOD: Again, I've not  
16 go a lot to add to this but I think part of  
17 the difficulty in trying to compare these two  
18 methods is that both of them have got a series  
19 of steps. And maybe you need to do some sort  
20 of sensitivity analysis to see if there is a  
21 discrepancy, where is it coming from? What's  
22 the weighting of these various steps?



1           Because what you've got is quite a  
2 difficult set of data to untangle. And I  
3 think as other people have said, you will have  
4 the opportunity if you've got some biological  
5 data to have a common -- a connection between  
6 the two.

7           But I don't think that will make  
8 it immediately obvious as to which parts of  
9 the two algorithms are actually generating any  
10 observed differences. So I think you will  
11 probably need to look very carefully at the  
12 impact of the different components in the  
13 algorithm.

14           CHAIR HEERINGA: Comments from  
15 other members of the panel?

16           (No response.)

17           CHAIR HEERINGA: Just out of  
18 curiosity, the one sort of case that you've  
19 done where you had 3.7 and 3, that's a fairly  
20 high level of agreement. Was that sort of an  
21 easy pick? Or was that a random choice?

22           MR. DAWSON: No comment.

1 (Laughter.)

2 CHAIR HEERINGA: I'm not being  
3 judgmental. I'm just trying to establish --

4 MR. DAWSON: There are definitely  
5 ones that we've looked at where there is a  
6 great diversity.

7 CHAIR HEERINGA: We would expect  
8 that in Dr. Reed's --

9 MR. DAWSON: And if you recall  
10 from like the 2008 -- within that PHED data,  
11 there is a wide range of -- that you see in  
12 the results. So we'll be looking at that,  
13 trying --

14 CHAIR HEERINGA: -- you know I  
15 think Dr. Reed's and Dr. Greenwood's point --  
16 Dr. Hayton, too, everybody is sort of, you  
17 know, getting at the components of each of  
18 these final estimates.

19 Other comments from panel members?  
20 Dr. Reed?

21 MEMBER REED: Well, we've talked  
22 so much about what's in the future in

1    distributional analysis and what can and  
2    cannot be done within PHED, I just want to put  
3    that in the record and I think it is a good  
4    one.

5                   MR. DAWSON:   Right.   Absolutely.  
6    And within the new dataset that we're working  
7    on generating, that will give us more ability  
8    to look at the issues of accuracy and  
9    uncertainty and variabilities.   So we're very  
10   hopeful about that.

11                   CHAIR HEERINGA:   Steve Heeringa.  
12   I would just add, too, you know, I really  
13   support this effort because those of us who've  
14   been party to hearing the presentations on the  
15   Agricultural Handlers Task Force and all of  
16   that work that's going in there, we all  
17   recognize that the expense of collecting that  
18   type of data any way we can gain of amplifying  
19   our estimates of exposure under these  
20   different scenarios, maybe by borrowing  
21   strength from the two data sources, it's  
22   clearly a benefit.

1 Dr. Lu?

2 MEMBER LU: I was reading the  
3 question and I just want to emphasize the  
4 scientific value of this comparison of this  
5 activity is huge. It is because the cost to  
6 do the study again and so on and so forth but  
7 I would not use comparisons because it is  
8 really orange to apple.

9 Instead I would say using the data  
10 collect by the Agricultural Health Study into  
11 the regulatory arena and using the regulatory  
12 standard to come up with the measurement, I  
13 don't think comparison is a good word.

14 CHAIR HEERINGA: Dr. Reed?

15 MEMBER REED: Just one comment.  
16 Before Jeffrey mentioned that with the new  
17 data, that he can do better comparisons. When  
18 I'm talking about distribution analysis, I'm  
19 actually talking about what you are about to  
20 do in terms of comparing the AHS. And PHED,  
21 it's occurring in PHED. And that you still  
22 have some ability to do distributional

1 analysis, not waiting for the new database.  
2 Is that what you were referring to? The new  
3 database? Or current database?

4 MR. DAWSON: It would mainly be on  
5 the new database. But we're going to try to  
6 incorporate as much distributional elements as  
7 we can in the other aspects of it. For  
8 example, I think it's more readily accessible  
9 on some of the exposure factors information,  
10 for example, that we could glean from the  
11 questionnaires about the use patterns for the  
12 individuals.

13 MEMBER REED: The other sort of  
14 follow up with Dr. Lu's comment was that when  
15 I said that when it comes to something that is  
16 entirely too complex for you to, you know,  
17 chew through, I was talking about setting  
18 priorities perhaps, you know, on chemical-  
19 specific evaluation, specific to whatever  
20 chemical, atrazine or anything that you want  
21 to look at.

22 I'm also thinking of the ability

1 to fine tune or improve on the use of PHED-  
2 type of data when the new PHED data comes.  
3 And so the comparison between the old and the  
4 new might reveal a lot more than, you know,  
5 this particular plane of comparison. I guess  
6 I need to clarify that. Not to put PHED  
7 evaluation aside as if it's not important.

8 CHAIR HEERINGA: Steve Heeringa.  
9 Was it not correct that some of the studies  
10 that are in the current PHED will be brought  
11 forward into the new database as well  
12 following an evaluation?

13 MR. DAWSON: Very limited number.

14 CHAIR HEERINGA: Okay.

15 Dr. Portier?

16 MEMBER PORTIER: I have to admit I  
17 didn't read this document that carefully but  
18 I was just looking at it and in Step 1, you  
19 state the overall objective of this kind of  
20 analysis is to evaluate whether or not there  
21 are differences in the predictions for  
22 exposures, regardless of approach, right?

1                   So you're going to be kind of --  
2   you're trying to relate these to it.  Again,  
3   I get the feeling that you are trying to  
4   relate point to point on an individual basis.  
5   And you might actually want to back away and  
6   think in terms of distributions and say can I  
7   get the distribution from this population from  
8   the Ag Handlers Survey to match the  
9   distribution from a scenario approach, right?

10                   I don't know.  That doesn't --  
11   that kind of concept doesn't seem to be in  
12   this writing.  But I think you understand what  
13   I'm talking about there.

14                   MR. DAWSON:  I think your point is  
15   well taken.  And I think that was -- we didn't  
16   articulate it well but we wanted to start with  
17   the simplest and then move to that.  But --

18                   CHAIR HEERINGA:  Dr. Bailar and  
19   then Dr. Chambers?

20                   MEMBER BAILAR:  Well, I would not  
21   abandon the point-by-point comparison.  There  
22   might be a lot to learn from those subjects

1 that are high on one and low on the other  
2 versus the ones with the reverse.

3 CHAIR HEERINGA: Especially on the  
4 sensitivity parameters.

5 MEMBER BAILAR: No, it would be a  
6 good way to find out which one might be more  
7 closely related with outcome.

8 CHAIR HEERINGA: Dr. Chambers?

9 MEMBER CHAMBERS: It occurs to me  
10 during this discussion -- excuse me -- that  
11 the reason for the Ag Handlers Task Force  
12 updating those data is that the PHED data is  
13 based on more historical types of equipment  
14 and that sort of thing when the exposures may  
15 have been higher because currently there are  
16 more protective types of spraying exposure --  
17 or of apparatus and what have you.

18 So in trying to do lifetime  
19 exposures with this, that creates a challenge.  
20 And I don't know how you are going to deal  
21 with that. The exposures may have been higher  
22 in the past than they are currently. So you



1 may have to kind of lend a differing exposure  
2 assessment into that for several years ago to  
3 when the equipment changed more recently. Am  
4 I making any sense? I guess -- you're  
5 nodding.

6 MR. DAWSON: No, I think you are.  
7 And I think just in general as we transition,  
8 we're going to have to understand that element  
9 of it. And, you know, try to be very  
10 thoughtful about what's -- how the new data  
11 will be representative of agriculture now as  
12 its practice in all its forms.

13 But that's a very good point. I  
14 think in certain cases where, you know, there  
15 might be higher exposure scenarios, we might  
16 prioritize there and look at, well, how did  
17 airblast technology change over time or  
18 something like that. That's a good point.

19 MEMBER CHAMBERS: Because in  
20 follow up, the point of the Ag Handlers is are  
21 workers being protected at present with the  
22 current protective measures and that sort of

1 thing, right? Not to estimate lifetime  
2 exposures. So it's very different goals.

3 MR. DAWSON: I would think that's  
4 a fair -- we would use it to predict lifetime  
5 exposures but it would -- I guess the way you  
6 first described it is we want to capture  
7 current cultural practices would be the way to  
8 describe it.

9 CHAIR HEERINGA: Okay. Dr.  
10 Greenwood?

11 MEMBER GREENWOOD: One way that  
12 you might get something useful out of the  
13 comparison when you do the plot is if you can  
14 identify in that plot where different levels,  
15 using the HS classification, you can maybe  
16 identify the different categories and see how  
17 they map onto it.

18 It just occurred to me that may be  
19 one way of getting a reasonably easy picture  
20 because if you do start to see separation in  
21 there, it may also explain if you've got  
22 discrepancies between the two methods.

1                   CHAIR HEERINGA:  What I'd like to  
2 do at this point is call a break until ten  
3 minutes after ten.  And at that point, we will  
4 reconvene and address the final charge  
5 question and wrap up.  And I think we should  
6 be finished before the noon hour.  I want to  
7 thank everybody for their comments this  
8 morning.

9                   (Whereupon, the foregoing matter  
10                   went off the record at 9:53 a.m.  
11                   and went back on the record at  
12                   10:13 a.m.)

13                  CHAIR HEERINGA:  Welcome back.  
14 Just one more reminder to the panel.  Make  
15 sure you bring the microphone very close to  
16 you even though up here it sounds like we're  
17 plenty loud, I think with the vibrations  
18 generated by these video screens here, it is  
19 sometimes hard to sort of discriminate your  
20 talking in the back.  So make sure you get the  
21 microphones very close and speak loudly into  
22 them.

1                   At this point in time, we are on  
2 our last subpart, Question 4.3. Again,  
3 questions related to the application of the  
4 Agricultural Health Study in the context of  
5 both exposure and risk characterization. And  
6 Shalu Shelat, if you would be willing to read  
7 the final question into the record please?

8                   MS. SHELAT: If it is okay with  
9 the panel, I'd like to make a clarifying  
10 statement at the end of the reading of the  
11 question.

12                   Question 4.3, the Agency has a  
13 long-term goal to understand the extent to  
14 which findings from the AHS are generalizable  
15 to other populations, such as pesticide  
16 applicators in states other than North  
17 Carolina and Iowa or those who may be exposed  
18 to pesticides through other pathways under  
19 different use conditions. Please provide  
20 suggestions for analyses which could be  
21 conducted to make best use of the results of  
22 AHS in a broader regulatory context.

1           As a clarifying statement, based  
2 on the discussions we've had with the panel,  
3 we'd like to make total utility of this  
4 information that is provided to also be  
5 considering generalizability in terms of  
6 bystanders as well as general population. And  
7 if there is anything anyone else would like to  
8 add to that?

9           MR. DAWSON: Just -- and also  
10 because we focus our case study in  
11 occupational handler in part but there are  
12 other people involved in the cohort. So we  
13 want to make sure that we ultimately make as  
14 much utility of that information as well.

15           MEMBER REIF: Can I just ask what  
16 do you mean by bystanders?

17           MR. DAWSON: That's -- there is a  
18 broad definition of bystanders but, for  
19 example, probably in the context of the Ag  
20 Health Study, it's the farm family folks who  
21 are living with the applicators and, you know,  
22 whoever they might be involved with in that

1 cohort. So to the extent possible, their  
2 children, those kind of --

3 MR. DAWSON: Just to clarify, with  
4 response to Dr. Lu's comment earlier, some of  
5 the Agricultural Health Study cohort members  
6 are not occupationally exposed on the farm.  
7 Those spouses, for examples, but the children  
8 are not -- as far as I know, are not  
9 considered directly as part of the cohort.  
10 They might constitute bystanders. But the  
11 non-employed spouses of the applicators are,  
12 in fact, in the cohort.

13 CHAIR HEERINGA: Our lead  
14 discussant is Dr. Harris.

15 MEMBER HARRIS: Thanks. Thanks.  
16 And I'll just follow up. Can you just read  
17 that statement one more time. You said you  
18 were interested in the generalizability for  
19 bystanders as well as -- and I missed that  
20 last part.

21 MR. DAWSON: The general  
22 population as much as feasible with this

1 dataset.

2 MEMBER HARRIS: Okay. Well, I  
3 appreciate that clarification because I  
4 wondered if you wanted us to even venture into  
5 that territory at all with that question.

6 I'll just start with saying --

7 DR. LOWIT: Just maybe one more  
8 big picture thing. Something that we've  
9 thrown around the idea is handlers in the Ag  
10 Health cohort, handlers in other states, post-  
11 application markers, farm families, the  
12 general population as you get further and  
13 further away from the cohort, how far then do  
14 you stretch that data? That's the sort of  
15 things that --

16 CHAIR HEERINGA: Like the low end  
17 exposure pyramid.

18 (Laughter.)

19 CHAIR HEERINGA: Dr. Harris?

20 MEMBER HARRIS: Okay. So I read a  
21 little bit of that into the question and so  
22 I'll attempt to give you my thoughts on these.

1           First of all, it is a difficult  
2 question because -- for a number of reasons.  
3 But when you talk about generalizability or  
4 how we can generalize results from the AHS to  
5 these other populations and once you get  
6 further and further away in exposures, I'm  
7 assuming that you're talking about past  
8 exposures? Are you talking about other  
9 exposures? What kinds of outcomes are we  
10 talking about here because how we generalize  
11 will depend on the outcome of interest.

12           And so if it is a cancer endpoint  
13 or a respiratory endpoint or a cardiovascular,  
14 whatever it may be, it may be more difficult  
15 to translate these findings to other  
16 populations, other geographic locations, and,  
17 again, that's an outcome-specific thing.

18           So I would -- you know, my focus  
19 would be looking at the effect of pesticides  
20 with cancer and frame the comments a little  
21 bit better that way. So if that's one of the  
22 priority outcomes that you'd be looking at.



1 I think -- so first of all, if we  
2 were taking -- if we're trying to generalize  
3 the results of pesticide exposures and the  
4 cancer risks to other -- what's your first  
5 level here -- other pesticide applicators in  
6 other states -- then I think that would be  
7 more of a direct -- it would be easier to do  
8 and easier to generalize.

9 And I think making the assumption  
10 that we're dealing with similar doses so I  
11 realize the pesticide application patterns and  
12 seasonality and things like that vary within  
13 the United States or even internationally --  
14 certainly internationally. And so those  
15 things would be taken into consideration. So  
16 variations in dose.

17 But you probably can, given  
18 certain racial and ethnic backgrounds and  
19 mixes, generalize to other states, again, it  
20 depends on the cancer, it depends on the  
21 pesticide, and it depends on whether there are  
22 any kind of interactive effects or synergistic

1 effects how well you could do that because  
2 there is quite a variation across the United  
3 States and that kind of make up.

4 I think the next question was --  
5 oh, exposed to pesticides through other  
6 pathways and under differing conditions of  
7 use. So primarily we're looking at dermal  
8 exposures in this setting for the Agricultural  
9 Health Study and so can we translate these  
10 findings for oral exposures or inhalation  
11 exposures?

12 And maybe in this case you're  
13 starting to move towards the residential and  
14 bystander exposures. I'm not sure what you're  
15 getting at with this question. But, again, if  
16 we assume that we have a similar age group and  
17 a similar ethnic or racial makeup and similar  
18 internal doses, that it wouldn't be too  
19 difficult to generalize those results. That's  
20 my first thought on that.

21 And then we move down to -- okay,  
22 so then you'd expand the question a little bit

1 -- so generalizability for bystanders, general  
2 population, farm families, children, et  
3 cetera, so we've got our occupational  
4 exposures, our applicators with the highest  
5 potential levels. And then we have bystanders  
6 -- I took that -- I mean you would have  
7 bystanders in occupational settings and  
8 bystanders in residential settings so like it  
9 all depends on how you define it.

10 But I would look at exposures  
11 probably decreasing from the occupational to  
12 the worker bystanders, like migrant farm  
13 workers, whatever they may be, to potentially  
14 spouses on the farm, children. And I would  
15 expect those exposures typically would be  
16 higher than those you would observe in  
17 residential settings. And residential  
18 applications may be a little higher up there  
19 individually but not over seasonally lifetime  
20 cases of exposures.

21 So, you know, the degree to which  
22 the age S results are generalizable to these

1 populations which have much lower exposures,  
2 is a very difficult question. And then also  
3 we're dealing with adult versus childhood  
4 exposures and susceptibilities and that type  
5 of thing.

6           So my guess is that that will be  
7 something that will be done on a case-by-case  
8 basis. So, again, it's difficult to come up  
9 with a broad answer. But I think I'll step  
10 back from there and let the rest of the panel  
11 address that one.

12           But we all know how difficult it  
13 is to extrapolate exposure in occupational  
14 settings down to residential and make that  
15 information relevant for risk assessment.

16           I'll just move on to the second  
17 part of the question, for suggestions for  
18 analyses that would make the age in a broader  
19 regulatory context. And this is not my idea.  
20 This is something that I talked to Michael  
21 Alavanja yesterday before he left. And I'm  
22 not sure if he has called in today or not.

1                   But I just want to put it out  
2 there and I have to find it. He said one of  
3 the things that didn't occur to me at all was  
4 that they have these HPEE and they're called  
5 high exposure -- high pesticide -- thank you -  
6 - exposure events. And he said there were a  
7 number of applicators in the cohort -- and I  
8 didn't get an exact number from him how many  
9 people reported these but my guess is it is,  
10 you know, maybe ten percent. I'm just  
11 guessing, you know, you probably experience  
12 these fairly frequently.

13                   And he said of those people that  
14 reported these high pesticide exposure events,  
15 approximately 20 percent of them had symptoms,  
16 chronic neurologic, respiratory such as  
17 wheeze, and detached retina, interestingly,  
18 and -- but less than five percent were  
19 reported to healthcare providers. And that's  
20 their data that they've collected.

21                   And so going back to one of the  
22 questions with the diazinon, the database,

1 that case example, it really would be  
2 interesting to take that data and look to see  
3 if you could link it all into any of these  
4 databases, either reported by industry or the  
5 poison control or -- I'm not too familiar with  
6 those databases -- and what would be key is  
7 the type of personal identifying information  
8 that is collected in those databases. And  
9 that I'm not aware of.

10 So, you know, it would be  
11 interesting to link those databases if at all  
12 possible and also to try to link them to  
13 reports in the AHS, given the appropriate  
14 ethics approvals and that type of thing. So  
15 that was one of his ideas -- one of his  
16 suggestions on making use of the AHS data.

17 And I'll let other speak.

18 CHAIR HEERINGA: Dr. Greenwood is  
19 our next discussant.

20 MEMBER GREENWOOD: I think that to  
21 some extent the answer to this question will  
22 depend on the outcome of the earlier studies

1 because it will depend to what extent, I  
2 think, that you can produce a common algorithm  
3 that is applicable.

4 And certainly the same categories  
5 I don't think would apply to people who are  
6 not handlers and so on. And certainly at the  
7 moment I don't think that the Agency's  
8 algorithm would cover this adequately.

9 So I think you probably would have  
10 to think about developing a modified  
11 algorithm. And, again, before you started to  
12 move outside the cohorts for which you've got  
13 a lot of information, I think you'd certainly  
14 need to do a sanity test.

15 And you'd certainly need, again, I  
16 think to spend some money on some biological  
17 data in terms of exposure because at the  
18 moment, what you're looking at in the earlier  
19 parts of the -- the earlier questions this  
20 morning, is how can you compare the two  
21 algorithms, what can you achieve with them?  
22 Will they be equivalent? What can you -- or

1 where can you take that in terms of maybe  
2 producing something which involves both of  
3 them? And looking at populations.

4           And I think probably -- and  
5 talking to Dr. Portier while we went for  
6 coffee, I think his idea of introducing the  
7 study by looking at populations rather than  
8 individuals -- getting hung on individuals --  
9 and then starting to look at which of these  
10 categories are actually going to give you the  
11 sort of measure of biological exposure --  
12 which ones are really going to be important  
13 for you to measure?

14           But I think in order to  
15 extrapolate or go outside to handlers and so  
16 on, you've probably got -- by the time you  
17 finish doing that work, you'll have an easy  
18 mechanism. I think you can do that because  
19 you won't have to modify things very  
20 generally.

21           But I think as soon as you want to  
22 start moving out to other categories of



1 exposure, then I think -- or roots of  
2 exposure, I think you're certainly going to  
3 have to rethink the algorithm.

4 But I think that you'll have  
5 enough experience by then to be able to  
6 identify which are the more important  
7 variables to put in there.

8 CHAIR HEERINGA: Dr. Hayton?

9 DR. HAYTON: I found this question  
10 a little difficult to address. In terms of  
11 extending to other states, I thought the  
12 approach could be along the lines of Step 2  
13 for trying to compare the Agency and the AHS  
14 metrics. And that is to look at a common  
15 population and try, you know, try the two  
16 methods on those two populations.

17 And I don't know if it is feasible  
18 to think that way but, you know, take a  
19 population from North Carolina and/or Iowa and  
20 then as far as going to other states, why not  
21 try to find a similar population and, you  
22 know, see how that works along the lines of

1 the Step 2 plan.

2           And in terms of going out from  
3 applicators to other populations, it seems to  
4 me that the intensity level metric does have  
5 flexibility to handle multiple pathway and use  
6 conditions. And if novel situations arise, it  
7 seems to me you just have to modify or add  
8 determinants of the intensity level  
9 calculation to accommodate those novel  
10 situations.

11           That's very general and it may be  
12 a lot easier suggested than done but it  
13 doesn't seem to me that you are limited with  
14 that AHS metric to just the particular facets  
15 or subcategories that make up the calculation  
16 at the moment.

17           CHAIR HEERINGA: Dr. Portier?

18           MEMBER PORTIER: I wish I had  
19 another hour to think about this.

20           So -- yes, it doesn't always work  
21 -- yes because the last question has brought  
22 up all kinds of ideas. I mean you start

1 thinking about these things and Dr. Greenwood  
2 and I were talking at the break and thinking  
3 through this.

4                   And I agree that the answer to the  
5 last question where you link the AHS intensity  
6 metrics with some kind of a distribution of  
7 personal exposure values, right, that's kind  
8 of Step One. And then you have to take these  
9 intensity metrics or these categories and link  
10 them to demographic conditions in the sample  
11 so that you can link them back to demographic  
12 scenarios in other states and other  
13 populations.

14                   Because from my thinking, it's a  
15 little bit like a stratified sampling  
16 approach. You are going to be defining strata  
17 based on these demographic or other  
18 characteristics. And then you are going to  
19 use something about what this intensity metric  
20 translates to to apply them to those strata.  
21 That's the only way you are going to be able  
22 to extrapolate that out again.

1           I don't know how successful you  
2 are going to be able to do it. I'll try to  
3 write this up a little better than I'm saying  
4 it so it will show up.

5           But I mean there are -- you know -  
6 - and Dr. Heeringa can probably speak to this  
7 -- in the sampling world, there are techniques  
8 of taking data on subpopulations and trying to  
9 rationally extrapolate that out, generalize it  
10 to the broader population. But you can only  
11 go so far.

12           You know the problem I had with  
13 the AHS is that it is a high exposure  
14 population. So when you start trying to  
15 extrapolate that to low exposed individuals,  
16 you don't have a lot of information from the  
17 cohort to make that relationship, right?

18           The nice thing is that's not the  
19 people you are that worried about, right? You  
20 are worried about the high-end exposure from  
21 a public health and safety point of view. So  
22 you've got the right population.

1 I'm going to stop at this point.

2 I'll write something together.

3 CHAIR HEERINGA: Dr. Harris?

4 MEMBER HARRIS: I'll just jump in  
5 because I think we answered two entirely  
6 different questions. Are you talking about  
7 generalizability of generalizing the results  
8 of the AHS let's say cancer risk estimates to  
9 others? Or are you talking about generalizing  
10 results as a comparison of the two exposure  
11 metrics to other populations? Because I think  
12 we've -- between the four of us, we've  
13 answered both of those somewhat.

14 MR. DAWSON: I say no reasonable  
15 offer refused.

16 (Laughter.)

17 MR. DAWSON: So actually you could  
18 think about this question, I think, in both  
19 ways. So it's -- and we struggle with this so  
20 I think it's good that people are thinking  
21 about it at different levels.

22 What -- I would like to add one

1 clarification on -- it probably was not clear  
2 at all or even mentioned in our document as  
3 far as kind of the other populations that we  
4 look at in risk assessment. For example, for  
5 folks that go in and harvest crops or kids  
6 that are playing on lawns that get exposed.  
7 We actually have developed and used exposure  
8 metrics for those kinds of scenarios as well.

9           So part of the discussion, we  
10 already have something we can build on there.  
11 So the good part about it is, we don't have to  
12 go and create all of that for this aspect. We  
13 can just kind of build on it like we would  
14 with the PHED and the replacement data as  
15 well.

16           CHAIR HEERINGA: Dr. Lu?

17           MEMBER LU: The farm family,  
18 including kids, has a high exposure was the  
19 hypothesis in the `90s. And there are  
20 actually many studies shows that those kids,  
21 if you are comparing their exposure to city  
22 kids, their levels are not necessarily higher.

1                   So I mean the statement that Dr.  
2 Portier just made in terms of you are  
3 comparing -- you have data from the very high  
4 exposure group to a very low exposure kid, I  
5 don't think we have any data to say that's the  
6 case. Pesticide applicator may know how to  
7 protect themselves very well in terms of farm  
8 pesticide exposures. Whereas citizens living  
9 in Crystal City just part of a pesticide just  
10 over-spraying his lawn. And it's really case  
11 by case, right?

12                   And my comment on this question is  
13 you can't do it because exposure pattern is  
14 different. Pesticide use is very different.  
15 And the pathway is very different.

16                   I understand why EPA wants to do  
17 this but the reality is you can't accomplish  
18 what you want. You may just focus on your  
19 resources and do a good job on categorizing  
20 occupational exposure.

21                   CHAIR HEERINGA: Dr. Gold and then  
22 Dr. Reif.

1                   MEMBER GOLD: I'd like to  
2 interject a note of caution about the  
3 generalizability not being an exposure  
4 assessment expert. So I'll put that caveat in  
5 there.

6                   But I think there are two aspects  
7 to this. One is I think that if you think  
8 about the crops to which these agents are  
9 applied and the say weather conditions under  
10 which they are applied, they are very  
11 different in Iowa than they are in other parts  
12 of the country or North Carolina. So that's  
13 cautionary note number one.

14                   And cautionary note number two is  
15 as I mentioned yesterday, the samples being  
16 studies in the AHS are fairly uniform -- not  
17 completely. In California where I come from,  
18 that's not the case. And certainly the farm  
19 workers who enter the fields after the  
20 applications are a very diverse population in  
21 terms of susceptibilities and so forth.

22                   And so my note of caution comes



1 from those two sources. That I think the  
2 applications are different. And I think the  
3 populations are different. And the  
4 susceptibilities in those populations are  
5 different.

6 And I would be very cautious about  
7 generalizing from the age as to other  
8 populations. That said, I don't know if you  
9 have other opportunities, you know, where you  
10 could garner some additional information. And  
11 I think the answer to those cautionary notes  
12 is not necessarily found within the AHS.

13 Certainly the second one isn't.  
14 The first one perhaps you could be enlightened  
15 by some of the data that you have in the AHS.  
16 So I would just -- I guess I'm at a little bit  
17 of a disagreement with my colleagues around  
18 the table.

19 I think I would be remiss, being  
20 from California, if I didn't say something  
21 about the diversity of the population. And I  
22 think the AHS is pretty uniform. There is a

1 little more diversity in North Carolina but it  
2 still is nothing like what we have in  
3 California.

4 MEMBER BOVE: I have a question.  
5 It goes back to something that I do in my  
6 spare time, which is work with farm --

7 CHAIR HEERINGA: Dr. Bove, pull  
8 your mic up real close.

9 MEMBER BOVE: -- work with farm  
10 labor organizing groups. And there is a very  
11 strong farm labor organizing group in North  
12 Carolina. In fact they just won a union a  
13 couple of years ago.

14 And so my question is that there  
15 are these diverse populations in North  
16 Carolina of migrant farm workers, particularly  
17 in the pickles in a couple of other crops.  
18 But they're not picked up in the Agricultural  
19 Health Study. Or are they? They're not.  
20 That's unfortunate because then some of the  
21 issues that Dr. Gold just raised could be  
22 addressed. So that's something to think about

1 because, as I said, there is a large migrant  
2 population in North Carolina that could be  
3 evaluated. But difficult because they come  
4 back and forth between here and Mexico.

5 CHAIR HEERINGA: Jeff Dawson.

6 MR. DAWSON: And definitely we're  
7 interested in looking at those populations and  
8 kind of review this as methodologically what  
9 can we learn about how to do this and begin to  
10 look at other sorts of epidemiologic data to  
11 do that kind of analysis. Absolutely.

12 CHAIR HEERINGA: Dr. Lowit?

13 DR. LOWIT: I think not to get us  
14 off on track but just as a natural add-on to  
15 what Jeff just said is as some of you are  
16 probably aware, that EPA and NEIHS have  
17 several cohorts of mother/children pairs, two  
18 in Harlem, one in California. The one is  
19 California is the so-called Chemakus dataset  
20 cohort of somewhere between 300 and 400  
21 primarily Mexican-born farm workers. And  
22 there's lots and lots of very rich data coming

1 from all three of those cohorts that we're  
2 very interested in using in other things that  
3 we're doing.

4 So a lot of the things that we're  
5 talking about here, even on the Ag Health  
6 Study because those are also prospective  
7 cohorts, really applies to the way that we're  
8 thinking about those cohorts, which are on  
9 acceptable populations. They're on lower  
10 income. The Harlem populations tend to be  
11 lower income. They are people who live in  
12 housing -- urban housing. And the Chemakus is  
13 primarily farm workers.

14 So we're talking a lot about Ag  
15 Health here today but there are other epi  
16 studies that we're extremely interested in.  
17 And will probably using over the next year.

18 CHAIR HEERINGA: Dr. Lowit, just  
19 out of interest, what data are you gathering  
20 on those cohorts? Do you get drinking water  
21 concentrations? Do you get blood? What are -  
22 -

1 DR. LOWIT: It varies. The three  
2 cohorts are actually very nicely complemented.  
3 And some of you may remember from a couple of  
4 summers ago where we talked about the  
5 chlorpyrifos dataset because the Columbia  
6 University cohort is one of those three.

7 And it varies by the three. And I  
8 might have misspoken but certainly they all  
9 have urinary measures in moms and in kids.  
10 There are some blood measures. They've done  
11 some things at birth. They've tracked -- the  
12 mothers were recruited during pregnancy. And  
13 so they're tracking the children from birth.

14 A lot of the kids are now in the -  
15 - five to seven years old. So it's actually  
16 a really rich dataset, particularly when you  
17 put the three together.

18 CHAIR HEERINGA: Dr. Reif?

19 MEMBER REIF: Just briefly, I  
20 think first, you are absolutely right. This  
21 is an important question to raise.

22 From my understanding of the

1 Agricultural Health Study, there was  
2 considerable thought put into the selection of  
3 the two states because of the diversity of  
4 agricultural practices. And I agree with Dr.  
5 Gold that California would have been an  
6 excellent third state because there are clear  
7 differences in agricultural practices as well  
8 as in the demographic characteristics of  
9 farmers and farm workers in that state.

10 That said, I mean there are a few  
11 sort of straightforward approaches where the  
12 data permit. So looking at the -- in the  
13 first steps of whether data are generalizable,  
14 for example, first comparing findings for the  
15 two states with respect to a common chemical  
16 exposure, second, again, where the data  
17 permit, doing stratified analysis, Dr. Portier  
18 says to compare the effects, for example, in  
19 a Caucasian population and in an African  
20 American population, which one could do  
21 probably in North Carolina.

22 So those are some initial steps

1 that can be taken. And I'm sure will be taken  
2 in any publications that come from the AHS or  
3 should be because those are sort of  
4 straightforward steps that we would always  
5 apply to the data analysis to look for that  
6 internal consistency across racial subgroups,  
7 gender, age, because that's kind of an  
8 important biological question is if a  
9 pesticide is active in increasing risk, is the  
10 risk uniform across the strata of age? Is it  
11 uniform across the strata of gender? And is  
12 it uniform across strata of ethnicity or race?

13 So there are some internal checks  
14 that can be done and I'm sure would be done.  
15 The limitation is that if there aren't  
16 adequate numbers of persons in the cohort,  
17 particularly of diverse racial and ethnic  
18 groups, then the ability to test those  
19 internal hypothesis is limited by the  
20 distributions of the cohort.

21 CHAIR HEERINGA: Dr. Bailar?

22 MEMBER BAILAR: I think I agree

1 with Dr. Gold. The human biologic responses  
2 we're interested in depend on the details of  
3 exposure and on the demographic  
4 characteristics of each exposed person. They  
5 certainly don't depend on state boundaries.

6 And if I were starting over on  
7 this, I'm not sure I would use state  
8 boundaries as the primary limiting factor.  
9 What matters in a sense is agricultural areas.

10 And I would like to have the data  
11 on perhaps subareas of states that could be  
12 separately analyzed and then build those up to  
13 get a composite for the state rather than  
14 start with the state as a whole and try to  
15 break it down.

16 CHAIR HEERINGA: Steve Heeringa.  
17 I'll add my comment.

18 I would also support, I think, Dr.  
19 Gold's caution, particularly going vertical in  
20 the pyramid because I know the extrapolation  
21 from this data, it's the same issue we face  
22 when we talk about the agricultural handlers



1 task force issue.

2           You know you get so many scenarios  
3 to essentially define parameters. But to any  
4 extrapolation or implementation of that data  
5 requires a set of model assumptions. And I  
6 agree that I think the geographic constraints  
7 is really one of agricultural practice and  
8 differences, you know, among the states.

9           That can be handled by, you know,  
10 potentially in a model framework by some  
11 stratification, getting down to levels where  
12 you assume that you have some homogeneity.  
13 But that would, in my view, apply to  
14 applicators and people who are actually  
15 working with this.

16           To then extrapolate exposures from  
17 what we see there or what we estimate there to  
18 children, to spouses, to neighbors, even to  
19 people working, I think that requires another  
20 set of data. And I don't see that data in the  
21 Ag study.

22           It may be -- some of it we're

1 talking about it coming from the applicators,  
2 you know, the task force datasets in terms of,  
3 you know, variability among applicators.

4 But there is a big jump when you  
5 start -- I don't deal with a lot of this data  
6 but I've seen data on dioxin, which would be  
7 intensively looked at both in environmental  
8 measures, individual measures, family  
9 measures, soil measures. And there is a lot  
10 of heterogeneity in these data.

11 And the differences, you know, I  
12 think it was mentioned with regard to children  
13 and households, too. Dr. Lu mentioned it. I  
14 don't know what that mechanism is but I would  
15 assume the extrapolation from the applicators  
16 that we're studying, the farmers who are  
17 making the application even to the next level  
18 of their children and their spouses, it is a  
19 different mechanism of exposure.

20 And so I don't think you can  
21 generalize the exposures. I don't know once  
22 the exposure happened, maybe you can

1 generalize the mechanism. But I think you  
2 have a real challenge in generalizing the  
3 exposures.

4 Anybody want to react to that?

5 Dr. Reed?

6 MEMBER REED: I agree with you.

7 CHAIR HEERINGA: That makes me  
8 feel very good. Thank you.

9 MEMBER REED: Sorry. I mean --  
10 no, I agree with you. And the reason is  
11 because you have different currency. You have  
12 different algorithms in calculating or  
13 estimating the exposure. Just about the only  
14 thing that is shared is the use pattern.

15 But you have far more differences  
16 than -- I mean different parameters than just  
17 use patterns. And so that extrapolation  
18 certainly would require far more than just AHS  
19 studies to allow you to do that.

20 So actually when I was reading the  
21 framework document and you said, you know, you  
22 future sort of goal is to extrapolate from the

1 applicators to even just all agricultural  
2 workers, I said no, that must be a typo from  
3 applicator to applicator, yes. You know there  
4 is that possibility.

5           And so if we're talking about farm  
6 families and children and even bystanders,  
7 non-occupational bystanders, that is a totally  
8 different kind of algorithm, you know. I  
9 would encourage that the Agency map out what  
10 exactly you were thinking of instead of just  
11 sort of free floating idea. What is your  
12 current practice? And at what point where  
13 thing a bridge can be connected?

14           And I think that would help in  
15 this discussion much better, I think.

16           CHAIR HEERINGA: Just to sort of  
17 restate my comments -- Steve Heeringa -- I  
18 think the potential for sort of geographic  
19 extension of your inference or, you know,  
20 focusing on subgroups that are represented in  
21 the North Carolina and Iowa samples, even  
22 though they may not generalize to the Central

1 Valley, I think there is a little more  
2 potential for that than going vertically in  
3 the pyramid. But again, I want to defer to  
4 the real experts here.

5 Other comments? Shalu? Oh, Dr.  
6 Greenwood?

7 MEMBER GREENWOOD: I think that  
8 was what I was trying to say in my clumsy  
9 manner. That you'd need to do a whole lot  
10 more development work if you wanted to move to  
11 other groups. You'd have to establish, again,  
12 the populations in the same way that's been  
13 for the applicators and users.

14 And I think if you wanted to put  
15 the effort into that, then you could certainly  
16 move that around, I think, as well. But you  
17 have to look at a whole new set of -- a whole  
18 new approach, I think, to a whole new set of  
19 maybe sources of contamination associated with  
20 behavior of the applicators and so on.

21 And that could be difficult  
22 because I think people are going to be less

1 open and honest if they feel that they are  
2 contaminating their kids and their wife.

3 CHAIR HEERINGA: Thank you, Dr.  
4 Greenwood.

5 Other comments on this issue?  
6 It's obviously -- Dr. Bailar?

7 MEMBER BAILAR: It isn't directly  
8 on this issue. I'd like to go back a bit to  
9 the comparison of the two metrics.

10 As I understand it, you're doing  
11 it for every person who is in the study? You  
12 want to have the two metrics for each of the  
13 subjects?

14 MR. DAWSON: Jeff Dawson. I'm not  
15 sure we would commit to every person in the  
16 study but perhaps a subset at some point.  
17 That we would definitely be interested in  
18 doing that for a subset of them. And as far  
19 as the scope of the exercise, I think it will  
20 be -- we view this as an iterative process so  
21 as we kind of march along our plan and as far  
22 as the resources and such allows, I think, you

1 know, we'll try to do that as much possible.

2 But there may be a point where it  
3 is a diminishing return or something. So  
4 we'll just have to kind of evaluate that as we  
5 go. But I would say we probably definitely  
6 would not for every person but probably  
7 selected subsets is my guess.

8 MEMBER BAILAR: Well, selected  
9 subsets would be helpful. But even with that  
10 approach, you might learn very nearly as much  
11 by looking at truly random samples. They  
12 don't have to be simple randoms. You could  
13 use stratified random, random according to,  
14 you know, well you might want to talk to a  
15 sampling expert about it.

16 But do it for a random subset and  
17 that will tell you -- first give you the  
18 characterization of the relationship between  
19 those two. And even if you are interested in  
20 specific outcomes, relatively uncommon  
21 outcomes, you could do it for 100 percent of  
22 the people with that outcome and a random

1 sample of the others.

2 You know if you try to do it for  
3 everybody, you'll end up with a ratio of cases  
4 to controls of one to 100, one to 1,000, maybe  
5 one to 100,000. And that makes absolutely no  
6 sense statistically.

7 So you might want to think about,  
8 you know, getting some help in doing this on  
9 a random basis.

10 MR. DAWSON: No, I think your  
11 point is an excellent point. And to the  
12 extent you can incorporate that into the  
13 discussion, I think it would be very  
14 worthwhile for us.

15 CHAIR HEERINGA: Any other  
16 comments on this final part of Question 4 from  
17 the panel?

18 (No response.)

19 CHAIR HEERINGA: I'll turn to  
20 Shalu Shelat or to Dr. Lowit, Jeff Dawson for  
21 any --

22 DR. LOWIT: I just have one thing.



1 I was listening to the discussion and  
2 envisioning in my head something akin to what  
3 I think Dr. Portier was talking about with  
4 respect to once we understand the translation  
5 between the Ag Health algorithm and the way  
6 that we do exposure assessment and on a  
7 distributional way that you can overlay the  
8 distributions and compare those.

9           And we certainly have experience -  
10 - I'm thinking about the distributions of  
11 residential exposure. And we're really good  
12 at food. And we're really good at water. And  
13 compare those distributions and how far you  
14 incrementally get away from the Ag Health  
15 population.

16           Then the second step is what Dr.  
17 Gold very eloquently described with the  
18 extrapolation from a relatively homogeneous  
19 group to what is not across the country.

20           But what hasn't been talked about  
21 is the relative uncertainty of doing that  
22 compared to the default situation of starting

1 with an animal in the absence of let's say a  
2 pharmacokinetic model and dividing by ten. Or  
3 ten and ten. And the relative uncertainty of  
4 those.

5 CHAIR HEERINGA: Dr. Lu?

6 MEMBER LU: In my opinion, the  
7 uncertainty that Agency just mentioned is  
8 almost impossible to quantify because, again,  
9 this is really case-by-case situations. Say,  
10 for example, the methyl pyrithione  
11 misapplication case, for example, it involved  
12 quite a few people. We may be able to come up  
13 with an algorithm that you can calculate the  
14 uncertainty in terms of ag case versus the  
15 form it was illustrative.

16 But based on my experience of  
17 doing pesticide exposure research, there are  
18 many cases that -- you call them outlier but  
19 I think those cases are very important for the  
20 regulatory activity to examine the cause of  
21 the exposure and the manner of exposure and so  
22 on and so forth.

1                   And I just don't see how can you  
2 generate something like this and try to come  
3 out with uncertainties so you can apply it to  
4 your approach. There are many risks that you  
5 will over estimate or under estimate the true  
6 exposures. And that would lead to a  
7 significant uncertainty as well.

8                   MEMBER PORTIER: This is Ken  
9 Portier. Alex, when you mean case-by-case,  
10 are you thinking in terms of a scenario set to  
11 a scenario set? Or are you talking about an  
12 individual -- you know I keep thinking in  
13 terms of the way EPA looks at this in terms  
14 of, you know, a worker is really a set of  
15 scenarios that kind of get strung together.  
16 And then you are cumulating or integrating  
17 that exposure by looking at what they do  
18 during the day.

19                   And I'm trying to figure out if  
20 you are thinking in terms of that or if you  
21 are thinking in terms of an individual, like  
22 an AHS individual who might be on the high end

1 of exposure with some kind of biomonitoring  
2 measurement.

3 MEMBER LU: Well, when I say --  
4 what I meant by case-by-case is if you look at  
5 the distribution of pesticide exposure in say  
6 kids, you know, age three to five, if the  
7 Agency plans to use the Agricultural Health  
8 Study in a way that you can generalize for  
9 this population using some kind of a -- come  
10 out with the terminology right away, you  
11 actually tend to bring in those extremely high  
12 and extremely low exposure cases to the  
13 middle.

14 And that really dilutes the  
15 significance of this practice. And as I can  
16 recall, the principle of conducting cumulative  
17 research assessment for the pesticide within  
18 the Agency is to come out with some kind of a  
19 percentile. And then look at either the 90th  
20 percentile or above or 95th percentile or  
21 above.

22 By doing this generalization, that

1 95 or 97.5 percentile will become very flat  
2 and very similar to the 50th percentile. So  
3 that's the problem that I can foresee.

4 I'm not really talking about  
5 single case-by-case study like, you know,  
6 California cases versus North Carolina. But  
7 if you think about the much bigger picture,  
8 that's the case. You know bring everybody to  
9 the central tendency and you don't really see  
10 the cause and effect.

11 MEMBER REIF: That's a really  
12 interesting question and I'm fascinated. Has  
13 anyone ever done that for anything? For  
14 example, for benzene or for any of the  
15 industrial chemicals where you've actually  
16 taken the standard approach, you know, the no  
17 L and low L and the animal extrapolation in  
18 the ten then the ten? And then compared what  
19 you get for let's say a reference dose?

20 And then compared that with human  
21 data where there are really robust human data,  
22 which is not really the case here?

1 DR. LOWIT: I'm not necessarily  
2 really familiar with the benzene case but to  
3 my knowledge in the cases, with the exception  
4 of arsenic, the number we, or the Agency, has  
5 used an epidemiology study to drive a  
6 regulatory value, that has been done.

7 But how you interpret that has to  
8 do with the question that I asked about how  
9 you weigh the value, how you weigh those. I  
10 mean we spent several days and I've talked to  
11 many epidemiologists. And their first comment  
12 is always epi data is better than animal data  
13 because you don't have to extrapolate.

14 We only spent 30 minutes talking  
15 about I think very appropriate cautions of  
16 making -- going too far with the Ag Health  
17 Study but we're losing a little bit -- sight  
18 of, the default is a rat divided by ten and  
19 ten unless there is a PBPK model. And then,  
20 you know, you're still relying a lot on in  
21 vitro and everything else.

22 So the intellectual question I'm

1 asking myself is which is more uncertain? And  
2 their degrees of uncertainty.

3 CHAIR HEERINGA: I think the --  
4 Steve Heeringa here -- let's try to break this  
5 down. When you go back to the extrapolation  
6 from the rat, you're really talking about dose  
7 response. And so I think there is a question  
8 about generalizability.

9 If a response was observed in the  
10 population of agricultural applicators, could  
11 we extrapolate that for equivalent exposures  
12 to their spouses and to their children? I  
13 mean that's one. In other words, can you  
14 extrapolate the mechanism?

15 I think what we're worried about  
16 is extrapolating the exposures. And I think -  
17 - at least that's what I'm catching. So I  
18 can't answer the question about the  
19 mechanisms. Somebody else might be able to.

20 But I think I would be inclined to  
21 be more comfortable if you, in the ag handlers  
22 epidemiologic study observe a response to

1 exposure that that mechanism might be more  
2 easily extrapolated than certainly information  
3 that you collect on the exposures themselves.

4 But, Dr. Reif?

5 MEMBER REIF: Yes, you're right.

6 That's the answer you would get from an  
7 epidemiologist. But let me just point out one  
8 thing. Both IARC and EPA, in their definition  
9 of carcinogenicity, reserve the premier class  
10 or the Class I carcinogens to those chemicals  
11 that have adequate evidence of carcinogenicity  
12 in humans.

13 So both your Agency and IARC have  
14 taken the position that if you don't  
15 sufficient epidemiologic evidence of  
16 carcinogenicity in human populations, then you  
17 are a 2A or a 2B or wherever you come out in  
18 that framework.

19 So there's two independent bodies  
20 who have thought about this extensively. And  
21 their answer to that specific question is you  
22 must have epidemiologic data to classify the



1 chemical as a human carcinogen.

2 DR. LOWIT: Not being an expert on  
3 cancer classifications, in practice the Agency  
4 does cancer calculations on a number of  
5 chemicals that aren't in that first category  
6 based largely -- solely on animal data.

7 CHAIR HEERINGA: Dr. Bucher?

8 MEMBER BUCHER: I think I'd have  
9 to slightly disagree with that. I think that  
10 certainly the NTP categorizations and the IARC  
11 categorizations will rely on information from  
12 human studies but it doesn't have to  
13 necessarily be human epidemiology studies. It  
14 can be studies from humans in the sense of  
15 looking at similar mechanisms of action. And  
16 with respect to certain listings that we've  
17 made.

18 Certainly the epidemiology has not  
19 carried the day. It's been combinations of  
20 animal studies with other information that  
21 indicated that similar mechanisms occurred in  
22 humans. So it's not cut and dried.

1 I agree in general that  
2 epidemiology is considered needed to carry the  
3 day. But it's not exclusive.

4 CHAIR HEERINGA: Dr. Meek?

5 MEMBER MEEK: A couple of points.  
6 Fortunately we rarely have to exclusively use  
7 one or the other. So I, in fact, see the  
8 value of the framework as actually bringing  
9 the data together. And we need to distinguish  
10 qualitative considerations from quantitative  
11 considerations.

12 So the kinds of classification  
13 schemes that we're talking about that weigh  
14 epidemiological data do so -- or hazard  
15 characterizations, simply hazard  
16 identification has a characterization.

17 The kinds of information that we  
18 are generally seeking to do the risk  
19 characterization has to be dose response  
20 relationship data. So based on our experience  
21 in industrial chemicals, certainly there are  
22 some epidemiological datasets that provide us

1 with the dose response characterization that  
2 we need. And we use the data maximally.

3 And our experience there has been  
4 that the relative sensitivity of animals and  
5 humans isn't significantly different.

6 There are many, many issues  
7 embedded in the extent to which you weight the  
8 animal and the human data, some of which  
9 include, for example, if we talk about  
10 arsenic, you're talking about levels in the  
11 population that were tenfold above the kinds  
12 of guidance values that we're setting for  
13 drinking water.

14 I look at that data quite  
15 differently than if I have three or four  
16 orders of magnitude difference between an  
17 occupational population and a population  
18 exposed in a general environment. So there  
19 are a number of factors that are weighted.

20 The reason I made the comment the  
21 first day that clearly the qualitative  
22 considerations needed to be distinguished from

1 the quantitative considerations in this -- in  
2 the framework to use the data, we use the  
3 quantitative data as much as possible in  
4 epidemiology. We are rarely in the situation  
5 that we have sufficient quantitative data. So  
6 that's kind of where we've been.

7 CHAIR HEERINGA: Thank you, Dr.  
8 Meek.

9 Dr. Gold?

10 MEMBER GOLD: I'm fearing that I  
11 caused a problem here by putting in the  
12 cautionary note. So I'm going to put in as  
13 strong a cautionary note because I have the  
14 same concerns about extrapolating from animals  
15 to humans, namely that the modes of exposure,  
16 the applications, the routes of exposure, the  
17 dosages in animals are different. And the  
18 susceptibilities are different.

19 It's the same parallel I made  
20 between the AHS populations and other  
21 populations. So my cautionary note is the  
22 same.

1 CHAIR HEERINGA: Dr. Lowit?

2 DR. LOWIT: I think we've heard  
3 everything that we had hoped to hear, given  
4 that we didn't actually give you an example.  
5 It was in many ways an intellectual discussion  
6 of where to put our resources and how to think  
7 about it.

8 But I think it is actually the  
9 value of applying the mode of action framework  
10 under the context of the way that it has been  
11 used in the past and the way that we hope to  
12 put it here, is that by putting everything  
13 down, and all those uncertainties whether they  
14 are the cautions that Dr. Gold talked about  
15 and the similarities of what we know about the  
16 pharmacokinetics of animals and humans that by  
17 building that case in a stepwise, very  
18 transparent way, that those -- that that  
19 weighting becomes apparent as you go through  
20 the analysis.

21 The reason I asked the  
22 intellectual question was because I was

1 getting this very negative vibe and I wanted,  
2 as a group, I wanted you to step back and come  
3 back to our reality of that the alternative is  
4 if you come out a little too strong on, you  
5 know, nothing other than applicators, that's  
6 a challenge because the default is something  
7 that most people find fairly dissatisfying.

8 CHAIR HEERINGA: I won't speak for  
9 the group but I think that won't get precisely  
10 that message. It will be a more diffuse  
11 message, appropriate with a question, I think.

12 Other comments on this last point?

13 (No response.)

14 CHAIR HEERINGA: Okay. What I'd  
15 like to do is to go around the panel and give  
16 everybody an opportunity to sort of address  
17 anything that you think has not been addressed  
18 relevant to this particular topic that we've  
19 been discussing for the last two-and-a-half  
20 days. Something that relates to one of the  
21 charge questions you haven't mentioned. But  
22 anything you'd like to offer.

1 Let's start with Alex, Dr. Lu?

2 MEMBER LU: No, I have nothing to  
3 add.

4 CHAIR HEERINGA: Dr. Hayton?

5 DR. HAYTON: No, nothing further  
6 to add.

7 CHAIR HEERINGA: Dr. Reed please?

8 MEMBER REED: I don't really have  
9 anything to add into this -- the context of  
10 the questions. But I do have a risk assessors  
11 sort of same point. When we talk about human  
12 data being more desirable in terms of having  
13 advantages, in the context of pesticide risk  
14 assessment, it is a little bit unsettling to  
15 me because I've always thought that if we do  
16 risk assessment correctly, then you wouldn't  
17 see any of these human data in terms of  
18 illnesses and all that.

19 And so when we put it out as wow,  
20 you know, human data is much better advantage  
21 over the animal data, I'm hoping or wishing  
22 that there is a way to express it in a way so

1 that it is not conveyed as we're looking for  
2 that human data to make risk assessments  
3 better because there is a component of risk  
4 assessment which is predictive. And human  
5 data observation in populations and incidences  
6 of illnesses is not predictive.

7 And so I don't know how to, you  
8 know, put it in a sentence like that but I  
9 think something like that would be a useful  
10 conversation or communication.

11 CHAIR HEERINGA: Dr. Reif?

12 MEMBER REIF: I just want to  
13 really commend the Agency for taking us on.  
14 You go back to the original description, at  
15 least from my recollection of the NRC's  
16 monograph in whenever it was -- 1983 -- and  
17 think about the number of years that have  
18 elapsed where we really haven't successfully  
19 and adequately, in my view, integrated  
20 epidemiology into the risk assessment process.

21 This is a real challenge. And it  
22 isn't easy by any means. But I think that the



1 fact that you are clearly interested and  
2 committed to seeing how and to what extent it  
3 can happen and it can work and consider it is  
4 a huge step forward. So I just think it is  
5 very worthwhile.

6 CHAIR HEERINGA: Dr. LeBlanc?

7 MEMBER LeBLANC: I have nothing to  
8 add.

9 CHAIR HEERINGA: Dr. Portier?

10 MEMBER PORTIER: One of the things  
11 that has been in the back of my mind through  
12 all of this discussion is how we used a lot of  
13 the human data in the CCA risk assessment by  
14 passing it through some kind of a model. And  
15 I haven't seen any kind of conceptual model.

16 And I think, you know, while the  
17 conceptual framework that you've had is nice  
18 for thinking about these things, it's almost  
19 like a lot of these questions could have been  
20 answered if we had had a more concrete model  
21 about how you are looking at how these, you  
22 know, exposures occur and everything else.

1           So I would encourage the Agency to  
2 continue to think in terms of how we use the  
3 scenarios and modeling to actually compare to  
4 the epi data and use the epi data as more of  
5 validation that our understanding of this  
6 process is clear and logical.

7           MEMBER CHAMBERS: I don't have  
8 much to add but I think Ruby just brings up a  
9 very interesting point. If the risk  
10 assessments have been done right up to this  
11 point, then you might not get any positive  
12 adverse -- or any adverse effects out of the  
13 human study and you will have to revert to the  
14 defaults to look at what the adverse effects  
15 might be in an animal system.

16           So, anyway, good luck.

17           (Laughter.)

18           MEMBER BUCHER: Well, picking up  
19 on that also, if, in fact, the Agency does  
20 find with the review of atrazine or any other  
21 pesticide with significant human data that  
22 there are significant human risks that are

1 associated with the use of these pesticides,  
2 I think one needs to go back and reassess the  
3 entire paradigm that you are using to protect  
4 the public. And maybe readjust some of the  
5 safety factors that are in use and some of the  
6 assessment techniques because obviously that  
7 would represent a failure of current  
8 practices.

9           So it is a very important thing  
10 that you are doing here and I encourage --  
11 even though there has been some tendency  
12 toward some critical comments towards the  
13 Agency's approach, I certainly do encourage  
14 you to go forward with this because this is  
15 very, very important.

16           MEMBER POPE: I'd start just by  
17 saying that I think -- I appreciate the idea  
18 or the concept of using any kind of data to  
19 input into the risk assessment process. But  
20 I am an animal toxicologist so I have biases  
21 just like epidemiologists and other people in  
22 different disciplines.

1           And Dr. Meek just mentioned  
2 something about when you have the situation  
3 where you've got really widespread differences  
4 in apparent dose response relationships, for  
5 example between epidemiological studies and  
6 animal studies, and I also, like Ken, have  
7 been sitting here for the last couple of days  
8 mulling over something and it's what Dr. Lu  
9 had just brought up about the 2008 SAP meeting  
10 on chlorpyrifos.

11           And my recollection from that was  
12 that animal studies and epidemiological  
13 studies were both kind of a suggestion that  
14 there were neurodevelopmental effects that  
15 were being listed by chlorpyrifos early  
16 exposures or possibly chlorpyrifos and other  
17 OPs.

18           But the distinction was that in  
19 the human studies, the doses appeared to be  
20 incredibly much lower than the animal studies  
21 were. And so I've been sitting here trying to  
22 figure out how do you epidemiological data

1 versus animal data under those conditions?

2           And on page 31 of the white paper,  
3 there are a couple of points there that say  
4 when animal and epidemiological data do not  
5 provide a consistent toxicological picture,  
6 more weight would likely be given to those  
7 studies with robust study design and  
8 availability of replication or confirmatory  
9 data.

10           Robust seems like a good term for  
11 definition. Further it asserts that in most  
12 situations, the epidemiological study may not  
13 be sufficiently robust for deriving  
14 quantitative risk assessment values. And as  
15 an animal person, I think I agree with that.

16           And that animal studies have a  
17 better chance of more quote robustly  
18 describing dose response relationships and  
19 mode of actions than epidemiological data  
20 would be able to do. And I'm wondering, you  
21 know, what the epidemiologists think about  
22 this.

1 CHAIR HEERINGA: Dr. Bailar?

2 MEMBER BAILAR: I'd like to echo  
3 Dr. Reif in commending the Agency on taking on  
4 a very difficult problem but one that I think  
5 is necessary. I'd like to go further and  
6 commend them on what I think is a very sound  
7 first draft.

8 It's the very quality of this  
9 draft that has made it possible for us to  
10 address the questions that the Agency has put  
11 to us. Also, it's really a lot more fun to  
12 try to make a good thing even better than to  
13 make a lousy document just marginally  
14 acceptable.

15 CHAIR HEERINGA: Dr. Meek?

16 MEMBER MEEK: A couple comments  
17 along the same lines. First of all I very  
18 much appreciate the efforts of the Agency.  
19 And having been on the other side of the table  
20 for Health Canada many times, I understand  
21 what you go through in these review processes.  
22 And I hope that you come away with something

1 very helpful in the discussions.

2 I would encourage the Agency to  
3 think not only in the context of  
4 epidemiological or human incident data in the  
5 context of human data as we transition to  
6 think more broadly about the kinds of, you  
7 know, early events that we'd be looking at in  
8 populations.

9 And I really think that our, you  
10 know, our context of epidemiological studies  
11 is going to need to change as well. So rather  
12 than considering epidemiological studies as  
13 our having failed in some context because  
14 we're counting very adverse effects, we  
15 probably need to be thinking about how do we  
16 look at biomarkers that can more robustly  
17 inform us in the context of mode of action.

18 MEMBER GREENWOOD: I think having  
19 sort of listened through the presentations by  
20 various people and having listened to the  
21 discussions over the last few days, I guess  
22 really for me the way that the Agency started

1 to approach this, using a series of  
2 frameworks, I think is probably a very, very  
3 good way to deal with this.

4 I mean I think actually I would  
5 encourage them to provide frameworks which  
6 look at all of the individual stages so that  
7 you have a framework for setting toxicological  
8 data, epidemiological data, the exposure, and  
9 so on. So on all of the designs, that you  
10 have something which is transparent, which is  
11 the sort of thing you are working to across  
12 the board.

13 And I think maybe you need to look  
14 in more detail in some areas where it is  
15 critical to try and develop a step of criteria  
16 by which you assess the validity so you can  
17 apply it to any of the studies in exactly the  
18 same transparent way.

19 And certainly I think what I see  
20 happening where you are beginning to bring  
21 different disciplines together is really  
22 something which will help you achieve what



1 really otherwise would be, I think, a very,  
2 very difficult job.

3 But I think the approach, using a  
4 series of frameworks you've started on, is  
5 probably going to allow you to make -- have a  
6 lot of success in looking at what are some  
7 very difficult problems.

8 MEMBER HARRIS: Well, I don't  
9 think I can add much more that hasn't already  
10 been said. But as someone who was trained in  
11 toxicology and exposure assessments and, you  
12 know, I jumped camp over to epidemiology and  
13 I did that because of my absolute frustrations  
14 of looking at the exposure assessments in the  
15 pesticide exposure health risk studies.

16 And then after many years of  
17 working in that field of epidemiology, I  
18 realize that yes, it is very difficult. And  
19 we haven't gotten much better at doing it.

20 So I might just reemphasize that  
21 the need to really expand work in the exposure  
22 assessment as it relates to both. And I thank

1 you for being here because it has been quite  
2 a pleasure trying to wear two hats. I don't  
3 know if I've done that effectively or not but  
4 I will continue to try to do that for many  
5 years.

6 Thank you.

7 CHAIR HEERINGA: Dr. Bove?

8 MEMBER BOVE: I just want to echo  
9 what a number of people have said. I think it  
10 is just great that you are moving in this  
11 direction. And go forth.

12 CHAIR HEERINGA: I'd like to  
13 express my thanks to all of the members of the  
14 panel and to the scientific staff of the EPA.  
15 I would especially like to thank some of the  
16 younger scientists who have made presentations  
17 here over the last three days. I can only  
18 imagine that it is challenging and you are  
19 being thrown into the lion's den of sorts  
20 here.

21 Because the purpose of this is to  
22 critique. And so the criticism comes more

1 easily than the praise. But I think you just  
2 heard a fair amount of praise here as well,  
3 too.

4           And I think that you should be  
5 commended for I think the quality of your work  
6 and the clarity of -- I don't know many first  
7 drafts that I've written that would have had  
8 that sort of clarity.

9           And following Dr. Bailar's  
10 comments, we were able to follow it and we  
11 were able to consider it and comment on it.  
12 So it's very effective. And hopefully you'll  
13 take any "criticism" not personally but as  
14 part of the scientific process of getting to  
15 where you want to get to.

16           I thank you also to all of our  
17 public commenters for the information that was  
18 shared. I agree with the other panel members  
19 that this is an important deliberation. I  
20 think it was an important deliberation to have  
21 at the start of what is going to be a very  
22 year for this Science Advisory Panel, some

1 very, very serious deliberations. I hope that  
2 the sessions that we've had here the last two-  
3 and-a-half days will essentially inform us and  
4 inform the EPA in the process that we are  
5 about to go through in this coming year.

6 So any additional comments or  
7 suggestions? Dr. Lowit?

8 DR. LOWIT: We would just like to  
9 take a second and thank each one of you. Your  
10 participation in this process is absolutely  
11 vital to our everyday work of making sure our  
12 assessments are scientifically robust and  
13 transparent. And pushing and prodding us to  
14 do better and better.

15 And I'd also like to thank Myrta  
16 Christian and Laura Bailey who have once again  
17 put together a stupendous meeting. Everything  
18 runs smoothly in the background, which is  
19 wonderful.

20 And I'd also like to thank my  
21 team. It's a small army of people you've seen  
22 and some that you haven't.

1 CHAIR HEERINGA: Thank you.

2 I'd like to turn it over to Dr.  
3 Myrta Christian, our Designated Federal  
4 Official.

5 MS. CHRISTIAN: Yes, I'd just want  
6 to thank you the panel for their advice to the  
7 Agency, the public commenters for presenting  
8 their views to the panel, and especially the  
9 Agency for their excellent presentations.

10 And in addition, I want to remind  
11 everyone that the report and meeting minutes  
12 for this meeting will be available in about 90  
13 days.

14 CHAIR HEERINGA: Okay. With that,  
15 I'd like to again thank all of you for your  
16 participation. And we will bring this meeting  
17 to a close.

18 Panel members, let's meet next  
19 door to plan the afternoon's writing sessions.

20 (Whereupon, the above-entitled  
21 Scientific Advisory Panel meeting was  
22 concluded at 11:22 a.m.)

<b>A</b>				
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**8**

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**8:30** 1:17  
**8:37** 4:2  
**84** 20:15

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**9**

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**9** 3:20  
**9:53** 82:10  
**90** 148:12  
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**95** 124:1  
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