

FIFRA SCIENTIFIC ADVISORY PANEL
OPEN MEETING

REVIEW OF WORKER EXPOSURE
ASSESSMENT METHODS

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FIFRA SCIENTIFIC ADVISORY PANEL (SAP)
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DR. HEERINGA: Everybody's in a hurry to get out of there. That quieted it down and, okay. I think we're qualified to begin, here, so, let's get underway. Good morning, everyone, and welcome to the fourth and final day of the meeting of the FIFRA Science Advisory Panel, and the topic of review of worker exposure assessments.

As most of you well realize by now, we've had three days, I think, of very successful and informative presentations and discussions. And we are wrapping up this morning with an update, potentially some new information, added information, initially in the session, and then we are going to turn to the sixth and final charge question that was presented to the panel by the EPA. And that's the one dealing with sample size.

I think a very critical, very critical issue. This point in time, I'd like to turn to, first, Jeff Evans and Jeff Dawson, to see if there are any follow up comments or information that you'd like to provide us from the previous dates, and Jeff Dawson.

MR. DAWSON: Jeff Dawson. No, I think

1 we're fine, and we appreciate the level of the
2 discussions. Thank you.

3 DR. HEERINGA: I, we have one additional,
4 Tim Leighton from the antimicrobials division of the
5 EPA, spoke to me at the end of the day yesterday, wants
6 to also bring in a few points about their design,
7 because it's relevant to the sample size discussion.
8 Again, we probably shouldn't confuse it with the
9 discussion on the age, ETF, the ag handlers exposure
10 task force plan, but I want to make sure that we also
11 address it, because they're part of this meeting as
12 well.

13 So, Tim, if you would just like to give your
14 introduction, we'll make sure that, before we wrap up
15 today, that we get a specific discussion and focus on
16 your issue, to the extent that it may differ from the
17 AGTF plan.

18 MR. LEIGHTON: Thank you. Again, I'm Tim
19 Leighton from the antimicrobials division. Day one,
20 back on Tuesday, Dr. Cassie Walls made a presentation
21 and discussed the antimicrobial side. She went over
22 the similarities and differences. It's been a good
23 meeting for the antimicrobials. We didn't have as much
24 date to go back on to bring up these examples, so we
25 were very happy to piggyback on what HED has been

1 presenting over the last three or four days. And we're
2 going to have a lot of information to take back, make
3 revisions to the protocols, and move forward.

4 What I want to do now for this one is just to
5 highlight some of the differences that Cassie had
6 mentioned in day one, so when we discuss clustering and
7 the number of samples that are needed, that we also
8 look at what we have for the antimicrobial database.
9 So, in the next slide, and what this, actually,
10 specifically, pertains to is within the first day as
11 presented by the antimicrobial task force, Dr. Ryan
12 Williams.

13 On slide number 8, we don't need to pull it
14 out, but it just contained a table of 19 exposure
15 studies that are going to be collected, scenarios,
16 actually; and each scenario has one study and 15
17 replicates. Next slide, and the basis for why it is,
18 why it is what it is, is that exposure scenarios of
19 interest have been identified. Initially, there, I
20 think there was 23 exposure scenarios.

21 They have been discussed by EPA, PMRA, and
22 also California Department of Pesticide Regulations.
23 And what we decided on is that we can get what's, what
24 we want as representative antimicrobial type uses with
25 about 17 handler scenarios. The data have been

1 required or in the process of, through data call ins,
2 through our re-registration eligibility decision
3 documents, also known as reds. Each one of them has
4 call-, confirmatory data call in for each of these,
5 basically, 17 exposure scenarios. So, the task force,
6 instead of having each company repeat the same study 17
7 times, you know, it's best to do this by task force,
8 and as we've discussed, there's a lot of history to
9 that.

10 And where the 15 monitoring units came for
11 each study, each scenario, they were, initially, based
12 on EPA guidelines, the guideline recommendations. So,
13 from here, what I want to point out and highlight,
14 there's differences. In the initial plan, I'm calling
15 it the initial plan because I know the task force, EPA,
16 Health Canada, and California, we're going to make
17 modifications from what we've learned.

18 But, I would just want to go over an example.
19 So, for an aerosol spray study, that's in the sample
20 plan. There's going to be one study, 15 replicates, or
21 20, they may have said 20. We will be looking at an
22 applicator applying aerosol spray with no gloves.
23 We'll be using a disinfectant. That's the initial
24 plan. And we get into, what we're calling simulating
25 this study in a laboratory. First, there'll be a pilot

1 study. And we're going to look at 4 scenarios. We'll
2 be looking at hard surfaces, soft surfaces, such as
3 somebody applying this to bedding, to couches, et
4 cetera. Look at aerosols for air sanitizers in a room.
5 Looking at exposures, also, to foaming products they
6 put on a toilet.

7 And, basically, within the laboratory,
8 they'll be setting up two or three bathrooms. And a
9 bathroom will, each bathroom will consist of a sink,
10 shower, and toilet. So, a configuration there, you
11 can, you know you have single sinks, double sinks,
12 showers, stall, a bathtub. These are things that we're
13 going to consider. And one monitoring event or
14 monitoring unit, however we want to call that, is going
15 to be a separate individual spraying this aerosol
16 product over the sink, shower, toilet. And that will
17 give us, basically, in this context for discussion, one
18 cluster, 15 monitoring events.

19 Now, other options we're looking at, and I
20 think, this is the reason why I wanted to bring this up
21 for clarification today, if we discuss is there a need
22 for clusters, and using clusters, clusters different
23 sites, if that effects the number of samples versus
24 having one simulated site, how many samples we would
25 need. You know, we had been discussing for the AG

1 side, looking at orchards. So, I want to bring us out
2 of the orchards, now, and into the bathroom, so, if you
3 actually did a field site for a bathroom, you know,
4 what could you do. We, I, you know, there's different,
5 you know, there's apartment buildings, townhomes,
6 single family homes, would we want to find five
7 apartments, monitor five different people, and so
8 forth.

9 Next slide, and this is the final slide. So,
10 for consideration by the SAP here today, it would be,
11 it, be good to discuss the clustering options of having
12 a one simulated site. How many monitoring units or
13 monitoring events would we need, versus if we go to
14 three field locations. And field locations, you know,
15 either geographic, I'm not sure how we'd want to define
16 that, but it also could be apartment, townhouses,
17 houses.

18 And then, final note here, 'cause I know this
19 question came up yesterday, is, well, to figure out how
20 many sample sizes you want, what part of the
21 distribution are you going to regulate on. And for us,
22 now, for the antimicrobials, and I think, you know, for
23 a lot of them, we have not selected that end point,
24 what we're going to regulate on yet. Most of our
25 assessments are deterministic. We have done one

1 assessment, and that was the, the sheds wood that we
2 worked with, ORD. In fact, it came to the SAP. That
3 would be interesting to find out where we regulate on
4 that one, except for the fact that, that the product
5 already has been canceled, so we're not regulating on
6 it.

7 We're going out and just show them what we
8 have. If somebody wants to see the 99 percentile, they
9 can see it, but you know, we still haven't made a
10 selection. You know, it would've been nice to, you
11 know, for us to make a decision, but we haven't. And,
12 then, again, and finally, what are we looking at for
13 most of these antimicrobial ones. Lot, you know, most
14 of them are short term, short to intermediate term,
15 actually; but we do have some chronic scenarios that
16 are like a metal work in fluid, where somebody's
17 everyday using a material preservative within that
18 fluid, the machinist, and they're exposed every day.
19 So, I mean, at this point, with the data we have, we
20 want to make an incremental leap to have more data,
21 it's still going to be deterministic.

22 We'll certainly be interest in the central
23 tendencies. And from there, if we have to go to a
24 higher tier, such as a probable-, probabilistic
25 assessment, we will have the option for that particular

1 chemical to go back and require more data. So, even if
2 we have, let's say, 15 replicates for painting and
3 PHED, the task force can monitoring, at this point,
4 another 15, now we have 30.

5 If we need 45 or such, or 50 or 60, for a
6 specific probabilistic assessment, we can make those
7 registrants go back, collect additional data at that
8 time, and continue forward. And that's just what I
9 wanted to say for, to make sure that this type of
10 consideration gets input today for clusters and sample
11 sizes. Thank you.

12 DR. HEERINGA: Thank you very much, Dr.
13 Leighton. Members of the panel, any questions for Dr.
14 Leighton on the specific elements of the data needs
15 within the antimicrobials division as they may be
16 distinct from that in general agricultural pesticides?
17 Dr. Johnson.

18 DR. JOHNSON: On the, I'm thinking about
19 the bathroom study and the simulation thing. I guess,
20 I'm wondering whether wiping down a dirty bathroom is
21 different than wiping down a clean bathroom, in terms
22 of the amount of exposure someone might get. And so,
23 how do you, how do you get dirty bathrooms, I guess,
24 and, in a simulation study or in a, in a study that
25 involves clusters.

1 DR. LEIGHTON: The, although these will be
2 simulating in a laboratory, the toilets won't be
3 connected to the plumbing, so.

4 [All laugh.]

5 DR. LEIGHTON: But, I mean, that's a fair
6 question. And it's also a fair question for the
7 mopping study. There's a mopping study that, rent a
8 wedding reception hall and go in and clean the floor.
9 Now, if we do that cleaning the floor 15 times, they're
10 not going to get 15 weddings to go through there.

11 So, you know, this is a concern, but I think,
12 overall, for mopping, I'd, and also for spraying, you
13 know, if it's dirty or not dirty, as long as somebody
14 is doing the job, at this point, that what's we were
15 going to go with. Might have to think about spraying
16 dirt around. I'm not sure.

17 DR. HEERINGA: Dr. Portier.

18 DR. PORTIER: The answer is college
19 students. It's always the answer, right.

20 [All laugh.]

21 DR. HEERINGA: I see we're going to have
22 to put a bridle on him this morning. Okay. Dr.
23 MacDonald, please.

24 DR. MACDONALD: So, would it be fair to
25 say that the sources of variation in these studies are

1 considerably less than what we've been dealing with up
2 to now, with the farm workers using different spray
3 application, that this is really much more like a
4 controlled experiment. In fact, in practice, it would
5 seem to me that there's going to be less variability in
6 the use of these chemicals?

7 DR. LEIGHTON: Yes, for some of them,
8 that's certainly the case. When we get to mixing load
9 in studies, there will be some variability, because,
10 again, there are thousands, tens of thousands of
11 products.

12 They're packaged from small containers up to
13 five gallon buckets for open pouring. So, for that
14 one, we're going to see some more variation. But if
15 you were spraying a sanitizer in a room, and if, and we
16 would control for more of the worse case, where the air
17 exchange rate would be potentially zero. And spray for
18 ten, twenty seconds, whatever's going to be
19 representative, I would think that, yes, we would see
20 less variability.

21 DR. HEERINGA: Thank you, Dr. Leighton.
22 We'll definitely consider this also, not only in the
23 discussion, but in our report response, too, I think
24 we'll make sure that we single out or distinguish any
25 unique features of your particular situation that are

1 distinct from those for the general agricultural worker
2 exposure.

3 DR. LEIGHTON: And if it be considered
4 fairly generically, 'cause, again, we've got 17 of
5 these scenarios, and there is going to be changes. I
6 know there'll be changes from that.

7 DR. HEERINGA: You have almost as much
8 variability as we've seen in the ag exposure scenario.
9 Well, not quite, but some at task, clearly, appear to
10 be much more systematic, and this is a controlled, as
11 yours suggest, but, okay. At this point, do we have
12 any additional comments from other groups that have
13 presented from either of the exposure task forces, any
14 updates, any corrections or clarifying information?
15 Dr. Landenberger.

16 DR. LANDENBERGER: I just wanted to add a
17 little bit to what Tim Leighton has presented as well
18 for the antimicrobials. When we initially started with
19 those, we were looking at simulation, because we were
20 trying to cover some very broad waterfront. The
21 initial matrix that we looked at was a, approximately,
22 19 by 13, 19 application methods, 13 general categories
23 of usage. And the request was that we fill the cells
24 completely, which was beyond the capacity of our task
25 force to do. So, we started looking at breaking down

1 some of the tasks into segments that we could then
2 combine over particular use patterns. That's why we
3 had a pour liquid study that we were looking at doing,
4 in terms of a simulation mode.

5 As Tim pointed out, there are tens of
6 thousands of applications that use either pour liquid
7 or pour solid or some of the other studies that we
8 have. And this has caused us to stop and think, how do
9 we get at that type of information. The other issue
10 that comes along with this, that we are looking at
11 simulation in some of these cases as well, is the
12 extremely low quantities that we're using, often
13 milligrams inside of a bucket of active ingredient, and
14 that's it; which has caused us to try and look at
15 simulation, what we can control, some of the
16 confounding factors.

17 One of the products we've at for some of
18 these studies is didec, which if you're familiar with a
19 spray, trigger spray, a lot of them use it. So, we
20 have to have a controlled environment so we can figure
21 out what's coming from the usage in that particular
22 case, and avoid having interferences from what might
23 just be in the household already presented. So, these
24 are some issues that have come into play in our, in
25 terms of our thinking on how we have to try and get at

1 this information. And how we can try and get it across
2 this entire grid of 13 by 19 that we initially started
3 out with. Tim's correct. This has been useful for us.
4 I appreciate the discussion that's gone on with the
5 SAP.

6 We certainly are trying to re-think of some
7 ways we can try and get at this. We have some issues
8 that are going to be hard for us to deal with, just
9 because of our detection limits being low. The
10 quantities used being low. And trying to cover as much
11 as we can, in terms of usage, which is quite, quite
12 broad. Just to give you a little thought starter, if
13 you have something on the shelf that can degrade
14 biologically, it probably has a biocide, and that's in-
15 can preservative and all those need to be covered by a
16 pour liquid study, or they have to be covered by some
17 of the other usages that might go along with that,
18 brush roller if it's a paint.

19 But, as you can see, there's just thousands
20 of products that would have biocides in them, and this
21 has made it a little bit more difficult for us to try
22 and figure out how do we get our arms around this. How
23 do we get our arms around just a normal usage pattern
24 for an in-can preservative. These are some issues that
25 are probably a little bit different than what the ag

1 guys are dealing with. And so, we're looking for some
2 solutions. We'd appreciate input that the SAP could
3 give us on that.

4 DR. HEERINGA: Thank you very much, Bryce.
5 Okay, at this point in time, I think, again, if we are,
6 this is a critical discussion question this morning.
7 And if we reach any points in the discussion where I
8 feel we need clarification of information, I may invite
9 individuals to return to the mike, but otherwise, we'll
10 confine it to panel discussion.

11 So, either Mr. Miller or Mr. Dawson, Mr.
12 Evans, could you read the charge question number six
13 into the record for us, please. Before you begin, Dr.
14 Portier just reminded me, too, that we really didn't
15 answer in detail the second part of question number
16 five.

17 And what I would propose, is that we'll read
18 charge question six into the record, and that panel
19 members, when you respond to charge question number
20 five, can fold in whatever sample size related comments
21 that you had. Excuse me, to question six, fold in
22 whatever sample size related comments you have from
23 question number five. So, sorry for the interruption,
24 please.

25 MR. DAWSON: Charge question six. The

1 agency's goal is to ensure that monitoring studies rely
2 on sample sizes that adequately represent the range of
3 exposure of people who engage in a particular handler
4 scenario and activity.

5 It is also recognized that occupational
6 monitoring studies are costly, and have many
7 logistically obstacles. The agency is also concerned
8 about limiting the numbers of participants in these
9 studies, in accordance with the ethical requirements
10 described in sub-part K, 40 CFR 26, and the recent
11 criteria outlined by the human's, agency's human
12 studies review board.

13 The agency's current guidelines recommend 15
14 monitoring units for each scenario. In addition, the
15 AHETF has provided a rationale for the number of
16 samples and their study design. Please comment on the
17 uncertainties associated with the agency's and AHETF's
18 recommended number of monitoring units.

19 In your comments, please include any
20 recommendations you may have regarding specific
21 statistical analyses that may assist the agency in
22 developing better understanding of these uncertainties
23 and characterizing them in a complete and transparent
24 manner in agency assessments based on these data.

25 DR. HEERINGA: Our lead discussant is Dr.

1 Johnson.

2 DR. JOHNSON: Thank you. That's a tough
3 charge. The, particularly, the last sentence there,
4 complete and transparent manner. I'm not sure I've
5 ever been able to do that. Sample size questions are
6 always tough questions.

7 I think back a number, over the years, a
8 number of scientists that have come into my office and
9 says, how many samples should I take. And I, usually,
10 respond with, well, how many were you planning to take.
11 And if they answer a thousand, I say, well, you
12 probably don't need that many. If they answer ten, I
13 might say, can you take a few more. So, it's, it's a
14 tough, it's a tough thing to say when you have enough
15 and when you don't have enough.

16 Particularly, well, you're in better, in a
17 better situation here, because you have some old data
18 to work with to, sort of, help give you some guidance
19 as to what types of samples to have, or how many
20 samples to take. Yesterday afternoon, as we were
21 getting ready to leave, it seemed that maybe the
22 emphasis in this charge might have shifted a little bit
23 from, exactly, how many monitoring units, and how they
24 would be selected, to the process that the task force
25 is planning to use to determine the sample size. And,

1 that's a lot easier charge. I think that the task
2 force has done an excellent job in looking at past
3 data, doing some simulations, talking about K fold
4 accuracy.

5 And I'm pretty happy with the process that
6 they've used to, sort of, get some idea as to an
7 appropriate number of samples. And, for the
8 antimicrobial group, I guess, they might need, since
9 they don't have all that much data to start with, they
10 might need to do some pilot studies to, and maybe try
11 to do, go through a similar kind of process that the
12 agricultural handlers exposure task force has done. I
13 think Dr. Portier is going to come at things from a lot
14 different perspective, and probably has a lot more good
15 suggestions to add than what I might have.

16 So, the rest of my comments are just sort of
17 generic in some sense, things that we've already said,
18 I think, and, but, and may not even need to be re-said,
19 but I'm going to re-say them anyway. First, if you're
20 going to fix the total number of monitoring units, then
21 I agree, that it's generally better to have more
22 clusters, and fewer numbers of monitoring units per
23 cluster, than it is to have fewer clusters and more
24 monitoring units per clusters. I think we've discussed
25 a little bit already, and everybody seems to be in

1 agreement with that particular statement. In the EPA
2 report, botanical report, there's a table 5.2 that
3 suggests the number of monitoring units that will be
4 selected for each scenario, but that table did not give
5 any information as to the number of clusters and the
6 number of monitoring units within each cluster.

7 And so, that table might need to be updated
8 when that kind of a decision is finally made. Also,
9 when reading the report, the report seemed to have a
10 fair amount of information about what data will be
11 collected, but there was not much information about how
12 the data will be collected.

13 There wasn't anything that I could find in
14 the report when I was reading it, as to how the
15 clusters will be selected, how the monitoring units
16 within a cluster will be selected. Will there be
17 control over the amount of ingredient handled. I think
18 the, the task force has indicated that there will. How
19 the participants are selected, and when the data will
20 be collected. Fortunately, the presentations did a lot
21 better.

22 The presentations that were given seemed to
23 address the answers to a lot of these kinds of
24 questions, and I'm much happier with that now, than I
25 might have been earlier. Now, the problem with this

1 is, those answers to those questions might, actually,
2 have been in the report, but there was 114 pages of
3 report, and I, there's lots and lots of materials, and
4 I had trouble finding everything.

5 Sometimes with respect to sample size, last
6 night, I just loaded the report, and then did a search
7 for the word size or sample or and equals to see what I
8 could find, and there, really, wasn't much in any of
9 the reports about that. The latter part, then, and
10 this, sort of, addresses the second question, I guess,
11 include recommendations you may have regarding specific
12 statistical analyses that may assist the agency in
13 developing a better understanding of the inherent
14 uncertainties, and characterizing them in a complete
15 and transparent manner.

16 As I said before, if we're going to fix the
17 total number of monitoring units, then I agree that
18 it's better to have more clusters and fewer numbers of
19 monitoring units per clusters, than the other way
20 around. You've heard me say this before. I don't know
21 why you need to worry about whether the slope
22 coefficient in the regression equation is equal to one
23 or not.

24 Just use whatever slope it is to, to predict
25 the exposure level. And it seems to me that would

1 provide all the information that you need. And, of
2 course, if you're going to estimate that slope
3 coefficient, as the task force has indicated, you need
4 to have a nice spread in the amount of ingredients
5 handled.

6 And preferably, we want a nice spread within
7 each cluster. And if one is sure that the relationship
8 is linear then you just need small and large values of
9 HIJ of the amount being handled. Maybe to test
10 linearity, you want something pointing in the middle,
11 'cause if you have a low amount and a high amount and
12 something in the middle, then it gives you some handle
13 on whether you have linearity or not. Also, in
14 estimating the slope parameter, it only used up one
15 degree of freedom in your, in your data analysis. So,
16 you're not, you're not spending much of your data used
17 to estimate that slope parameter.

18 The next little bit I have here has to do
19 with the primary benchmark as stated in the, in the
20 task force document stated that the number in
21 configuration of sampling, sampled monitoring units
22 should be adequate so that selected measures of the
23 dermal exposure distribution means the percentiles and
24 so on are accurate to within K fold, when the exposures
25 are normalized, that is divided by the amount of active

1 ingredient handled. And so, the question then is, what
2 value of K is appropriate and reasonable.

3 And I'm not sure as a statistician that I can
4 answer that question. I think the scientists have to
5 answer that question. But, some of the possibilities
6 that, that might exist that, using some numbers that I
7 took out of Jeff Dawson's presentation as to some
8 representative values, perhaps.

9 If the geometric mean is equal to 12, then at
10 3-fold range, would go from 4 to 36. And in that case,
11 if the 95th percentile, and I'm just guessing where it
12 might be, but say it was at 21, then a 3-fold range of
13 that would go from 7 to 63. On the other hand, if the
14 geometric mean is smaller, the exposure rate is smaller
15 at, say, 6, then a 3-fold range would go from 2 to 18,
16 95th percentile might be 15, and 3-fold range on that
17 would be 5 to 45.

18 On the other hand, if there's a lot of
19 exposure so that the geometric mean is 900, then a 3-
20 fold range is 300 to 2700, and a 95th percentile might
21 be 1500 and a 3-fold range on that would be 500 to
22 4500. So, I guess, the agency needs to decide if that
23 kind of accuracy is okay. If it's, if you, if, as I
24 say, as a statistician, I don't really have any way to
25 judge whether that's a reasonable range or not. And so

1 the agency has to make that decision, and, obviously,
2 the sample size is going to be determined by whatever
3 that value of K is.

4 The secondary benchmark was that the number
5 and configuration of monitoring units should be
6 adequate so that it is possible to distinguish between
7 complete proportionality and complete independence of
8 dermal exposure and the amount of AI handled. I like
9 this sentence 'cause now I know that there's a
10 difference between proportionality and complete
11 proportionality.

12 Complete proportionality, I assume, means the
13 slope is one, and proportionality just means it's
14 something but doesn't have to be one. And, as I've
15 mentioned before, I guess I don't think this is worth
16 worrying about too much, but just use a model where the
17 slope is estimated, but it does say something about how
18 you need to collect the data so that you can get an
19 accurate estimate of that slope parameter.

20 So, I guess the bottom line is, I think that
21 the task force has done an outstanding job, I guess, of
22 looking at past data and trying to use that to get some
23 ideas about what the sample size should be. The
24 simulations that have been done and the estimates have
25 inter-class correlation and so on that seem reasonable.

1 I think the process that is, has been suggested is, is
2 a good process and I think it can be recommended.

3 So, I think the issue comes down as to what
4 kind of accuracy do you need. And so, the emphasis,
5 then, is on this value of K. How much accuracy do you
6 need? What value of K is appropriate and reasonable?
7 And as a, unfortunately, as a statistician, I don't
8 know how to tell you that. I'll pass on, then, to the
9 rest of the - -

10 DR. HEERINGA: Thank you very much, Dr.
11 Johnson. I'll go in order. Cynthia Hines?

12 DR. HINES: I don't know when H came so
13 close up in the alphabet, but it seems to in all of
14 these. As Dr. Johnson alluded to, I think Ken is going
15 to be having some additional ideas, so I'll just
16 comment for the moment on what has been proposed by the
17 task force. I just have a few additional comments in
18 addition to Dr. Johnson's.

19 Maybe the first comment would be, and you
20 alluded to this, the selection of the clusters. As I
21 thought about this some more, this is really a critical
22 decision, how you select these clusters, and whether or
23 not they're really building in the stratification that
24 you desire. And it may be somewhere in the large
25 document, but it's not real clear to me what the

1 criteria are for selecting these clusters in a real
2 field practical sense. Is it going to be a combination
3 of state and crop? Is it, could it go down to the
4 county level? Could you be within a state and would a
5 different cluster be in, say, northern Arkansas versus
6 southern Arkansas?

7 So, I think there needs to be some tightening
8 up, if this cluster approach is used of what the
9 definition of these clusters are, so that it's not
10 something you're kind of doing on the fly. And, you
11 know, maybe there's no intention of doing that, but
12 it's just not real clear at this point.

13 Because, and the reason I think this is
14 critical, 'cause in inspecting the data analysis that
15 you've presented, it's very clear, of course, that
16 increasing clusters as opposed to increasing numbers of
17 monitoring units per cluster, gives you the best
18 efficiency in sample size.

19 So, there may be a tendency to want to
20 maximize those clusters, and so, will you end up doing
21 that, perhaps, in a way that really isn't improving
22 your condition stratification, just because it becomes
23 more practical and more expedient. So, I would give
24 that some serious thought if you continue with the
25 cluster approach. My next comment, there was some

1 discussion yesterday about whether or not the agency
2 would be using the 95th percentile versus say the
3 geometric mean. And, again, as I inspected the data
4 last night, this is clearly a critical decision,
5 because it has major implications on the sample side.
6 And it, also, means that the selection of the ICC and
7 the GFD is very critical.

8 And if those numbers are off from what you
9 are projecting at this point, and it is helpful that
10 you have some data already to go on, that could have
11 some consequences for the utility of the data down the
12 line. So, one thought might be, since this is a multi-
13 year study with a lot of scenarios, that, as you
14 progress through the study, that there might be some
15 points where you stop and actually evaluate, what are
16 we seeing for an ICC.

17 What are we seeing for our GFD's. Are we on
18 target, or do we need to make some adjustments. My
19 next comment refers to this evaluation of
20 proportionality. Again, looking at the data that's
21 been presented, you clearly will help yourself, in
22 terms of power, if you can get to, say, 100-fold
23 difference on your range of active ingredient, as
24 compared to a 10-fold difference. Now, I know there's
25 going to be some practical limitations on that. If you

1 have, say, a herbicide applied by ground boom to a row
2 crop, and if your threshold applied is 5 pounds, it may
3 be very feasible in those situations to find farmers or
4 applicators who are applying 500 pounds, 600 pounds.
5 And, in reading through the document, it sounds like
6 you are going to evaluate on each chemical what it's
7 range is, and so you have some sense whether you can go
8 to that upper range, and I would encourage you to think
9 about that to the extent that you have people normally
10 exposed to those levels, because it will help with that
11 sample size.

12 But, on the other hand, there are going to be
13 chemicals, either applied at low application rates, or
14 the application method itself, you would never, with a
15 5 pound threshold, be able to get to 500 pounds. You
16 know, you may even be struggling to get to 50 pounds on
17 some of those. And so, I don't know whether that means
18 you're going to have to rethink a little bit the 5
19 pound threshold to really get this 10-fold range that
20 you're interested in.

21 And, I think, I think, that's my comments for
22 now. I may have additional ones after.

23 DR. HEERINGA: Thank you very much. Dr.
24 Lu.

25 DR. LU: I think I'm going to give the

1 heavy duty statistics to other panel who have expertise
2 on it. I would just like to comment on two things. I
3 think, I agree with task force approach when it come to
4 the sample size determination. And sometimes you just
5 have to take logistic matter into consideration.

6 Sometime you will probably outweigh the science-, um,
7 statistical consideration.

8 The task force group justification of how
9 they come to the conclusion of using 5 pound to a unit
10 per cluster for 5 cluster per scenario seems adequate
11 and feasible. The group has assured the panel that if
12 the proposed 5 monitor unit / 5 cluster are deemed
13 grossly inadequate, they will seek for additional
14 monitoring unit or cluster. I think unclear to how
15 inadequate is grossly inadequate. I think that's a
16 little bit too conservative.

17 And, also, I don't know how this inadequacy
18 will be assessed, whether it's at a monitoring unit
19 level, or the cluster level or in combined. The other
20 concern is, I mentioned yesterday, is the selective
21 target populations. As the task group people
22 represented a way that it seems like it's not finalized
23 yet, but they're going to follow this criteria as a
24 guideline. The concern, actually, is related to the
25 sample size and the overall data distribution as well.

1 I think I, my concern is that the task group may end up
2 selecting a group of pesticide handler and pesticide
3 applicator that is deviated from the true population.
4 Meaning, I mean, I really cannot tell whether the
5 distribution will be higher or lower.

6 The language speaking ability is a concern.
7 English, Spanish and vices versas. So, again, since
8 it's not finalized yet, the task group need to present
9 a much clearer guidance. And as I can tell, that many
10 people have told me they have Hispanic people working
11 in the orchard, and they get a much better job than
12 anybody else.

13 So, if your delivery is through this group of
14 people, the, my prediction will be, the data will look
15 much worse than it should be. So, those concern need
16 to be take into account.

17 And I totally agree with the agency's charge
18 question is that, especially for these two, the two, my
19 two concerns is that, it has to be complete and
20 transparent, that the agency and the public should know
21 how you're going to assess the inadequacy, and also,
22 how you select those people, and basis on what
23 criteria. That's it.

24 DR. HEERINGA: Thank you very much, Dr.
25 Lu. Dr. MacDonald is the next associate discussing.

1 DR. MACDONALD: You know, to design the
2 monitoring program that will then be used for a variety
3 of regulatory purposes by various organizations,
4 challenges the developers to anticipate all possible
5 future applications, while keeping costs in mind. The
6 cluster sampling design proposed by the AHETF makes
7 good sense, as there are cost savings in sampling a
8 number of pesticide handlers in a single field
9 operation.

10 The usual practice and survey design when
11 there is inter-class correlation within clusters is to
12 consider the costs of getting to a cluster relative to
13 the cost of sampling individuals within the cluster.
14 The optimal cluster size and number of clusters can
15 then be chosen to minimize the variance of the
16 estimate, subject to a constraint on the total cost.
17 For this study, the task force has determined from
18 experience that the inter-class correlation is modest,
19 and that it is usually practical to monitor five
20 pesticide handlers at a time, so no further argument is
21 needed for a cluster size of five. This means that
22 only the number of clusters needs to be chosen.

23 The first benchmark objective is to estimate
24 the parameters of the distribution of dermal exposure
25 to an adequate level of precision. The criterion

1 chosen that the upper 95 percent confidence bound for
2 the parameter being no more than K times the parameter,
3 and the 95 percent lower confidence bound be no less
4 than the parameter divided by K , makes sense under the
5 log normal assumption, and we were told that regulatory
6 personnel have not had difficulty in specifying what,
7 for them, would be an acceptable value of K . A closely
8 related criterion giving similar results is to require
9 that the upper 95 percent confidence limit be no more
10 than K squared times the lower 95 percent confidence
11 limit.

12 I think that this might be easier to
13 communicate, and has the advantage of not requiring the
14 true parameter value explicitly in the formula. I have
15 no problem with the values of geometric standard
16 deviation and interclass correlation used for these
17 examples. However, I would expect that as more
18 monitoring data are collected in this program, it will
19 become evident that some scenarios may have very
20 different interclass correlations from others.

21 I think the variation in interclass
22 correlations observed to date comes from sparse data on
23 variability and monitoring methods, and can't be
24 attributed to specific scenarios. The examples shown
25 to the panel assumed that the most extreme upper

1 percentile of exposure that anyone would want to
2 estimate was the 95th, in which case, K equals 3-fold
3 relative accuracy can be achieved with 5 clusters,
4 which means 25 monitoring units per scenario.

5 However, this sample size will be inadequate
6 if, at a future time, it is necessary to estimate the
7 99.9th percentile. This example was not included in
8 the tables, but using the sass coat provided to the
9 panel, it appears that ten, eleven, or twelve clusters
10 would be needed to achieve K equals 3. So the total
11 number of monitoring units would be more than doubled
12 to 55 or 60.

13 The second benchmark objective, testing a
14 proportionality of amount of AI handled, does not seem
15 to me to be so interesting. It is clear that, at best,
16 the amount of AI handled is a weak surrogate for
17 potential exposure. There is error in every variable
18 measured, and it seems to me, unreasonable to expect
19 perfect proportionality in the regression line with
20 unit slope.

21 I don't think it is worth testing. If you
22 chose a large enough sample, you could end up
23 projecting the hypothesis that slope equals zero and
24 the hypothesis that slope equals one, so what would you
25 do then? The only analyses of past data that showed a

1 clear unit slope were combinations of several studies
2 spanning an extreme range of amount of AI handled. As
3 far as I could see, no single study gave any indication
4 of proportionality.

5 If the data will be used to compare
6 scenarios, for example, to compare different
7 application methods with the same pesticide, then the
8 design needs to be considered more as a stratified
9 sample, and there have to be enough observations in
10 each stratum to make the test powerful enough to be
11 worthwhile. I suspect if the sample size meets the
12 first benchmark objective, it will also be good enough
13 for this, but it would be worth checking this out.

14 The panel has talked a lot about measuring
15 within worker variants and determining all three
16 variance components that is between clusters, between
17 workers within clusters, and within workers. It might
18 be worthwhile to carry out some limited studies, but I
19 can't see that it would be worthwhile to say triple the
20 size of the entire study by monitoring every individual
21 three times.

22 Note, by the way, that within worker
23 variation, is still confounded with error in the
24 monitoring technique and the chemical analysis. So,
25 I've given three reasons why it may be advisable to

1 have at least 50 monitoring units per scenario;
2 estimation of upper percentiles of exposure, effective
3 comparisons of scenarios, and the possibility of
4 measuring within worker variations.

5 I think the database will be of greater value
6 into the future if costs are controlled by a thoughtful
7 choice of scenarios, rather than by using small
8 samples. If, at a future date, it is found that a
9 sample size is inadequate for regulatory purposes, it
10 will be impossible to return and get more observations
11 that are consistent with the original sample. It will
12 be much easier to do a complete study of new scenarios
13 as they are needed.

14 In contrast, the AEATF study plan is dealing
15 with a very different situation, and is much more
16 amenable to experimental control. In particular, it
17 should be feasible to increase the sample size for any
18 scenario at a future date if more observations are
19 needed. The proposal to take 15 monitoring units
20 initially is adequate to give an overview.

21 For probabilistic assessments and
22 determinations of extreme upper percentiles of
23 exposure, 15 units will not be enough. We were asked
24 whether the AEATF study should be one simulated site or
25 three field locations. The simplest way to answer this

1 is to try both a few times in a pilot study and
2 compare.

3 Perhaps, the three field sites should be
4 treated as blocs or strata rather than clusters. But,
5 I think, in summary, the biggest difference between the
6 two plans is the possibility of increasing the sample
7 size in future. It's much easier when you're working
8 with an experimental bathroom than when you're working
9 with real life crop scenarios.

10 DR. HEERINGA: Thank you very much, Dr.
11 MacDonald. A question to you, which I think the
12 statements you made regarding the 95th percentile and
13 sample size, that's all conditioned on the log normal
14 distribution model.

15 So, once we estimate its mean and geometric
16 standard deviation, we have assumed a log normal
17 distribution, and assumed the appropriate properties
18 for the 95th percentile. If, empirically, the world
19 differs in the tails from a true log normal, we have
20 different conclusions on that.

21 DR. MACDONALD: Yes, that's correct. But,
22 remember, too, if you have a small sample size, then
23 any extrapolation into the tails is going to be heavily
24 dependent on the distribution you've assumed. And your
25 larger samples, certainly, if you're talking about the

1 95th percentile, you're talking, sort of, wha-, 19 out
2 of 20, so you don't want to be using less than 20
3 observations. You talked about 99.9th. You don't
4 really want to be talking about less than 1,000. So,
5 if you want to get up into the extremes, you need
6 sample sizes that are large enough that you're not just
7 purely extrapolating into an assumed model.

8 DR. HEERINGA: Right. I just wanted that
9 clear here. We, many sample size calculations,
10 including the information Dr. Holden presented
11 yesterday, and our statements made here, are obviously,
12 conditioned on the log normal probability distribution
13 model holding.

14 And I think, we can ask the panel, but I
15 think that's an assumption we have to live with, but we
16 want to be explicit that that's the model that is
17 driving, in fact, not only sample size estimation, but
18 the estimators of the point values and their confidence
19 bounds. Turn now to Dr. Portier, please.

20 DR. PORTIER: I hate going last. You
21 know, it's kind of like sitting in the first pew in
22 church. Everybody's looking at you.

23 DR. HEERINGA: You only sit there if you
24 get there late, though.

25 [All laugh.]

1 DR. PORTIER: Not everybody. I'm going to
2 preface my remarks by saying my concentration's going
3 to be on the AHETF task force studies, but I don't, it,
4 I think it holds very much for the antimicrobial
5 exposure studies as well.

6 My feeling, I think, mirrors what was said,
7 that we feel that the antimicrobial stuff, we have a
8 little more control, and maybe have a little better
9 handle on the scenarios and the situations, so we're
10 probably not as worried about them as we are with the
11 agricultural task force because of the, just the sheer
12 number of factors and the complexity of what's going
13 on.

14 The discussion in the AHETF background
15 document on numbers of clusters and monitoring units,
16 was relatively straightforward, clear, proper, and what
17 I think is representative of good statistical thinking.
18 I compliment Dr. Holden on creating a clear, conceptual
19 model for the sampling process and following it through
20 to the particulars of the sampling design.

21 My issues are not with the sample size
22 determination methodology, but with the assumptions
23 underlying the sample size analysis. And we just
24 talked about one, which is a log normal distribution,
25 but there are a couple others that really need to be

1 addressed. In particular, I want to address the
2 statement that users, and this is a quote, must also
3 assume that the purposive sampling, sampler of the MU's
4 approximates some type of probability sample from the
5 target population.

6 My understanding of risk assessment is that
7 the exposure value input into the risk equation is
8 expected to be representative of the average exposure
9 that would be experienced by the population potentially
10 exposed to the chemical. For probabilistic risk
11 assessments, individual exposure values are drawn from
12 a distribution of exposures that are expected to
13 describe the distribution of long-term, average
14 exposures for individuals in the population potentially
15 exposed.

16 So, I look at the proposed sampling design
17 through this lens of representativeness. So, I'm
18 thinking more, as much statistically as, you know, is
19 this design going to produce a representative
20 distribution of exposures that really reflect the
21 population that are going to be exposed. The first
22 assumption made is that a surrogate of cluster sampling
23 model, which assumes underlying random selection, can
24 be used to estimate sample sizes, even though the
25 proposed sampling methodology does not advocate random

1 sampling for clusters. The second assumption relates
2 to the normality of variance components and the nested
3 effects linear model on log normalized exposure. I
4 don't take issue with the second assumption, but I have
5 some real concerns with the acceptability of using the
6 surrogate random sampling model.

7 The discussions in section 5152 of the AHETF
8 technical summary background document is excellent in
9 that it provides a good framework for thinking about
10 sampling for exposure assessment. I'm going to use a
11 slight modification of their conceptual model to
12 illustrate my concerns with the sampling protocol
13 proposed. And you might want to get the slides up at
14 this point.

15 The goal of the AHET-, AHEP data set, is the
16 estimation of the true exposure E , for a specific
17 handler task. To collect these data, AHETF proposes a
18 cluster sampling or hierarchal sampling design in which
19 clusters or studies, I might refer to them as studies,
20 rather than clusters, but so, if I say studies, think
21 clusters, are essentially examinations of handlers
22 performing the handler tasks of interest at specific
23 locations in time.

24 All right, so this is the illustration that
25 was from the presentation yesterday. So, as mentioned

1 in the background documentation, there exists a very
2 large number of potential studies, right.

3 So, in this space, you know, we can move each
4 of these studies a little bit, and we're in a different
5 time, a different location, all right. And there's,
6 since it's a continuous space, there's an infinite
7 number of studies that are out there. Conceptually,
8 each of the cease of eye, each of the clusters or
9 studies, is characterized by specific settings for a
10 large number of factors. For example, climatic
11 conditions, environment combinations, task times, et
12 cetera, and we've talked a lot about that in the last
13 few days.

14 The no-, each se-, each unique set of factor
15 conditions, we'll call each set of factor conditions as
16 a scenario, and I'll refer to that as S of I. So, in
17 theory, if we know all the conditions that effect
18 exposure, we could compute a true average exposure
19 concentration for each scenario. Next slide. So,
20 let's change the space from a location time, now, to a
21 condition space. So, this is, you know, if we can
22 conceptually think of what the population is not being
23 places and times, but now they're situations, they're
24 scenarios. And this is following the discussion in the
25 background document, so, I'm just, kind of, slightly

1 changing it. So, those studies that looked nice and
2 round in the previous series, now have some meaning on
3 a particular measure. So, the top one is climate, for
4 example.

5 Study C-3 was done at a particular location
6 and time, so it had a fairly tight climate range. It
7 doesn't have a lot of variability on climate, but the
8 other conditions could have been quite variable. All
9 right, the equipment they dealt with; the individuals,
10 the people, the workers, the handlers, themselves, have
11 situations that cause variability. So, C-3 is, has
12 more variability in one dimension than in the other.
13 Each cluster study is, essentially, a replicate of some
14 scenario.

15 Since many of the factors that impact
16 exposure are continuous, theoretically, there are an
17 infinite number of scenarios, and, hence, there's an
18 infinite number of potential studies. So, we've just
19 kind of shifted the space to talk about conditions and
20 scenarios, rather than locations and times. But we
21 haven't reduced the complexity of problem any at this
22 point.

23 Click one time. So, if you think about the
24 PEHD data set, when it was created, it was created,
25 supposedly, to address the conditions at the time that

1 people were sampling, and they were doing the sampling
2 to handle, to prove lack of risk under the situations
3 that the handlers were going to be doing with, this
4 pesticide.

5 Click it one time. What happens over time is
6 that the core conditions, my blue circle, which, might
7 have represented conditions in 1990, now in 2006, for
8 some of these factors, the conditions have changed.
9 The equipment's changed. The scenarios, the scenarios
10 under which the workers are working has changed, and
11 so, the database is now out of sync with the conditions
12 that the workers are looking at. And so these studies,
13 they haven't changed, right. They're the same data
14 we've had since '85, but they no longer are
15 representative of the core conditions that we're
16 worried about, right.

17 So, what the AHETF is trying to do is put
18 studies back in the center of the blue. Click it one
19 more time. So, they're trying to come up with studies
20 that, actually, fit, you know, fit in the middle here,
21 that are more representative of current conditions,
22 current scenarios, right. One way to think of the true
23 exposure, the parameter we're trying to get at, would
24 be to av-, would be the average exposures for the
25 handler task across all possible scenarios. So, my

1 little equation up at the top here, sums one to
2 infinity, actually, I'm going to show you an integral
3 next. I'm sorry for that, but really, since the space
4 is infinite, you can't sum over an infinite space, but
5 you can integrate over it.

6 But, if we have a, if we could generate an
7 exposure for every one of these possible scenarios,
8 really, what we're trying to do is average across all
9 those things, and get that estimate. So,
10 theoretically, that's what we're trying to do. And you
11 can think of the exposure as a function of the
12 scenario. Again, this comes out of the background
13 document.

14 That G of S just says that if we knew this
15 relationship between how exposures effe-; how exposures
16 are a function of scenarios, we could calculate that,
17 right. But this equation assumes that each possible
18 scenario has an equal probability of frequency of
19 occurrence. And we know this is not true. Best
20 application task of certain climatic conditions that
21 define when they must and can be performed, sometimes
22 their equipment are more common than others.

23 If we knew the relative frequency of each of
24 the scenarios, then the true exposure would be
25 estimated as an average weight, a weighted average, I'm

1 sorry, and I think, I hope that's on the next slide.

2 Next slide.

3 Oh, just to point out that, again, my concern
4 here is, that while AA-, the study conceptually, we're
5 thinking the study is being designed to have the
6 studies in the blue circle, and conceptually in the
7 current conditions. One of my concerns is that, well,
8 let me just get back to that, so, this is finding an
9 average. Let's go back to the sampling and talk about
10 the surrogate random sampling model means in terms of
11 clusters and scenarios.

12 With random selection of clusters, we're,
13 essentially, randomly selecting scenarios for inclusion
14 in the study in proportion to their relative frequency
15 in the population of interest. If the scenario is a
16 high relative frequency, in a random sampling design,
17 there will be a number of studies included that are
18 replicates of that frequency.

19 So, if it were a common scenario, by random
20 sampling, we'd have replicates of that common scenario
21 in proportion to its, if you like importance of
22 relative frequency in the population. This means that
23 averaging the study's specific average exposures would
24 produce an unbiased estimate of the true handler task
25 exposure. In a sense, random sampling self-weights all

1 the scenarios, and when we just, kind of, add things up
2 like that equation, we get the right estimate of the
3 overall average exposure.

4 Now, consider the diversity sampling approach
5 as proposed by AHETF. The approach does not include
6 randomness. Though thoughtful consideration of
7 location and time, it is possible that a large number
8 of scenarios will be examined. In fact, the background
9 document to the panel seemed to indicate that the
10 locations and time would be selected to ensure the
11 different scenarios would be considered. The problem
12 with the approach is that the relative frequency of
13 scenarios will not, necessarily, be considered in the
14 selection of the scenarios.

15 If it's possible that only one of a really
16 common high-relative frequency scenario will be
17 included in the sample set at the same time as one of a
18 really rare, say, low-frequency scenario is included.
19 When the sample average of estimated study exposures is
20 computed, estimated exposure for the rare scenario is
21 weighted equally with the estimated exposure for the
22 common scenario, and as a result, the sample average
23 will be a biased estimate of the exposure that we're
24 really trying to get at.

25 So, the concern is that, that the diversity

1 sampling approach won't, kind of, properly represent
2 the population.

3 The issue is even worse if what we want is
4 not just the mean exposure, but an estimate of the true
5 dist-, exposure distribution, or some other
6 distributional parameters, like the standard deviation
7 and the upper or lower quartiles, or some upper
8 percentile. The non-probability sample will not
9 produce a faithful estimate of the population
10 distribution. Worse, we cannot predict the directions
11 of the bias.

12 The study design could produce over-
13 estimates. For example, if the rare scenarios produced
14 high exposures, our design could produce under-
15 estimates, for example, if only the common scenarios
16 are included and the common scenarios have low risk.
17 So, the problem with a non-probability based sample is
18 that we know it's going to produce biases and we don't
19 know which way it's going to produce biases.

20 This, then, is the basis for the statement
21 made by the AHETF statistician that, in quotes, non-
22 random sampling means that statistical methods alone
23 are insufficient for generalizing to the target
24 population. Most statisticians and many risk assessors
25 are aware of this problem. And the problem's not new.

1 Almost every environmental data set has this problem,
2 right. The question is whether we want to support the
3 creation of another environmental data set with this
4 problem, right. So, my concern is that we're going to
5 spend \$18,000 dollars a person to generate another data
6 set, which will produce biased estimates. And I, and
7 so my issue here is to think, can we, can we move
8 forward.

9 AHETF acknowledges the above problems in the
10 background document, and points out that rarely are the
11 relative frequencies of the scenarios known. At the
12 same time, it's not possible to create a simple random
13 sample of studies that are guaranteed to approximately
14 represent the scenarios.

15 So, the goal of the diversity sampling
16 approach propose for populating AHED, is to achieve a
17 diversity of major factors that are likely to influence
18 exposure, and again, that's a quote. And to attempt,
19 in quote, to capture the major aspects of the actual
20 distributions of exposure.

21 In essence, AHETF will attempt to identify
22 specific CI's to sample in a representative of the
23 whole set of possible conditions and such that the
24 distribution of exposures from the diversity sample is
25 approximately equal to the distribution exposures

1 appropriately weighted for all scenarios.
2 Statisticians have heard this kind of proposal many
3 times before, and have never really seen true success.
4 It's actually impossible to purposely define a sample
5 that produces a distribution of exposures that
6 duplicates the true population distribution, when one
7 has no knowledge of the true population distribution to
8 start with.

9 So, it's like a, you know, it's a catch 22.
10 I want to produce this distribution. I don't know what
11 it looks like, but I think I can create a set of
12 samples that are going to pro-, it's actually a common
13 exercise we do in sampling class with our students to
14 see if they can purposely sample to produce a true
15 distribution. And they're surprised every time how far
16 off they are.

17 Rare events are seldom given proper
18 consideration, and common events are often under-
19 represented. Selecting to get true representation does
20 not work. There needs to be random selection used
21 somewhere in the process. So, is this really a
22 hopeless situation. I don't think so. We have, at
23 this point, the opportunity to rethink these issues and
24 possibly come up with some new approaches that might
25 get us closer to our stated goal. So, what might I

1 suggest. Consider the following approach. Create a
2 list of all the factors that are known to impact
3 exposure levels. The list may be long, but it's not
4 infinite.

5 So, you just sit down and start writing all
6 these things, and I think, I get a feeling that the
7 antimicrobial task force has done this. I wasn't as
8 sure that the agricultural handlers task force has, and
9 it probably has, we just haven't seen it. But it's
10 going to be a long list, right. There's a lot of
11 factors involved here.

12 Rank order the factors by their expected
13 magnitude of impact on exposure variation. I might
14 suggest using something like a Delphi approach with a
15 panel of expert risk assessors to accomplish this
16 ranking. So, you've got this list. Let's get some
17 people who know what's going on, and discuss this, and
18 come up with a rank ordering.

19 What do you think's most important, down to,
20 what do we not care about. You know, we've had a lot
21 of this discussion over the last few days, but we
22 really, I still don't know what's the most important
23 condition, what's the most important factor. Is it
24 climate. Is it equipment. I think that's another four
25 day task for a panel of people to come up with that

1 list. Select the top two to four factors and identify,
2 for each factor, two to three categories or levels.

3 Next slide.

4 Essentially, what we're going to do is create
5 a set of possible co-, all possible combinations of
6 these important factor levels. Consider these
7 combinations as strata of the population of interest.
8 In a sense, these become the scenarios or scenario
9 categories of interest. And I'm going to call them SI*
10 star, now, because they're not points in this space.
11 They're not chunks, right, they're areas, right. So,
12 we've taken this condition space.

13 We've reduced its dimensionality by selecting
14 the most important factors, and now we've stratified
15 that, that space. Next assign weights to each scenario
16 that approximate their relative frequency in the
17 population. Sampling theory tells us that the weights
18 don't have to be exact for us to gain a large
19 improvements in the estimated precision.

20 Here a panel of agricultural experts could
21 help, right. So, now we've reduced the dimensionality,
22 but we still have to figure out which of these are
23 important scenarios, my blue circle; and which of them
24 are less important. Now, Cynthia Hines tells me that
25 this is not as easy to do as I might think. Her last,

1 well, you just say your last use of agricultural
2 experts, they made recommendations, and then when you
3 actually went into the field, you found out they were
4 wrong.

5 So, we may make mistakes, there, yeah, there
6 are experts and there's experts, right. So, I'm not
7 saying this is easy, but at least it produces a, it
8 would produce some weights that would tell us what's
9 important and what's not important. And at this point,
10 you have, kind of, two options. In option one, you
11 could go in and select at random studies and or MU's
12 for each scenario, since the relative number of MU's or
13 exposure estimates obtained for that scenario equals
14 its weight.

15 The population exposure estimate is then the,
16 just the simple average of the estimated exposures for
17 the MU's. So, here's an example where C1 may not have,
18 I mean, that first strata in the top left hand corner,
19 might not be a very heavily weighted strata, so we only
20 do one small study with one person in it, just to kind
21 of see what's going on.

22 We don't really care where in that box that
23 C1 is. It could float around, right. But at least
24 we've got some representation in that part of the
25 space. C3, C5, C6 are representing the core scenarios,

1 the more common, highly weighted ones. So, we're
2 putting more of our sampling effort into that area.
3 And then we're allocating stuff around it. And there's
4 no more than 24 MU's in this study here, right. So,
5 that's one option. Next slide.

6 Option two is to select, at random, a fixed
7 number of studies, or MU's, for each scenario and
8 assign each scena-, and then assign to each estimate
9 estimated exposure value the weight of that scenario,
10 in which case, now the exposure estimate is going to be
11 a weighted average.

12 A kind of, I don't like this option as much
13 as the previous one, because I think the users of the
14 AHED data set are not going to be thinking in terms of
15 weighted averages for estimation. They're going to
16 want to do some kind of simple averaging. So a self-
17 weighted, stratified design, which was the previous
18 slide, works just fine then. You don't have to be
19 worrying about weights every time you're calculating
20 some exposure.

21 This in, these approaches incorporate both
22 representation and randomness into the creation of the
23 database, because at any stage, you could define a
24 couple of locations and times that match the scenarios
25 in a particular strata, and you could randomly select

1 from those, right. It's a little bit of work to
2 develop that, but at least you could be randomly
3 selecting them. And, at this point, even if you didn't
4 randomly select within those studies, I'm happy,
5 because I, you've done a lot more toward creating a
6 more representative sample, than the approach that, I'm
7 afraid, was going on before.

8 The above approach might be quite similar to
9 what AHETF is actually doing. I mean, it's a little
10 hard to tell. They may actually be doing this, in
11 which case, I'm happy, and I'll erase everything from
12 the report here. But, I have a feeling they haven't
13 quite gone to this level of design thinking to make
14 sure of what's going on.

15 The major differences that, in the approach
16 outline here, an attempt has been made to first map out
17 the possible condition space, although in a rough
18 categorized way, to assign relative importance to each
19 category, and finally to sample according to that
20 relative importance.

21 The above approach is almost, certainly, not
22 the best design that could be created. There are a
23 large number of statisticians out there much cleverer
24 than I am, who could produce some sampling protocols
25 that would be much more efficient, and produce less

1 biased estimates, if someone would only ask. All I'm
2 asking is that EPE and AHETF give some thought to this
3 kind of approach. And, I picked up a word from, I
4 think it was what Dr. Lu said, complete and
5 transparent.

6 One of the things I like about this approach
7 is that, for any user of the database, it's very
8 transparent what conditions you're covering. And as
9 the conditions shift, it also becomes very transparent
10 that your database is losing its representation and
11 where we have to go in the future.

12 One of the things Dr. MacDonald talked about
13 is, how does this design help us in the future. Well,
14 one of the things this design does is helps us identify
15 where we are, what the database is expected to cover,
16 and as change, things change, we know where to fill in.
17 Maybe we have to add another set of strata and do
18 samples as the, as the core shifts, but at least we
19 have a, we have, kind of, a transparent picture.

20 I feel that this is much more dependable in a
21 sense of the science of the database, and the science
22 of the utili-, the statistics of the utilization of the
23 database, than something a lot looser, which is what
24 I've felt is occurring in the diversity sample. And I
25 think that ends my comments.

1 DR. HEERINGA: Thank you very much, Dr.
2 Portier. Dr. MacDonald.

3 DR. MACDONALD: It's, using the weights
4 when you're estimating an overall mean level, of
5 course, is a very well-known problem in survey design.
6 Can you say anything about how you would approach
7 estimating upper percentiles, using the weights?

8 DR. PORTIER: I can think of at least one
9 way to do it, right, well, and one way would be, again,
10 working within the log normal distribution. You could
11 use the weights to calculate the parameters of the
12 distribution, and then use, through that fitted
13 distribution, estimate the upper percentiles.

14 That's, I mean, it's doable, so at least we
15 have a proof that it can be done once, right. Now, and
16 I was sitting here thinking. I looked at this one time
17 trying to figure out, can you get directly to
18 estimating upper percentiles with weighted observations
19 without having to specify the distribution. And I
20 don't think there's any theory out there that supports
21 that.

22 DR. MACDONALD: Yeah, I guess I was
23 thinking in terms of fitting a model, and then getting
24 percentiles on the residuals, and then working back
25 from that. And that's a little more distribution free.

1 DR. PORTIER: So, your, yeah, I was trying
2 to avoid, I mean, we don't want to talk about research,
3 right. And I, what Dr. MacDonald was saying is, well,
4 you already know what these factor levels are.

5 Why don't you go ahead and fit a model that
6 removes the factor level effects from the exposure
7 estimates, and what's left is the residual. That
8 residual is likely to be normally distributed or have
9 nice properties, and then you could, kind of, figure
10 out the upper percentile value from that. And then you
11 back, go backwards through the model to a percentile
12 estimate. Something like that, right.

13 I don't know. I want to make the point that
14 this kind of looks like research, I know, right. I'm
15 not really, I'm not really in a model-fitting sense
16 here, though. I'm not using it from the context of
17 trying to understand and predict exposures from factor
18 levels. I'm using the factors really to stratify the
19 sampling space so that we get appropriate coverage,
20 right.

21 DR. HEERINGA: Steve Heeringa, here. I
22 guess I'll weigh in with a few comments, sort of,
23 prompted by Dr. Portier's recommendation. And I, in
24 general, agree with the principle of what he's driving
25 at, in that is, I think it would be beneficial, in

1 terms of the ultimate utility of the AHED database to
2 think about, you're trying to span ranges of
3 variability, to span the distribution of exposure under
4 appropriate and realistic end relevance sets of
5 operating and other conditions. One area, I think, we
6 ought to be very clear about it.

7 Introducing randomization into the sampling.
8 If your, if you cannot observe more than 15 to 20
9 clusters, it's not a beneficial thing to do. And,
10 Ken's right. You may not, you may have biased
11 estimates, but with fewer than 20 clusters, you cannot,
12 your variances are going to be enormous, and they're
13 going to swamp the bias.

14 You're worried about total error, variance
15 and biased squared. And, until you can get, and
16 there's no better source than Ed Demming for this
17 comment, and that is, that if he were forced to choose
18 more, fewer than 10 observation units, or I would
19 extend that to 15, he would rely on judgment sampling.
20 And what Ken's point is, is that, we're really in that
21 place at this point, unless we start to think about
22 going to 20, 30, 40, 50 or even hundreds of clusters of
23 observation, which is where the survey world lives, and
24 probability sampling inference lives.

25 We have forced, with some sort of judgment

1 or, I forget Dr. Holden's term kind of dressed that up,
2 but I still like judgment sampling. But it's expert
3 judgment, potentially, as Ken said. And we may not be
4 in a position to determine all of those factors that
5 appropriately define the distribution.

6 DR. HEERINGA: I'm talking sites, these
7 clusters. The things that are generating these ICC's
8 of .3, and by the way, .3 in a probability sampling
9 framework is an enormous inter-class correlation.
10 Voting behavior only has inter-class correlations of
11 something like .05 or .06, so the types of inter-study
12 correlations that we are seeing in these data sets, as
13 they've been estimated, and I think Dr. Kim even showed
14 that, I guess, that was worker inter ICC's in there.
15 But my sense is that, until we get into this range
16 where you could, within each of these scenarios, work
17 with 20, 30, 40, or more clusters, that to actually
18 think about a detail probability sampling approach,
19 while theoretically, potentially, desirable, in
20 practice, doesn't work; because variability and
21 instability of variance estimates just swamp the
22 potential bias that you might even get from even the
23 worst of judgment sample.

24 So, that's my comment on that. The average
25 cluster size of five, I think, I've actually brought it

1 with me. I've got class notes from last term here. I
2 don't commit these optimum sample sizes for two-stage
3 samples to memory, unfortunately. My memory's failing.
4 I can't use that many cells to do that, but I'll look
5 that up, but an optimal cluster size of five, I agree
6 with Dr. MacDonald.

7 I think it's, obviously, you've sort of
8 tested it empirically in your minds. I suspect it's
9 fairly close to the optimum for a cost structure in
10 which the analytic costs are roughly 50 percent of the
11 total cost of an observation.

12 The, therefore, increasing the precision and
13 the effectiveness, both in terms of estimating the
14 geometric mean and standard deviation, but also in
15 terms of Dr. Portier's push for ensuring representation
16 suggests that I wouldn't increase cluster sizes, but if
17 you extend the sampling, you would move to adding
18 additional clusters.

19 One thing that I would also recommend, based
20 on Dr. Holden's presentation yesterday is, we know
21 these clusters are not going to come in a nice, neat
22 units of five. He did a nice simulation, effectively
23 simulating the distribution of estimates under a fixed
24 distribution, samplings with five clusters and five
25 units. I might suggest it's possibly exploring

1 something in which we have clusters that average five
2 clusters, but you allow a little bit of variability on
3 the actual number of observations, 'cause in reality,
4 you won't get exactly five observations.

5 Some places you may get two, some you may get
6 four, some you may get seven. It's a, I don't know
7 what that'll show, but it's worth doing, just to make
8 sure that you have a sense that there is some
9 robustness to these results that have been developed
10 for equal size clusters.

11 I agree with, with Dr. Portier that if you
12 are able to develop, within each scenario, a fairly
13 gross level prioritization with some measure, not only
14 of, essentially, a stratification of type, with some
15 measure of the frequency of that type of application,
16 that might well guide your choice of the cluster units.
17 Again, with only five clusters per scenario, you only
18 cut the pie five ways, and it's very difficult to, sort
19 of, proportionately allocate five units to even as few
20 as two or three strata.

21 So, again, that's a challenge. I agree in
22 principle with what he has suggested as a way to go,
23 but I think you're going to find it very difficult with
24 only five clusters per scenario to do much of this type
25 of work. But I think the thought process that he's

1 outlining clearly is beneficial on this. My sense is,
2 and I know money's a restriction here, that you would
3 be greatly served for each additional cluster you add
4 to this, I think that we could certainly go to much
5 higher levels, but my sense is that, in some of the
6 critical scenarios, why assign five clusters to every
7 scenario.

8 If you as a task force, and the EPA, Health
9 Canada, California DPI, could think through these
10 different scenarios and, you know, which are those most
11 critical scenarios, in terms of total population
12 exposed, allocate resources into these different
13 scenarios. Maybe you want ten or fifteen clusters for
14 the most common.

15 If they, you know, if twenty or fifteen
16 percent of applications are in one scenario, or fifteen
17 percent of population exposed are in one scenario, I
18 would certainly not constrain that to five clusters,
19 and then have another, say, .5 or one percentile
20 scenario, also with five clusters in terms of
21 resources.

22 Again, some of this will depend on how data
23 sets come to the task force. The ta-, how the task
24 force can purchase data sets, but I think if you're
25 planning about new work, I would look at putting the

1 effort, essentially, where the population of workers,
2 exposed workers, is best served. And that, you know,
3 relates not only to the potential severity of
4 exposures, but also the extent of the population
5 exposed. So, those are comments that I had, and turn
6 it over to other members of the panel at this point.
7 Dr. Bucher.

8 DR. BUCHER: So, I weigh into this as a
9 non-statistician, however, for many years, I reported
10 to a statistician, and for many, many, many years, I've
11 been married to a statistician, so I understand the
12 territory that I'm going to try to tread on. So, we're
13 dealing with a question of sample size.

14 But I'd like to go back and look at the
15 benchmark objectives for data adequacy that were
16 presented yesterday by Dr. Holden. And I wonder, these
17 benchmarks, basically, stated that the primary
18 objective is to select measures of a distribution means
19 percentiles that should be accurate to within a certain
20 degree of accuracy.

21 And the secondary objective is to use, the
22 users of the data should be able to distinguish between
23 complete proportionality and complete independence of
24 exposure and amount of the active material handled.
25 So, we've been asked to comment on sample sizes for,

1 what I would consider to be, a fairly modest objective
2 as spelled out here.

3 I would, I would hesitate to endorse Dr.
4 Johnson's suggestion that the slope of the line be
5 calculated and used for all different proportions
6 material, active ingredients over the actual amount of
7 material used, because I don't think that the overall
8 objectives for data adequacy really are precise enough
9 to believe that the data that has been, will be
10 generated under this program are going to be sufficient
11 to be able use, to be able to be used in that manner.
12 So, what I would suggest, and this has troubled me
13 throughout the entire meeting, is that it seems to me
14 that, that EPA needs to look at these benchmark
15 objectives for data adequacy very closely, and decide
16 whether, in fact, you believe that the data that are
17 generated, using this as a target, are really going to
18 be adequate to be used to set up a generic database
19 that's going to be used for thousands, potentially,
20 thousands of materials in the future.

21 Because, if, in fact, you're accepting
22 something that isn't as good as it should be, it's
23 going to be, and I understand that you're dealing with
24 a database right now that's very inadequate and very
25 limited, but there has to be some compromise, and I

1 think I may be saying the same thing that some of the
2 statisticians have been saying, but in a, in a,
3 certainly, a more ignorant manner.

4 But, I really would hesitate to, to move
5 forward with a program like this, unless you a priori
6 set some guidelines on how you're going to use the
7 data. How you're going to interpret the adequacy of
8 the data for a prospective use in a database that's
9 going to be used in the future.

10 DR. HEERINGA: Cynthia Hines.

11 DR. HINES: Just a clarifying question of
12 Ken on his proposal, where you have factor A and factor
13 B, I assume that you want them to be fairly
14 uncorrelated, because if you do a list of factors,
15 you're going to have quite a number of them correlating
16 highly with each other.

17 DR. PORTIER: Clearly, using factors that
18 would be correlated with each other would not benefit.
19 I mean, I, if we got into the mathematical thing, I'm
20 thinking, principle component A and B, you know, kind
21 of orthogonal dimensions that use it, but I'm not
22 expecting them to do that.

23 I'm just, most of the people who look at
24 these factors know which ones co-vary, right. So, I'm
25 just saying, pick one of them, and divide the space on

1 that one. Again, I bring it, I bring it down to this
2 complete and transparent manner.

3 It, part of what we've been talking about is
4 being able to make transparent to future users what
5 you've really sampled. And I think the location time
6 space doesn't make it very transparent what exactly
7 you're sampling. It tells you where you sampled and
8 what you sampled, but it doesn't necessarily say how
9 you covered this condition, or this space.

10 DR. HEERINGA: Dr. Popendorf.

11 DR. POPENDORF: Might as well add my two
12 cents here to this, as another non-statistician visit.
13 I think a lot of us are, really, also, saying the same
14 things from our individual perspectives. And I, you
15 know, the value of that virtual study that we were
16 shown the other day seems, seems very, very useful,
17 whether or not we did it.

18 I think it was a good exercise to give you
19 that sense of in. When you look at the numbers like
20 Cindy mentioned, the, this range issue, you, five
21 pounds and I think, somewhere, one of the documents
22 says range of something like trying to get fi-, between
23 5 and 2,000, and that's a good range. It's a little
24 over two orders of magnitude, but I kind of wonder
25 about the real feasibility of doing that, within the

1 context of a given application method in trying to
2 assure that you get a half-day's worth or more. And
3 what artifacts are you adding by putting that into,
4 which kind of gets to Ken's point of study design.
5 It's not representative if, if, you know, how many
6 would apply 2,000.

7 How often does that happen. So, you end up
8 with this bias, and then you end up with the upper
9 percentile issue. You know, a lot of this whole idea
10 of clustering was driven by question three, having to
11 do with linearity, and the idea of active ingredient
12 handled being the driver, which is an agency driver.
13 And I can see some rationale for that, in terms of
14 using other compounds or f-, I guess I'm looking down
15 the line in terms of how it's being used in terms of
16 registration and label restrictions.

17 'Cause I, you need to assume some maximum
18 like agricultural acreage or something along those
19 lines. The concentration, then, will drive the amount
20 used. So, you're going to run a proportion. I don't
21 know, I haven't really thought through, from the
22 regulatory agency perspective, other options that you
23 might be able to put on the label that might be more
24 driven by the kind of physical models that were
25 suggested. I think you suggested, Ken suggested

1 experts. The idea, you know, the experts, I've been
2 there and done that, too. The experts, you know, if we
3 really had experts to do what we were, what happens out
4 there, we wouldn't need to take measurements.

5 And you're looking at observations that you
6 think you know what's going on, but you don't really
7 know what the, where the chemical is. A lot of things
8 happen that you can't see, so the experts, really,
9 don't know until they take measurements. So, it's
10 really tough to derive those categories. And, again,
11 I, sort of, put some of the burden back on the agency
12 to think about, or perhaps, explain.

13 I was talking about the idea of putting the,
14 walking through a physical mechanisms modeled for each
15 of those scenarios that would, sort of, justify why
16 active ingredient handled is a variable, but, perhaps,
17 think about other ways that you could use this type of
18 data that might effect, you know, do the clustering
19 another way, perhaps, along the lines that were
20 suggested, that would be more, well, wouldn't bias the
21 data as much.

22 It needs to be used in a practical sense, in
23 terms of, you know, labels or restrictions. So, I
24 think that through. What are other options. I'm not
25 sure.

1 DR. HEERINGA: Dr. Johnson.

2 DR. JOHNSON: Yes, I'm thinking about this
3 amount of active ingredient handled, if you're going to
4 vary that within each scenario, each scenario,
5 probably, has some, some range that is reasonable, may
6 differ from scenario to scenario, but it maybe is
7 reasonable for that scenario. And I don't think it
8 matters whether that's 100-fold range, a 10-fold range,
9 a 5-fold range, whatever range it happens to be.
10 There's a high value.

11 There's a low value. There's places in the
12 middle, and those are probably the three main places
13 that ought to be, ought to be considered. I wonder,
14 Steve, if the, if it might be helpful for the panel to,
15 to give opinions or thoughts about the value of this K,
16 in terms of getting K-fold accuracy. I don't know
17 whether that's part of the, par-, something that the
18 EPA needs to decide upon, or whether members of the
19 panel want to weigh in on what values of K might be
20 reasonable to use.

21 DR. HEERINGA: I think that if there, if
22 the panels' members are willing to, sort of, stick a
23 foot out there on that issue, I think it's fair game to
24 heard at this point. Do you personally have - -

25 DR. JOHNSON: I don't have any

1 suggestions.

2 DR. HEERINGA: I suspect there aren't,
3 nobody's going to step in the breach here, then, so.
4 Dr. Popendorf, do you, or Dr. Portier. I think that,
5 you know, that issue of K really gets down to the data
6 and all of the other sources, and, Mr. Dawson.

7 MR. DAWSON: Jeff Dawson. I think we
8 would concur that K is going to be, ultimately, it's
9 going to be a policy call for us. So, maybe the more,
10 the most utility for this discussion would be, maybe,
11 outline some factors that you think we should consider
12 in our discussions around how we select the K. That
13 would be very useful for us.

14 DR. HEERINGA: Yes, Mr. Villanueva.

15 MR. VILLANUEVA: Yeah, just a point of
16 clarification on Larry's simulations with the K-fold
17 and everything. I guess, one of the caveats that the
18 panel members mentioned was that the model was based on
19 the log normal distribution. I think that's only true
20 for the data generation process. If I read it
21 correctly, the confidence intervals that Larry
22 presented empirical confidence intervals?

23 DR. HEERINGA: Right, and that's a good
24 clarification. The data generation for the 1,000;
25 10,00 simulations that produce the empirical

1 distribution, that underlying distribution was log
2 normal, and assumed the inter-class correlation, and
3 cluster sizes of 5 clusters and 5 elements per cluster.
4 That's my understanding. So, the final results, the
5 coverage properties and the confidence bounds were
6 based on the empirical simulation distributions, right.

7 DR. VILLANUEVA: Right, which would imply
8 that the estimate of the 95th percentile would have
9 been an empirical estimate, so I think, as far as the
10 sampling weights go, Dr. MacDonald mentioned, would
11 just be estimating empirical percentile, based on the
12 sample, so that's pretty easy to incorporate weights as
13 opposed to, I guess, a parametric estimate of the
14 percentile incorporating no weights.

15 DR. HEERINGA: I think the difference, if
16 I can answer. Ken can correct me there. When you say,
17 if you refer to empirical, there's a world out there,
18 that if we drew 10,000 samples from the real world,
19 that would be the empirical distribution. 10,000
20 samples from a log normal distribution, with a fixed
21 mean and variance, gives us a simulation under a world
22 that perfectly follows that log normal distri-, they're
23 two different things. So, a true empirical
24 distribution, we would interpret as 10,000 samples from
25 the real world, and then I would be happy with the

1 confidence bound set. So, I think that's the
2 distinction. It's a good point to make. The people
3 agree with me on that, with regard, it's a good point
4 to raise, but a, the simulations that are being done
5 here, really, put all of the world in the form of a log
6 normal distribution. And all we're trying to do is to
7 estimate the two parameters of that log normal
8 distribution.

9 DR. PORTIER: An interesting exercise
10 would be to replace that log normal with something like
11 a gamma. And then see if that, and see if those, those
12 bounds are relatively robust. So, if you did a log
13 normal, you did a gamma, and things didn't change all
14 that much, then we'd be much more likely to believe
15 that, because, because those kind of represented
16 extremes of possible bi-, yeah, what, skewed
17 distributions that we might encounter, right. So, if
18 those bounds were not that driven by the shape of the
19 distribution, then, then I might be happier, right.

20 DR. HEERINGA: I think the suggestion
21 there would be, actually, two. If you are going to,
22 pretend that you are going to analyze it as though it's
23 log normal, but then, in your simulations, generate
24 from slightly deviating distributions, maybe with
25 longer tails, sticker tails, and then see under the

1 long normal distribution, just how your confidence
2 bound coverages for the true values actually conform.
3 Peter, do you have comments on that?

4 DR. MACDONALD: Yeah, I did try some
5 simulations where I was simulating from the log normal,
6 and then using the empirical distribution to get upper
7 percentiles. And the, from modest samples of about 25
8 or more, they came out very close to the distributions
9 you got extrapolating with the log normal. So, that
10 was interesting, but I was still generating the data
11 from the log normal, but it does show that the analysis
12 doesn't have to be log normal dependent. I just don't
13 know where that information comes from to get the
14 extreme tail, though, when you've only got 20
15 observations.

16 DR. HEERINGA: Any other questions on
17 that. Yes, Dr. Appleton.

18 DR. APPLETON: Well, if Will Pependorf's
19 not a statistician, I guess I know where I stand on the
20 food chambers statistics, but.

21 [All laugh.]

22 DR. APPLETON: This is really a belated
23 question that I'll try to couch as a comment, but I may
24 be the only person on the panel that represents the
25 regulated community, such as it is. The government

1 agency that actually uses pesticides, and occasionally
2 sponsors worker exposure studies. And, I'll address
3 this, primarily, to EPA representatives, past and
4 present. I wasn't with the pesticide agency in the,
5 say, in the period of 1984 to '86, when the original
6 selection of 15 replicates or monitoring units per
7 scenario was chosen.

8 I would presume there was something more
9 rigorous than, well, 10's not enough, and 20 is what we
10 want; 15 sounds good and the industry will buy it.
11 But, presuming that the task force recommendations of
12 10 monitoring units per scenario is sufficient and EPA
13 agrees.

14 The question I really have is, will the EPA
15 need to revise subdivision U guidelines again to
16 address only the agricultural uses. It looks like the
17 antimicrobial group is going in its own direction, in
18 terms of staying with 15, at the moment. And, how will
19 non-agricultural uses, whether those are home uses, you
20 know, wasp sprays, foggers, crack and crevice, or some
21 of our oddball forestry uses, be addressed.

22 Will they still fall under subdivision U
23 requirements of 10, if that's what it turns out to be
24 for a database? Again, it's, maybe we're too far down
25 the line to look at that yet, but.

1 MR. EVANS: This is Jeff Evans. I guess
2 I'll step into that a little bit. We certainly want to
3 update out guideline requirements, and I wish I could
4 say more clearly why the 15 for handler and 9 for
5 aerial applicators was chosen, but I think it was some
6 sort of mixture of logistics, feasibility, costs, and
7 you know, I guess some robustness. And, also, the fact
8 that we do mostly pouring estimates, we do central
9 Tennessee values, and kind of beef up our estimates
10 with higher estimates of amount AI handled and acres
11 treated, things like that.

12 Obviously, we're getting much more into a,
13 maybe, more representative sample. And, I mean, just
14 thinking about what Dr. Johnson pointed out, the
15 comparison between what we have now, and what we plan
16 on getting, and how we think about that, with respect
17 to clusters. And quite rightly so, you put the onus on
18 us to make us think about how many we really need, and
19 how many we desire. And where we do want to regulate
20 in the future. So, the short answer is yes. We are
21 going to update our guidelines, but just what that's
22 going to end up being, will require a fair amount of
23 thought on our part.

24 DR. HEERINGA: I wonder at this point, I
25 could ask Dr. Johnson to try to summarize the sort of

1 views of the panel.

2 [All laugh.]

3 DR. JOHNSON: You could.

4 DR. HEERINGA: I think, specifically, with
5 regard, the one question that came forth yesterday is,
6 is the task force and the EPA and Cal DPA and Health
7 Canada working with them on the right track in terms of
8 thinking through these issues, regardless of what K
9 winds up being, et cetera. Are we approaching it in
10 the correct.

11 DR. JOHNSON: Well, I guess, I, I'm know,
12 think I know where the panel is kind of heading. I
13 think that Dr. Portier's suggestions and Dr. MacDonald
14 are both know a lot more about sampling than I do.
15 Most of my career has been spent in designed
16 experiments. And without looking at observational type
17 studies, and observational type studies like this are
18 always a lot harder to design and a lot harder to
19 sample. And so, I defer to them, with respect to the
20 kinds of recommendations that they made.

21 They sound reasonable to me, and are
22 recommendations that should be considered. I think the
23 panel is, generally, in agreement that, that the, given
24 a choice between increasing the number of units per
25 cluster, and increasing the number of clusters, they

1 would go to increasing the number of clusters. In
2 terms of the K-fold accuracy, I guess, that, the
3 panel's not expected to, sort of, answer that question,
4 which is a good, I'm happy with that. I don't know how
5 I would want to estimate that value of K anyway.

6 I think that, that the goal is to consider
7 different amounts of ingredient handled, and you can
8 get that, get that 100-fold range, I guess, by
9 decreasing the amount handled, as well as, increasing
10 it. And, perhaps, that as the EPA comes up with their
11 plan, or the pesticide handlers exposure task force
12 comes up with their plan, they might address it from
13 the point of view of picking some maximum amount that's
14 legal to use, and then decreasing that, rather than,
15 and use the words decrease, rather than increase, and
16 they might have a better chance of getting by the human
17 factors board, human studies board.

18 I guess that, I know, I'm kind of stumbling
19 around a little bit, because I'm, I've, I think I, kind
20 of, get the sense of where the panel is, but I'd really
21 need some time to get the responses that, in writing,
22 and then put it all together in our final document.

23 DR. HEERINGA: Thanks. I didn't mean to
24 put you on the spot, but I, I guess, you're up to it, I
25 think. And, Dr. Portier.

1 DR. PORTIER: Something Dr. Johnson just
2 said kind of clicked off a thought. You know, we've
3 got this primary and this secondary objectives, and if
4 it were my druthers, I would forget the secondary
5 objective's regards to the database. I would do a
6 separate study to figure out whether proportionality
7 seems to hold.

8 I mean, that, the agency has assumed
9 proportionality for ye-, for decades now. That
10 question, obviously, wasn't that important twenty years
11 ago, and is it that important for us to spend a lot of
12 money on that today. I mean, let's do a study, and if
13 it still looks reasonable, that's fine. And you have
14 your justification.

15 If I'm going to spend a unit on a increased
16 amount of material, versus a replicate of a scenario,
17 I'd rather do a replicate of the scenario. I'd rather
18 not spend a lot of, my personal preference would not be
19 to spend a lot of effort trying to do the secondary
20 question. And, I don't know, John may argue with me on
21 that, but, I, you know, it's what's the purpose of the
22 database, and where is it going to, and whether we're
23 served by diverting our attention onto that secondary
24 issue.

25 DR. HEERINGA: Dr. Bucher.

1 DR. BUCHER: Well, I'm not sure I can
2 answer the question of which, where I would put my
3 money, but if one is going to generate a database, and
4 I, I presume that most of the new data and the new
5 methodologies are going to, in terms of the
6 proportionality of active ingredient handled versus the
7 total amount of material, as the, I would imagine that
8 as the, with the new technologies, as the amount of
9 material goes up, the proportion of active ingredient
10 is, actually, going to go down for the exposure.

11 So, that's going to be a very important
12 aspect of the overall risk assessment. And what I'm
13 afraid of is that if we generate a database that just
14 has a very few data points, and it changes the shape of
15 that slope of that curve in a quite a substantial way,
16 you're going to really affect the overall risk
17 assessment.

18 And, unless the agency has criteria for the
19 acceptance of data that are going to actually move them
20 away from this very conservative position that they're
21 taking now, then, it's a troubling, troubling situation
22 in my mind.

23 DR. PORTIER: Ken Portier, here. I don't
24 disagree, but I, and I'm not thinking about the
25 secondary study having a few data points. I think you

1 need a lot of data points.

2 The problem is you-, you know, it's like Dr.
3 Johnson said. Some scenarios are going to be able to
4 only accommodate a small range, and other scenarios
5 accommodate a wide range. And if you're allocating a
6 lot of effort to making sure that's covered across the
7 board, we're going to lose a lot of representativeness.
8 So, I'd rather do a side study on one set of scenarios,
9 with a lot of, a lot of power for actually looking at
10 that secondary question, and answer it.

11 And, you're right. If the question is, there
12 is no proportionality, that changes your whole,
13 underlying risk equation, right. And we may need to
14 know that answer first, before you go through much
15 further in a representation.

16 DR. BUCHER: So, it, could I?

17 DR. HEERINGA: Tom Bucher, yes.

18 DR. BUCHER: It could be then, that money
19 would be well spent in picking out those scenarios,
20 where you think that that proportionality is, is
21 absolutely wrong.

22 The linear and, you know, the slope of one is
23 absolutely wrong, and verifying that, in a very limited
24 sense. And then, but, but for the vast majority of all
25 of these unstudied or poorly studied scenarios, one

1 might want to continue to, to take the conservative
2 approach of linearity with a slope of one.

3 DR. HEERINGA: Yes, Paul Hamey.

4 DR. HAMEY: It struck me when I was
5 listening to Dr. Portier's stratification approach,
6 that in some instances the amount handled might be one
7 of those factors it would include, and in others, that
8 it wouldn't. So, I just put that comment on the table.

9 DR. PORTIER: Ken Portier here. You mean
10 for a certain handler task, that may be a major factor.
11 Another handler task, it has no impact on it, right.

12 DR. HAMEY: Exactly, yes.

13 DR. HEERINGA: I think there's a general
14 sense in the conversation this morning that, probably,
15 at, relative to the costs of these data, the cost of
16 your time, which are relatively inexpensive for us,
17 more expensive for you, to invest some time in thinking
18 through the 30 scenarios that have been outlined, and I
19 would say the same applies for the antimicrobials, that
20 to look at those in the context of these things.
21 Because, I think, while I understand fully that expert
22 judgment on actual exposure levels and those models,
23 and those models may not even be that good in the end,
24 because of all the other variables involved, but to
25 think through that, and to think through

1 prioritization, in terms of your ultimate objectives,
2 with the task force, to say, you know, this is where
3 people are being exposed. This is where, really, the
4 greatest impact for our 30 times 25 observations times
5 \$18,000 dollars is going to do.

6 And so, I think that's worth doing, and maybe
7 it's already been done very much internally within the
8 task force. And I think that affects a number of
9 things. Not only where the priority for the sample
10 cluster placement, you're really restricted in the
11 numbers of clusters, and we understand that. But where
12 you place those, but also for this issue of really
13 studying these secondary objectives. And, as I've
14 thought about it, too, I think Dr. Holden had it right,
15 theoretically, if we could completely manipulate the
16 world out there, we would put the range of X in each of
17 the separate clusters. That's clearly the most
18 efficient.

19 He demonstrated that. But if you think about
20 that, if you have to manipulate the essential
21 application conditions, in other words, if somebody
22 wants to apply at a certain rate, plus and minus 10
23 percent, that's not going to give you the 100-fold
24 range that we saw was really needed to achieve power in
25 a number of situations. And if you had to manipulate

1 that by having somebody apply twice as long as the next
2 person, that would affect this. That changes, I think,
3 another very fundamental condition, which the task
4 force said, we want these people, you know, working a
5 normal workday or a normal half workday in this
6 application.

7 So, I think you don't want to get into a
8 situation in these scenarios where you change the
9 application conditions or the measurement conditions so
10 much, simply to get a variability on the applied active
11 ingredient. I think that's fairly intuitive. But I
12 think this, so I think some thought through each of
13 these scenarios like that, based on the discussions of
14 the last four days, and all of you have a lot more
15 insight in some of the particulars here, to think
16 through where best to invest the effort.

17 And, I think, particularly on the cluster
18 sampling, to the extent that you have a few of these
19 scenarios that really dominate your registration,
20 dominates the health concerns, I think, clearly it
21 would pay to invest there, maybe, slighting some of
22 those that, while important and define scenarios,
23 really, in terms of overall aggregate risk for the
24 population aren't quite as important.

25 MR. MILLER: So, in essence, kind of be a

1 little bit more strategic in our thinking, so.

2 DR. HEERINGA: Yeah, and where, I don't
3 think we're being critical of you. You've done a lot
4 of thinking to this point, but I think, given the cost
5 and the fact that this is a process that stretches out
6 over time, you can and should afford to be strategic a
7 little bit at this point, too. Dr. Lu.

8 DR. LU: I think I would agree that EPA's
9 approach to thinking about the disproportionality
10 issues, I mean, as Dr. Johnson point out, if slope
11 equal one, and yesterday the agency justified why they
12 want to stay with this slope one, instead of 0.8
13 because to work to the, you know, higher amount of
14 active ingredient handled become protocol, and they
15 want to protect the high end exposures.

16 But if you think about this, and then the
17 proposal they make by the task force that, they're
18 going to only include data that's been more than four
19 hours. If anything below four hours, they will just
20 kind of cut off.

21 This kind of, it pose problem because, and
22 not to get in a lot of, you know, high amount of active
23 ingredient handled data, and if we compromise the slope
24 equal to one, then what happens. And to me, I think,
25 these four hour application time is rather conservative

1 or strange, because in the real world scenario, for
2 example, if the manager called for the applying
3 pesticide today, everything is just fine. There's no
4 wind, sunny, and so on and so forth. And in the middle
5 of the two hour application, they have to call off
6 because wind started picking up. And it's not ideal
7 situation.

8 Then what happens. Base this on the task
9 force criteria, the data will be thrown away, because
10 no, it's only applied two hours, but everything is fine
11 until that moment. So, I think, in this case, the task
12 force has to modify their criteria so, in this case,
13 the data will be in there, and they will be on the
14 lower end of the active ingredient handled, and that
15 will be just fine.

16 DR. HEERINGA: What I'd like to do at this
17 point, we're at 20 after 10:00. I'd like to have a
18 fifteen minute break. And then we'll come back to wrap
19 up on this question, and get any concluding remarks and
20 comments from the panel. And I would aim to finish by
21 11:30 or 20 to 12:00. So, let's take a fifteen minute
22 break and reconvene at 25 of 11:00.

23 (WHEREUPON, a break was taken.)

24 DR. HEERINGA: Okay, welcome back
25 everybody to the final late morning session of our

1 four-day meeting of the FIFRA Science Advisory Panel on
2 the topic of worker exposure assessments in pesticide
3 handling. I want to pick up where we left off and wrap
4 up at this point. I think before we continue our
5 conversation, that Jeff Dawson had one point of
6 clarification.

7 MR. DAWSON: Thank you. I'm Jeff Dawson,
8 HED. We've been talking amongst ourselves over here
9 with regard to the latest conversations around
10 proportionality, and several panel members have
11 commented around the fact that our working assumption
12 at this point of a proportionality of one to one is a
13 conservative approach, so it would be good if that,
14 somehow, made it into the record.

15 And the other, I guess, issue around
16 proportionality for us is, we're certainly not wed to
17 that over time, and appreciate all the suggestions as
18 to, you know, how we might evolve for certain
19 scenarios, depending up on, you know, the nature of
20 the data and such as we move forward, so thank you.

21 DR. HEERINGA: Thank you very much. Just
22 one additional point that I'll add. I think Peter
23 MacDonald had mentioned, too, that there is, you know,
24 theoretically, a formula for optimum cluster size,
25 given cost structure and, over the break, I just did

1 the calculation, and it, 4 or 5 is in the ball park.
2 It is what, it'd be closer to 4 than to 5, but the
3 optimum is generally very flat for this over a narrow
4 range.

5 So, the point that we made that the optimum
6 cluster size, given your cost structure that Dr. Canez,
7 sort of, hinted at yesterday, that's crude, we know,
8 but it suggests that this cluster size of 5 is
9 probably, fairly, near the optimum, in terms of your
10 resource expenditure on the data collection, under the
11 current cost structure.

12 Additional comments from the panel on the
13 general issue of sample size determination, and the
14 process by which the task force have gone about
15 thinking about sample size determination; and its
16 relationship to the precision or ultimately accuracy of
17 final decisions made with these generic databases. Dr.
18 Portier.

19 DR. PORTIER: Ken Portier. I wanted to
20 clarify something just to make sure. I used the term
21 scenario, and I used the term handler task. And I
22 realized that in the discussion up until today, the
23 scenario, really, was a handler task in the terminology
24 used in the task force. And I'll have to come up in my
25 report. I'll change my scenario term to something

1 else, but I don't want to use condition, because that
2 implied, maybe, one dimensions, and it's really a
3 multi-dimensional problem. I'm going to come up with
4 another word. It might not be an English word, but it
5 will be [laughs] another word, well, maybe Native
6 American word for scenario.

7 The whole idea, though, is the stratification
8 would have to be looked at by handler task. So, it's
9 not, it's not everything thrown in together. It's kind
10 of looked by task, or goal, task group by task group,
11 rather than everything in one big picture. That
12 doesn't mean that the studies, themselves, might not go
13 across these individual strata.

14 I mean, one study might address a strata for
15 a mixer operation, and at the same study; you may be
16 doing an individual in another, another task that would
17 be in a different strata for that task. So, it's, it's
18 a little more two-dimensional than I, three-dimensional
19 than I, than I illustrated it, but English is hard to
20 come up with a lot of good words, so I'll come, I'll
21 correct that so it doesn't get confusing.

22 DR. HEERINGA: There must be a Cajun word
23 for scenario. Dr. Lu.

24 DR. LU: I think I would like to put this
25 point in record. In terms of a sample size

1 determination, my concern is that if the task force has
2 come up with a very narrow defined selection criteria.
3 Chances are the data that they were going to go out and
4 collect would probably satisfy their assumptions, and
5 that's why they lead to the 5 monitoring units, 5
6 cluster, which is okay, but the overall concern is that
7 the pop-, the subject they're going to include may not
8 be representative of the true work force in the field.
9 And it satisfy their need, but not necessarily the
10 agency's desire.

11 So, I think the selection criteria should be
12 phrased like, any pesticide handler or pesticide
13 applicator, as long as they are licensed to do their
14 job, they should have the equal opportunity to be
15 included in the study, except for the human subject
16 review board concern like pregnancy and so on and so
17 forth.

18 DR. HEERINGA: Thank you very much. And
19 that's consistent with your earlier comment, too, I
20 think, don't you. Dr. Robson, did you want to make a
21 comment about the active ingredient issue?

22 DR. ROBSON: Yeah, I - -

23 DR. HEERINGA: Microphone.

24 DR. ROBSON: Oh, sorry about that. I was
25 thinking more about Dr. Johnson's comment earlier, and

1 I have to respectfully disagree with Dr. Portier, and
2 support Dr. Johnson on the AAIH.

3 I think, I had the opportunity a few years
4 ago, to participate in an evaluation of agricultural
5 health study, which many of the people from the agency
6 and the regulator, regulated community are very
7 involved in as well. And as we struggled with trying
8 to reconstruct pesticide histories that go back
9 decades, and people tried days of applications and
10 realized that some days, a day was an hour, and some
11 days a day was twelve and fourteen hours, that probably
12 the thing that many people argued for was to do acres
13 treated by crop, which really translates into active
14 ingredients.

15 So, I, as I think about this more, I really
16 am still pretty convinced that active ingredient is one
17 that we want to weigh in a little heavier on, or at
18 least, I would like to weigh in a little heavier on,
19 and support comments that Dr. Johnson made earlier in
20 the day, and throughout the week.

21 DR. HEERINGA: At this point, I think I'd
22 like to turn to the EPA scientific staff, to see if
23 they have any questions of clarification for the panel.
24 Obviously, we've had a lot of discussion, and it's
25 covered a lot of topics. With regard to the sample

1 size issue, is there anything that you still have
2 questions about, or you, confusion on some of the
3 responses?

4 MR. DAWSON: No, no, I think we're good,
5 and I think the topic's been covered in a very thorough
6 manner.

7 DR. HEERINGA: And I believe I had
8 promised, too, that with the antimicrobials, that we
9 would, in fact, address that, and I think that Dr.
10 MacDonald's comments, initially, covered that. And
11 that, maybe, Dr. Leighton, do you have?

12 DR. LEIGHTON: Tim Leighton from the
13 antimicrobials. Yes, you did cover this a lot. And
14 one thing I do want to make sure is the follow up
15 written report also includes some of the comments that
16 were made on experimental design versus, you know,
17 going out in the field observational type.

18 DR. HEERINGA: We'll make a note of that,
19 and I think working with Dr. Portier and Dr. Johnson on
20 these last two responses, that we'll make sure that
21 that does get covered for you.

22 At this point in time, are there any other
23 comments on charge question number six? I think that
24 we have, at least in our discussion, covered a fairly
25 wide range of views and opinions and information, and

1 that our written comments will reflect that, and will
2 reflect consensus or lack thereof on the part of panel
3 members.

4 Hopefully, that has been informative. What
5 I'd like to do now is, I'd like to go back through the
6 panel systematically, to see if there's anything over
7 the course of the past three and a half days where you
8 would like to make some additional, sort of, concluding
9 remarks or bring forth something that maybe, at this
10 point, that you haven't had a opportunity to say. And
11 I'll start over here with Dr. Landers.

12 DR. LANDERS: Thank you, Mr. Chairman.
13 I've no extra remarks to make, only just to confirm the
14 remarks I've made already. And I think we've seen that
15 as the week's progressed. But there is such
16 variability in application technology, that the idea of
17 some formal matrix which will allow you to categorize
18 tec-, application techniques into high risk, low risk,
19 old or new, or whatever criteria you choose. I think
20 that's the main conclusion I would draw. I agree with
21 other speakers who've mentioned that there is such
22 variability.

23 The variability in people is one of the
24 greatest concerns. And that opens up a whole can of
25 worms, if you start discussing how well trained

1 operators are in different parts of the country. And
2 so, how you cope for that is up to others to decide.
3 At any given time, of course, there's always danger
4 with these pesticides and machines from things falling
5 off. And so, what might be a perfectly good study
6 which shows that the limited amount of exposure is
7 correct until it goes wrong. And then, of course, we
8 can't cope with that. And so, I leave that as a
9 thought with you. Thank you.

10 DR. HEERINGA: Dr. MacDonald.

11 DR. MACDONALD: Pass.

12 DR. HEERINGA: Mr. Hamey, Paul Hamey.

13 MR. HAMEY: Nothing technical to add, but I would just
14 like to thank all the people that submitted documents
15 to us with a high quality of that material. I thought
16 that was very good.

17 DR. HEERINGA: Dr. Robson.

18 DR. ROBSON: Mark Robson. One of the
19 things that we talked a little bit about during the
20 break was, as we had a chance to reflect on four days
21 of excellent presentations, as Paul just mentioned, is
22 just some of the terminology. I think it helped us all
23 remember, those of us that have been doing this for a
24 while, that we use different words to describe
25 different things. And I think back to Jeff, one of

1 your earlier slides, where we gave a range of time for
2 people loading. I think it was one of your earlier
3 slides in the case study.

4 We talked about someone who ranged from two
5 and a half hours to just a few minutes. And what we
6 were talking about was probably the person wasn't
7 really load-, and it's, we're not, I'm not singling out
8 the presentation you made.

9 It just reminded us of some of the
10 terminology. That was probably two and a half hours of
11 a monitoring event, versus two and a half hours of that
12 activity. And, of course, since none of us in the room
13 were there to witness the study or participate in it,
14 we have to read it as we review the study as activity
15 and loading or, so I think as the regulated community
16 goes forward, and as the agency requires information,
17 that we just try to be better housekeepers and define
18 things better so that, when other folks read this, as
19 well as yourselves, that we, when it, if it's a
20 monitoring activity, that's really what it is.

21 The time that one spends to actually do the
22 task, which, I just could not imagine that someone is,
23 actually, consistently for two and a half hours loading
24 granular material. It just doesn't, seems to be, a
25 piece of farm equipment on the other end that could

1 receive that much material, but, you know, that's the
2 term that was used, and we have to take it as written.
3 So, I think it's a real opportunity for everybody to,
4 to come up with a set of terms that we agree on and
5 descriptors that help us understand exactly how the
6 study was carried out. But I, like Paul, am very
7 grateful for the really thoughtful and well-organized
8 presentations. For those of us that teach everyday, it
9 reminds us of how poor some of our teaching is, and
10 we'll steal some of your Power points.

11 DR. HEERINGA: Dr. Popendorf.

12 DR. POPENDORF: Yeah, thank you. Will
13 Popendorf. Just two points come to mind. One is, sort
14 of, for the record is the comments about that K value,
15 and a couple of conversations out during the break and
16 whatnot, but the idea, I think, seems to be pretty
17 consistent, and I, maybe, this might not be news to
18 you, perhaps, to the panel is the idea of just, this is
19 all going to be used back to eventually look at that
20 MOE, and the idea, then, if you have a very large MOE,
21 you can tolerate a very large K.

22 As your, in your confidence, it doesn't make
23 that much difference. And I think that just, you know,
24 make sure that it was sort of on the record that you
25 guys are thinking along that way, too, in terms of

1 letting that K value fall into play. The other thing
2 that I've thought about earlier, and have not, really,
3 commented on, and the ideas have been floated,
4 particularly in this last question about
5 representativeness.

6 The reality is, we do not, there is no data
7 that indicates what is representative. You know, it's
8 that judgmental type of thing. That's really what
9 you're looking at, and I don't know how the agency or,
10 it's not really a requirement of the task force. I
11 don't know what the mechanisms are, but it would
12 certainly be nice if there were data that would, survey
13 type data, that would say, what are the equi-, what is
14 the equipment that are out there.

15 What is the range of equipment and the
16 frequencies. What are those application rates, the
17 kinds of things that go into that selection process.
18 We really don't know, and I don't know how they really
19 generate that, but it would be nice if it were
20 available.

21 DR. HEERINGA: Dr. Curwin.

22 DR. CURWIN: Just to echo what Dr.
23 Pependorf just said. I think we had this in discussion
24 on data needs and we're largely focusing on this
25 database in exposure, but there is certainly a big

1 portion of the exposure estimate equation is what's
2 called pesticide use information, and that hasn't
3 really been discussed so much during this meeting, but
4 it's certainly something that's critical in the
5 exposure assessment.

6 And as Dr. Pependorf just said, that
7 information needs to be captured and better estimated,
8 in terms of the amount of AI handled, if that's your
9 normalization. I mean, there's things such as the
10 acres applied and the application rates that are being
11 used, so, just to keep that in mind.

12 Back to the normalization issue, I think it
13 was brought up earlier, it was asked if there was a
14 conceivable time where you might find the exposure, the
15 slope of the proportionality is greater than one, and
16 what comes to mind would be, and this happens, you
17 know, on a regular frequency, I think, is things that
18 aren't anticipated.

19 What you'll see, you have your exposure going
20 on, and the, your applicator or your handlers doing
21 their basic tasks, but they, they spill that chemical
22 on them, and so you have much more exposure, given a
23 certain amount of handle-, uh, active ingredient
24 handled. And then that also includes things like clean
25 up and repair activities, which hasn't really been

1 discussed. And I don't know how that information can
2 be captured in this database, but these certain things
3 can actually increase the exposure, without actually
4 having an increase in active ingredient handled.

5 DR. HEERINGA: I'd like to move over to
6 Dr. Hughes, now, and around the table.

7 DR. HUGHES: Again, thanks to everybody
8 who made presentations here, and appreciate the fact
9 that what has been brought out with regard to doing
10 bio-monitoring with adding additional monitoring units,
11 that there are just complexities that go on with trying
12 to do this in the field, and not only complexities, but
13 the unpredictableness of weather conditions and other
14 conditions that are outside your control in order to do
15 these studies.

16 And our charge, I'd also like to appreciate
17 the risk analysis that was brought forward. Whenever
18 you have parameters and a risk analysis, you have to
19 look at those parameters, and look at which ones are
20 the risk drivers, and to which degree they are the risk
21 drivers. Whether they're going to drive your analysis
22 greatly, or whether they're not going to drive your
23 analysis to any great degree.

24 And then, there's also the risk management
25 decision. If you have something that is a great risk

1 driver, and you feel that in a tier one, you might have
2 had conservancy in it, where it is a risk management
3 decision to go after a more realistic value.

4 You may say that, okay, there is a realistic
5 way, I mean, there is enough, how can I say this. It
6 is never a risk driver, and it is highly overestimated
7 that we want to go and spend the resources to do that.
8 Also, to the extent that you might not have a high risk
9 driver, and it might not be very variable away from the
10 assumed risk in a more deterministic approach, and then
11 it might no-, the bark might not be worth the bite.
12 And so, you know, as we go ahead and we have also
13 looked at doing some additional bio-monitoring studies
14 to look at the final risk analysis to see whether or
15 not that impacts the final result significantly.

16 And so, I think we've made some decisions
17 with regard to our charge regarding, we just don't have
18 enough data, and we could get that data. And I think
19 that question is, do we find that within the certain
20 scenarios, there is enough justification to go ahead
21 and do that. And I think that within our charge, we
22 felt that there was.

23 And, again, even though we looked at the risk
24 analysis, and our trying to determine from that whether
25 or not, again, the sensitivity is there, and if it

1 would make a difference in the risk output.

2 DR. HEERINGA: Thank you very much. Dr.
3 Lu.

4 DR. LU: I think the agencies and the task
5 force did a great job to outline this piece of the
6 work. And I understand the still ongoing process.

7 The task force will go back and refine their
8 protocol, and probably going to see for another round
9 of approval from the human subject review board.

10 I would suggest that by the time the dust
11 will settle, and this final working plan that's agreed
12 upon between task force and agencies, at the end of
13 this data collection period, agency should consider
14 conducting their own studies selectively, in terms of,
15 taking one, select scenarios, base this on what cluster
16 and then monitoring, just to see whether the data that
17 generate by the EPA will fall into the range of the
18 data that generate by, collected by the task force.
19 If, if that's the case, I think the mission has
20 accomplished and it's very successful. Thanks.

21 DR. HEERINGA: Dr. Barr.

22 DR. BARR: Thank you. Like everyone else
23 before me, I'd like to congratulate the task force and
24 the appeal for putting together the volume of
25 information, the quality of presentations that really

1 helped us in evaluating the charges that were put forth
2 to us. In going back and re-evaluating all the data
3 that is a part of our charge, I am convinced that the
4 whole body path of dosimetry is a suitable way to
5 assess overall exposure, and this is a pretty painful
6 thing to admit for somebody who's made their career off
7 bio-monitoring, but it was, it was a great amount of
8 information.

9 I definitely think the need for additional
10 information is warranted, and I think that's something
11 that you can strongly suggest and strongly argue with
12 the HSIB. And I think that all of the discussions here
13 really helped to provide that input into the new
14 database. I also want to say that, I really hope that
15 somehow, the differences in pesticides can be captured
16 in the generic database, perhaps with the KOW's or some
17 other mechanism, because there are, you know, a large
18 degree of differences between different pesticides.
19 But, again, thank you for the fine presentations and it
20 was a pleasure to be here.

21 DR. HEERINGA: Thank you, Dr. Barr. Dr.
22 Kim.

23 DR. KIM: My final comments have to do
24 with how you're going to use the data. We've talked a
25 lot about how to collect the data, and how to measure

1 and what types of data to use, how to sample, but
2 oftentimes, when we use not the most state of the art
3 scientific equations, or methods to use that data,
4 we're going to make some wrong policy decisions.

5 So, I think, I'm talking in particular about
6 how to use dermal exposures, inhalation exposure
7 measurements to estimate the internal dose. And I
8 think that there are methods available that are better
9 able to predict the internal dose more accurately, and
10 those should be used.

11 DR. HEERINGA: Dr. Appleton.

12 DR. APPLETON: I couldn't have said it
13 better myself, Dr. Kim. I was going to. So, I'll
14 second all that, and bio-monitoring did not die in
15 vain, but I do think that there are techniques
16 available to make a stronger distinction between an
17 externally deposited exposure and an internal dose for
18 the applied quantitative risk assessment. Other than
19 that, my kudos to all the participants.

20 DR. HEERINGA: Dr. Johnson.

21 DR. JOHNSON: Yes, I also thank the task
22 forces and the EPA for their presentations, and I
23 strongly encourage them to include some of the material
24 in the presentations into their re-, into the
25 protocols. I think that's, that, there was a lot of

1 material presented that was very helpful and would have
2 been nice to have seen that in some of the protocols.
3 So, I encourage you to make use of that material, now
4 that you have it generated.

5 DR. HEERINGA: Dr. Hines.

6 DR. HINES: I would just like to take the
7 long view and express, despite all the holes that we've
8 been poking at various times in the various proposals,
9 that I have optimism that we are moving toward a better
10 database. There are some issues that need to be worked
11 out, and I think there have been some excellent ideas
12 here at this meeting on, perhaps, how that might be
13 approached. And, looking back, we now have another
14 twenty years of experience, both in the industry and
15 within EPA on how to assess pesticide exposure. We
16 have a much larger literature base to go on, and so,
17 that gives me some optimism that, at the end of this
18 whole process, maybe we won't have completely 30
19 scenarios rigorously evaluated, but we'll be a lot
20 closer, I'm hoping.

21 DR. HEERINGA: Dr. Bucher.

22 DR. BUCHER: I'd just like to add my
23 thanks to the agency and to the industry for the
24 efforts of putting all this together. And thanks for
25 the opportunity to learn a little bit about exposure

1 assessment.

2 DR. HEERINGA: Dr. Portier.

3 DR. PORTIER: Ken Portier. Steve said he
4 wanted to get out of here at 11:30, no, it's.

5 [All laugh.]

6 DR. PORTIER: I have a few short things.
7 I'm encouraged that the proposed database will
8 represent a true advance to risk assessment. I mean,
9 I, I'm really convinced of that. First-, one thing I'd
10 like to do is request that the HED computer system
11 interface, the, the, when the user's going to interface
12 with this database, there's going to be software, that
13 this software include modern methods for handling non-
14 detects and testing distributional forms in the
15 presence of non-detect data with these modern
16 statistical methods.

17 The previous PHED system provided pre-
18 packaged reports to users based on selection criteria,
19 and presented such things as estimated means and
20 standard deviations for exposure, and did a Kolmogorov-
21 Smirnov test for log normality. Today there are much
22 better methods for estimating the mean and standard
23 deviations and replacing the non-detects with half the
24 detection limits, and there are much better statistical
25 tests for looking at normality and log normalities in

1 the Kolmogorov-Smirnoff test, including test statistics
2 that incorporate or, at least, take a count of the non-
3 detects.

4 So, I just encourage the developers of the
5 database to not look at the PHED interface, and to talk
6 to some statisticians about incorporating modern
7 estimation techniques, so what you get is, really, the
8 best estimate, not the easiest estimate. And then the
9 last comment is regard to representativeness. I think
10 in the past, representativeness has been defined by the
11 agency risk assessor who is responsible for the
12 analysis.

13 That person, playing the part of a god, would
14 say, this data's good, let's move forward. I think it,
15 it's, it would nice if there were some kind of external
16 definition or assessment of representativeness with
17 this database, so that all the onus isn't back on the
18 risk assessor to make that decree that the risk
19 assessor can assume, to a large part, that what they're
20 looking at is representative and that doesn't become a
21 point of contention in the risk assessment. You can
22 move on to the risk questions, rather than the data
23 questions, right. That was it.

24 DR. HEERINGA: Well, thank you very much.
25 And, at this point in time, too, I would like to extend

1 my appreciation as the Chair of these meetings for the
2 past four days, to all of the presenters, to the task
3 force, to the representatives from the Cal DPA, and
4 Health Canada, and also, obviously, to the
5 Environmental Protection Agency. It's been, sort of, a
6 complex series of presentations. I think it's
7 extremely well organized, given the breadth and amount
8 of detail that we had to go into.

9 I appreciate all of the contributions of the
10 panel members, too, to, literally, spend a better part
11 of a week at the first of the year, which is a very
12 difficult time to do this, but again, congratulations
13 to the SAP for assembling such an expert panel, and my
14 thanks to all of you for giving your time to, I think,
15 what is a very, very, very important activity in this
16 process.

17 I appreciate the process. I learn something
18 every time that I participate in one of these. I hope
19 that it's been beneficial. I think, you're, obviously,
20 all in a tough place of trying to maximize a data
21 utility, resource utility in a situation where there's
22 extreme variability and high costs. And that's not an
23 easy world to work in. And I think we all have to, we
24 take that perspective. And I think you heard that here
25 from Cynthia Hines, too, in her comments, that this is

1 a, we pick apart little pieces during the week, but in
2 the overall picture, I think we represent the
3 importance of studying these efforts, even though they
4 aren't as clean. I'd still like to go back to that
5 one, one regression line, and a, a .7R squared and,
6 sort of, live my life there. But that's not where we
7 live our lives, and - -

8 [All laugh.]

9 DR. HEERINGA: - - so, again, I think
10 that, I appreciate the panel's willingness to be open
11 to this. I appreciate everybody's willingness to
12 present their points of view and get them out in the
13 open, and we'll proceed from here. And I wish you all
14 the best as you continue your collaborations on these
15 efforts. I look forward to seeing the results of this.
16 This point in time, I think if there are not any
17 additional comments from the Environmental Protection
18 Agency?

19 MR. DAWSON: We just wanted to mirror the
20 theme that's been occurring the last couple of minutes.
21 We really appreciate everyone's thoughtfulness related
22 to the charge that we've put to you, and the amount of
23 time and investment that you, clearly, took to address
24 our questions, because this is an extremely important
25 activity for us, and recognizing the time of year and

1 over the holidays, and such, so we really appreciate
2 it, and we view this activity as highly valuable as we
3 move forward.

4 DR. HEERINGA: Thank you very much, Mr.
5 Dawson. At this point in time, before we wrap up the
6 meeting, I'd like to turn the mike over to the
7 designated Federal official, Myrta Christian, for just
8 a few last minute administrative notes.

9 MS. CHRISTIAN: Okay, thank you, Dr.
10 Heeringa. One more time, I want to thank the panel,
11 the presenters, and the public for participating in
12 this meeting. I think it has been a very successful
13 meeting. Also, I would like to remind everyone that
14 the meeting minutes for this SAP meeting will be
15 available in approximately eight weeks. Thank you,
16 again.

17 DR. HEERINGA: And also, a member, to all
18 of the members of the public in the audience, that
19 materials presented during the course of these meeting
20 will be available on the docket for this meeting, the
21 EPA website, and can be reviewed there. And, again,
22 participants, if you have not submitted materials for
23 that docket, if you would see that they get to Myrta.
24 So, at this point in time, again, I think we've
25 concluded three and a half days, and I want to thank

1 everyone for their participation and safe travels home
2 today, and best wishes for the start of this new year,
3 so, thank you everyone. Members of the panel, if we
4 could collect in the break room, I, it's not my intent
5 to hold you very long, because I know you have travel
6 plans and things that you've scheduled, but I would
7 like to just get a quick organizational session on the
8 report writing, just to make sure that we don't let
9 anything slip through.

10 (WHEREUPON, the CONFERENCE was concluded at 11:08 a.m.)
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