

FIFRA SCIENTIFIC ADVISORY PANEL (SAP)

OPEN MEETING

SCIENTIFIC ISSUES ASSOCIATED WITH THE
AGENCY'S PROPOSED ACTION UNDER FIFRA 6(b)
NOTICE OF INTENT TO CANCEL CARBOFURAN

U.S. ENVIRONMENTAL PROTECTION AGENCY
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OPEN MEETING

February 6, 2008

DR. MATTEN: Good morning. We're going to start the second day of our meeting on carbofuran issues. My name is Sharlene Matten. I work in the office of Science Coordination and Policy. I'm the designated federal official for this meeting. We're going to continue our discussions that follow Dr. Reaves' presentation yesterday. And I'm going to turn the floor over to Dr. Heeringa, who will then continue leading the panel through the various discussions. Thank you.

DR. HEERINGA: Good morning, everyone, and welcome back to the second day of our multi-day session of the FIFRA Science Advisory Panel; addressing the topic of scientific issues associated with the Agency's proposed action under FIFRA 6 (b) -- Notice of Intent to Cancel Carbofuran.

I am Steve Heeringa of the University of Michigan. I am the President Chair of the FIFRA Science Advisory Panel. Today, we're joined, as yesterday, by an expert panel, to address the specific charge questions and scientific issues associated with



1 this meeting topic.

2 I'd like to have them introduce themselves
3 again this morning, beginning with Dr. Chambers.

4 **DR. CHAMBERS:** I'm Jan Chambers with
5 the College of Veterinary Medicine at Mississippi State
6 University. And I'm a member of the permanent panel.
7 My area of expertise is pesticide toxicology.

8 **DR. HANDWERGER:** I'm Stuart Handwerger.
9 I'm Professor of Pediatrics and Cell and Cancer Biology
10 at the University of Cincinnati College for Medicine.
11 I'm an endocrinologist whose primary research is in
12 molecular and developmental biology.

13 **DR. PORTIER:** Good morning. I'm Ken
14 Portier, Director of Statistics, the American Cancer
15 Society National Home Office in Atlanta. And I'm a
16 member of the permanent panel.

17 **DR. SCHLENK:** My name is Dan Schlenk.
18 I'm a professor in the Department of Environmental
19 Sciences at the University of California, Riverside.
20 My area of expertise is aquatic toxicology and I'm a
21 member of the permanent panel.

22 **DR. CLARK:** My name is Larry Clark. I'm
23 the Assistant Director of the USDA's National Wildlife
24 Research Center. And my areas of expertise are
25 wildlife oncology, sensory biology and wildlife

1 diseases.

2 **DR. DELORME:** Good morning. My name is
3 Peter Delorme. I'm currently Acting Director of the
4 Environmental Assessment Director of the Pest
5 Management Regulatory Agency at Health Canada.

6 **DR. GRUE:** Good morning. My name is
7 Chris Grue. I'm leader of the Washington Cooperative
8 Fish and Wildlife Research Unit, University of
9 Washington. My area of expertise is fish and wildlife
10 toxicology.

11 **DR. HILL:** I'm Elwood Hill. I am a
12 wildlife toxicologist. My area is primarily organic
13 phosphorus, carbamate and mercury toxicology.

14 **DR. MCCARTY:** My name is John McCarty.
15 I'm a Professor of Biology at University of Nebraska at
16 Omaha. I'm an ecologist, and specialize in the ecology
17 of birds.

18 **DR. MONTGOMERY:** I'm Cheryl Montgomery.
19 I'm a consultant with Montgomery and Associates. I am
20 a chemist, and I practice risk assessment.

21 **DR. SAMPLE:** I'm Brad Sample -- CMSM
22 HILL, ecological risk assessor.

23 **DR. SPARLING:** Don Sparling with
24 Cooperative Wildlife Lab in Department of Zoology at
25 the Southern Illinois University. My area of expertise

1 is wildlife toxicology.

2 **DR. STINCHCOMB:** Audra Stinchcomb,
3 University of Kentucky, College of Pharmacy. I'm an
4 associate professor there. And my area of expertise is
5 dermal absorption.

6 **DR. REED:** Nu-may Ruby Reed. I'm with
7 the California Environmental Protection Agency. I do
8 pesticide health risk assessment.

9 **DR. MACDONALD:** Peter Macdonald,
10 Professor of Mathematics and Statistics at McMaster
11 University in Canada. I have general expertise in
12 applied statistics.

13 **DR. LU:** Alex Lu from Rollins School of
14 Public Health at Emory University. I do human exposure
15 to pesticides and the hazard factor and biomarkers.

16 **DR. KEHRER:** Jim Kehrer, Dean of the
17 College of Pharmacy at Washington State University.
18 I'm in molecular toxicology.

19 **DR. HATTIS:** Dale Hattis, Clark
20 University. I specialize in issues of uncertainty and
21 variability in mechanistic modeling.

22 **DR. EDLER:** Lutz Edler, German Cancer
23 Research Center -- head of the Bio-statistics
24 Department there, and responsible for experimental and
25 clinical studies, and also interested in risk

1 assessment.

2 **DR. BUNGE:** Annette Bunge. I'm a
3 Professor at Chemical Engineering at the Colorado
4 School of Mines, and I specialize in dermal absorption
5 issues and risk assessment.

6 **DR. BAILEY:** Ted Bailey, Department of
7 Statistics at Iowa State University.

8 **DR. HEERINGA:** Thank you very much,
9 again, members of the panel. Before we begin, just a
10 little synopsis of where we are in the agenda. If
11 you're joining us for the first time today. We do have
12 a floating agenda that is currently scheduled over four
13 days -- or three-and-a-half days. We are about two or
14 three hours behind the posted times on the agenda. I
15 guess I anticipated that. We are in the process of
16 hearing and asking questions of clarification of the
17 EPA scientific staff of their presentations. After
18 that, we'll turn to the period of public comment, and
19 it will be an extensive period of public comment today.

20 Throughout this process, it's my intent that
21 we fully develop each of these issue and have
22 appropriate time to ask these questions of
23 clarification. So, I would anticipate us to sort of
24 remain behind the agenda schedule today; probably about
25 the same lag that we experienced yesterday.

1 It's also my current thinking in terms of
2 planning for the week that I anticipate that we will,
3 in fact, return Friday morning for a continuation and a
4 wrap-up of this session on Friday -- just based on my
5 experience with these and the fact that I don't intend
6 to have us rush through things. This is a very serious
7 matter here. We want to make sure we have full
8 development and exploration.

9 So, with that, this morning, I'd like to turn
10 to Dr. Debbie Edwards or to Steve Bradbury possibly for
11 some opening comments.

12 **DR. BRADBURY:** Thank you, Dr. Heeringa.
13 Again, welcome to the panel and I'm looking forward to
14 the second day of discussions. I know there's a couple
15 of follow -up -- at least one set of follow-up
16 questions that we want to handle shortly with regard to
17 drinking water half-life question and we'll cover that.
18 And then, I believe we'll continue with clarifying
19 questions.

20 There's one topic that came up yesterday a
21 couple of times, and if I could just touch on that very
22 briefly. It has to do with the conditional label
23 changes that the registrant has submitted. And I know
24 a couple of times there were panel members that had
25 some questions about that.

1 The proposed label changes that were
2 submitted to the Agency in mid-December include
3 continuing, I believe, four uses, but also, adding a
4 new use for their further use of the product on cotton.
5 And that requires -- that would be a new use, a new
6 registration, and would require both an ecological and
7 dietary risk assessment. And that goes through a
8 process. It typically takes for a new use about twelve
9 to fifteen months to go through the process of that
10 evaluation.

11 So, it's important to realize that some of
12 these changes on the current label are contingent upon
13 the addition of a new use. So it isn't a use by use
14 proposal that was submitted to the Agency. It's sort
15 of package deal. It includes adding further use on
16 cotton in addition to reducing a number of uses that
17 are currently on the label.

18 Now, having said that, I believe the charge
19 questions or the issues that the Agency's focusing on
20 in terms of ecological risk and human health risk, and
21 the feedback we'll get from the panel will be helpful
22 regardless of whatever you chair -- use patterns -- may
23 or may not occur for carbofuran.

24 On the context of human health risk
25 assessments, as we were starting to discuss yesterday,

1 the Agency's primary interest in getting feedback from
2 the panel concerns aspects of the cholinesterase. How
3 to take a look at red blood cells versus brain. How to
4 be taking a look at the dose response curves for those
5 response. How to think about oral route to dermal
6 route extrapolation -- those kinds of issues, which
7 will be important regardless of what food-use pattern
8 may exist or not exist for carbofuran in the future.
9 Certainly the overall dietary exposure that could exist
10 with a different pattern of uses will change, but the
11 underlying interpretation of the cholinesterase
12 inhibition and -- and the various extrapolation issues
13 are sort of even dependant of what the uses would be at
14 the end of the day. So we don't think that has a major
15 impact in the deliberations we'll be having in the next
16 few days.

17 In terms of the ecological risk assessment,
18 as we discussed yesterday, the risk assessment is
19 focused at a spacial scale of the field. And, so,
20 you're looking at the scenarios that have been done
21 thus far for the ecological risk assessment while
22 there's alfalfa and corn being used as a surrogate, the
23 idea is -- or the issue is that those are spanning a
24 range of use patterns that transcend the use patterns
25 that are on the label in terms of application rates,

1 and kinds of application methodologies, and the alfalfa
2 analysis, for example, isn't a water fowl risk
3 assessment, it's a risk assessment on passing birds in
4 row crops.

5 So alfalfa and corn are being used as
6 surrogates for row crops across a span of application
7 rates, application methods, and trying to get handle on
8 how to estimate risk on a field where carbofuran or
9 foliar carbofuran has been applied.

10 So, again, from the Agency's perspective
11 understanding how to interpret studies to try to get at
12 matrix effects on carbofuran potency. Trying to
13 understand how to take into account recovery of
14 cholinesterase in brain tissue of birds in terms of the
15 probabilistic risk assessment -- how to interpret
16 incidents data or field studies with foliar carbofuran
17 -- how to interpret the risk quotient methodology in
18 assessing the potency of carbofuran to birds in many
19 ways transcends what use patterns may exist in the
20 future.

21 So all the use patterns may change. The
22 underlying fundamental scientific issues in assessing
23 the risk transcend the use patterns to -- in the
24 Agency's opinion. And so we think that as we move
25 forward in the charge questions we'll get useful

1 information, regardless of what the use patterns may or
2 may not be in the future.

3 If there are any follow-up questions, I'll be
4 happy to handle that. But then maybe we could move
5 into the clarifying questions from the Human Health
6 Topic.

7 **DR. HEERINGA:** Thank you very much, Dr.
8 Bradbury.

9 Dr. Brimijoin?

10 **DR. BRIMIJOIN:** Could I ask a follow-up
11 question? Supposing that the Notice of Intent to
12 Cancel is, in fact, carried through to cancellation,
13 and yet the company has a new-use application pending
14 -- I mean, is there -- what would -- is there an open
15 procedure for them to go forward with the request for a
16 new registration, let's say for cotton -- providing, of
17 course, new data to convince EPA then, in fact, the
18 product is safe?

19 **DR. BRADBURY:** Yeah, there is a -- there
20 is a process to do that. When -- and Debbie you could
21 help me, or GC could help me, but I believe if we go
22 through a process then it's cancelled there is a
23 process whereby a cancelled pesticide can have a use
24 come forward, but there's a process that you have to go
25 through to do that.

1 **MR. HEERINGA:** Okay, let's return then
2 to the presentations yesterday afternoon from Jack
3 Housenger and Anna Lowit and Elissa Reaves on the human
4 health risks. And I know that there have -- certainly
5 are some residual questions from this afternoon and
6 some new questions that may have occurred to people as
7 they thought more about this last evening.

8 Dr. Bunge, you had a question before we --
9 are we ready to go?

10 **DR. LOWIT:** We had a couple follow-ups
11 from yesterday.

12 **DR. HEERINGA:** Okay. Well, let's

13 **DR. LOWIT:** Do you want us to start with
14 those?

15 **DR. HEERINGA:** -- do those to start
16 with, please.

17 **DR. LOWIT:** And, I believe David Jones
18 also had a follow-up from yesterday on the --

19 **DR. HEERINGA:** Please, go ahead then.

20 **DR. LOWIT:** I'll start and then Dick can
21 go, and then return it back to the panel.

22 **(WHEREUPON, conversations took place off the record.)**

23 **DR. LOWIT:** There was a question from a
24 Dr. Hattis conceptually around biological time -- the
25 differences between rats and humans. And as we stated

1 previously as part of review of the review board, you
2 won't hear us talking about the carbofuran human study,
3 however, there are three human studies for carbamates
4 that did go through the review of the HSRB and were
5 okayed for use in the risk assessment. And they do
6 provide some context for that question. And I've got
7 some tables in front of me with the parallel rat data.
8 So just in sort of basics of those studies they're each
9 ascending -- ascending acute single doses with the
10 number of subjects ranging from somewhere in the order
11 of twenty to thirty or fifty.

12 They each have pretty good time course
13 ranging from a few minutes after post-dose up to the
14 following day. Clinical signs, as we said yesterday,
15 it's very difficult to match clinical signs with
16 cholinesterase inhibition. In some ways that's a very
17 chemical specific situation. You can have some
18 carbamates where you get signs of very low levels of
19 inhibition and others where you see clinical signs they
20 don't sort of kick in, for a lack of better term, until
21 much greater inhibition.

22 But the question from Dr. Hattis was around
23 the half-life in a relationship between the humans and
24 the rats. So you see the last two levels here in this
25 slide that Dr. Reaves put together (Indicating.), the

1 half-life for each of those is roughly about two hours
2 with decent confidence limits of a little bit less --
3 about an hour -- somewhere in the order of three to
4 four hours. And with regard to the rat for those three
5 compounds, just as point of comparison, in the adult
6 rat, I didn't have at my fingertips quickly this first
7 thing this morning, the RBC numbers, but brain and RBC
8 are usually not that different.

9 For aldicarb in the adult rat, the recovery
10 half-life is an hour-and-a half. For methomyl, it's
11 between three-quarters of an hour and an hour depending
12 on the study. For oxamyl it's approximately an hour.
13 For both methomyl and oxamyl, they tend to have -- both
14 of those compounds have very strong data bases, and the
15 confidence limits on the rat numbers are very tight --
16 arranging from about half-an-hour to one-and-a quarter-
17 hours for both.

18 For aldicarb, the confidence limits on the
19 half-life range from about an hour to about two hours.
20 So, still pretty tight. So, regarding -- at least in
21 adults, I would say that the rats and the humans are
22 pretty comparable of about two hours.

23 For the pups, for methomyl and oxamyl in
24 rats, for methomyl, the half-life in a PND 11 brain is
25 about -- roughly half-an-hour -- point four hours, so

1 about half-an-hour. I don't have the confidence
2 limits. And oxamyl, the half-life is about an hour-
3 and-a half. But if we look across the carbamates, and
4 this is a table right out of the accumulative -- it's
5 more like other situations that -- keep in mind it's a
6 dose dependent situation. So, it ranges in the table.
7 The low being methomyl about point four hours, the high
8 being fermitinite of about nine hours. So what we
9 call sulpha-carbofuran is somewhere in between those.

10 I think I had --

11 **MR. HATTIS:** So why? Carbofuran is a
12 little unusual in having an appreciatively different
13 half-life for the pups versus the adults?

14 **DR. REAVES:** I wouldn't say it's
15 appreciable. I'm not sure if we have enough data to
16 really set a trend. But what we do know from the pups
17 is that the range across the class is much greater than
18 what's seen in the adults. The range in the pups
19 across the class, we got -- I've got data for five
20 chemicals, carbaryl, carbofuran, fermitinite, methomyl
21 and oxamyl. The shortest being methomyl of point
22 four, the longest being fermitinite of nine,
23 carbofuran is in the middle there (Indicating).

24 **DR. HATTIS:** So, there is a tendency for
25 the pups to be longer half-lives -- shorter -- lessor

1 inhibition rates then the adults in the examples we
2 have in front of you.

3 **DR. REAVES:** Yes, yes, with caveat that
4 there's a dose dependance to it.

5 **DR. HATTIS:** Yes.

6 **DR. REAVES:** And we would have to go
7 back to see

8 **DR. HATTIS:** Yes.

9 **DR. REAVES:** inhibition

10 **DR. HATTIS:** Right.

11 **DR. REAVES:** -- was in the studies to
12 make sure you're comparing apples and apples.

13 **MR. HATTIS:** Right.

14 **DR. REAVES:** I think we had one more
15 slide. Just of point of transparency, I'd shown a plot
16 yesterday out of the 2005 --

17 **(WHEREUPON, conversations were held off the record.)**

18 **DR. LOWIT:** I had shown a plot yesterday
19 out of the 2005 preliminary accumulative assessment for
20 the carbamates. Making two points -- one of them was a
21 derivation of the original five factor for the 2006
22 risk assessment, the other one where I was trying to
23 make the point that aldicarb and carbofuran really
24 aren't that different of potency. Just for point of
25 transparency so the panel has a more recent

1 information, we pulled these plots -- this plot and the
2 next one (Indicating.), excuse me, out of the 2007
3 revised assessment, which includes updated data for
4 most compound including carbofuran. So there are two
5 of them. The first one is for RBC -- go back -- you
6 can see the blue dots where the aldicarb and
7 carbofuran were essentially the same; so they are
8 similar in potency when you compare apples and apples
9 with regard to the brain. You can see carbofuran is --
10 I think that's a three-fold difference. That's a log
11 scale right there (Indicating). I'm pretty sure
12 aldicarb and carbofuran in the brain is about three-
13 fold difference.

14 So I just wanted to make sure the panel had
15 the most recent information.

16 **DR. HEERINGA:** Dr. Lowit, that
17 particular plot is -- is that in a document that we
18 have received?

19 **DR. LOWIT:** It's not on a document
20 you've received. We certainly can make copies.

21 **DR. HEERINGA:** That would be great.

22 **DR. LOWIT:** It is publically available
23 in the -- in the risk assessment.

24 **DR. HEERINGA:** Both the

25 **DR. LOWIT:** The accumulative assessment.

1 **DR. HEERINGA:** Both that and the half-
2 life chart I think we could use.

3 **DR. LOWIT:** Definitely.

4 **DR. JONES:** I'm responding to -- first,
5 I'm Dave Jones of EFED. I'm responding to the question
6 about drinking water treatment and environmental
7 degradation rates. Yesterday, I indicated that it is
8 driven by hydrolysis and pH dependent. At pH 5, we
9 have no evidence of degradation. It's a thirty day
10 study, so take that into account. At pH 7, it's
11 twenty-one days. And at pH 9, it's fifteen hours.
12 That's the twenty-five degrees. It's faster at higher
13 temperatures and slower at lower temperatures, and we
14 do have some data on that.

15 We have an aerobic slow metabolism study. We
16 had two of them done in the same soil, and the second
17 one was limed to raise the pH. It was three hundred
18 and twenty-one days at the lower pH, and a hundred and
19 twenty-nine days when it was raised above seven. That
20 study is a little hard to interpret because there was a
21 great deal of un-extractable residue in the study and
22 it's hard to say whether that was truly un-extractable
23 or just poorly extracted. There was -- degrade, three
24 hydroxy carbofuran. We do occasionally see that in
25 water resources.

1 In -- if carbofuran is on a surface or in
2 clear shallow waters it does degrade by photolysis with
3 about a six day half-life. But that would only be
4 operative in certain environments where a lot of light
5 can get to it.

6 Carbofuran is not bound tightly. The median
7 K/F is point 7. So it's below one most of the time.
8 The range is -- the measurements we had goes from point
9 one to thirty point three. So this is a pretty mobile
10 compound.

11 One comment to add on the drinking water
12 treatment. The water sources we are most concern
13 about, which are private rural wells, tend not to have
14 a whole lot of treatment done to them. So, the
15 question about treating it mostly relates to community
16 water supplies that are both surface and ground water.

17 **DR. HEERINGA:** Thank you very much.

18 In summary -- I don't -- Mr. Jones, with
19 regard to community water systems and the original I
20 read, I didn't see much concern there in terms of
21 community water systems levels, sub-part per billion.
22 Is that correct or is that

23 **DR. JONES:** For ground water, our
24 concern is mainly with the private rural wells and that
25 certain environment -- shallow, a lot of sandy soil,

1 organic carbon acid water.

2 **DR. HEERINGA:** Right. Okay.

3 Are there additional clarifications from
4 yesterday from the EPA Scientific staff?

5 Well, let me open the floor to questions --
6 clarification from the panel. Dr. Bunge?

7 **DR. BUNGE:** Thank you. Annette Bunge.

8 Just a couple points of clarification, and I
9 apologize. As you can imagine, we've been overwhelmed
10 both by information and piles of papers. So there will
11 probably be really simple things that we've just lost,
12 or I've just lost. So just a point of clarification --
13 on the red blood cell, cholinesterase measurements by
14 FMC, they use the modified Elmans Assay in the two
15 dermal studies, and I thought from yesterday's
16 presentation in the second oral study, but I didn't
17 catch what assay was used in the first oral study?

18 **DR. LOWIT:** Yes, in the first FMC
19 comparative study, they used the modified Elmans, but
20 it was performed at a different laboratory.

21 **DR. BUNGE:** Okay. I see.

22 **DR. LOWIT:** So the dermal study for
23 carbofuran and the second FMC CCA study were performed
24 at the same laboratory.

25 **DR. BUNGE:** Okay. Thank you.

1 Now, I'd like to ask just a few questions
2 then about the dermal-tox studies, and especially
3 directed towards the decision to not use the results in
4 the risk assessment.

5 As I understood it -- okay, first of all
6 point of clarification. The -- I see cholinesterase
7 measurements were done -- it says one hour post
8 exposure, and just to be sure I understand when that
9 occurs relative, does that mean one hour after the six
10 hour exposure on the last day?

11 **DR. LOWIT:** Yes, that's correct. One
12 hour post exposure, so actually, seven hours from the
13 beginning of exposure. One after the six hours.

14 **DR. BUNGE:** But it's the exposure on the
15 last day?

16 **DR. LOWIT:** Correct.

17 **DR. BUNGE:** Okay. Now

18 **DR. LOWIT:** Just to be clear. As this
19 is a carbamate and recovery is rapid, the fact that it
20 was a twenty-one day study, and it was the last day, is
21 less important than the hours and the minutes.

22 **DR. BUNGE:** I appreciate that. I
23 understand that.

24 And of course there's two studies. There's
25 the seven day study also. And so it would be on the

1 last day of the seventh day study.

2 Now, in my understanding of the decision
3 making for not using the dermal studies in the risk
4 assessment, the first was that the red blood cell data
5 were considered unreliable; correct?

6 **DR. LOWIT:** Because there was concerns
7 from the CCA study with the same protocol, the red
8 blood cell data, there was no dose response. So,
9 correct.

10 **DR. BUNGE:** Right.

11 But the brain data were considered adequate?

12 **DR. LOWIT:** In the CCA study; correct.

13 **DR. BUNGE:** Okay.

14 **DR. LOWIT:** But not the dermal.

15 **DR. BUNGE:** No, I'm talking about the
16 dermal -- just the data themselves, not back to the
17 time course, which I'm going to address in my next
18 question.

19 **DR. LOWIT:** Okay.

20 **DR. BUNGE:** But in the list of reasons
21 why the dermal-tox study was not included -- or not
22 used in the risk assessment, the list said that the red
23 blood cell data were considered unreliable. I assume
24 then -- though -- that the brain data -- the time
25 course issues aside for the moment, were considered

1 adequate or apparently reliable?

2 **DR. LOWIT:** For that compartment.

3 **DR. LICCIONE:** Yes, we had -- hi, my
4 name is John Liccione from ATB. We had like the CCA
5 study -- more confidence in the brain cholinesterase
6 measurements.

7 **DR. BUNGE:** Okay. So there's not a
8 question of reliability on the data from the brain,
9 it's now the time course issue that's the critical one?
10 Is that correct in the decision making?

11 **DR. LICCIONE:** Yes.

12 **DR. BUNGE:** Okay.

13 **DR. LOWIT:** There are two points here I
14 just want to make sure that you don't mix them up. One
15 is the reliability of the conduct of the study itself.
16 And then the second issue is the usability of that for
17 point of departure. So make sure in your mind that
18 you're separating that.

19 **DR. BUNGE:** I understand that.

20 Okay. So, it seems to me that the really
21 crux-point then in the decision making on whether or
22 not to use the dermal study in the risk assessment
23 relies really on the time course; is that right?

24 **DR. LICCIONE:** Well, there's two issues.

25 One is the time course, but also, the RBC that we --

1 it's a method problem. All those factors that were
2 considered. So the -- of the oral studies are showing
3 the RBC to be more sensitive. So there's two levels.
4 One is that the RBC is just simply unreliable, and
5 that's the more sensitive compartment. And then you
6 have the issue about the time to course. That would be
7 relevant to the brain, but also would be relevant to
8 the RBC, if they did RBC properly. We would still have
9 to make sure you're -- in the dermal study that you
10 have the right kind of peak measurements and things
11 like that.

12 **DR. BUNGE:** Let me clarify it then. So,
13 the fact that -- so, you've decided that the red blood
14 cell assay is the key one. And so if that is deemed
15 unreliable then the other issues aside is still -- the
16 fact that the brain data seemed to be consistent and
17 has a dose response and so forth, you wouldn't use it
18 even if the time course wasn't a separate issue?

19 **DR. LICCIONE:** Right. We would -- we
20 would want

21 **DR. BUNGE:** I mean, you made the
22 decision that the red blood cell is the assay that
23 matters here?

24 **DR. LICCIONE:** Right.

25 **DR. BUNGE:** Okay.

1 **DR. LICCIONE:** That's the most

2 important.

3 **DR. BUNGE:** Now, if I can, then, because
4 I want to be sure that I understand better the rationale
5 for the time course data. And I think that could be
6 best explained is if you could explain what data you
7 would have needed to make it possible to use the
8 dermal-tox study -- you believe? What was missing --
9 just saying time course is not helpful. We need to
10 know a little more specifics about what sort of time
11 course information you required?

12 **DR. LOWIT:** Typically -- specifically,
13 from the carbamates, we like to have -- you say time
14 course -- but measurements within that peak inhibition
15 and recovery phase -- like I showed yesterday. So,
16 for other dermal studies for carbamates, we have
17 measurements taken, say for example, at fifteen
18 minutes, thirty minutes, you know, every fifteen
19 minutes for the first, at least, hour to two hours.

20 **DR. BUNGE:** Can you identify whether you
21 mean post exposure?

22 **DR. LOWIT:** Yes, post exposure.

23 **DR. BUNGE:** Or how about the length of
24 the exposure?

25 **DR. LOWIT:** Six hours. Six hours of

1 exposure. So, like it was done here. But then we
2 would need the fifteen minute post exposure
3 measurements so that we can define the peak inhibition
4 and the recovery phrase.

5 So, like I said yesterday, for this dermal
6 study, we have a snap-shot in time. And we don't know
7 where that fits. So we don't know if these inhibition
8 data that we have now for brain is the peak or if we're
9 coming back off the peak, in order to be protective.

10 **DR. BUNGE:** Can I ask you a question
11 then about the six hours? Why not eight, why not ten,
12 why not four or two, is there a reason for the six?

13 **DR. LICCIONE:** Well, the typical --
14 well, the guideline studies requires -- asks for six
15 hour exposure -- just by convention. That's been
16 considered usually relevant for an eight hour exposure
17 roughly. They could do it longer if they wanted to.
18 But the guideline specifies six.

19 **DR. BUNGE:** Right. I didn't know that.
20 I'm more familiar with the dermal absorption guidelines
21 then the dermal-tox guidelines. Thank you. Those are
22 my questions.

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

24 **DR. BRIMIJOIN:** This is a real quick
25 follow-up.

1 Do the guidelines also specify that you want
2 the fifteen minutes, the thirty minuets, the one hour,
3 etcetera?

4 **DR. LICCIONE:** The guidelines don't
5 specify that specifically. However, in the dermal-tox
6 guidelines do say that you should consider formal
7 pharmacal-kinetics and what you know about the
8 information about the chemical. So knowing that this
9 is a rapid reversible inhibitor and that reactivates,
10 and that we see this to be an issue with the oral
11 studies, why shouldn't it be pertinent to the dermal,
12 as well. Because the dermal pharmacal-kinetics might
13 be actually a little more complicated, because some
14 evidence that we have on the dermal absorption although
15 be it limited on carbofuran is that it follows more the
16 -- it doesn't follow fixed law diffusion. So it could
17 be a little more complicated then the oral absorption,
18 which is just rapid.

19 So that -- that should be included in the
20 assessment of the Cholinesterase inhibition in dermal
21 if you really want to get down to the bottom-line where
22 you're looking at the time course and being able to
23 reliably measure the cholinesterase inhibition.

24 **DR. HEERINGA:** Just a reminder to all of
25 the panelists and the speakers. State your name for

1 the record so we could that on the transcript. No
2 problem though.

3 Dr. Brimijoin?

4 **DR. BRIMIJOIN:** That was essentially my
5 question, and I think you answered it. And, in fact,
6 it wasn't in the guideline that they must do this. It
7 was a rather vague understanding and

8 **DR. LICCIONE:** Correct. But it's open
9 to -- so that anyone that really wants to do it can do
10 good science.

11 **DR. LOWIT:** The -- I have one comment
12 about the guideline issue. The guidelines are meant to
13 be flexible. They're not meant to be recipes to
14 follow. Carbamate studies tend to come in with time
15 course. FMC did time course with the oral studies. It
16 would make sense to do some sort of time course.

17 **DR. HEERINGA:** Dr. Bailey and Dr.
18 Macdonald.

19 **DR. BAILEY:** Good morning. I wondered
20 if I could see slide number -- it's on page 16, or
21 slide 16?

22 **(WHEREUPON, there was no response.)**

23 **DR. BAILEY:** Last night when we left we
24 were looking at some graphs.

25 **DR. HEERINGA:** Of what?

1 **DR. BAILEY:** Oh, yes, right here

2 (Indicating).

3 **DR. LOWIT:** For which study?

4 **DR. BAILEY:** That was -- the PMD 17, the
5 carbofuran, and it was just before the carbofuran acute
6 database. Okay. Thank you.

7 These are two statistical questions. I
8 believe this is a plot of means here; is that correct?
9 And the dots represent means?

10 **DR. REAVES:** Yes, that's correct.

11 **DR. BAILEY:** Okay. And can you tell me
12 how many number were used to compute those means?

13 **DR. MOSER:** Yes. Good morning, Ginger
14 Moser.

15 We had, in that study, ten animals in each
16 dose group. And the motor activity and both
17 cholinesterase were measured in the same animals. So
18 it was ten animals per dose.

19 **DR. BAILEY:** Thank you.

20 **DR. MOSER:** And those are standard
21 errors shown.

22 **DR. BAILEY:** And I'm curious why the
23 lengths of the bars are so different as you go around
24 the different means?

25 **DR. MOSER:** I'm assuming you're talking

1 about the motor activity data. Because that's really
2 the one where the variability changes so much of the
3 doses?

4 **DR. BAILEY:** Yes, I am. But this is
5 characteristic of a lot -- almost all of the graphs
6 that I've seen.

7 **DR. MOSER:** What tends to happen is when
8 you get to the higher doses, for instance with the
9 motor activity, pretty much all the animals are down
10 around zero and so you do end-up having less
11 variability when you get at the lower doses or in the
12 controls. You can look at the controlled values, even
13 though that's a hundred percent, that's the average of
14 the, you know, the main control, and you can see there
15 that the motor activity in the PMD 17 animals are much
16 more variable and that rank -- that variability is the
17 same in the lowest dose animal -- of animals. But then
18 as you go up in dose, and you start having the effect
19 of the chemical, they become more consistent as they
20 get down to zero, which of course you can't get below
21 zero.

22 **DR. BAILEY:** Yes, and that's a -- I
23 understand that. That's a very good answer. But then
24 on slide number 12 -- then I see that -- that doesn't
25 seem to hold -- that was -- the slide I'm referring to

1 is carbofuran acute database oral -- the slide just
2 before that section?

3 It's the time course data?

4 **DR. REAVES:** For which? The FMC study?
5 Or the EPA study? Or?

6 **DR. BAILEY:** I'm sorry. I've lost track
7 from where we were yesterday afternoon. Let -- the one
8 in the middle would be fine. So some of these -- now,
9 here again -- they're quite different lengths. It's
10 indicating the variability is -- of the estimation of
11 those means is quite different. No matter -- sort of
12 throughout the range and during the time course. I've
13 seen this in many of your graphs, and I'm just curious
14 as to why those -- there's so much variability?

15 **DR. MOSER:** I think one of the answers
16 could be provided by FMC, but I know that as you saw in
17 the tables with what they call the DNRs and the cases
18 where they had to throw out the data completely.
19 Sometimes the sample size would go from ten to maybe
20 only four, and I believe those are still standard
21 errors. And so it's heavily dependent on the sample
22 size. So, it -- I don't -- those are my data of
23 course, but I know that there were many cases where
24 some of those groups only had two to three animals, and
25 other groups for some reason didn't have as many data

1 points thrown out and they may have eight, nine or ten
2 animal, and so of course the standard error is going to
3 be much lower. I believe that to be the case to at
4 least contribute to that -- those differences in the
5 variability.

6 **DR. REAVES:** And maybe later on today,
7 FMC could answer more questions around their specific
8 data.

9 **DR. HEERINGA:** I think that's fair to
10 assume. And I think an explanation of not only the
11 natural variability in the original measurements, but
12 the changes in sample sizes resulted the DNRs and the
13 development.

14 **DR. BAILEY:** Right. Though our concern
15 is does this just -- does this represent -- my question
16 about reliability in the data or is this, in fact,
17 reflect an underlying biological process that's going
18 on?

19 The second question I had -- back to the
20 first draft we were looking at and the mark on the
21 scale lines was in percent change, and I'm concerned
22 about using percent as the scale -- as the scale,
23 because you could go -- a ten percent change could be
24 one hundred on the basis of a thousand if the units are
25 in the thousands. You'd take -- ten percent of that

1 would be a hundred, but if the basic levels are at ten,
2 the change would be only one unit. And isn't the
3 actual units that it's measured in of interest to
4 biologists? Or is the percent change around a thousand
5 or is it around units of, you know, ten units or
6 something? That was my second question about -- aren't
7 we interested in terms of the actual units, as well as
8 the percent change?

9 Thank you.

10 **DR. MOSER:** We are interested in both.
11 And because of that, the statistical analysis are
12 always conducted on the actual data -- the raw values.
13 The reason we put everything as a percent control for a
14 lot -- for these comparative graphs, was because there
15 is such difference in the control values. For
16 instance, the brain Cholinesterase is, you know, the
17 numbers that we get for the brain Cholinesterase is
18 about ten-fold that what we get for the red blood
19 cells. So to put the actual raw values on the same
20 graph it would look, you know, you would have to change
21 the scale and it would be very difficult to compare.

22 But the statistical analysis are always
23 conducted on the raw values.

24 **DR. BAILEY:** One last comment. Then
25 maybe you could use both axis -- on the right vertical

1 axis, you could put down there what their scale is and
2 then people could see both what the actual units are.

3 **DR. MOSER:** Well, that would be possible
4 --

5 **DR. BAILEY:** Thank you.

6 **DR. MOSER:** But would be difficult with
7 the motor activity as well, but if you care to see
8 those data, you know, the raw data at some point, we
9 could provide it. But there are differences obviously
10 in the control values. Especially -- and also across
11 ages. The younger animals have much less brain
12 Cholinesterase activity than the adults do.

13 **DR. HEERINGA:** Dr. Setzer?

14 **DR. SETZER:** Yeah, this is what -- from
15 the U.S. EPA If I could expand on that just a little
16 bit First of all, when we're trying to put different
17 say data from different age groups or whatever on the
18 same graphs, what Ginger just said is exactly right.
19 You really want to represent that as percentage control
20 just so you can see things because the background
21 levels change a lot.

22 Secondly, in terms of the biological effect
23 or the significance of the biological effect, since
24 this is -- since this is an enzyme and it sort of -- it
25 tends to act sort of multiplicatively. So what matters

1 is relative changes from backgrounds. So it really
2 doesn't matter what -- I mean, if you were going to
3 actually try to build a mathematical model of recovery
4 of nerve function, you certainly would want to know
5 absolute units. But if you want -- but if you're
6 trying to get an idea of the relative effect, what you
7 really care about is the fractional change. So one
8 percent -- one percent is different from ten percent,
9 but the actual units you use aren't so important.

10 When we do the analysis for these data
11 regardless of how we're doing them, we always work on
12 the original scales and -- because obviously sort of
13 re-scaling like that can be risky. But -- and if
14 you're not careful can introduce correlations you've
15 got to then deal with in the analysis. But for
16 representational purposes, we use percent change, and
17 that's actually the right way to think about it
18 mechanistically as well.

19 **DR. HEERINGA:** Thank you, Dr. Setzer.
20 Dr. Macdonald?

21 **DR. MACDONALD:** Yesterday, we saw a very
22 useful table entitled EPA and FMC Net Analysis
23 Estimates for Juvenile and Adult Rats. Page 25. Next
24 time, it would help if you would numbered the --
25 numbered the individual slides. It was just before --

1 the end of section three.

2 Yeah, I think this is very useful. And I
3 think this is very important for our discussion of
4 charge question one in human health and I would find it
5 really useful if I could have a list showing the source
6 of each of those numbers. Because I know they've come
7 from various -- various sources. But it would really
8 help if I could find out where each one came in the
9 background material so we can have a discussion of that
10 when we get to charge question one.

11 **DR. LOWIT:** Can I ask a clarification on
12 what you mean by source?

13 **MR. MACDONALD:** Sure.

14 **DR. LOWIT:** Do you mean which of the
15 mountain of papers we have?

16 **MR. MACDONALD:** Yeah.

17 **DR. LOWIT:** Those numbers came from --
18 or the source being which data -- which studies --

19 **MR. MACDONALD:** No, I --

20 **DR. LOWIT:** -- including the numbers?

21 **MR. MACDONALD:** Where can I find them in
22 the pile of paper?

23 **DR. LOWIT:** Okay.

24 **MR. MACDONALD:** You see at the moment,
25 being a distrustful statistician, I won't even -- I'm

1 not even willing to assume there aren't typos on that
2 table. So, as well as just making sure that the
3 numbers got transcribed correctly, I'd like to know
4 where each one came from, and then, if I could find it
5 in the background material, I can get some idea of the
6 reliability of each of those numbers, which makes the
7 comparison easier to do.

8 **DR. LOWIT:** I think we know roughly
9 where they come from, but I can't quote you the titles
10 right this second. At the break, we'll talk about some
11 titles.

12 **MR. MACDONALD:** If we can have this --
13 if I could see this before we have to prepare for
14 charge question one and Human Health that would be
15 really useful.

16 **DR. HEERINGA:** Dr. Lowit, is that
17 something that you can do I guess in a reasonable
18 period of time?

19 **DR. LOWIT:** It should only take a few
20 -- I hope it should only take a few minutes, but
21 there's a mountain of stuff there. I'm pretty sure it
22 will only take a few minutes.

23 **DR. HEERINGA:** It certainly is a
24 reasonable request.

25 **DR. LOWIT:** Very much so.

1 **DR. HEERINGA:** And I think that's --
2 given the amount of material I think certainly the
3 comparative tables are very useful, but to have this
4 side by side and then others the opportunity to
5 actually go to those original sources and make sure
6 that he understands.

7 **DR. LOWIT:** As a point -- just to make
8 sure that we give you what you want, Dr. Macdonald and
9 this may be for the whole panel -- because you each
10 come to the table with a different skill set. Are you
11 just interested in the -- let's see -- the code and the
12 stats behind the numbers? Or you're interested more of
13 the summary information and that sort of thing?
14 Because they may be two different places.

15 **DR. GRUE:** This is Dr. Grue. I'm kind
16 of interjecting because he can't help it.

17 **DR. LOWIT:** I'm thinking that you want
18 something different than he does.

19 **DR. GRUE:** I think these tables that
20 you're showing here are very nice for a talk for sort
21 of presentation of data -- for leading an audience
22 through your thinking process. I think we're going to
23 be asked to get at the nitty-gritty, and I think you
24 should treat these tables the way you would do if you
25 were submitting this for a peer review publication.

1 And, in such a case, a table would come with a detailed
2 legend that would indicate where the numbers come from,
3 which study, etcetera. I think that would help Dr.
4 Macdonald and the rest of us.

5 **DR. LOWIT:** Okay. If you want
6 something like that it will take longer than the break.
7 But certainly by the time -- certainly -- we can
8 probably do it this evening or maybe first thing in the
9 morning.

10 **DR. HEERINGA:** Dr. Macdonald?

11 **DR. MACDONALD:** Yeah, the other picture,
12 I'd like a little bit more explanation of, which I
13 can't locate it in mine. It was Dr. Setzer's work on
14 giving -- you had a grey band around the fitted line
15 indicating the uncertainty in the extrapolation. And
16 it would be good if you could give us a little more
17 technical detail on how you did that calculation. It
18 would save us having to do it.

19 Yes, that one. Yeah, that's very pretty.
20 Thank you.

21 **DR. SETZER:** I'll see if I can submit it
22 somewhere -- okay, let me remember this. The issue --
23 okay, what we have here are predictions of inhibition
24 based on the dose response model in the PND 11 data set
25 in red blood cell and in brain. So we have two

1 different dose response models predicting brain
2 activity -- from those you derive inhibition. The --
3 so the solid line through the middle is just -- is just
4 the prediction based on the maximum likelihood of
5 approximate maximum likelihood estimates for those --
6 for the parameters for those models.

7 The little cloud on either side -- the intent
8 here was to sort of get an indication of the relative
9 -- the relative uncertainty and estimates of BND 10 and
10 BND 50 on these curves. So the way the clouds were
11 generated were by drawing a sample of parameter
12 estimates with multi-variant normal distribution with
13 mean and covariance matrix derived from the maximum
14 likelihood affixed to the data. Since I didn't
15 actually calculate Cholinesterase of that distribution,
16 that simply two draws from that distribution. Again,
17 it wasn't intended to be quantitative, but suggested.
18 So it's two hundred draws from those distributions, but
19 for the red blood cells is the gray and the brain is
20 the light blue. I should say Carolina blue, I guess.

21 **DR. HEERINGA:** Yes, Dr. Lu?

22 **DR. LU:** Just quick question. Could you
23 comment on the use of six percent dermal absorption
24 versus 8.8 percent as actually concluding the paper you
25 cite in the document?

1 The six percent dermal absorption reverses

2 8.8 --

3 **DR. LOWIT:** We're bringing someone else
4 to the table.

5 **DR. HEERINGA:** Make sure you identify
6 yourself.

7 **DR. LICCIONE:** John Liccione, oh, pardon
8 me, John Liccione from HEV.

9 Of the six percent from dermal absorption --
10 what's your question?

11 **DR. LU:** Because you refer to a paper
12 that published earlier

13 **DR. LICCIONE:** Right.

14 **DR. LU:** -- which did an animal study on
15 dermal absorption. And the conclusion in the paper, as
16 I remember, I read through is that it was about twelve
17 percent for the juvenile rat and about eight point
18 eight percent for the adult rat -- the absorptions, so
19 in the article I couldn't find six percent anywhere.

20 **DR. LICCIONE:** Okay. I could show you
21 -- in fact, I've got the paper her and I can actually
22 show you the actual chart. It's one of the tables
23 where they show the six percent actually goes with the
24 24 hour measurement. Because there was no eight hour
25 or ten hour measurement that we would use for work or

1 risk. So it's in the table and it was the one -- where
2 they looked at one dose for a certain amount of time.
3 And the absorption is greater in younger rats as you
4 mention. However, for work or risk, we usually use the
5 adult number. But I could go get the

6 **DR. HEERINGA:** May I suggest that you
7 just have a copy made to provide to him.

8 **DR. LU:** Yeah, the copy is actually on
9 the cd.

10 **DR. LICCIONE:** Right. I could actually,
11 if you'd like just show you the exact

12 **DR. LU:** Okay. Sure. That would be
13 great.

14 **DR. LICCIONE:** I'd be more than
15 grateful.

16 **DR. HEERINGA:** Dr. Bunge?

17 **DR. BUNGE:** So just to clarify, the six
18 percent number was from the adult rat?

19 **DR. LICCIONE:** Exactly.

20 **DR. BUNGE:** After a twenty-four hour
21 exposure?

22 **DR. LICCIONE:** Right. We did not have
23 an eight to ten -- ten hour exposure, which we usually
24 use for adult work or risk. Because we typically

25 **DR. BUNGE:** Right. I understand that.

1 But on the other hand a dermal-tox study is a six hour
2 study; is that right?

3 **DR. LICCIONE:** That's correct.

4 **DR. BUNGE:** Okay. You do have a six hour
5 dermal absorption number in that paper. Was there a
6 reason to not use the six hour number since you would
7 have normally used a six hour dermal-tox results if
8 you'd had the time course data network to make it feel
9 comfortable in your risk assessment?

10 **DR. LICCIONE:** I'm going to turn it over
11 to the author of the actual study -- PV could explain
12 more.

13 **DR. HEERINGA:** Please introduce
14 yourself.

15 **DR. PRAKASHCHANDRA:** P. V. Shab, USEPA.
16 I think the reason the six hours that I did not use is
17 that in this study, the skin bound residue couldn't
18 actually remaining on the skin was considered as an
19 actual dose. Typically, the EPA guideline requires six
20 hours exposure, washing and then we follow it through
21 forty-eight hours, seventy-two hours depending on that.
22 And look at the activity in the urinary excretions.
23 That will help us in deciding whether the skin bound
24 residue is acerbic, acerbic or not. In this study, the
25 data did not -- the skin was not washed. The skin

1 bound residue was considered as an incidental. So to
2 be on the conservative side twenty four hours later
3 were used -- which is six percent in the adult.

4 **DR. BUNGE:** If I can follow up, I have
5 further -- at least one further question. If I recall
6 the paper correctly, it says that in six hours,
7 seventy-five percent of the absorbed dose had been
8 eliminated in urine. And, so, you've -- it seems as
9 though the dose -- we're assuming the six percent dose
10 that was observed over those twenty-four hours was all
11 absorbed as one bolus when we do the risk assessment.
12 Whereas we know from your data in the paper that in
13 that same six -- in a six hour period already, you
14 didn't -- you may have quoted the other number for the
15 twenty-four hour, but I don't remember it, but already
16 only 25 percent of that bolus is even still in the
17 body.

18 I don't know what how that would exactly
19 affect the risk assessment yet, because I haven't
20 thought it through that whole process, but would you
21 like to comment on the fact that in the risk assessment
22 calculation, we're using this twenty-four absorption
23 number -- twenty-four hour absorption number basically
24 assuming it's all introducing into the body or the
25 bolus even though we know that most of it, at least

1 three quarters of it, probably isn't there any longer?

2 **DR. PRAKASHCHANDRA:** The only thing the
3 data indicates that at six hours in an adult there was
4 two percent absorption. And in twenty-four hours we
5 had five point seven. So it looks like it's not a
6 bolus because we have a continued absorption appearing
7 in that.

8 **DR. BUNGE:** But in the risk assessment,
9 basically it's being assumed to be introduced as a
10 bolus. We understand that it's not, and your data
11 shows that it's not, but in the risk assessment the
12 assumption is six percent absorption, and then it's --
13 that number is used based upon the oral, which is
14 assumed to be a hundred percent absorbed; correct?

15 **DR. PRAKASHCHANDRA:** Correct.

16 **DR. HEERINGA:** Thank you, Dr. Shab.

17 Other questions of clarification? Again, we
18 can return to some of this later.

19 Dr, Bunge, are you -- Dr. Brimijoin, I think
20 -- no, no. I'm turning to you because I think you're
21 probably are -- have questions of most of everybody
22 here. Are you satisfied at this point? And again, if
23 anything else comes up, let us know, we'll ask it.

24 Yes, Dr. Schlenk? Oh, that's Dr. Bunge.

25 **DR. BUNGE:** Having said I didn't have

1 anymore questions. Annette Bunge. I do have one last
2 one. I think it was the very last slide where you talk
3 about the dermal exposure for workers, and this is in
4 the risk assessment. And going from the 2006 risk
5 assessment to the 2007/08 risk assessment, and the
6 number that you're using now increases by two-fold, you
7 may have said why that was, but I missed it?

8 **DR. REAVES:** Right. In the 2006 -- this
9 is Melissa Reaves. In the 2006 risk assessment, we
10 only had the first FMC study to base our oral end point
11 for the dermal scenario. The same for the oral end
12 point from the CCA study. However, in 2007, we
13 received all the other oral data; the EPA data, the
14 second FMC/CCA study, and so new BMD analysis was rerun
15 with all the data, and the difference in the BMDs then
16 is two-fold.

17 **DR. BUNGE:** Okay. So, it's just the
18 difference in the oral

19 **DR. REAVES:** Right.

20 **DR. BUNGE:** -- calculation of the BMD?

21 **DR. REAVES:** Right. So there's more
22 data in the point oh two BMDL.

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

24 **DR. SCHLENK:** Dan Schlenk. I just
25 wanted to follow-up on a question that was asked

1 yesterday before everyone left. I forget who -- maybe
2 it was Jim or somebody. But there was a question that
3 was asked -- the correlation between the RBC inhibition
4 of Cholinesterase with some of the motor activity, or
5 was there actually some Cholinesterase measurements
6 done in diaphragm or in the neuromuscular tissues, and
7 I think there was somebody who said that there was a
8 correlation somewhere. I went to the McDaniel and
9 Padia papers -- and I didn't see -- the only
10 correlation I saw was with motor activity. I didn't
11 see any correlation with sort of muscular enzyme
12 activity.

13 I was wondering has that been done? And just
14 so that I understand this, it seems to me -- because
15 it's very confusing because of all the different age
16 groups I think. But in that paper, at least the last
17 line says that brain Cholinesterase activities -- let's
18 see if I get this right -- says, these current data
19 support the use of brain Cholinesterase activity of all
20 RBC when evaluating neuro-toxicity for these chemicals.
21 Now, I assume that that's in the adult rats.

22 And then when I was looking at the
23 presentation yesterday, you have a presentation that
24 shows where the PMD 11 rats that motor activity was not
25 evaluated. So -- but brain and RBC data was -- or

1 Cholinesterase was. So, my question is, are you
2 extrapolating -- well, first of all, is there any
3 measurement of toxicity in the PMD 11 animals? And has
4 that measured toxicity been compared to the indicator
5 of exposure, which is RBC Cholinesterase? I guess
6 that's my question -- in PMD 11 animals?

7 **DR. MOSER:** This is Ginger Moser.
8 That's a great topic, and I could spend all morning
9 talking about it. But in the McDaniel paper, as you
10 say, we did the regression analysis with the brain
11 Cholinesterase and the motor activity, which is what's
12 up there right now. We actually did look at the same
13 regression with the red blood cell data, and the
14 correlation coefficient was a little bit lower. Now,
15 whether that was because of the higher variability in
16 the red blood cell data or is it just that it's less
17 correlated with motor activity -- it could be either
18 one -- you can't tease that out.

19 Some of the statements of the -- I had made
20 about corresponding to other types of motor effects or
21 other types of toxicity effects comes from some older
22 data that we published at least ten years ago. Mostly
23 with organic phosphates, and in particular,
24 chlorpyrophos. And in one paper we did actually look
25 at a lot of different kinds of in points, including

1 salivation and lacrimation some of the ergonomic end
2 points some of the other motor end points, as well as
3 tremors and fasciculations, and we did aggression
4 analysis with many different Cholinesterase measures,
5 including diaphragm, and including muscle, and
6 different areas of the brain, as well as plasma and
7 blood, and whole blood and red blood cell. And
8 basically, the bottom line from that was that the --
9 there was no one -- one tissue Cholinesterase
10 inhibition that correlated much -- much better than
11 anything else. And because the Cholinesterase
12 inhibition is all kind of correlated within the same
13 animal anyway, I think that's part of the reason why.
14 And that was all on adults.

15 Now, when you switch to the younger animals,
16 PMD 17, we have used a lot because of the fact that at
17 PMD 17 the animals are mature enough to start showing
18 motor responses and that sort of thing. At eleven days
19 of age, they don't move. They're very little. The
20 nervous systems are very immature. And, in fact, it's
21 somewhat difficult to even see signs of toxicity in the
22 PMD 11 pups because, for instance, tremors is one that
23 I'm always a little skeptical about. If you've ever
24 watched a PMD 11 pup, when it tries to take a step it
25 will kind of shiver, and some people call that tremors.

1 It's not tremors. It's, you know, just something that
2 they're doing. It's the way they're moving. They're
3 not very -- they don't have fine movement yet. The
4 nervous system is not myelinating at all. And, so, you
5 can't look at that. You can't look at motor activity.
6 Their cholinergic system is not well developed either.
7 So some of the cholinergic responses are sometimes not
8 there. So it's much more difficult to see clear signs
9 of toxicity until you get to the really high does where
10 you're getting out right convulsions and death and we
11 don't go that high. We don't want to.

12 So that's why in the PMD 11s, we have just
13 limited our analysis to the Cholinesterase inhibition,
14 and I think that that's why when other laboratories do
15 try to do some kinds of observations on those animals
16 it's variable -- a lot of it's going to depend on the
17 technician who's doing the observations. But maybe
18 they don't even understand the very limited repertoire
19 of the PMD 11 animal. So, therefore, we don't have
20 much of the toxicity data. We've never tried to do any
21 analysis of regression or correlations with
22 Cholinesterase inhibition in those animals.

23 I think that answers all your questions.

24 **DR. SCHLENK:** I think so. I just --
25 just to make sure that -- so you're basically

1 extrapolating from the PMD 17 to the PMD 11 as far as
2 the toxicity's concerned? Because you only have motor
3 activity in the 17 animals, and you're assuming then
4 that the toxicity would be the same in the 11 animals.
5 Is that -- would that be accurate?

6 **DR. MOSER:** We're assuming that because
7 we see changes in the adults -- in a lot of different
8 affects we see changes in the PMD 17 animals at low
9 dose -- you know, variable low levels Cholinesterase
10 inhibition -- that there is some toxicity going on in
11 the PMD 11 that we can't observe. But there is so many
12 other things going on in that PMD 11 animal that you
13 need to predict. You still got the whole nervous
14 system is being developed, and we know that
15 Cholinesterase has a major role on the development of
16 the nervous system that we're not going to get into
17 developmental neuro-tox at this point. But, I mean,
18 the assumption is that you need to protect against the
19 very low levels of Cholinesterase inhibition in the
20 young just like you do in the older animals.

21 **DR. SCHLENK:** Okay.

22 **DR. LOWIT:** Can I answer -- add one more
23 clarification.

24 **DR. HEERINGA:** Yeah. I want to move
25 things along here at this point.

1 **DR. LOWIT:** Sure.

2 **DR. HEERINGA:** Because I want to make
3 sure -- we're pressing on the point where we may not
4 even get public comment in. Dr. Lowit?

5 **DR. LOWIT:** I'm glad you're the chair.
6 We need to keep moving.

7 There's a context saying to the McDaniel
8 paper I just don't want to lose. That the McDaniel and
9 the Padia papers were developed in part of
10 accumulative to look at the class as a whole. But
11 certainly our experience has shown us that where
12 classes have patterns -- that each individual chemical
13 has it's own unique properties and unique
14 characteristics. So, take the conclusions on those
15 papers with the caveat that each chemical has it's own
16 properties.

17 **DR. SCHLENK:** Yeah. Actually, I looked
18 at the table that actually shows the piercing
19 coefficients for each chemical and actually that's what
20 I was basing my comments on is that table.

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

22 **DR. MCCARTY:** John McCarty. Just a
23 quick follow-up about the correlation here, and you've
24 shown some of the correlations, and you've also shown
25 Cholinesterase recovery in the rats. Is the same --

1 I'm assuming these are based on point estimates of
2 maximum inhibition. Is the same trend going to be
3 evident if we look at recovery? Will recovery of
4 behavior follow a similar time course as the recovery
5 in Cholinesterase activity based on this figure?

6 **DR. MOSER:** This is Ginger Moser, and
7 that's a very tricky question. Because it has been
8 shown that recovery of the behavioral of functional
9 deficits happens actually a bit more quickly than the
10 Cholinesterase recovery. Mostly the POPs because the
11 Cholinesterase inhibition lasts for so much longer.
12 But somewhat with the carbamates as well, and there are
13 other transient things that go on at the nervous system
14 synapse that are producing that recovery at a quicker
15 level.

16 **DR. HEERINGA:** Dr. Lowit, any last

17 **DR. LOWIT:** Yes, we're going to make --
18 Bill Jordan, who's now sitting here next to me, wants
19 to provide a little bit of context around -- to help
20 the panel, before you cut us off.

21 **DR. HEERINGA:** Okay. And there will be
22 opportunities to return to this, because I think you
23 have summaries before the charge questions. Dr.
24 Jordan?

25 **DR. JORDAN:** Thank you, Dr. Heeringa.

1 I understand that earlier in the discussion,
2 a question arose regarding the 21-day dermal toxicity
3 study in rodents, and some questions arose about the
4 basis for rejecting -- EPA's decision to reject that
5 study as a starting point for our analysis.

6 Our decision is grounded on concerns about
7 the methodology used in that study, which have been
8 explained. And I want to attempt to recover -- cover
9 that ground again. But another question arose about
10 whether it is appropriate to look at the human toxicity
11 -- human dermal toxicity study with carbofuran in order
12 to make some sense out of the 21-day dermal toxicity
13 study in rodents.

14 EPA has in place, as some of you will know, a
15 regulation regarding the consideration of human
16 intentional dosing studies. And we have evaluated the
17 human dermal toxicity study with carbofuran and
18 determined that we are not going to rely on it in our
19 decision making. That judgment, therefore, means that
20 we -- EPA -- have not cited that as part of our -- part
21 of the factors that we consider in evaluating the 21-
22 day dermal study in rodents.

23 However, if the SAP wishes to look at the
24 human study, we don't regard under our regulation that
25 EPA is relying on it. And if you think it is relevant

1 to evaluate the -- compare, for example, the levels in
2 human dermal toxicity study that elicited clinical
3 signs with levels in the 21-day dermal study that were
4 tested that would be permissible under our regulation.

5 **DR. HEERINGA:** Thank you, very much.

6 I guess, Dr. Bunge is taking notes.

7 **DR. BUNGE:** Just one clarification.

8 Under the Federal Advisory Committee Act, the two
9 separate functions of the two advisory committees are
10 distinct, and one doesn't revisit in a second federal
11 advisory committee of another advisory committee's
12 recommendations, so we're not going to discuss that
13 study at all during this meeting.

14 The human studies review board has already
15 made their decision. The agency's made their
16 recommendations, and those issues are not on the table.

17 **DR. HEERINGA:** Okay. At this point,
18 what I would like to do -- is we are about to enter the
19 period of public comment. And the period of public
20 comment -- if you just do the simple addition -- as
21 I've done -- on the agenda, which stretched for six
22 hours without any questions -- that obviously the
23 likelihood that there will be no questions is very
24 small. Not impossible, but probably small. So we'll
25 move right now to -- I want to call just a twelve

1 minute break to give people a chance to stretch and --
2 everything's going to be shortened up. We're on march
3 time today. So, a twelve minute break. Let's meet
4 back here at 10:00 a.m., and we'll continue with a
5 period of public comments.

6 **(WHEREUPON** Session A was concluded and a break was
7 taken.)

8 **DR. HEERINGA:** Okay, welcome back,
9 everybody, to the continuation of the morning session
10 from the second day of our meeting of the FIFRA Science
11 Advisory Panel on Scientific Issues Associated with the
12 Agency's Proposed Action under FIFRA 6(b) of a Notice
13 of Intent to Cancel carbofuran.

14 At this point in time, we are at the period
15 of public comment. The period of public comment will
16 include a number of contributions from people who have
17 registered to speak with the Designated Federal
18 Official, Sharlene Matten. Presentations will be given
19 in the order established by Dr. Matten which, I
20 believe, is the order of initial requests to speak.

21 We begin with a series of presentations by
22 FMC that we expect to last about three and a half
23 hours. I think that's in presentation time, and I
24 suspect it will go longer than that with questions,
25 followed in order by other registered public

1 commenters.

2 If anyone is in the audience and has not had
3 the opportunity to register as a public commenter, if
4 you would like five minutes...and that's sort of the
5 late arrival time limit...please see Dr. Matten during
6 the break or at noon hour. Otherwise, I think we're
7 set to being.

8 At this point in the process, I'd like to
9 open it up by turning to Dr. John Cummings of FMC
10 Corporation who will do introduction and overview on
11 new carbofuran use patterns and use production. Dr.
12 Cummings?

13 **DR. CUMMINGS:** Okay, thank you, Dr.
14 Heeringa, and thank you to the panel for allowing us
15 the time on the agenda, because this is a very
16 important action. And good morning.

17 What I'd like to start with is...is this
18 morning is to present a brief presentation prior to the
19 scientific presentations to set the stage for our...for
20 our comments and our...for our scientific position.

21 I would like to echo a couple of the EPA's
22 opening comments from yesterday and would agree with
23 their...their comments. One, obviously, is this is a
24 very important SAP panel hearing and, to a degree,
25 historic. I think I'd use...I heard that word

1 yesterday.

2 And the other comment I would like to echo
3 from the EPA's opening remarks yesterday is that
4 certainly, the SAP should consider all relevant and
5 currently available data in determining the nature and
6 magnitude of risk that carbofuran presents to public
7 health and the environment.

8 Also, as you heard yesterday, FMC, the
9 registrant, has submitted significant amount of
10 new...new data, new information that refines the risk
11 assessments, and following the scientific
12 presentations, hopefully, you will conclude, as we
13 believe, strongly supports the continued registration
14 of carbofuran in the United States. Said another way,
15 that it meets...carbofuran meets the FIFRA and FQPA
16 scientific standards for registration and re-
17 registration.

18 So, the format of the presentations today, as
19 Dr. Heeringa has mentioned, is that I'll be providing
20 a...an introduction which primarily focuses on two
21 pieces. One is on the use of carbofuran, how much is
22 used and where it is used and the relevance for risk
23 assessment. And then, also, to focus in on registrant-
24 initiated mitigation measures that have occurred over
25 the past several years to mitigate potential concerns

1 as well as to detail, provide a little bit of detail,
2 on the proposed label as we've...as we've briefly
3 discussed over the last day to provide some context for
4 that as well.

5 Following the introduction, I think it
6 probably appropriate to pause after that, any
7 clarifying questions if the...if the chair chooses to
8 do so, and then move into the scientific presentations
9 on avian risk, worker risk, human health and dietary
10 risk, as well as water risk, and you'll hear that from
11 a panel of experts which I'll detail in a few moments.

12 On this slide, really, the key message here
13 is that if you look at the table to the right-hand side
14 of the screen, carbofuran used to be widely used in the
15 late '70s, early '80s very widely on numerous crops.
16 If you look at it, for a typical year in the peak year
17 of sales was around...typ...typical use was 10 million
18 pounds of active ingredient per year. And, again, this
19 was in the late '70s and early '80s.

20 Primarily due to market forces, the
21 introduction of alternatives and...and...and other
22 elements, this use has declined in 2006 to roughly 6
23 percent of its peak year sales. So, only 600,000
24 pounds of active ingredient per year.

25 This is important, I think, in consideration,

1 as you heard yesterday from the incident reports and
2 other elements that the Agency presented. We certainly
3 do need to consider this...this limit, very limited use
4 in the relevance of the incident reports, incident
5 reporting, that were pre-1995. Is that information
6 relevant? And...and...and it is our position that that
7 probably should be weighted much less than the most
8 recent data post 1995.

9 As you see on this slide also, there is a
10 projected sales, and this is projected at about 300,000
11 pounds, only half of what is currently being used. And
12 this...I'll...I'll spend a little bit more time on
13 this, and this is really what FMC and many of our
14 experts project will be used in the future based on our
15 proposed label changes.

16 The...and, also as you heard from the Agency
17 yesterday, really, the 99 percent of this...of the use
18 of that 600,000 pounds currently being used is in the
19 flowable or liquid formulation. There is a very small
20 use of granulars, accounting for 2500 pounds, 2,500
21 pounds of active ingredient per year, and this was
22 arrived at with a...through negotiated settlement with
23 the Agency back in 1991. So, very limited use, and the
24 focus will be on the liquid formulation.

25 A question may arise from the panel on why is

1 FMC, the registrant, interested in...in...in retaining
2 carbofuran for 300,000 pounds of active ingredient per
3 year when we used to sell 10 million pounds, and that's
4 a very good question to ask. Really, there's two
5 primary reasons.

6 One is that we have gotten strong indications
7 from the growers, from the users of our product, that
8 there are essentially five uses that are critical.
9 There are no viable alternatives available out on the
10 marketplace today or in the near horizon. And,
11 certainly, from an economic perspective as the company
12 who sells this product, we see that there is an
13 ec...economic reason to continue that registration.

14 The other reason is we are firm believers, as
15 members of...responsible members of the agricultural
16 chemical industry, that regulatory decisions should be
17 based on sound scientific principles, and I think
18 that's why we're all here today. And, certainly, as
19 you'll hear throughout the day, our position is that if
20 sound science is used, then carbofuran should be
21 registered, and, certainly, we are willing...we
22 are...we are interested in keeping this product on the
23 market because risks are acceptable. Okay? So, you
24 factor those two pieces in together.

25 Now, I mentioned the critical uses, and I'm

1 not going to spend a lot of time on this. However, I
2 think it's important as context.

3 Benefits assessments, both from a biological
4 and economic perspective, have been provided to the
5 Agency. They have not been provided to the science
6 advisory panel. However, there is extreme economic
7 value for retaining the following uses, that is, use on
8 corn, use on cotton. I'll spend a little bit more time
9 on that. Potato growers have indicated it's critical
10 for use in the Pacific Northwest. Melon growers and
11 sunflower growers have all said there is not a viable
12 alternatives, and there's significant information
13 that's been provided to the Agency to show the economic
14 and biological value of these products...of this
15 product on these uses.

16 Moving to the scientific part...portion of
17 this discussion, when the interim re-registration
18 eligibility decision came out in 2006, August of 2006,
19 FMC assembled a world class panel of experts in these
20 four areas, avian, worker, acute dietary, and ground
21 and surface water, to advise us to say this is the
22 current risk assessment by the Agency. Assess the
23 scientific validity of their assumptions, recommend are
24 there other studies, data that could be developed to
25 refine this, and are there refinements in the

1 risk...other refinements in the risk assessment that
2 would be useful in reducing the uncertainty and
3 improving the risk assessments.

4 As I mentioned previously, also in that time
5 period, experts were assembled to address the benefits
6 of these products as well, working closely with the
7 commodity organizations and the individual growers of
8 these...of...of these commodities.

9 There have been significant mitigation
10 measures that have been put in place, and I think
11 the...the EPA did highlight some of these yesterday and
12 mentioned that FMC has implemented significant
13 mitigation measures over the years, over the last 20
14 years, primarily the first...I'm not going to walk
15 through these individually, but the first five bullet
16 points, really, I think the Agency had similar
17 presentation yesterday indicating that FMC has
18 initiated an effort to mitigate any concerns in
19 potential vulnerable areas on risks for carbofuran to
20 reach groundwater and surface water.

21 And many of these are geographic
22 restrictions, reducing number of application rates,
23 reducing...or, I'm sorry...application rates and
24 numbers of application rates, and the geographic
25 restrictions being focused on vulnerable soils.

1 Again, these are...these have been
2 implemented. They are on the current label, that is,
3 in the marketplace today.

4 Shifting to worker exposure, the next to last
5 bullet point on the slide before you, all furidan,
6 carbofuran-containing products, are...liquid products
7 are in state-of-the-art mixing and loading closed
8 systems. You'll hear a lot more about that when
9 our...our panel of experts from work...from the worker
10 risk assessment come up to show that, really, there is
11 minimal exposure to...minimal occupational exposure to
12 the workers.

13 Also, last but not least, there is an
14 extensive product stewardship program that FMC heads
15 up, including brochures, extensive education programs
16 out for the users of our products. Unfortunately, with
17 the time today, we don't necessarily have a lot of time
18 to cover that, but it is extensive.

19 Unfortunately, as you look at this list of
20 already implemented programs and...and label changes, a
21 lot of these mitigation measures have not been
22 accounted for in the current EPA assessment that's
23 been...that's before you at this point and really led
24 to overly conservative assump...conclusions from our
25 perspective.

1 Let me shift now. What I just talked about
2 was the mitigation measures that have been implemented.
3 Let me shift to saying...to...to the major items of the
4 proposed label that has been briefly discussed over the
5 past day.

6 Essentially, what FMC has proposed is to only
7 retain five uses, those critical uses that I mentioned
8 before, in the current label. That results in the
9 removal of 12 federally registered uses, removal of 13
10 state registered, what's known as special local need
11 uses, as well as additional prohibitions and
12 restrictions in areas essentially vulnerable
13 to...vulner...in vulnerable water bodies, and I'll
14 detail that in a little bit more in...in...in a future
15 slide.

16 So, if we look at the uses...and this is just
17 more of a...a graphic representation of what uses are
18 being proposed to be retained. If you look on the
19 right-hand side of the slide, there are those five uses
20 which I touched on before, melons, sunflowers, field
21 corn for post-application only, potatoes in the Pacific
22 Northwest, and the pending cotton use.

23 And I do want to pause there briefly to just
24 mention some...provide some clarification, because
25 there were...Dr. Bradbury this morning did mention the

1 cotton use not being registered. I just want to
2 provide some clarification on the situation there.

3 If you look on the left-hand side of the
4 screen, there is a registered use on cotton at plant.
5 We are proposing to cancel that use. The pending use
6 which EPA petitioned EPA for adding the use of cotton
7 foliar treatments for control of aphids in 1995. That
8 petition has been pending at the Agency since 1995.
9 Okay?

10 We have included that in our proposed label,
11 and after we submitted the label in early December or
12 mid December of this past year to the Agency, we
13 received notification from the EPA that there was a
14 deficiency in that pending petition. Okay? So, we
15 are...we feel it is our right to include cotton,
16 because it is a pending use. It is not a new
17 submission. We're not proposing to add a new use. It
18 has been pending at the Agency for the past 13 years.

19 Included on the retained...in the proposed
20 label are also the phase-out crops which the Agency has
21 proposed to phase out over four years as well as, as I
22 mentioned before, the existing granular uses that are
23 very limited, limited to 2500 pounds per year.

24 Also included on the...included on the
25 proposed label are further limitations, mitigations, to

1 address potential for surface and groundwater...well,
2 for carbofuran reaching surface and groundwater. These
3 are based on our panel of experts which you'll hear
4 from shortly, looking at the data, identifying
5 vulnerable areas, and we took those recommendations and
6 included those conservative mitigation measures on our
7 proposed label.

8 They include geographic restrictions, best
9 management practices, and they are consistent in as you
10 look at currently registered labels of other
11 carbamates. These mitigation measures are consistent
12 with other carbamate labels.

13 The end result, from our perspective and in
14 our conservative risk assessments, that these result in
15 drinking water concentrations estimated below the level
16 of concern by the Agency.

17 And I'm not going to go through this slide in
18 detail. You have this packet before you. But,
19 essentially, this highlights the restrictions that we
20 are proposing on the label for both...vulnerable both
21 ground and surface water areas. They include
22 prohibited applications within a certain distance,
23 buffers, in specific counties and, in some cases,
24 statewide, to address surface water areas. And from a
25 groundwater perspective, there are statewide

1 prohibitions, as you can...as you can read from the
2 slide in front of you, as well as applications being
3 prohibited within a certain distance, well setbacks,
4 from all wells in several states and several counties
5 that have been identified by our experts as being
6 potentially vulnerable.

7 The final mitigation measures in the proposed
8 label address avian concerns, and, again, our avian
9 effects advisory panel, again, which you'll hear much
10 more in detail in a few moments, have done conservative
11 risk assessments on...on the five critical uses as well
12 as alfalfa. And the inclusion for alfalfa is it is a
13 very economically important critical use. However,
14 based on our...our avian effects advisory panel's
15 recommendation, we are proposing to remove alfalfa
16 because of the risk assessment did identify relatively
17 higher risks on gorge feeding waterfowl.

18 Generally, the remaining uses, the five
19 critical crops, have low or de minimis avian risk, and
20 you'll hear much more in detail from the avian panel
21 shortly.

22 Let me just introduce...and this is the order
23 of...of presentation. Let me just introduce the...the
24 principal presenters and the members of these various
25 advisory panels.

1 The first presentation will be on avian
2 effects. Dr. Dwayne Moore and Dr. Keith Solomon will
3 be presenting on behalf of this avian effects advisory
4 panel, made up also of Lou Be...Dr. Lou Best and Larry
5 Brewer and Dr. John Geisy.

6 Dr. Solomon will be...will be reviewing the
7 additional studies that have been submitted by the
8 Agency...or by...submitted by FMC, and then, Dr. Dwayne
9 Moore will be presenting the Liquid PARAM which was
10 briefly discussed yesterday.

11 That will be followed by a worker risk
12 presentation. Dr. Jim Lam will be presenting the
13 toxicology studies that will be the dermal tox studies
14 and the...and our position on the appropriate
15 endpoints, and then, Dr. Jeffrey Driver will be
16 presenting the exposure and risk assessment for
17 workers.

18 The third presentation will be on human
19 health and dietary risk. Again, Dr....Dr. Lam will be
20 presenting on the toxicology point of departure and use
21 of uncertainty factors. Then, Dr. Bob Silken will be
22 presenting a statistical analysis on this data, and
23 finishing off will be Dr. Robert Morris to again do the
24 exposure and risk assessments for dietary.

25 The final presentation will be from...will be

1 from our water panel of experts, Dr. Engel, Dr.
2 Fawcett, and Martin Williams, addressing exposure and
3 risk assessments relating to ground and surface water.

4 So, prior to concluding, I just want to make
5 a couple of conclusion...concluding comments. As you
6 heard from the Agency yesterday, carbofuran has been
7 registered since 1969. FMC has been the sole
8 registrant in the U.S. for 40 years. We take very
9 seriously our responsibility to comply with the law as
10 well as steward our products.

11 We feel confident, based on real-world
12 experience using carbofuran for the past 40 years, that
13 it can be used safely in the United States and does not
14 pose unreasonable adverse...unreasonable risks or
15 adverse effects to human health and the environment.

16 As you will see over the next several hours
17 as we present the additional data and the refined risk
18 assessments, we further believe this more strongly
19 supports, in addition to the...the 40 years of use,
20 that carbofuran does meet the FIFRA and FQPA regulatory
21 standard, and its products should not be canceled.

22 At this point, I'll turn it back to the...Dr.
23 Heeringa.

24 **DR. HEERINGA:** Thank you very much, Dr.
25 Cummings. Any quick questions of clarification for Dr.

1 Cummings? Yes, Dr. Brimijoin?

2 **DR. BRIMIJOIN:** So what happens to the
3 projected volume of use if the foliar treatment of
4 cotton is added?

5 **DR. CUMMINGS:** That is actually included
6 in those projections, yes.

7 **DR. HEERINGA:** Dr. McCarty and then Dr.
8 Montgomery.

9 **DR. MCCARTY:** One of the, quote,
10 special...special local needs uses is for Conservation
11 Reserve Program land.

12 **DR. CUMMINGS:** Yes.

13 **DR. MCCARTY:** I...in the documents,
14 there may be something there, but I haven't seen
15 anything about the extent or frequency that that's
16 permitted. Do you have any comment on when this...when
17 and how often this is used on CRP?

18 **DR. CUMMINGS:** I actually don't have
19 that information. I'd ask Dr. Carlson if he has...if
20 he'd like to come forward and address that.

21 **DR. CARLSON:** My name is Don Carlson...

22 **DR. HEERINGA:** Step up to the
23 microphone, Dr. Carlson.

24 **DR. CARLSON:** My name is Don Carlson.
25 I'm with FMC Corporation. My responsibilities are

1 product development and registrations for carbofuran.

2 The answer to your question is that there is
3 relatively little use in the Conservation Reserve
4 Program at the current time. The primary use was for
5 control of grasshoppers, and there are other
6 alternatives for that particular use.

7 **DR. HEERINGA:** Dr. Montgomery had a
8 question, too.

9 **DR. MONTGOMERY:** Hello, this is Cheryl
10 Montgomery. I just have a quick question for you on
11 your slide that deals with amended label reflecting the
12 limited uses of carbofuran.

13 On the alfalfa, you specified on a slide
14 subsequent to this was being removed because of the
15 potential for gorge feeding of wildlife. I was
16 wondering, without going into detail, just kind of
17 categories, what the reasons for removal of...there was
18 quite a few removals that are here, and I was wondering
19 if you could give us some broad categories of reasons
20 why you are voluntarily removing these.

21 **DR. CUMMINGS:** Well, generally, there is
22 still limited use in some of these areas, but
23 generally, there are adequate alternatives, and in some
24 cases, there...they may be identified as a critical,
25 very niche use of the product, very small volumes, but

1 in some cases, they may be aligning with some of
2 our...the vulnerable areas that our experts have...have
3 identified, for instance, in Florida. There are some
4 uses that just fit the Florida use pattern that we're
5 proposing to remove. Okay?

6 So, I think broad categories, it's limited
7 use, adequate alternatives, and really, the predominant
8 geography where that would be used is we're proposing
9 to remove from the label. Those are kind of the
10 two...two buckets.

11 **DR. HEERINGA:** Thank you very much, Dr.
12 Cummings. And I think at this point, let's move on to
13 the first of the scientific presentations, and I think
14 Dr. Keith Solomon of the University of Guelph is here,
15 along with Dwayne Moore, and Dr. Solomon will be up
16 first.

17 Panel members, I...I think Dr. Solomon can
18 confirm, but I'd let both individuals do their
19 presentations before we open it up for questions.

20 **DR. SOLOMON:** Mr. Chairman, panel
21 members, EPA staff, others, I am Keith Solomon from the
22 University of Guelph, and I'm here at the request of
23 FMC Corporation and a panel member of the avian panel
24 that advised FMC on risk assessment, additional
25 studies, and also modeling issues.

1 So, next to me, is Dwayne Moore who will
2 present the modeling part of the presentation, but also
3 at the table, Lou Best and Larry Brewer. Larry Brewer
4 conducted many of the studies that were talked about
5 yesterday and that we will touch on briefly today. Lou
6 Best has extensive experience in field work and perhaps
7 best answer questions from the panel members in that
8 regard.

9 Dr. John Geisy has a longstanding teaching
10 assignment in China, and he sends his apologies for not
11 being able to attend.

12 The RED and the Notice of Intent to Cancel in
13 2006 and 2008 concluded that carbofuran poses an
14 unreasonable risk to the environment based on effects
15 on avian species. In coming to this conclusion, EPA
16 used a TIM 1 model which predicted high mortality in
17 some species of birds and was based on a number of
18 conservative assumptions.

19 The TIM 1 model which was talked about
20 yesterday is...is inappropriate, I think, for the
21 use...for risk...doing risk assessments on carbamate
22 pesticides, because, for one...just for one thing
23 alone, the time step involved is not...not appropriate.
24 But we did try to use the TIM 2 model, but,
25 unfortunately, could not get it to function on our

1 computers. The TIM 2.1 model which we heard about on
2 January 8th this year we have not been able to use.

3 So, based on that, we set up our own model
4 which Dr. Moore will talk to you about a little bit
5 later.

6 The avian effects advisory panel conducted a
7 refined risk assessment, and we started off by
8 identifying data gaps. We then commissioned studies to
9 fill these gaps. We developed a higher tier risk
10 assessment model, Liquid PARAM, and we also looked at
11 other lines of evidence from real-world studies and
12 incident data.

13 We have concluded that carbofuran can
14 continue to be safely used on all of the crops
15 considered in this...in the assessment. The exception
16 to this...and you heard about this earlier...was for
17 the unique situation where waterfowl gorge feed in
18 alfalfa, and this is now being removed from the label.

19 All of the documents that support our
20 discussions here today have been provided to the panel.
21 The slides are in hard copy. There are some overview
22 reports in hard copy, and there's also a CD which has
23 all the information on...in PDF and other files.
24 There's also a copy of the model, if anybody's
25 interested in that.

1 So, our objectives were to define...to refine
2 the risk assessment and to generate new data and also
3 to incorporate this in a more definitive model to
4 consider several lines of evidence, and this was based
5 on, as you heard yesterday, advice that came from
6 earlier saps in 2001 and 2004.

7 And for the studies that we developed, there
8 are no guideline studies here. These are...these are
9 really studies to understand the science and not yet
10 used widely, so no guideline studies, and at least in
11 my experience, if you take those protocols in to EPA,
12 they will decline to comment on them.

13 So, we did studies on avoidance repellence,
14 on the effect of dietary matrix, and rate of recovery
15 of cholinesterase, as you heard about from Robert
16 yesterday. We also incorporated in the model the
17 significance of time distributed feeding and increased
18 the number of use scenarios and also increased the
19 number of species in the model, as Dr. Moore will tell
20 you about later.

21 And these results were then verified...this
22 is perhaps a touchy word, verified...against field
23 data, but if you go back to 1992 guidance on ecological
24 risk assessment, this is one of the points that they
25 make about models, that they can be verified against

1 field data.

2 Just to explain some of the issues that we
3 were looking here in terms of avian effects, when one
4 thinks of a bird and how it becomes exposed and how the
5 carbofuran might get to the target site, there are a
6 number of steps involved in this...in this process. Of
7 course, the first of these is the uptake of the
8 material by the animal and repellence, whether it's
9 gustatory or symptomatic, can reduce uptake of the
10 material.

11 And then, the other fact, it's quite
12 different from a laboratory study where you dose an
13 animal with a single gavage dose. Feeding would be
14 spread over a period of time, short or long, depending
15 on the nature of the birds involved, but all of these
16 would change the way the material enters the organism.

17 Once in the gut, one can see that the
18 absorption rate might be affected by the matrix that is
19 present in the gut at the same time as the...as the
20 substance, so if it's on food particles or in the water
21 that's consumed while the animal is feeding, the matrix
22 in the gut could reduce uptake into the body.

23 After that, metabolism...and this is well
24 understood...can remove the material from the blood and
25 the other organs, and then finally...and you can see

1 the diminishing size of the arrows...some material will
2 get to the target site, cholinesterase in the central
3 nervous system which, we know, recovers quickly via
4 hydrolysis of the carbomanated enzyme via K3.

5 So, this results, really, in a...in a
6 diminishing of the potential for adverse effects
7 through all of these intermediate steps in the process.

8 These processes are additive and, possibly,
9 multiplicative. We don't know. But all of them appear
10 in...in the real world, and there's a sequence that you
11 have to go through.

12 And the TIM 1 model really only addresses
13 metabolism. It doesn't address these other factors
14 that we've listed on this slide.

15 So, our first approach was to do a study on
16 repellence and avoidance, and this is not captured in
17 acute toxicity studies where a material would be
18 administered in a water bolus or an air bolus. And,
19 incidently, there's no formal guideline for this, but
20 there is an OECD draft guideline from 2003, and there
21 has been work done in the literature on this as well,
22 and we used this as guidance to develop the protocol
23 with a choice of uncontaminated and contaminated feed,
24 as you heard yesterday.

25 Mallard was used as a test species,

1 consistent with the literature, and food consumption
2 and spillage was very carefully measured. And if you
3 need more detail on that, Larry Brewer will be able to
4 help you out there.

5 To basically go to the results fairly
6 quickly, what this shows here is...first of all, you
7 heard yesterday that there was a...a change in the
8 feeding pattern of the animals in both the controls and
9 the treated animals, the animals in the...in the test.
10 So...and this is probably because of the increased
11 observation that occurred over the changeover time and
12 the animals reacting to the presence of humans in the
13 system, but it occurred in both the controls and the
14 test organisms.

15 So, what we did here was to take the initial
16 weight adjusted, because animals of different weight
17 consume different amounts of food, and we took the zero
18 day weights, and we did a mean reduction in food
19 consumption relative to the controls. So, this is
20 standard biological experimental technique, is to
21 compare results to control.

22 And what you see here is a very significant
23 reduction in food intake shown in these numbers
24 below...zero would be the control...with increasing
25 exposure in the diet. We then took this data and

1 modeled it on the...on the presumption that turned out
2 to be correct, that there was a threshold of avoidance.

3 And this, on the y axis, you see the
4 reduction in food intake rate which is abbreviated as
5 FIR, and concentration in the diet in a log scale on
6 the x axis, and there's a threshold of repellence or
7 avoidance here at 3 mg/kg in the diet which translates
8 to 0.119 mg/kg body weight.

9 And then...so, this would not be considered
10 in the model below this threshold. However, exposures
11 above the threshold we would use the...the slope of
12 that regression there to factor this avoidance into
13 a...a model which you'll hear about later.

14 We believe this was an appropriately
15 conducted study. One of the suggestions was to scatter
16 the food around on the surface to more directly mimic
17 the environment, but it's extremely difficult to get
18 accurate measurements if you do this or even if you put
19 it in numerous feeders.

20 If you do it on an hourly time scale which
21 would, we agree, would be very useful, the hourly
22 disturbance of the birds in...in the cages would, I
23 think, have a greater influence on the results than the
24 actual chemical itself.

25 Starved birds, we don't believe it's

1 appropriate to use them. It distorts the initial
2 feeding rate, and it's not realistic. Birds in the
3 field would not starve themselves in anticipation of
4 the carbofuran application.

5 There's no learning of the location of the
6 food or contaminated food items, because the feeders
7 were switched each day to prevent that from happening,
8 and we heard yesterday some discussion about feeder
9 location bias, and there was no consistent propensity
10 to use left or right, and so, we had, I guess, right-
11 wing and left-wing birds in our system, and we...I'll
12 show you the data for that in a moment, but this was
13 basically controlled for by switching feeders each day.

14 This is just a distribution of all of the
15 birds used in the study color coded. I apologize for
16 the Christmas tree-like effect here, but it's...so, the
17 birds that are on the right-hand side of that line in
18 the center, they were biased towards the right feeder
19 consistently over the study. On the other side, they
20 were biased towards the left feeder, and there's no
21 obvious relationship here to the treatments that they
22 were receiving or the control or the different doses in
23 the...in the feed.

24 So, repellence and...and avoidance, this
25 reduces the food intake rate at dietary concentrations

1 that are relevant to field exposures. It's not
2 applicable to gorge feeding waterfowl, and...and we
3 have never claimed that or...and we would not use it in
4 that situation anyway.

5 The reduced food intake rate did not lead to
6 mortality. The animals continued to eat, and they ate
7 both the treated and the untreated feed but at...at a
8 slower rate. The increased food...the increase that we
9 might expect in food intake rate at...after cessation
10 of exposure was only observed at the highest
11 concentration, and, again, this is consistent with what
12 you see in the literature.

13 I think also interesting is the fact there
14 was no weight loss in the birds. They didn't gain
15 weight, but they didn't lose weight, either, so they
16 were able to maintain at least their baseline metabolic
17 needs over the period.

18 The next issue I'd like to address, a lot of
19 evidence here, is the absorption of carbofuran from out
20 of the food matrix. The food...the food matrix is
21 basically toxicologically inert, and any binding to
22 this or just the mere physical presence of a matrix
23 there will slow diffusion of any chemical
24 into...through the gut to the body wall and then, of
25 course, up...the subsequent uptake.

1 So, both of these factors may reduce the rate
2 at which the chemical enters the body, and this,
3 obviously, can have a significant effect when you have
4 metabolism and recovery of cholinesterase operating at
5 the same time.

6 The animals were given a bolus dose in a
7 mixture, a slurry of water and food, by gavage. These
8 were compared to animals that were given a water bolus
9 which is common in toxicity testing. And this was the
10 hypothesis we were testing, is there a difference
11 between a feed bolus and a water bolus?

12 The control...you heard some discussion about
13 controls yesterday. The appropriate control for this,
14 in fact, is the food matrix bolus, because this is an
15 unusual dosing technique. The water boluses are used
16 routinely, and...and we know what they mean in terms of
17 acute toxicity testing, but the food matrix bolus here
18 was used as a control to make sure that the matrix
19 itself and the handling the birds were receiving was
20 not causing any adverse effects, and there were no
21 adverse effects in the control.

22 Then we look at the data showing initially
23 bobwhite quail and the increase in response to
24 increasing doses of carbofuran via the water bolus
25 route. When you give those same animals...or

1 not...sorry, not the same animals, but when you give
2 bobwhite quail the slurry of the food matrix, you see
3 it shifts the toxicity values to...to much higher
4 concentrations or doses, in this particular case.
5 You'll see no response in the matrix dosed animals
6 there and only the initiation of response at this
7 concentration here.

8 You see essentially the same effects in
9 mallards, although there were fewer doses tested here
10 because of availability of animals, but, basically, one
11 sees the same general pattern.

12 But when you take a percent mortality...and
13 this is in the bobwhite data...and you look at the dose
14 of carbofuran in mg/kg body weight which would be then
15 equivalent to the LD50 via a water bolus route, you'll
16 notice the data there with an LD50 of 2.64. When it's
17 mixed with a matrix, what you see is a different LD50.

18 Now, this doesn't mean that the...and I'm now
19 teaching you to suck eggs here, I guess, but this does
20 not mean that the...that there's toxicity. It means
21 there's less exposure, and in conjunction with
22 metabolism, there is less material reaching the target
23 sites. So, 3.8 times less toxic.

24 This study, we believe, again was a good
25 quality study. There was no initial regurgitation of

1 food. There were very careful procedures put in place
2 to observe this, a white paper put under the animal
3 cages so that anything that was regurgitated could be
4 seen. There was some regurgitation of opaque fluids,
5 not food matrix, and this was seen later and was
6 probably a symptom related...in relation to the effects
7 of cholinesterase inhibition on saliva production, et
8 cetera.

9 There was a slight delay in symptoms in the
10 matrix fed birds, but, of course, you needed a much
11 higher dose in them anyway, but this was expressed
12 within the 1-hour time step that was appropriate to use
13 in Liquid PARAM, so this was used in the modeling.

14 So, the rate of absorption of carbofuran is
15 significantly reduced from a food matrix, and,
16 therefore, the use of acute toxicity test results such
17 as the traditional water bolus or oil bolus, LD50,
18 overstates the potential risks posed, and for this
19 reason, we used a dietary adjustment factor that Dr.
20 Moore will talk to you about in a minute in the Liquid
21 PARAM model.

22 The last issue I wanted to just introduce
23 quickly was the recovery of cholinesterase, and we
24 heard a lot about that yesterday afternoon and more
25 this morning. What this does is really gets around all

1 of these issues and focuses just on the target site
2 which there's a well-known process that occurs here
3 that you're already familiar with, but the key reaction
4 here is the hydrolysis of the carbomanated
5 cholinesterase which releases the serine hydroxyl to
6 allow the enzyme to return to its normal function, and
7 this is governed by K3.

8 This is dependent on the tertiary structure
9 of the enzyme itself, and the group, the carbamyl group
10 here, which is the same for most carbamates and is
11 consistent across many of the carbamates.

12 So, what you're really doing here is looking
13 at a combination, in a sense, of metabolism, because
14 the chemical is now in the animal, and the target site,
15 and this is important, because this is the target site.
16 This is the mechanism by which the chemical is directly
17 toxic. So, this integrates a very important effect
18 measure that is relevant to the assessment in point of
19 mortality.

20 So, in this study, we used animals that were
21 dosed with water, so there's no matrix effect, and the
22 brain cholinesterase, acetylcholinesterase, is measured
23 at time intervals after dosing, and then recovery
24 assessed against control values. So, plotting the
25 cholinesterase activity on the y axis in terms of brain

1 weights and time since initiation of exposure, when you
2 look at the controls, what you see is a mean of around
3 12, with a 95 percent confidence interval going below
4 and above that, so that would be the range we would
5 normally expect to see the controls in.

6 At the lowest dose tested, we saw rapid
7 recovery into the control range. At...and this, with
8 increasing dose, became longer.

9 Now, the reason for the increased length
10 here is not because the cholinesterase is somehow
11 changing. It's because there's a combination here of
12 metabolism trying to catch up, and if there's a larger
13 amount in the body, if the enzyme is reactivated, then
14 there still may be enough carbofuran to re-inhibit
15 again which would lengthen the recovery time.

16 These recovery times were used to calculate
17 the half-lives, but it's perhaps interesting that the
18 half-life of recovery of cholinesterase is used as sort
19 of a forensic threshold, and in the...in the trade, if
20 an animal is above half of the control value in terms
21 of brain cholinesterase, it will be likely to survive.
22 So, this would be an indication of no permanent adverse
23 effect.

24 So, using this relationship between the half-
25 life on the y axis and the dose on the x axis in mg/kg

1 body weight, we chose from this relationship a
2 conservative value of 4.4 hours as the half-life for
3 integration for recovery into the Liquid PARAM model.

4 So, it's a rapid half-life. It's...it's a
5 little bit conservative, and it's definitely quite
6 different from EPA's elimination half-life which is
7 based on metabolism in chickens that was used in TIM 1,
8 and that is...it's probably inappropriate to use that
9 type of data for carbamates because of the very rapid
10 recovery of cholinesterase in those organisms.

11 So, with this, I would pass over directly to
12 Dr. Moore, and with the permission of the panel, we'll
13 hold our questions until the end of his presentation.

14 **DR. HEERINGA:** Thank you, Dr. Solomon.
15 Dr. Moore?

16 **DR. MOORE:** I thank you to the panel, to
17 the chairman, and interested observers for the
18 opportunity to speak this morning. My name is Dwayne
19 Moore. I'm with Intrinsic Environmental Sciences in
20 Canada. As...as with Keith and the rest of the panel,
21 I was asked by FMC to assist with the avian risk
22 assessment for carbofuran.

23 What I want to talk about over the next 45
24 minutes to an hour, very briefly, a little bit about
25 model development history, talk about the exposure

1 assessment, and that would be the majority of my talk.
2 Will talk about model structure, the inputs, and also
3 spend some time talking about how we evaluated model
4 performance. Then finish with discussion about the
5 risk characterization and results that we obtained, the
6 results that we obtained when we looked at better lines
7 of evidence, and then have some conclusions and
8 thoughts for the panel to consider.

9 Just for your information, the...the model
10 itself that I'm going to spend most of the time talking
11 about is described in, I would consider, in exquisite
12 detail in the...the refined risk assessment report that
13 was included in your package. It's Moore, et.al., 2007
14 is how I refer to that. If you're like me, you have a
15 social life...or don't have social life, you would
16 consider it exquisite, and otherwise, you would
17 consider it excruciating.

18 The exposure assessment is described in
19 chapter 3, the effects portion of the model is
20 described in chapter 4, and the risk portion of the
21 model is described in chapter 5.

22 A little bit of background, and you've heard
23 some of this yesterday and this morning. TIM Version 1
24 was originally developed by EPA and submitted to the
25 science advisory panel for review in 2001, and as you

1 heard yesterday, EPA believes that that review plus the
2 subsequent review in 2004 of a different version of the
3 model allows them to then us that model and not have to
4 worry about questions concerning model structure for
5 this carbofuran assessment that you're charged with
6 reviewing here today.

7 But I would like to suggest, at least, that
8 the mere act of reviewing models does not constitute
9 endorsement of the models. Lou Best and I were both
10 participants in those science advisory panel meetings,
11 and there was no endorsement of those models.

12 What there was was encouragement to continue
13 the model development. I think that's a very important
14 point. Avian risk assessment models for flowable
15 pesticides are just really getting going. That model
16 that was developed in 2001 was the first probabilistic
17 avian risk assessment model for pesticides, and so, as
18 you would expect with any young science, there is as
19 need for continued development, maybe a need for
20 continued development going forward from today
21 and...and I hope five or six years from now, we're
22 talking about new versions and...and better models than
23 what we have before us.

24 At that science...science advisory panel
25 meeting in 2001, as I said, the panel was encouraging,

1 but they made many suggestions for improvement of that
2 model. And as you heard from Keith, new studies have
3 also been commissioned and completed by the registrant,
4 and there's new information available in the literature
5 that are relevant to model development.

6 So, it...it's...it seemed an opportunity,
7 then, for FMC to take advantage of the model
8 development that had already occurred, the
9 recommendations that had been provided by the science
10 advisory panel, and with the new information that had
11 been commissioned by the registrant as well as what's
12 in the literature, it seemed time to develop a much
13 more refined risk assessment model.

14 That's what FMC commissioned this panel to
15 do. That model and the accompanying avian risk
16 assessment was presented to the Agency on July 12th,
17 2007. Subsequently, we submitted the full risk
18 assessment report to the Agency on September 7th, 2007,
19 and the model and the accompanying user guide were
20 submitted to the Agency on October 19th, 2007, and I
21 believe you have all those documents as part of your
22 package.

23 EPA recently used TIM Version 2.1 to
24 investigate the relevance of some of the studies that
25 FMC had submitted to the risk assessment conclusions,

1 but I would caution that TIM Version 2.1 was not used
2 in the ecological risk assessment that you're charged
3 with reviewing here, the 2005 report, and I think even
4 more importantly, that model has not been released, nor
5 has information on model structure and inputs been
6 provided to the public, the SAP, or the registrant.
7 And so, we are in no position to evaluate the model
8 structure or the inputs or...or its outputs.

9 And a final caution, in...in the comments we
10 heard yesterday, there was the argument put forth that
11 the fact that the outputs from TIM Version 2.1 and
12 Version 1 tend to agree with each other somehow
13 constitutes validation of the model. I'd have been
14 surprised if they didn't agree, for the most part,
15 because they're obviously heavily related models. The
16 fact that they had similar outputs means that they
17 either did things really well and they both do it
18 really well, or they do things badly and they both do
19 it really badly. It has no relationship to validation
20 against field data.

21 Since completing Liquid PARAM, we have
22 indicated our willingness to assist EPA with the use of
23 the model or answer any questions that they may have.
24 As you can see from up above, that was several months
25 ago.

1 I was a little disappointed to hear yesterday
2 that, you know, when they first evaluated the model,
3 they had some difficulties running the model. We were
4 never contacted to help them through that.

5 This model was developed in Excel with
6 Crystal Ball added. Anybody who uses Excel extensively
7 would know that you sometimes need to have exact
8 matching versions of the model. Microsoft does not
9 make them backwards compatible in all cases. So,
10 sometimes you have to make sure that li...library
11 references are checked off and things like that. All
12 very easy to do, and with a phone call, we would have
13 been hap...happy to assist EPA with that.

14 As EPA noted yesterday, there are no errors
15 in the model code once...once they had a chance to work
16 with the model.

17 Liquid PARAM or what it stands for is Liquid
18 Pesticide Avian Risk Assessment Model. That's what was
19 developed for this assessment. And we did incorporate
20 many parts of TIM Version 1 in this model.

21 There...as I said, the panel was very
22 encouraging in 2001, and so, for those things that
23 they...they were particularly supportive of, we kept
24 those pieces. But then we moved on and actually
25 systematically went through all the recommendations

1 provided by the science advisory panels and tried to
2 incorporate those that we could.

3 The model was expanded to include a number of
4 additional components related to things like avoidance,
5 the toxicity adjustment factor for the dietary matrix,
6 and so on. We added a number of crops so that we'd be
7 able to evaluate all the critical uses that John talked
8 about for the amended label as well as alfalfa, and we
9 added a number of focal species. We wanted to make
10 sure that we had bird species in the model that
11 frequent those six different crops that we are most
12 interested in.

13 The model has gone...undergone extensive
14 sensitivity analysis, and I'll talk about an evaluation
15 of model performance that was conducted.

16 Some of the similarities to TIM Version 1, we
17 kept three original crops, corn, cotton, and alfalfa.
18 Similar with the original focal species that were in
19 TIM Version 1, and we have three application methods,
20 in furrow, banded, and foliar broadcast.

21 Much of the information about the bird
22 species themselves, at least the focal species that are
23 common to both models, we kept, such as dietary
24 composition and body weight, and gross energy of
25 different prey items and the efficiency with which they

1 are assimilated by birds. That information was
2 retained.

3 The drinking water scenarios in the two
4 models are the exact same. So, we have puddle
5 scenarios day of and day after. We also have a dew
6 scenario for both. The drinking water ingestion rates,
7 concentrations in dew and puddles and so on, the same.

8 The food intake rate equations and dietary
9 nomograms aren't quite the same, but they're pretty
10 similar, certainly a similar approach, but we updated
11 the food intake rate equations to account for more
12 recent data, and we also include the error term
13 associated with those allometric equations in our
14 modeling which TIM Version 1 does not.

15 Degradation rates in water and food are the
16 same. The effects component, that notion of using
17 species sensitivity distribution to generate
18 hypothetical risk curves for a sensitive, a median, and
19 a tolerant bird species, that component is very similar
20 to what...to what is in TIM Version 1.

21 And, finally, the output from our model is
22 the same as TIM Version 1. Essentially, what Liquid
23 PARAM does is it determines the fate for each of 20
24 birds on each of 1000 fields for whatever use pattern
25 you're investigating.

1 It is a field level model. Dr. Sample
2 commented or asked yesterday whether the model, TIM
3 Version 1, can say something about landscape risk,
4 whether it's a mixture of fields that might be treated.
5 This model does not do that, nor do any of the TIM
6 version models.

7 The next few slides, I'm going to go through
8 some of the major comments that the science advisory
9 panel provided on TIM Version 1 and indicate how we
10 responded, very briefly, in developing Liquid PARAM.
11 Subsequent to this series of slides, I will then go
12 into detail about the major components in Liquid PARAM.

13 So, one of the first comments that science
14 advisor...the science advisory panel had in 2001 was
15 that the use of two time steps per day, that is, 12-
16 hour time steps, in TIM Version 1 is overly simplistic,
17 and that's because of the rapid processes associated
18 with compounds such as carbofuran. So, Liquid PARAM
19 has a 1-hour time step, as does TIM Version 2.0 and
20 2.1.

21 The panel commented that the use of an on/off
22 approach for each 12-hour time step misrepresents how
23 birds forage in the field. What happens in TIM Version
24 1 is that a...a draw is taken from a distribution by
25 random chance. That is entered into a binomial

1 distribution and, by random chance, the bird is
2 assigned to...for each time step as to whether it
3 forages entirely on the field for that time step or
4 entirely off the field for that time step.

5 In reality, birds forage...make many foraging
6 trips in a time step, even a 1-hour time step, and
7 they...they can quite commonly move to areas on the
8 field or off the field, depending on where they're
9 nesting and...and...and their preferences.

10 So, they're...they're not necessarily going
11 to spend one 12-hour time step completely off the field
12 and then, during a subsequent time step, completely on
13 the field. I think that's an unrealistic assumption.

14 So, this is just shown graphically here.
15 This is a horned lark nesting on the perimeter of a
16 field, and in any given time step, whether it's 1 hour
17 or a longer time step, it can make multiple foraging
18 trips, and it can go sometimes into the field or
19 sometimes off the field. This is a fairly simple
20 concept.

21 The panel noted that the distribution of
22 individual foraging behavior on fields is different
23 from the distribution average population behavior
24 between fields. I think that's fairly obvious.

25 The data, the census data that you heard

1 about yesterday where you do in and do counts of birds
2 on and off the field, essentially is a representation
3 of average population behavior for that field. To then
4 somehow assume that that represents the distribution of
5 individual foraging behaviors within a field is not
6 supported.

7 We partitioned these two sources of variation
8 in Liquid PARAM, and I'll describe how that was done in
9 a...in a few slides.

10 A similar concern was raised by the SAP with
11 regard to dietary residue levels. As you would expect,
12 there's variation between dietary resi...in dietary
13 residues between fields and within fields. In TIM
14 Version 1, those two sources of variation are merged
15 together. In Liquid PARAM, we partition those sources
16 of variation, and, again, I'll talk about that.

17 The SAP noted that it would be more logical
18 to look at recovery at the active site of toxicity
19 which Keith talked about, recovery of
20 acetylcholinesterase inhibition, rather than whole body
21 elimination, and FMC commissioned a study to quantify
22 that, and those results were incorporated in Liquid
23 PARAM.

24 The SAP noted that in birds, the
25 regurgitation could be important in reducing risk. A

1 study was conducted to determine that and quantify that
2 behavior, and those results were incorporated in Liquid
3 PARAM.

4 The SAP noted that acute oral sites do not
5 account for the effect of a dietary matrix for an
6 absorption rate of the...of a compound into birds. As
7 Keith described, a study was conducted to better
8 understand the importance of dietary matrix on toxicity
9 to birds and the results incorporated in Liquid PARAM.

10 And, finally, the panel noted that field
11 validation of a model, particular a model that's early
12 in the development for the...for this science of avian
13 risk assessment, is critical. As Dr. Bradbury alluded
14 yesterday, validation is kind of a hoary concept. I
15 like to think of it as evaluation of model performance.
16 I don't think you can ever fully validate a model, but
17 we do want to have some idea about performance relative
18 to what is observed in the field.

19 So, a little bit about Liquid PARAM. This is
20 the 30,000 foot view of Liquid PARAM. We certainly
21 don't have enough detail or time to get into the
22 details of the equations and so on, although there are
23 over 10,000 equations in the model, so it...it is a
24 beast. Takes about two and a half hours to run.

25 The first component of...of the model...and

1 I'm going to talk about the exposure side of the model
2 here...is to define the pesticide use scenario. Here
3 you would specify the crop, the application method, the
4 application rate and so on, and that information
5 determines what the initial concentrations of
6 carbofuran will be in food and water on the field.

7 Now, this model has a time step, and it
8 continues for 28 days. So, it's an hourly time step.
9 It goes for 28 days. The reason why it is twice as
10 long as TIM Version 1 is this model can handle two
11 applications, so we had to extend the...the time frame
12 out.

13 So, we want to then know something about how
14 those initial concentrations in food and water change
15 over time. To do that, we need some information on
16 degradation rates, and when you combine those
17 degradation rates in food and water that have been
18 measured with the initial concentrations in field, what
19 you get is a picture of concentrations in food and
20 water over time.

21 On the...the biological side of the model,
22 there are a number of focal species associated with
23 each crop use that you can choose from. Once you
24 select a species, you can then select a foraging
25 behavior, whether you want to look at gorge feeding or

1 more even feeding throughout the day. And so, that
2 information then determines the ingestion rates over
3 time for each hour of each day in the model.

4 Knowing what's in the dietary items and in
5 water over time and knowing ingestion rates over time
6 allows us to then estimate hourly pesticide dose. So,
7 we have an hourly pesticide dose for each of the 24-
8 hour time steps per day and 28 days in the model which
9 is 680 time steps.

10 As Ed and Christopher described yesterday,
11 the birds, however, carry over some of the preceding
12 doses in their body, and that's a function of rate of
13 metabolism. So, knowing something about the rate of
14 metabolism and how much dose they've already received,
15 we can specify a body burden. Then, in the current
16 time step, a new hourly pesticide dose comes in, and
17 so, we have something called hourly retained dose.
18 That's the current dose plus what was retained from
19 before. Hourly retained dose is the same as a body
20 burden.

21 So, that's the exposure side of the model.
22 What's carried over from the exposure side of the
23 model, that hourly retained dose or body burden for
24 each time step in the model, and what the model then
25 does is it searches through all of the hourly time

1 steps and finds the maximum retained dose, the maximum
2 body burden that occurred at whatever time period it
3 occurred at following application, and that is the
4 exposure metric that will be used in determining
5 whether the bird lives or dies.

6 And now, the effects side. As was described
7 yesterday, for almost all of the focal species, we do
8 not have toxicity data. We did have it for northern
9 bobwhites, and, as mentioned, there's also data for
10 red-winged blackbirds, and so, if that information was
11 available, we could use that dose response curve, and
12 that...that would be used in the estimation of risk.

13 For the remaining focal species, though, we
14 did not have species-specific toxicity data, so we used
15 that sensitivity distribution process described
16 yesterday, and I'll show a picture of that later on.
17 And knowing the LD50 for the 5th percentile species, a
18 very sensitive species, for the 50th percentile
19 species, and for the 95th percentile species and a
20 slope where we took the average slope measured across
21 all focal species or across all tested species, just as
22 EPA did, we can come up with three hypothetical dose
23 response curves that represent sensitive, median, and
24 tolerant bird species.

25 And for each simulation that we did, because

1 we didn't know the sensitivity of...of those focal
2 species, we did all three, and that at least allows you
3 to get an idea of what the range of risk could be for
4 untested species. This is all very similar to what EPA
5 did.

6 So, we have a maximum retained dose, we have
7 a value randomly drawn from each dose response curve,
8 and it's very simple. If exposure is greater than
9 effects, the bird dies. If exposure is less than
10 effects, the bird lives.

11 And then, this simulation is repeated for 20
12 birds on each field, and then the whole thing is
13 repeated for 1000 fields. And on the risk results we
14 show are just results for those 20,000 birds combined.

15 Talk a bit...a little bit about time step.
16 In the arguments yesterday and in the comments
17 previously submitted to the panel, EPA stated that
18 decreasing the time step from 12 hours to 1 hour did
19 not impact the exposure estimates, and that's a rather
20 surprising result, given how fast some of the processes
21 are associated with exposure to carbofuran, when you
22 consider the recovery rate from acetylcholinesterase
23 inhibition, decay in the field, avoidance behavior, and
24 so on.

25 So, let's consider a really simple example.

1 This is hypothetical. A food intake rate of 1 kg, wet
2 weight per kg body weight per day. We'll just assume
3 for simplicity that the bird feeds on only one item,
4 and that item had an initial concentration in the field
5 of 5 mg/kg wet weight. We'll further assume a half-
6 life on that dietary item of 3.1 days. That is the
7 measured half-life for carbofuran on seeds and insects
8 in the field. And we'll assume a metabolism half-life
9 based on the brain acetylcholinesterase recovery of 4.4
10 hours, and that was based on the...on the study that
11 Keith described. So, these are all values used in our
12 assessment.

13 Here are the results if we have a 12-hour
14 time step and a 1-hour time step. On the x axis is
15 time since application, going from zero hours up to 250
16 hours. On the y axis is body burden or maximum...or
17 dose retained in mg/kg body weight. The blue curve is
18 the results for the 12-hour time step; the red curve is
19 the results for the 1-hour time step. Note no other
20 differences between these two applications.

21 What you find is that the peak is much higher
22 with the 12-hour time step, peak body burden, and then,
23 of course, it started to decline. In fact, the maximum
24 body burden with the 12-hour time step is 5.23 mg/kg
25 which is more than double the maximum body burden with

1 a 1-hour time step of 2.4 mg/kg. And it is that
2 maximum body burden that is the exposure metric used to
3 determine whether a bird lives or dies.

4 And we have not considered avoidance in this
5 analysis and some of the other rapid processes that go
6 on when you estimate exposure and risk of carbofuran to
7 birds. So, this very simple example illustrates the
8 importance of time step.

9 Daily foraging behavior. As I mentioned,
10 birds vary somewhat in their foraging behavior over
11 time during the course of a day. To try to get a
12 better understanding of that, we reviewed the
13 literature to determine how daily foraging patterns
14 vary from species to species.

15 You can see there's a long list of passerine
16 bird species for which that information has been
17 determined, been determined over a number of years and
18 generally involve nesting birds. And what we found was
19 that most passerine bird species, during nesting, have
20 relatively even feeding throughout the day with slight
21 peaks early and late in the day.

22 This isn't really surprising. When they're
23 nesting, the...the nestlings have high demands, and
24 the...and the adults are quite active in trying
25 to...to, quote, provide for the nestlings as well as

1 for themselves, and so, they're...they're required to
2 feed throughout the day to...to be successful.

3 Both peaks in the early and late in the day
4 are just small peaks. It's relatively even feeding
5 throughout the day but a slight bubble in the pattern.

6 Waterfowl may exhibit gorge feeding...this is
7 a little bit different feeding behavior...particularly
8 during migration. Because they are flying for long
9 hours, when they...when they do alight on fields, they
10 may exhibit gorge feeding, and this has been
11 demonstrated in a number of studies.

12 So, in our model, we have two options to
13 explore these different range of foraging behaviors.
14 On the x axis is time. There's an overnight time step
15 right at the far left, and then we begin at 6:00 a.m.
16 in the morning and continue to sunset at the end of the
17 day.

18 For those passerine bird species that are
19 nesting, we would expect something like that bimodal
20 feeding pattern shown with the purple diagonal, shown
21 there. A slight peak in the morning, a slight peak in
22 the evening, and a little bit lower intake the rest of
23 the day.

24 For waterfowl, what we assumed in the model
25 is...was essentially a gorge feeding pattern, a large

1 intake in the early morning and a large intake later in
2 the day. The y axis is proportion of total daily
3 intake.

4 So, in Liquid PARAM, for our waterfowl
5 analyses, we assume that gorge feeding pattern shown in
6 black. For the remaining bird species, we assumed that
7 slight bimodal distribution shown in purple.

8 It's interesting to contrast that with what
9 is in TIM Version 2.0. Because TIM Version 1 has as
10 12-hour time step, there is no consideration of
11 variation in daily foraging pattern, but in TIM Version
12 2.0 and 2.1, there's a 1-hour time step, so it is
13 possible to consider variation in daily foraging
14 behavior.

15 And this...this figure here is based on a
16 report prepared by EPA and submitted to the science
17 advisory panel in 2004 for their consideration, and
18 what this shows is the kinds of patterns that their
19 model generated for individual birds throughout the
20 day.

21 And you'll note that those patterns...and
22 these are generated through a fairly sophisticated
23 randomization model...is that there's actually no
24 feeding in the middle of the day for the example shown
25 here and fairly large peaks in the early morning and

1 later in the day. And this is much more or at least
2 approaches gorge feeding pattern, and...and they used
3 these patterns for non-waterfowl species.

4 So, it's interesting to note that even though
5 we're considering similar bird species, very different
6 assumptions about daily foraging behavior.

7 Although the...the statistical model used to
8 generate these distributions is pretty sophisticated,
9 it's not in any way based or corroborated by field
10 data. There are no citations in their report referring
11 back to field observations to support these
12 distributions.

13 So that...and that gorge feeding pattern, as
14 you'll find out later, or...or approaching a gorge
15 feeding pattern almost certainly results in higher risk
16 estimates, as I'll show later.

17 So, that's daily foraging pattern. I want to
18 talk about proportion of time that birds spend foraging
19 in fields and foraging out of fields. This is a major
20 consideration in estimating risk to birds.

21 If you go back to the original data set, the
22 proportion time data for bird species is based on the
23 proportions of birds observed in and out of fields.

24 Lou Best was involved in reviewing much of that
25 literature. He's sitting here. And so, if they...this

1 is obviously a very simplistic example, but if the
2 field observer noted 3 birds within a field and 3 birds
3 outside of a field, then the proportion time foraging
4 in the field for that population, the average PT value,
5 would be 0.5. That's a very simple example.

6 So, each datum is, thus, an average PT for
7 the population of birds on the field.

8 PT varies, though, quite a bit between fields
9 even with the same bird species, and it also varies
10 between row crops versus a field crop such as alfalfa,
11 because alfalfa is quite a different crop. Birds
12 actually will consume alfalfa.

13 So, here's another example where we have 6
14 birds inside the field, 2 birds outside the field, so
15 the average PT for that population would be 0.75.

16 These differences arise because the relative
17 attractiveness of the fields themselves and the
18 surrounding habitat varies from field to field. So, in
19 some areas, the edge habitat would be far more
20 attractive to the species of interest, and so they
21 won't spend very much time in the field. In other
22 areas, the field itself might be more attractive to the
23 birds.

24 TIM Version 1 does not distinguish between
25 population or between field variation in proportion

1 time foraging in fields versus the variation that you
2 would expect to find between individuals within a
3 field.

4 For each individual in each field, what we
5 did is a distribution was developed that captures that
6 between field variation and average PT. We sample from
7 that. That determines...I'm sorry...for TIM Version 1,
8 that determines the probability for an individual
9 within a field of being on or off the field for that
10 time step. So, essentially, variation between fields,
11 the average PT is being used to determine for each time
12 step whether an individual is on or off the field.

13 Those sources of variability were partitioned
14 in Liquid PARAM. I'll show how that was done
15 momentarily, and...and reason we did that is it
16 re...represents a more appropriate use of the data. It
17 respects the source of data and...and captures the
18 variability as its represented in the data.

19 I would still caution, as you heard
20 yesterday, this variable still is uncertain. The mere
21 fact that a bird is in the field for a proportion, a
22 certain proportion of the day, does not necessarily
23 equate to that same proportion of their diet being from
24 that field. That's an assumption. It's an assumption
25 for all the TIM version models as well as our own.

1 So, how did we do it in Liquid PARAM? On the
2 upper left, we have a typical result for...from the
3 census data that...that Lou Best and co-authors
4 collected information on. So, this is for dickcissel,
5 and this is for row crops.

6 And the little red dots shown here on the x
7 axis are the actual observations for individual fields
8 or groups of fields in the same...similar location.
9 What you see for dickcissel is that you have some
10 fields where the birds rarely spend time in the
11 field...that would be down at the zero end...and you
12 have other fields where all of the individuals were
13 almost always on the field. Quite a range of behaviors
14 even though this is the same species foraging in row
15 crop fields.

16 What we did in Liquid PARAM is we fit or
17 estimated a distribution that would represent that
18 variability in average population behaviors between
19 fields. You'll note that this distribution is weighted
20 more towards the conservative end, that is, assuming
21 that birds spend more time foraging in fields. So, in
22 all cases where we had rather limited data such as in
23 this example, we were conservative.

24 Let's take an...a hypothetical example here
25 and say field number 4. What we do is we randomly

1 chose a value from that distribution. We combined that
2 randomly chosen value and assumed that a minimum of
3 zero and a maximum of 1 would represent the variability
4 of individuals within field number 4. We don't have
5 that information, so we maximized uncertainty by
6 assuming the two extreme values.

7 So, that was used to characterize a
8 distribution for field number 4, and that's shown here
9 in bright...in the thick orange line. So, if you
10 choose that value for field...field number 4, assume a
11 min of zero and a max of 1, what you get is this
12 distribution here shown as the thick orange line. What
13 that indicates is that for individuals in field number
14 4, the majority will spend more than 50 percent of
15 their time foraging in the field. A few will forage a
16 lot in the field, and a few won't spend much time in
17 the field at all.

18 And you repeat this exercise for all of the
19 fields. You'll get different curves that represent
20 proportion of time foraging in the fields within a
21 field. And in some fields, by random chance, almost
22 the entire population will always be in the field. By
23 random chance, other fields will spend...will have all
24 the individuals barely spending any time in the field.

25 Continuing on with this example, so for our

1 field number 4, we would next draw 20 values from that
2 thick orange distribution and come up with individual
3 PT values for each bird in field number 4. That's
4 shown here. So, we have a bird that spends about 27
5 percent of its time foraging in the field. We have the
6 majority of birds somewhere around 60 to 75 percent of
7 their time in the field, and a couple of birds that
8 spend almost all their time foraging in the field.

9 So, what we've done is we have effectively
10 partitioned between field and within field partitioning
11 dat...or foraging behavior in the fields.

12 This process was repeated for all the other
13 fields. It's quite a laborious process. You can see
14 in chapter 3 the exposure assessment part of our
15 refined assessment, all the distributions that we came
16 up with, all these green distributions that we came up
17 for each of our focal species for row crops and for
18 field crops such as alfalfa.

19 Dietary residues. As indicated yesterday,
20 TIM Version 1 samples from those between field residue
21 distributions at every time step within every field.
22 So, much like the case with proportion time foraging in
23 the field, the original data represent variability
24 between fields in dietary residues.

25 So, that information is then being used in

1 TIM Version 1 to look as an example of the variability
2 that you would get within a field and between time
3 steps. And because of this, you often get several fold
4 increases in dietary concentrations from one 12-hour
5 time step to the next which seems a little bit
6 counterintuitive, given the rapid decay of the compound
7 in the field.

8 And it's just by random chance. You would
9 have a distribution. By random chance, you could
10 select a rather low value in the first time step and
11 then, in a subsequent time step, by random chance,
12 select a higher value.

13 It's important to remember that those
14 original nomogram distributions by Fletcher, et.al. and
15 Garner, et.al. were based on between field variability,
16 and you would expect between field variability to be
17 important, because there are differences in slope, soil
18 type, operator skill, quality of the machinery, and so
19 on. And you would expect those differences to be much
20 more important between fields than you would within.

21 Just as a side comment, it was noted
22 yesterday that our insect residue values for the
23 nomogram differed from what EPA used in TIM Version 1.
24 We used the result from Fisher and Bowers, just as EPA
25 did, but we removed the granular value result, because

1 it obviously is not apply...applicable to a flowable
2 pesticide like...like we're looking at. And there were
3 a number of studies where they didn't specify the
4 application method, and being...wanting to be able to
5 be specific to in furrow, banded, or foliar, we removed
6 those studies from our distribution that we developed.

7 Those calculations are all spelled out in
8 gory detail in chapter 3 of our document.

9 So, Liquid PARAM samples from each nomogram
10 to determine initial residue concentrations from each
11 field and then declines them thereafter due to
12 degradation. We basically assume that intrafield
13 variability is unimportant.

14 As you found out in that...in the documents
15 that you received prior to this meeting, the EPA
16 believes that intrafield variability is important, and
17 they show that there are a number of studies that have
18 been conducted to determine coefficients of variations
19 within fields. They range from 0.08 to 0.93 for
20 vegetation, so the ratio of standard deviation to the
21 mean varied from .08 to 0.93 for vegetation, 0.23 to
22 0.71 for insects. These val...these coefficients of
23 variation are much lower than what you would find for
24 between fields, as you would expect.

25 But I think it's important to remember that

1 birds don't just go into a field once during a 12-hour
2 or 1-hour time step. They go in multiple times. They
3 make multiple foraging trips, and as a result, they
4 spatially and temporally average their exposures even
5 within a relatively short 1-hour time step.

6 Based on a review of the literature...and all
7 of the citations are provided in our document...we
8 found that birds typically make three to about 4 leaf
9 foraging trips per hour. So, let's just consider a
10 worst case example.

11 The highest coefficient in variation that was
12 found by EPA, that 0.93 value, and we'll assume a
13 minimum number of trips per hour, 3 trips per hour.
14 That would...if you add more trips per hour for a lower
15 coefficient of variation, you would expect even more
16 spatial and temporal averaging.

17 If you just characterize the distribution for
18 residue concentration as shown on the X axis, that blue
19 dash line would represent the...the dispersion that you
20 would expect within a field with a coefficient of
21 variation of 0.93. Now, if you assume that the bird
22 makes 3 foraging trips per hour and thus comes up with
23 a spatial average, and you do this for a simulation,
24 say, 10,000 times, what you find is the distribution
25 tightens up quite dramatically.

1 I'm sure the statisticians find this to be a
2 really simplistic example. But what you find is a...a
3 much stronger indication of centrality in the
4 distribution, much smaller dispersion in the
5 distribution, and as a result, intrafield variability
6 is a relative minor issue once you actually account for
7 how birds forage within a field. And remember, this is
8 a worst case example.

9 So, I'll just give you a pictorial
10 representation of...of how Liquid PARAM works then. We
11 take those between field nomograms, randomly sample
12 from them for each field. We do this for each of the
13 dietary items, such as grass, foliage, insects, seeds,
14 and so on.

15 Here are some randomly chosen values for
16 grams in mg/kg for the first 8 fields. You can see
17 they vary by quite a bit. There is a lot of between
18 field variability. Similar for forage on...in this
19 column.

20 And then what happens in Liquid PARAM, this
21 is for field 1, and we have an initial concentration,
22 as specified in the...on the upper left there, and then
23 it is just decayed through time according to the
24 degradation rate that has been observed for grass in
25 laboratory studies. So, there's no within field

1 variability once the application occurs.

2 The reason you see zeros up here is in Liquid
3 PARAM, we can specify what time of day the application
4 occurs. In this particular example, the application
5 occurred at noon.

6 Avoidance behavior. You heard a lot of
7 discussion about this yesterday. Keith described the
8 study itself. In Liquid PARAM, we incorporate a 1-hour
9 time lag, so it's the preceding body burden that
10 determines how much avoidance behavior they'll have in
11 the current time step. That's a 1-hour time lag.

12 In these studies that were conducted on
13 behalf of the registrant, we found that...that recovery
14 begins, actually, in about 30 minutes, so this is a
15 fairly conservative assumption. Dr. Sample raised the
16 issue yesterday or asked a question about whether the
17 error term in this regression model is incorporated in
18 Liquid PARAM, and it is not. It would be a
19 computationally challenging exercise to do that, but I
20 think it might be something worth exploring in the
21 future.

22 So, what is that regression relationship?
23 What we have on the x axis is average dose. This is
24 from the experiment. And on the y axis, reduction in
25 food intake rate. There's no effect at all on food

1 intake rate at zero, and what you find is at very low
2 doses, there was actually...indicates no change in food
3 intake rate.

4 Then at a certain dose, 0.119, there's a
5 threshold. Thereafter, as dose increases, there's an
6 increasing amount of reduction in food intake rate.

7 And so, in the model happens...is at the
8 preceding time dose, we have a body burden. To convert
9 it...so, what would normally happen is you would then
10 find that dose, read up to the curve, go across to the
11 left, and figure out what the reduction in food intake
12 rate will be for the current time step.

13 Now, as...as indicated yesterday, the...the
14 laboratory study was not able to determine food
15 consumption on an hourly basis. That would have been
16 too invasive. It was done on a daily basis, but the
17 time step in the model is an hourly time step. So, we
18 had to make an extrapolation.

19 The way we did that is if you go back to the
20 original protocol for the laboratory study, the
21 exposure period is 8 hours per day. It was 8 hours
22 light, 16 hours dark, and mallards wouldn't feed in the
23 dark.

24 So, what we did is then with the preceding
25 dose for the preceding time step, the 1 hour, we would

1 multiply it by 8, then go to this model, read off the
2 ax...x axis, so say 0.6 mg/kg body weight per day. Go
3 up to the curve. That would be roughly a 35 percent
4 reduction in food intake. Apply that to the dose for
5 the current time step, and continue on. Okay?

6 So, that's how we converted from...between
7 the two types, between the laboratory study and the
8 model. That's exactly how Ed explained it yesterday
9 later in the day, so the EPA did have a correct
10 understanding of it.

11 That is an extrapolation uncertainty.
12 Obviously, we are assuming basically even feeding
13 throughout the day, for example. We don't really know
14 that.

15 Species sensitivity distribution. You had
16 some questions yesterday about slopes and how much
17 difference there...there is between sensitivities when
18 you assume the 5th, 50th, and 95th percentile of
19 sensitivity, so I thought I'd throw this figure up.
20 Basically, what we have on the x axis is dose shown
21 here in mg/kg body weight. Percent mortality here.
22 And if you fit a distribution to the LD50s that have
23 been determined for other test species, you can get a
24 5th percentile LD50, 50th percentile LD50, and a 95th
25 percentile LD50.

1 And then, if you go ahead and obtain all the
2 slopes from those toxicity studies...and we averaged
3 them just as EPA did...you get an average slope as
4 shown here, and that information, the LD50 and the
5 slope, can be used to generate this dose response curve
6 for a very sensitive species, for a medium tolerant
7 species, and for a highly tolerant species. So, that's
8 how the SSD approach works.

9 And the major difference between what we did
10 in our effects component and what is done in TIM
11 Version 1 and TIM Version 2.0 and 2.1 is these three
12 curves are shifted to the right along this x axis by a
13 factor of 3.8, and that's to account for the
14 differences in toxicity between and oral or a water
15 bolus dose test that's done with the standard acute
16 oral test and what you find with the dietary matrix as
17 the vehicle for exposure.

18 Sensitivity analysis. As described in
19 section 3.4 of our refined risk assessment, we
20 conducted extensive sensitivity analyses for Liquid
21 PARAM. We created two exposure scenarios. One was a
22 high exposure scenario involving the maximum
23 application rate for potatoes in the Northwest and a
24 lower exposure scenario which involved application at a
25 much lower rate in cotton.

1 And then, we looked at two different bird
2 species, one that would be expected to spend a lot of
3 time in the field...horned larks spend a lot of their
4 time foraging within fields...and we applied that to
5 the high exposure scenario. For the low exposure
6 scenario, we...we focused on a bird species that
7 wouldn't be expected to spend much time in fields, and
8 that was the American bobwhite. So, we...we kind of
9 have two extreme scenarios that we used in our
10 sensitivity analysis.

11 When you do those analyses, we varied quite a
12 number of different parameters to find out which ones
13 were the most important. What you find is that there
14 are four key variables that have a dramatic impact of
15 predicted mortality of bird species. They are foraging
16 pattern...that's the difference between gorge feeding
17 and that much more even feeding pattern throughout the
18 day. That is critically important. As gorge...if you
19 strictly keep everything else constant and compare the
20 results between even feeding throughout the day and
21 gorge feeding, gorge feeding will have much higher
22 mortality.

23 Rate of metabolism, as you would expect, is
24 important. Whether you use a half-life of 4.4 hours or
25 9.4 hours, as used by EPA, makes a difference.

1 Incorporation of avoidance behavior makes a
2 big difference, and incorporation of a dietary matrix
3 adjustment factor makes a big difference, and I'm
4 showing that particular example here to the right.

5 And we have the results for the high exposure
6 scenario for horned lark on potatoes. What we have on
7 the x axis are the results for assuming high
8 sensitivity of the species, median sensitivity, and low
9 sensitivity.

10 For assuming high sensitivity, what you find
11 is that if you don't incorporate the adjustment for the
12 dietary matrix, mortality is quite high. You
13 incorporate that dietary matrix adjustment factor of
14 3.8, the mortality is...predicted mortality is reduced
15 by over a full third. So, this is a very important
16 variable.

17 For the more tolerant bird species, it's not
18 as important. We don't predict much mortality for
19 horned larks in potatoes if they are of median
20 sensitivity or if they're a highly tolerant species
21 whether or not you use that matrix adjustment factor.

22 We weren't able to do sensitivity analyses in
23 Liquid PARAM to investigate the importance of time
24 step. That would be a great structural reconfiguring
25 of the model, but based on that simplistic analysis I

1 showed you earlier, I would expect that time
2 step...time step is critical in explaining differences
3 in predicted mortality between TIM Version 1 and Liquid
4 PARAM. And I would also expect that the different
5 assumptions that TIM Version 2 and Liquid PARAM make
6 regarding daily foraging behavior is critically
7 important, because I know we have a much more even
8 foraging pattern for non-waterfowl species than does
9 TIM Version 2 or, presumably, 2.1.

10 And there are also differences between EPA
11 models and our model with regard to how proportion time
12 foraging in the field is dealt with, dietary residues
13 is dealt with. Food intake rates have been updated
14 somewhat in our model, and we also consider the error
15 term. So, there are a number of other differences
16 between the models that can also explain the dramatic
17 differences that you're seeing predicted mortality
18 between the two models.

19 Okay, evaluation of model performance. You
20 heard...you heard about some of the field studies
21 yesterday. We reviewed the literature for field
22 studies involving application of carbofuran and then
23 monitoring the impacts on avian species. In reviewing
24 the literature, it became apparent that the most useful
25 studies for actually quantifying mortality in the field

1 was Jorgensen, et.al., 1989 and Booth, et.al., 1989.

2 These were studies you heard about yesterday.

3 Those studies were conducted in Nebraska and
4 Texas-New Mexico for corn, in Kansas-Oklahoma for
5 alfalfa. These studies determined pre and post-
6 application bird mortality in treated and in control
7 fields. The experimental design was 8 times 2 paired
8 plots.

9 There was no randomization as to which of
10 those paired plots was control or treatment.
11 Essentially, what happened was a number of farmers were
12 identified that would apply carbofuran to their fields,
13 and then what the study authors did is they looked
14 around for a very similar field in terms of surrounding
15 habitat, surrounding...and the type of bird species
16 that used those fields. So, it was a paired
17 control/treatment.

18 And this was 8 times 2 paired plots per
19 state. Those paired plots were separated by at least a
20 quarter of a mile, so, hopefully, that minimized birds
21 foraging in both the control and treatment fields.

22 The protocol used for these studies followed
23 EPA guidance and took account of EPA comments that had
24 been provided on...on preceding field studies to the
25 extent that they could.

1 So, for example, dogs were used to assist in
2 carcass searches, and that...and dogs, they
3 don't...they don't care if it's a small little bird or
4 a large bird. They...they move by smell, so there's no
5 size dependence in...in their ability to find birds.

6 And it's really important to note here that
7 the results for every single plot were corrected for
8 carcass search efficiency and the disappearance rate of
9 birds from those fields. It was determined in every
10 single plot in these studies.

11 And so, when we determine percent mortality
12 for each plot, we corrected for these search
13 efficiencies and disappearance rates. So, all those
14 arguments you heard about well, might not be able to
15 find every single dead bird, we corrected for that.

16 It was a really well conducted study. There
17 was a lot of information collected, and that's what
18 allowed us to do a lot of these appropriate
19 manipulations of the data.

20 You heard yesterday that the control plots
21 may...may not be true control plots in the sense that
22 they had no pesticide applied. That is true.
23 Synthetic pyrethroids were used in the corn control
24 plots, and chlorpyrifos was used in the alfalfa
25 control plots.

1 I wouldn't expect any issues with the
2 synthetic pyrethroids, because they have low toxicity
3 to birds. The chlorpyrifos is toxic to birds, and so,
4 that's an issue.

5 Note that those pesticides that were applied
6 in the control plots were applied two to three weeks
7 before carbofuran treatment.

8 Also important to note that edge fields were
9 treated with a variety of pesticides. Some neighboring
10 fields were treated with a var...a variety of
11 pesticides but not carbofuran. Again, something to
12 consider.

13 But in the end, as I'll show in...in the next
14 two slides from now, there was little avian mortality
15 on control plots. And we will show you the results
16 corrected for mortality on the control plots and not
17 correct for mortality on the control plots, and you can
18 judge for yourself which is the appropriate method, but
19 we'll...we provided both in our report and in this
20 presentation.

21 So, how was mortality in the field estimated?
22 Christopher Salice yesterday noted that when
23 they...they applied the DREAP formula to try to
24 estimate how much mortality occurred in those treated
25 fields. That formula was deemed inappropriate by the

1 study authors, and there's a rationale provided in the
2 field study reports.

3 And it's primarily due to the fact that the
4 birds were in pre-migratory phase. They don't have
5 high site fidelity at the time that these studies were
6 conducted, and so, the DREAP formula really doesn't
7 work in that situation.

8 So, we took a different approach, as...we
9 took the approach suggested by the study authors where
10 we determined the number of live birds observed per
11 dead bird found. And we convert that to percent
12 mortality. We do that for each plot, and we did that
13 for all birds across each plot, each field.

14 These calculations, again, are shown in gory
15 detail in our assessment report. There's tables
16 provided of all the raw data, and then all the formulas
17 that were used to process the data are included in our
18 report.

19 Unfortunately, the calculation that EPA used
20 to calculate percent mortality using the DREAP formula
21 have not been provided to us, and I don't believe
22 they've been provided to the SAP. The first time we
23 saw that was actually yesterday during the
24 presentation.

25 So, that allowed us to estimate percent

1 mortality for treated plots and for control plots for
2 both the corn and the alfalfa field studies.

3 So, what did we do with Liquid PARAM? We ran
4 scenarios that replicated those field studies for each
5 of our focal species. So, that's 1 pound of active
6 ingredient per acre, foliar spray. And we determined
7 percent mortality across all of our bird species. So,
8 we combined the results for all of our focal bird
9 species across 1000 fields, and those calculations are
10 all shown in our report.

11 What were the results? On the x axis with
12 the two crops, corn and alfalfa. The y axis is
13 mortality per application expressed as percent going
14 from zero to 50.

15 Here are the results, depending on how you
16 calculate them for the field. Overall, there's very
17 low mortality for both corn and alfalfa in the field,
18 less than 1 percent no matter how you calculate it.

19 For corn, if you make no correction for pre-
20 application or control mortality, then observed
21 mortality was 0.88 percent of the birds. If you
22 correct for only pre-application mortality, that drops
23 somewhat, because some birds did die pre-application.
24 So, that's 0.69 percent, and in this case, control
25 mortality was so low for corn that it doesn't change

1 when you correct for that.

2 For alfalfa, even lower mortality, 0.3
3 percent if you don't correct for control or pre-
4 application mortality, 0.26 percent if you just correct
5 for pre-application mortality, and it actually drops to
6 a negative value if you correct for control mortality,
7 the reason being is that, in this case, control
8 mortality exceeded what was observed in the treated
9 plots.

10 And I would take that with a heavy grain of
11 salt, because chlorpyrifos was used in these control
12 plots. So, it's a reasonable argument to not consider
13 that correction for control mortality for alfalfa in
14 particular.

15 What were the results for Liquid PARAM? For
16 corn, we predicted 0.78 percent mortality across all
17 the focal bird species. A very low value. Certainly
18 comparable to what was observed in the field, depending
19 on which correction you want to compare to.

20 And for alfalfa, 0.33 percent. Again, pretty
21 comparable to the field.

22 Apparently, having a perfect model like this
23 is a bad thing. Had we not replicated observed
24 mortality very well, I'm sure we would have been
25 criticized for that, but it's interesting to see that

1 we're criticized for good performance. But, anyhow, I
2 take that with a grain of salt.

3 There...there was...this is only two field
4 studies. The model performed pretty well. We weren't
5 expecting, actually, this close a match. What we were
6 hoping for was that it was in the ball park, and I
7 think that's all you should take away from this. Let's
8 get realistic. There are issues associated with the
9 field studies.

10 So, all we can really say is that Liquid
11 PARAM is certainly within the ball park of what you
12 would observe in field studies. How about TIM Version
13 1?

14 Dramatically different predictions. With the
15 same scenarios that we ran in Liquid PARAM, using the
16 corn scenario, TIM Version 1 predicts 40 percent
17 mortality across all the bird species that would use
18 treated fields and 39 percent for alfalfa. That is a
19 mass mortality event, and there is no conceivable way
20 that a study as well conducted as these two studies
21 were that that kind of mortality would have been missed
22 in this kind of controlled field study.

23 I should note that waterfowl were not present
24 in the area during the conduct of the alfalfa field
25 study, so we do not include alfalfa in our model

1 simulations, nor did we include them in the TIM Version
2 1 simulations, and that's exactly analogous to what EPA
3 did when they did their alfalfa analyses.

4 Okay, so that's the model itself, and now I
5 want to talk about the risk results that we got.

6 To help communicate risk, because risk curves
7 are kind of a gnarly beast to communicate, we developed
8 a risk categorization scheme. So, we took each of our
9 outputs, and we categorized them as to whether they
10 were de minimis, mild, intermediate, or high risk.
11 This was strictly a communication tool, not meant to
12 imply anything with regard to decision making.

13 So, how did we come up with those risk
14 categories? If you read through the ecological
15 literature, there's a general understanding that
16 effects of less than 10 percent are unlikely to be
17 ecologically significant to a low pop...local
18 population. That...that statement would not include
19 threatened and endangered species.

20 And it's because of things like density
21 dependence. There's a certain amount of mortality that
22 local populations can observe...can absorb without
23 affecting overall abundance of the population.

24 Glenn Sutor, in a review of the literature,
25 concluded that effects of 20 percent or less are

1 generally acceptable in EPA regula...regulatory
2 practice. So, we kind of started with those two
3 concepts and...and started to think about how we would
4 categorize risk.

5 And what we figured is if there was a low
6 probability of...of 10 percent or greater effect, so an
7 effect that's, you know, unlikely to...to affect the
8 local population, if there's only a low probability of
9 exceeding that, then that's low risk. So, in our
10 analysis, we say if there was a less than 20 percent
11 probability of a 10 percent or greater effect, that was
12 low risk.

13 On the other hand, if there was a high
14 probability, a greater than 50 percent probability of a
15 20 percent or greater effect, the threshold that Glenn
16 Sutor refers to, we...we considered that high risk.

17 At any values between those two, we consider
18 it intermediate risk, and then we further came up with
19 something called de minimis risk, and that's a
20 situation where you have a very low probability, less
21 than 5 percent probability, of even a small effect, a 5
22 percent or greater effect.

23 And so, that's...that's kind of the...there's
24 more thinking to it than that, but that's just boiled
25 down to the simple situation that we came up with.

1 Now, we kind of extended this a little bit
2 further. If you take those probabilities and in
3 magnitude effect and multiply them together, you get
4 something called a risk product. So, if you take 20
5 percent probability times 10 percent effect or greater,
6 that's a...what we call a risk product of 2. If you
7 take the 50 percent probability of 20 percent effect,
8 that's a risk product of 10. And we can do that for
9 the other categories as well.

10 And so, what we did is we defined these
11 regions, and I'll show them, these regions that
12 describe high risk, intermediate risk, low risk and de
13 minimis risk using these risk products, and I'll show
14 you what that means.

15 So, on the x axis, we have percent mortality.
16 On the y axis is exceedence probability, and that whole
17 area to the right and above that blue line, if we get a
18 risk curve that goes into that area, that's high risk.
19 That's a high probability of a major mortality event.

20 That risk product of 10 that I alluded to as
21 the criterion for high risk is what is used to
22 calculate this line. So, 100 percent probability of 10
23 percent effect, that's a risk product of 10, just as
24 100 percent probability of 10 percent effect is a risk
25 product of 10, and if you do that at multiple points

1 along the line, you have this line here equal to a risk
2 product of 10.

3 Do that for the line dividing intermediate
4 and low risk, that would be a risk product of 2, and so
5 on for low and de minimis risk.

6 So, any risk curve that crossed into here is
7 high risk. Any risk curve that crossed into here is
8 intermediate risk, and any risk curve that was in here
9 is low risk, and any curve that had a very low
10 probability of even minor effects so it hugged the
11 axes, was categorized as de minimis risk. Again, this
12 is just a communication tool.

13 So now, I'm going to get into our actual
14 results. We looked at a number of use patterns
15 associated with the six crops that we were interested
16 in, the five that the registrant would like to have on
17 the amended label as well as alfalfa which has been
18 removed from that label. We looked at the application
19 methods that were on...on the label, the maximum single
20 application rate, and we applied it at the maximum
21 number of applications allowed according to the label.

22 For each of those crops, we identified a
23 number of focal species. These are species from field
24 studies that have been observed in these crops and
25 using these fields quite frequently. So, these are the

1 birds that you would expect to be most at risk in
2 treated fields.

3 Some of these overlap with what EPA considers
4 in TIM Version 1. The ones that are in bold italic are
5 species that we've added to Liquid PARAM.

6 Very...taken a lot of results, and
7 there's...there's every single risk curve that we
8 developed and all the statistics and assoc...associated
9 with those risk curves are all presented in our
10 appendices, but boiling it down to a couple of really
11 simple slides, here are the results. We looked at, all
12 together, 208 scenarios. That's combinations of use
13 patterns times focal species, and in the case
14 of...cases where we did not have species-specific
15 toxicity data, three different sensitivities.

16 We found de minimis risk, very low risk, in
17 other words, in 166 of our 208 scenarios, and if you go
18 back and look at the numbers, de minimis risk turned
19 out to range from 99.4 percent to 100 percent survival.

20 We found low risk for 27 of our 208 scenarios
21 that we looked at. And, again, if you go back to
22 the...the data that was generated to put those risk
23 curves together, that indicates 95.2 to 99.5 percent
24 survival, just to give you an intuitive feel of what
25 low risk means.

1 Intermediate risk was found in 10 of 208
2 scenarios. That's associated with 77.4 to 95 percent
3 survival. And we found high risk for 5 of 208
4 scenarios which range from almost complete mortality to
5 65.8 percent survival. All of the high risk scenarios
6 were associated with gorge feeding waterfowl in
7 alfalfa.

8 So, Christopher Salice's statement that
9 Liquid PARAM predicts no risk for modeled uses except
10 waterfowl on alfalfa, that was obviously false. That
11 was a statement that was provide yesterday.

12 Clearly, in the vast majority of modeled
13 scenarios, we did find risk, even if it was minor. No
14 risk would imply 100 percent survival for the entire
15 use pattern.

16 A little bit more discussion of risk results.
17 For non-waterfowl species which are mostly passerines,
18 de minimis risk in all scenarios if the species have
19 low...are assumed to have low or median sensitivity to
20 liquid carbofuran, generally de minimis or low risk if
21 species have high sensitivity to liquid carbofuran, but
22 we did find intermediate risk for highly sensitive
23 species if they forage extensively in potato fields
24 which has the highest application rate for the product.

25 Waterfowl species in alfalfa is quite a

1 different scenario. Alfalfa is...is actually
2 attractive to waterfowl. Waterfowl will actually feed
3 directly on alfalfa which is different from other
4 crops. And during migration, they have the potential
5 to gorge feed, because they...they've been undergoing a
6 high energy activity, flying, for a number of hours,
7 and so, they gorge feed quite often when they alight on
8 fields.

9 So, to account for this behavior, we assume
10 gorge feeding for waterfowl species in alfalfa, and we
11 further assumed 100 percent foraging time on treated
12 fields. And when you make those assumptions, American
13 widgeon are at high risk regardless of sensitivity, and
14 Canada goose are at high risk if they have high or
15 median sensitivity, intermediate risk otherwise.

16 Now, I think there's a little context needed
17 here. For a waterfowl species to actually gorge feed
18 in a treated field...this is actually a fairly
19 infrequent event, because the fields would actually
20 have to be in the flyways. They would have to be
21 treated at the time that the birds are migrating
22 through the area, and in fact, most of the time, by the
23 time treatment occurs in alfalfa, the waterfowl species
24 are much further to the north, but, occasionally, it
25 does happen, and so we wanted to look at this scenario.

1 So, it's a relatively infrequent event is the
2 message I want to say, but when all the things align,
3 flyways are in the area where there are treated fields
4 and the birds happen to land on treated fields shortly
5 after application, there can be very high mortality,
6 according to the model.

7 Let's look at a typical result. Here are the
8 risk categories shown here for the...that separate
9 high, intermediate, low, and de minimis risk. The
10 example being presented here is killdeer in corn.
11 Post-emergent foliar spray. Application rate of 1
12 pound of active ingredient per acre. So, what do the
13 risk curves look like?

14 Here's the result if we assume that killdeer
15 are a sensitive species, a 5th percent...a 5th
16 percentile species. That's that red line that just
17 came across here. And how you read this is there's
18 about just less than 20 percent probability that
19 mortality will be 5 percent or greater.

20 Whereas if you go over to, say, 30 percent
21 mortality and you read back across here, that would be
22 roughly about an 8 percent probability of 30 percent or
23 greater mortality for killdeer in treated fields. And
24 that's how you read one of these curves.

25 Because this risk curve, at least part of it,

1 is between this line here and this line here, that's
2 the low risk area. So, this outcome would be
3 categorized as low risk.

4 If we assume...if we assume that killdeer are
5 a median sensitivity...we really don't know what their
6 sensitivity is...here is the result, and, basically,
7 that's a de minimis risk result. There's a very low
8 probability of any mortality to killdeer in corn.

9 And, as you would expect, same sort of result
10 if they're a tolerant species. That's a green line
11 here. It's actually right underneath that blue line.
12 You can't see it here. Okay?

13 So, that's an example of what results look
14 like for a lot of our passerine bird species in crops
15 like corn, cotton. Potatoes, sometimes the curves are
16 higher than that, and if you look at the risk curves
17 for waterfowl gorge feeding in alfalfa, they would be
18 up here. They would be up in this high risk area, very
19 high probability of severe mortality.

20 All those risk curves are presented in our
21 report.

22 In the ab...as has become clear, I think, in
23 the absence of species-specific toxicity data, the
24 uncertainty regarding predicted mortality can be quite
25 high. This point was made yesterday, and we certainly

1 concur.

2 To get at that issue, what EFED did in their
3 2005 report is they used their mean mortality estimates
4 for the entire species complex...so that's all the
5 focal species they looked at...times the three
6 sensitivities to estimate what risk might be for the
7 community...at the community level for birds that
8 forage in treated fields. This is a...a very
9 interesting approach, and we repeated these analyses
10 for each of the exposure scenarios that we did.

11 Here's an example output. This is banded
12 application on corn, 1 pound of active ingredient per
13 acre. On the x axis is bird mortality going from zero
14 to 100 percent. And on the y axis, we have percent
15 species affected.

16 We did the analysis for TIM Version 1. This
17 is the exact same result that EPA got and presented in
18 their report, and we did the analogous simulations in
19 Liquid PARAM. That's the blue curve.

20 So, let's get an idea of what this really
21 means. If you look at the predictions from TIM Version
22 1, it's predicted that for this use pattern, 67 percent
23 of the species would have greater than zero percent
24 mortality.

25 28 percent of the species would have at least

1 27 percent mortality. So, if you go to the x axis
2 here, at 27 percent, go up and read across to the y
3 axis. That's a 28 percent of species would have at
4 least 27 percent mortality.

5 And for the species at greatest risk, they
6 would experience 86 percent mortality.

7 In Liquid PARAM, the vast majority of species
8 would not be predicted to have any mortality from this
9 scenario, and the species at greatest risk would
10 experience 3.3 percent mortality. Obviously, dramatic
11 differences between the two models, and I would state
12 that this kind of curve that you're seeing for a very
13 common application scenario in recent decades is a mass
14 mortality event.

15 This is even more dramatic for foliar spray
16 on corn, again, a common use pattern of carbofuran in
17 recent decades. Here, you're seeing greater than 50
18 percent of the species experiencing more than 50
19 percent mortality. That is a massive bird kill with
20 some bird species experiencing as high as 95 or even
21 100 percent mortality. Quite...quite a bit lower
22 predictions in Liquid PARAM.

23 Based on the evaluation of model performance
24 that we did for TIM Version 1 and Liquid PARAM, we
25 would argue that TIM Version 1 dramatically

1 overestimates risk. And why is that the case?

2 I think time step is a major reason, because
3 time step reduces...with a longer time step like 12
4 hours, that reduces the influence of rapid processes
5 such as metabolism and degradation in the field.

6 The rate of metabolism that was used by EPA
7 in their assessment was based on whole body
8 elimination. We used a value based on recovery of
9 brain...from brain acetylcholinesterase inhibition, a
10 much faster number..

11 Avoidance was not included in TIM Version 1.
12 It was in Liquid PARAM. Dietary matrix influence was
13 not included in TIM Version 1, but it was included in
14 Liquid PARAM.

15 And there are a number of other possible
16 explanatory variables as well, because we did do
17 dietary residues quite differently, proportion time
18 foraging in the field and so on quite differently.

19 And even in TIM Version 2.0 which does have a
20 better time step, a quicker time step, 1 hour, because
21 they use quite different daily foraging behavior
22 patterns, something approaching gorge feeding, I would
23 argue that that also leads to higher predictions of
24 mortality than you would see with Liquid PARAM which
25 has the same time step.

1 So, those are some of the reasons I believe
2 that TIM Version 1 and 2.0 over-predict risk.

3 A little bit...a little note on how we dealt
4 with uncertainty in Liquid PARAM. I think it's
5 apparent to anybody who's...who's been involved with
6 avian risk assessment of pesticides, there is limited
7 information for a number of the input parameters
8 that...that we need to...to estimate exposure and risk.
9 As I mentioned before, direct measures of the
10 proportion of diet obtained from treated fields by
11 individual birds is just not available for North
12 American bird species, at least the ones we're
13 interested in.

14 Toxicity data are not available for most
15 focal species, and what toxicity data are available
16 simulate gorge feeding, that bolus dose placed in the
17 crop of the bird or the esophagus of the bird. That is
18 not the typical feeding pattern in...in the field. And
19 no matter which model you're considering, TIM Version
20 1, 2.0, 2.1 or Liquid PARAM, they're affected by these
21 sources of uncertainty. I think we need to be up front
22 about that.

23 Like I said, I hope five, ten years from now,
24 we're going to have better data and improved models as
25 a result of that.

1 In this example when information was limited,
2 we took a number of steps to deal with that. The
3 preferred approach was to have studies conducted to
4 fill the data gaps, and you heard about those studies
5 from Keith.

6 To account for uncertainty where possible,
7 so, for example, the allometric model that was used for
8 food metabolic rate, that allometric model was a
9 regression model. It has an error term. We
10 incorporated that error term in our assessment and in
11 our model which was not done in TIM Version 1.

12 We partitioned variation between individuals
13 for...for dietary residues and proportion time foraging
14 in the field or between fields and within fields.

15 And failing all that, we used conservative
16 assumptions. For example, for brain...for recovery
17 from brain acetylcholinesterase inhibition, we used the
18 highest half-life that was from that study. You could,
19 in a refinement of the model, actually put the dose
20 dependence relationship between half-life and dose and
21 actually refine the model from there. That line only
22 had three points on it, so we're a little uneasy about
23 that and went with a conservative assumption instead,
24 but there's no reason why you couldn't refine the model
25 to...to deal with that dose response relationship.

1 Okay, that...that's the part of my talk to do
2 with Liquid PARAM. Talk very briefly about other lines
3 of evidence. Yesterday, you heard from Melissa Panger
4 a list of deficiencies that have been associated with
5 state monitoring studies. There have been a number of
6 monitoring studies conducted by states where they go in
7 and look for dead birds following application of
8 carbofuran.

9 And there are deficiencies in a lot of the
10 monitoring studies, and we acknowledge that. For
11 example, the use of ATVs to go look for carcasses is
12 obviously an inappropriate way to go look for dead
13 birds. You would...you would miss a lot of dead birds.

14 But there were some studies that were well
15 conducted. There was kind of a broad brush used
16 approach yesterday, you know, oh, there was all these
17 deficiencies, and they apply to all state monitoring
18 studies. Well, that isn't true. It applies to some,
19 but there are some studies that have been well
20 conducted.

21 These studies have been reviewed by Smith,
22 1997. That report is in the public docket. It's quite
23 an extensive review of all the state monitoring
24 studies. And I'm just going to touch on a couple of
25 these studies that were better conducted studies and

1 talk a little bit about the results that they got.

2 So, California, they undertook state
3 monitoring studies in 1995 and 1996. Searches were
4 conducted by foot of the perimeter and interior of the
5 field. All together, 153 miles were searched following
6 application of carbofuran, liquid carbofuran. Those
7 searches were conducted in zero to 3 days post
8 application. Searches included census counts for each
9 of the species observed in and around the fields.

10 I should further note that the searches that
11 are involved in that study were actually trained
12 searchers. They were trained by the California
13 Department of Fish and Game, I think. I just have the
14 abbreviation in front of me, but anyway, they were
15 trained by the state agency.

16 And what they found was they didn't find any
17 mortalities due to carbofuran in those 153 miles that
18 they searched. They did find 7 birds which...dead
19 birds which, when you did the residue analysis, it was
20 pretty clear that it was an organophosphate that caused
21 those mortalities. So, it wasn't a case of them
22 missing dead birds. They did find dead birds. They
23 just weren't due to carbofuran.

24 Oklahoma in 1995, 46 acres of edge and field
25 were searched by foot 2 days after treatment. Again,

1 census counts. Again, zero mortalities due to
2 carbofuran.

3 And just a clarification. In the RED report,
4 EPA 1996, it's claimed that ATVs were used in those
5 California searches. They were not.

6 Texas, I want to talk a little bit more about
7 Texas, because Texas has probably done the most
8 comprehensive state monitoring program for carbofuran.
9 In 1995 and '96, they surveyed 697 linear miles of
10 perimeter and edge habitat by foot 3 hours to 15 days
11 post treatment. They didn't do counts or abundance
12 determinations for each species of bird, but they did
13 note presence/absence of species, and no dead birds
14 were found.

15 1997, EPA requested that 30 acres be searched
16 on 30 randomly selected sites, that these be done 24
17 and 48 hours post treatment, that the transects be 6
18 feet wide in areas of wildlife use which would be
19 primarily the edge and border areas but also the field
20 interiors, and that the searches be done by walk at
21 less than 2 miles per hour. So, EPA had reviewed the
22 profile. This is what they asked for.

23 To the extent that the state could, they
24 complied with these requests. They search...all
25 together, they searched 273 acres. They did so 48

1 hours post treatment, because they were not allowed to
2 enter the field sooner than that. All together, 392
3 miles were searched at the pace requested by EPA.

4 These searchers were also trained researchers. They
5 were trained by state and federal wildlife agencies.

6 Numerous wild birds found in and around the
7 fields, and these were censused. Zero mortalities due
8 to carbofuran.

9 Just to give you an idea of how intense these
10 searches were, there actually was a mourning dove nest
11 that was found in a treated cotton field. It was
12 detected 2 days post treatment, so during the first
13 search, and they actually went back repeatedly to find
14 out how that nest fared. The eggs did hatch. The
15 birds did fledge. That's...that's an ancillary
16 comment. It's nothing about whether there's risk in
17 this field or not. It just gives you an idea of how
18 involved the searchers were in searching these fields.

19 A little bit about incidents. You heard a
20 lot about incidents yesterday. What I've got here is a
21 summary of the incident reports for liquid carbofuran
22 1998 to present. This is for birds. On the x axis are
23 a number of categories from abuse/misuse, unknown,
24 alfalfa, and then the five crops that are currently
25 included on the amended label.

1 What has happened, if we look at number of
2 dead birds, there has been a tremendous number of dead
3 birds that have occurred due to misuse, and I'll come
4 back to this in a little while, a few due...due to
5 unknown use. There was a large number of birds killed
6 in one incident for alfalfa, and then very few birds
7 killed for the remaining crops...that have been killed
8 on the remaining crops.

9 If you look at number of incidents, there are
10 a large number of abuse and misuse incidents, a few
11 unknown, one for alfalfa, one for corn, nothing for all
12 the remaining crops.

13 The reason we picked this interval of 1998 to
14 present is that reflects the current label. John, in
15 his earlier presentation, noted that there were a
16 number of label changes in 1997. The influence of
17 granular product on incidents has been removed at this
18 point. So, this is a...a more accurate picture of what
19 might be occurring in this time frame.

20 A little bit about this number here, 31,048.
21 At least 27,000 of those birds is due to one incident.
22 And that incident was an Illinois baiting incident.
23 The farmer actually was quite annoyed by all the birds
24 that were foraging in his field. He took seed...grain,
25 actually...treated it with undiluted furidan, and then

1 broadcast that over the field. It's hard to argue that
2 that's a clear misuse, an off label use of the product.
3 He was charged as a result.

4 So, 27,000 of those...those birds on there or
5 more were due to that particular incident.

6 Also included in that bar there is a...the
7 cauliflower...Colorado sunflower incident that you
8 heard about yesterday, that complicated scenario that
9 Melissa described. It was a large bird kill there.
10 The reason we've moved it from an unknown to the
11 misuse...yesterday, EPA had it in the unknown
12 chara...category, and we have it in the abuse/misuse
13 category...is because that grower entered a guilty plea
14 with the Department of Justice January 3rd of this
15 year, admitting to deliberate misuse of the product.
16 It's called an off label use, and so, that does not
17 apply. That incident is not an unknown; it is a
18 misuse.

19 One other comment. You'll note here the
20 value that there was 803 waterfowl birds that were
21 killed in this one incident in alfalfa. In the figures
22 presented yesterday, it was 1200 birds in this
23 incident. I don't know where the discrepancy comes
24 from. All I can say is that that value that we use
25 here was based on a Freedom of Information request that

1 the registrant submitted to the EPA, and EPA provided
2 this number to us as a result of that request.

3 Otherwise, I can't explain the discrepancy.

4 A little bit about incidents in New York and
5 California. As you remember...

6 **DR. HEERINGA:** Dr. Moore, if you could,
7 try to push to wrap up in about ten minutes.

8 **DR. MOORE:** I am so close to wrapping
9 up. Okay. Are we into lunch or...all right. You have
10 no concept of time when you're up at the mike.

11 Very quickly, then, you noticed yesterday
12 that the vast majority of incidents that have been
13 reported by states since 1972 were in New York and
14 California. There's a reason for that. 29 of the 38
15 incidents from New York State actually occurred in the
16 city, and they represent a clear misuse, the baiting of
17 pigeons.

18 California, 50 of the 111 incidents were
19 related to application on grapes. That's a unique
20 application method. Doesn't apply to any other crop,
21 and as explained yesterday, it has since been
22 mitigated.

23 So, I think that partly explains why there's
24 a lot more incidents reported by New York and
25 California compared to other inci...states.

1 So, to wrap up, which the chairman apparently
2 wants me to do, some final conclusions. We believe, as
3 a panel, an independent panel, that liquid carbofuran
4 poses minor risks to the field birds that forage in
5 treated row crop fields, such as corn, melons,
6 potatoes, and so on. That gorge feeding waterfowl may
7 be at high risk or...or intermediate risk in treated
8 alfalfa fields if they happen to forage in those fields
9 shortly after application.

10 We believe that the results from Liquid PARAM
11 are at least consistent with controlled field studies,
12 the results of field monitoring studies and incident
13 reports.

14 And we would contend that it is unlikely that
15 expert field researchers, trained searchers, farmers,
16 growers' associations, government officials, and so on
17 would have missed, over a long period of time, EPA's
18 predicted mass mortalities associated with labeled uses
19 of flowable carbofuran. That just seems very unlikely.

20 And so, if that's what's predicted by EPA
21 with TIM Version 1 and subsequent versions, it suggests
22 to us that there are issues with regard to model
23 structure for TIM Versions 1 and 2.0 and 2.1, and so,
24 we would argue that questions regarding model structure
25 are critical in considering the risk of flowable

1 carbofuran to birds.

2 There no questions addressing model structure
3 in your charge, and we would respectfully request that
4 you, if you have time at least, to consider questions
5 regarding model structure. Some possible questions to
6 consider, are refinements to the model structure of TIM
7 Version 1 required to adequately understand the risk
8 posed by liquid carbofuran to birds?

9 Is it better to ignore critical, albeit
10 uncertain, variables or incorporate the available
11 knowledge about the variables? And the reason we pose
12 that question is the EPA had a number of questions
13 about the avoidance study, the acetylcholinesterase
14 study, and the dietary matrix study. They noted that
15 there's uncertainty about that, and so, rather than
16 deal with that uncertainty in...in the confines of
17 their model, they would rather not include it in their
18 model at all.

19 I'm reminded of a famous quote by Charles
20 Babbage, errors using inadequate data are much less
21 than those using no data at all. We do have data here,
22 obviously, and...this is my...my own further
23 statement...using adequate data would be even better.
24 We obviously believe that the data from the
25 registrant's submitted studies are adequate, even if

1 there are uncertainties.

2 And, really, if you think about it, all
3 variables in the avian model are uncertain, and some of
4 them are really uncertain, such as proportion time
5 foraging in the field, and those variables were
6 included in TIM Version 1, 2.0, and 2.1, so that
7 argument doesn't hold for excluding some of the
8 variables that we've addressed in our studies.

9 We would like to see what the panel thinks
10 about Liquid PARAM. Is it a better model for assessing
11 avian risk? And as sort of a final grand question,
12 which of the EPA and registrant assessments represents
13 the best available science for characterizing the risk
14 of liquid carbofuran to birds?

15 We know you have a packed agenda with the
16 charge questions you already have, but we do hope that
17 there is time to address some of these more fundamental
18 questions regarding model structure.

19 And I thank you for your time and attention.

20 **DR. HEERINGA:** Thank you very much, Dr.
21 Moore and Dr. Solomon as well. A very detailed and
22 comprehensive presentation.

23 I would like to turn to the panel...we're
24 going to break for lunch shortly, but...to see if there
25 are several key questions, particularly for those of

1 you who have questions where you think that the...in
2 regards to the environmental exposure and avian risk
3 assessments. Yes, Dr. Clark?

4 **DR. CLARK:** This gets to the field
5 studies' differences. In terms of the detection
6 efficiency and observer reliability, were those
7 estimates included in the model? Were they known?

8 **DR. MOORE:** They were included in
9 the...sorry, Dwayne Moore. Those estimates of carcass
10 search efficiency and...and loss rates from the fields
11 were done by the study authors for each plot. They
12 provided that data in those field reports, and we used
13 that information, then, in making our calculations
14 regarding percent mortality. We provided the raw data
15 as well as the corrections.

16 **DR. CLARK:** As a follow-up, then, in
17 terms of the population estimates as well in terms of
18 the authors were estimating what the population numbers
19 were in the area, were the same sorts of reliability
20 estimates and...calculated for that as well?

21 **DR. MOORE:** I'm going to turn this over
22 to Lou Best.

23 **DR. CLARK:** And detection efficiencies.

24 **DR. MOORE:** Yeah, Lou Best is actually
25 more of an expert, so I'll let him answer that

1 question.

2 **DR. BEST:** No, as was stated, the...oh,
3 excuse me. I'm Lou Best. As was stated, they did make
4 a correction for disappearance rate and...and
5 efficiency searching for the carcass. There was no
6 such correction made for bird observations during the
7 surveys which merely means that those bird counts were
8 actually under-representative of the total bird
9 community that was there, because no adjustment was
10 made for detectability of the birds.

11 **DR. HEERINGA:** Dr. MacDonald, then Dr.
12 McCarty.

13 Just for for the panel members, too...Ken
14 asked for this question...I expect this period of
15 questioning to continue after lunch for a short period
16 of time, so you don't have to rush in, but I want to
17 take the proper time.

18 **DR. MACDONALD:** Yeah, I'd just like to
19 comment. I think we've had some extremely good
20 presentations, and I'm very impressed with the
21 description of the...the model, the Liquid PARAM, but I
22 think it's impossible for us to say which model is good
23 science, because we haven't had peer review of the
24 Liquid PARAM model. We haven't had EPA review of it.
25 We just have to take your word that it works as...as

1 you describe.

2 **DR. MOORE:** Dwayne Moore. Yeah, I
3 agree. I mean, if it had gone to peer review, I think
4 that adds credibility. No doubt about it.

5 What we have provided, though, is a very
6 detailed description of the model and all of its
7 inputs. Every calculation was described in our report,
8 and we do have a number of avian experts around the
9 table who have experience. And so, I think the
10 information is there to actually do that peer review
11 that you think is important. And I agree it's
12 important.

13 **DR. HEERINGA:** Dr. McCarty?

14 **DR. MCCARTY:** Two quick questions. One,
15 a quick follow-up on the bird observations and the
16 census of what's out there. Were those unlimited
17 radius counts that you did?

18 **DR. BEST:** In the alfalfa study, they
19 were transect counts. I can't remember...

20 **DR. MCCARTY:** Do you know the distance?

21 **DR. BEST:** ...the width, and I would
22 have to go back to the studies, but the studies do
23 describe the width of the transects and also the length
24 of the transects. And they...what they did is made the
25 surveys on the perimeter of the field, so they were

1 simultaneously counting birds on the field perimeter as
2 well as birds in the field edge.

3 **DR. MCCARTY:** But you don't remember the
4 width and...

5 **DR. BEST:** I haven't recently looked at
6 the study, no, but it is in the report.

7 **DR. MCCARTY:** And we don't...

8 **DR. MOORE:** We can get that information
9 for you after lunch.

10 **DR. BEST:** We can get that information
11 for you.

12 **DR. MCCARTY:** Okay, that would be good.

13 The second quick question is on page 18,
14 talking about the...the even daily feeding rates or
15 feeding rates through the day. I know some of those
16 studies, and I know at least some of them involved
17 feeding nestlings, and I'm wondering if the estimates
18 you...you use partition out the adults feeding
19 themselves versus adults going out foraging and
20 bringing food to the nestlings, because, of course, the
21 models, as far as I know, ignore nestlings, and they're
22 just focused on adults.

23 Do you know...were you able to partition out
24 how the distribution of adults feeding themselves
25 looked?

1 **DR. MOORE:** Dwayne Moore. In the model,
2 no. As...as I understand it, those observations were
3 just counts of how many trips the bird took away from
4 the nest and returned, but I'll let Lou expand on that.
5 He's...he was involved with some of those studies.

6 **DR. BEST:** That's correct. They were
7 simply frequency counts of...of bird forays from the
8 nest and then returning to the nest to feed the
9 nestlings. The assumption there would be that the
10 foraging pattern of adults would...would mirror the
11 foraging pattern for the young which I don't believe is
12 an unreasonable assumption in terms of the frequency of
13 forays, because much of the time they're...they're
14 going to return to the nest they're spending brooding.
15 They would be actually at the nest itself. So, they
16 have to feed at the same time they...they go on a foray
17 to seek food for their young.

18 **DR. HEERINGA:** Yes, Dr. McCarty?

19 **DR. MCCARTY:** Would that apply, say, to,
20 then, you know, a recently arrived migrant in May,
21 small passerine crashing down in a fence row or
22 something or a...a shore bird, say, a golden flubber
23 during migration in early May in a cornfield?

24 **DR. BEST:** Lou Best again. That's
25 certainly a valid question. There is, I think, an

1 important distinction to be made between waterfowl and
2 gallinaceous birds like bobwhite quail and passerines
3 in the fact that the passerines do not have a crop.
4 They do not have a storage organ which necessitates
5 them feeding more frequently throughout the day. So,
6 the comparison is confounded by that.

7 **DR. HEERINGA:** Dr. Sample and Dr.
8 Sparling have questions, but if...I'm going to ask them
9 to hold those till after the lunch.

10 Before we do break for lunch, I...I want to
11 just give you my synopsis of how things are moving
12 along. Clearly, we are behind schedule, and my deepest
13 apologies to public presenters who are here for a short
14 period of time to make their...their statements and
15 their presentations, but we have to stay with the order
16 of the agenda. It is floating, and these discussions
17 are absolutely critical to the scientific review.

18 So, my apologies, but I am going to proceed
19 with the careful review of this material.

20 Before we break for a one-hour lunch...I want
21 everybody back at 1:30...the Designated Federal
22 Official, Dr. Sharlene Matten, has a few comments to
23 make.

24 **DR. MATTEN:** Actually, Dr. Heeringa took
25 part of what I was going to say. The public

1 commenters, I understand that one or two may have to
2 fly back. If you would let me know what time you need
3 to fly back, with some adjustments with other public
4 speakers, we might...we certainly don't want you to
5 have to pay \$1000 to reschedule your flight. That's
6 not what we intended. While we're floating, we are
7 certainly cognizant of people's time, and if you could
8 come see me if you have a 5:00 o'clock flight or 6:00
9 or 7:00, we may be able to make some adjustments.

10 Our usual process is to take the oral comment
11 requests in the order in which they come to me, and so,
12 if there's some flight concerns, please let me know,
13 and we'll...Dr. Heeringa and I will...we'll talk about
14 it and we'll let...because FMC has several more hours
15 of presentations.

16 The other note I wanted to make is if you've
17 come to me with your scheduled time, please try
18 during...at least during the presentation to more or
19 less stick to the time in which you've at least given
20 me previously.

21 Thanks.

22 **DR. HEERINGA:** Thank you, everybody,
23 and we will break for lunch now. Again, we'll resume
24 at 1:30.

25 **(WHEREUPON,** Session B was concluded and a luncheon

1 recess was taken.)

2 **DR. HEERINGA:** As soon as we can get a
3 Designated Federal Official, we'll get under way.
4 We're still waiting a Designated Federal Official. I
5 can't start without either Sharlene or Steve. Can I
6 deputize somebody? I don't know.

7 In the process, we have entered a period of
8 public comment, and we are receiving presentations by
9 expert panels that have been assembled by the
10 registrant and have conducted various research and
11 developmentals and exploration activities. We have
12 heard the presentation on the avian risk assessment
13 additi...supplemental studies and actual modeling
14 efforts with Liquid PARAM, and we are at a point now
15 where the panel is addressing questions of
16 clarification to...to the presenters on this topic.

17 Dr. Matten, the DFO, reminded me, too, we
18 want to make sure we stay within reasonable time
19 constraints on all of our comments. That includes both
20 presentations and our questions, but, again, I'm going
21 to balance that to make sure that we get full
22 development and exploration on...on these issues. So,
23 I'll try to manage that accordingly, but you know where
24 I'm going with things.

25 So, let's...at this point, let's return to

1 questions of clarification.

2 **DR. MOORE:** All right, Dr. Heeringa, we
3 do have an answer to one of the questions posed before.

4 **DR. HEERINGA:** Yes, Dr. Moore, why don't
5 you provide that?

6 **DR. MOORE:** Well, actually, Lou Best
7 will provide an answer to that. That was with regards
8 to the field studies.

9 **DR. BEST:** There...there were some
10 questions asked about the...the length and width of
11 the...the nature of the transects. For the alfalfa
12 study, the transect width in the middle of the field
13 was 50 meters wide on either side of the midline of the
14 transect. On the field edge, it was 25 meters on
15 either side of the midline. They were fixed width
16 transects.

17 In the cornfield study, it was a bit
18 different there. They had a variable width transect
19 for the edge habitat, depending upon the extent of that
20 edge habitat, because they were dealing with, I think,
21 fence rows and so forth, and because of the difficulty
22 in making observations in tall corn, they actually did
23 their surveys from platforms. They were
24 positioned...they had two per field. They had three
25 surveys per week, and the radius that they surveyed

1 was, let's see, I think it was a 50-foot radius from
2 those...50-yard radius from those platforms.

3 **DR. MCCARTY:** So, would I interpret from
4 that the variable width on the edge means they tried
5 to...they just count birds in what they were defining
6 as edge?

7 **DR. BEST:** Right. What you typically
8 will find is...is something like a fence row or some
9 strip cover along the edge, and, basically, the width
10 is dictated by the width of that particular strip
11 cover.

12 **DR. HEERINGA:** Thank you very much, Dr.
13 Best.

14 Picking up where we left off before our lunch
15 break, I think Dr. Sample, Brad Sample, had a question.

16 **DR. SAMPLE:** Yeah, I was looking
17 through...or in the presentation, you were talking
18 about the application of the...a factor to adjust for
19 food matrix. I noticed that you used a value of, I
20 guess it was, 3.8.

21 **DR. MOORE:** Yes.

22 **DR. SAMPLE:** And there were...that was
23 based on the quail study. There was also the data that
24 were based on the mallards which was a lower value, a
25 value of about 2, and I notice you did not use that in

1 your model and did not discuss it. Is there a
2 particular reason, and how does that...how did that
3 affect your modeling results?

4 **DR. MOORE:** That value of 2 for mallards
5 was the value devised by EPA. In our analysis of the
6 mallard data...and this is in our...our report as
7 well...we calculated a worst case lowest value for the
8 mallard study for the adjustment factor and a best
9 case, and it...that range was from 2 to 4.6, depending
10 on what assumptions you made about slope of the curve
11 and so on, the probable slope. And that 2 to 4.6
12 actually brackets 3.8 in the middle. So, we felt that
13 3.8 was a reasonable factor to apply for all of our
14 analyses.

15 Obviously, that's a...an uncertainty as to
16 whether the results for two bird species apply to all
17 other focal species, but as...as a reasonable estimate
18 for both bobwhite quail and mallards, around the 3.8.

19 **DR. SAMPLE:** And you include that
20 parameter as a...as a fixed value?

21 **DR. MOORE:** We did, and honestly, I
22 think if we had enough to actually put a distribution
23 around that, if we had more species...I know where
24 you're going with that...I think we would treat that as
25 an uncertainty as well.

1 **DR. HEERINGA:** Dr. Sparling had a
2 question.

3 **DR. SPARLING:** Actually, if I could,
4 I've got several questions, but I'm going to ask two,
5 if I could.

6 **DR. HEERINGA:** Certainly.

7 **DR. SPARLING:** Okay. The first question
8 is with regards to the food avoidance study. In the
9 Liquid PARAM model, did you try to examine what the
10 effects would be if you did not have food aversion
11 going on there?

12 **DR. MOORE:** Yes, we did. In our
13 sensitivity analyses, we ran set exposure scenarios.
14 There's two of them, a high number and a low number
15 scenario, and we ran them with avoidance turned off and
16 with avoidance turned on, and it makes quite a bit of
17 difference.

18 **DR. SPARLING:** And so, with avoidance
19 turned off, there would be substantially more
20 mor...mortality?

21 **DR. MOORE:** Yes, there would be.

22 **DR. SPARLING:** Okay. The second
23 question, then, deals with the...and I think this is
24 might...might be a follow-up on Dr. Sample's. In your
25 studies, your extra studies that you submitted, you

1 indicated that the aqueous toxicity for the carbofuran
2 was inaccurate on a bolus, that it was far more toxic
3 than it was in a food bolus.

4 **DR. MOORE:** Mm-hmm.

5 **DR. SPARLING:** Okay. At the same time,
6 it's my understanding in Liquid PARAM, you're able to
7 model uptake or exposure from puddles?

8 **DR. MOORE:** We...in the...Dwayne Moore.
9 In Liquid PARAM, you have options whether to...for
10 drinking water scenario whether to do puddles day of
11 application, puddles day after, or dew only throughout.
12 For the results that we presented in our risk
13 characterization, it was dew only, and that was to
14 mirror exactly what was done by EPA in their assessment
15 report. So, there was a dew only drinking water source
16 in the...in our models.

17 **DR. SPARLING:** Okay. And then, when you
18 looked at the effects and you made your decision yes,
19 there was an effect or no, there wasn't an effect, was
20 that based on food bolus LD50 or the aqueous LD50 or
21 neither?

22 **DR. MOORE:** It would be based on the
23 food bolus. So, what essentially, you're...I think, if
24 I know where you're going...the dose response curves
25 were all moved three-fold to the right to account for

1 dietary matrix exposure, and we did not adjust that for
2 the drinking water part that would be coming in.

3 So, there's two dietary...or two routes of
4 exposure. There's a dietary, and there's an assumption
5 of dew.

6 Computationally, it would have been...I don't
7 even know how you would do it. It would be very
8 difficult to have...adjust that dose response curve for
9 how much they were getting from drinking water versus
10 diet. It would be an interesting exercise, albeit a
11 difficult one.

12 But what we found was that the contribution
13 that was coming from the dew drinking water sources was
14 relatively minor, and this...this is corroborated by
15 EPA in their assessment. They found that that source
16 of exposure was relatively minor.

17 So, as our interim solution, I guess, we just
18 simply went with the dose response curve adjusted for
19 the dietary matrix.

20 **DR. SPARLING:** Okay. And one other
21 question. This is going...going right back to what
22 I...my first question. You said there was a
23 considerable difference between the food avoidance
24 calculation on mortality and without the food
25 avoidance. Are we talking about an order of magnitude?

1 Are we talking about a two-fold? Can you give me a
2 ball park figure?

3 **DR. MOORE:** I can give you a ball park
4 figure. Be easier if I can use the graph for you.
5 Give me two seconds. Almost there.

6 Okay, for horned larks which is a high
7 exposure scenario, if you look at...at the results,
8 assuming high sensitivity for that species, we would
9 have predicted about 50 percent mortality if you do not
10 account for avoidance. If you account for avoidance,
11 assuming a 1-hour time lag in response, that drops down
12 to about 14 percent predicted mortality, and it...if it
13 were instantaneous, which it isn't, it would drop down
14 to just a few percent.

15 That's our high exposure scenario assuming
16 high sensitivity. If you assume median sensitivity or
17 low sensitivity, it really doesn't matter, very low
18 mortality, and if you do a low exposure scenario,
19 avoidance...turning avoidance on or off doesn't really
20 matter, obviously. Very low predicted mortality.

21 So, it's really just in a high exposure
22 scenario with a bird species that gorges in the field a
23 lot that it can make that sort of two and a half-fold,
24 three-fold difference.

25 **DR. SPARLING:** Thank you.

1 **DR. MOORE:** And that's on, for anybody
2 looking at it, it's page 118 of the report, Moore,
3 et.al., 2007.

4 **DR. HEERINGA:** Thank you, Dr. Moore and
5 Dr. Sparling. Dr. Clark?

6 **DR. CLARK:** It's Larry Clark. I'm just
7 trying to get some clarification on the food avoidance
8 studies, so...I don't know if you had all this
9 information. So, how long were the...the birds down
10 once they were exposed to their initial dose, inactive?

11 **DR. MOORE:** I think that's probably a
12 question for Larry, Larry Brewer.

13 **DR. BREWER:** Larry Brewer. In the food
14 avoidance study, we didn't have any birds that showed
15 any signs of exposure.

16 **DR. CLARK:** Okay. And...and then, two
17 other very simple questions is, were these studies run
18 over a standard work week? So, did they start on a
19 Monday and proceed through the Friday?

20 **DR. BREWER:** Not necessarily, no. Our
21 lab runs all week long, and there's someone there every
22 day of the week and usually a team of people.

23 **DR. CLARK:** Okay. I'm just trying to
24 understand, for example, the...you have a total daily
25 feed consumption data which is the...the food intake

1 adjusted for body weight over timer, and the controls
2 show a pattern as well. Were the birds visually
3 isolated?

4 **DR. BREWER:** From each other. I think
5 probably what we saw in that little pattern that you
6 saw in the control of the offering is a...is something
7 we see in caged birds quite often. When you initiate a
8 study, there's a substantial amount of activity, and
9 it...it has an influence on the birds. It...it...in
10 the form of stress. In a few days, they...they get
11 used to...especially ducks. They get used to your
12 patterns. They relax a little bit. They become
13 more...more likely to...to consume normal amounts of
14 food, and so you'll see that pattern.

15 And since it did happen in the controls,
16 everything we did with regard to comparisons, I'd say,
17 was back to the control, and so we felt that it was not
18 an issue.

19 **DR. CLARK:** Thank you.

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

21 **DR. MONTGOMERY:** Cheryl Montgomery. I'd
22 like to follow up on the slide number 10 that's titled
23 Appropriately Conducted Study. I believe Dr. Solomon
24 presented this information. It says here there's no
25 learning of location of contaminated food. Feeder was

1 switched each day.

2 And I was wondering if...I don't know if you
3 were present yesterday or not, but the EPA put up a
4 right and left side preference feeding for the birds,
5 and I was wondering if you would be willing to comment
6 on what EPA presented yesterday and how that reconciles
7 with this, if it does.

8 **DR. SOLOMON:** Keith Solomon. If I just
9 go to the next slide, perhaps, this illustrates the
10 distribution of left and right side preferences in...in
11 the birds in the study. This is all of the 70 birds
12 that were used in the study, and we've color coded
13 the...the various groups there, and we saw no...no bias
14 towards one side or the other. And this data,
15 obviously, we should probably do some more statistical
16 analysis of it. Because of the time, we couldn't do
17 that.

18 So, I will ask Larry Brewer who did the study
19 to perhaps explain in a little bit more detail the
20 points and how they were determined.

21 **DR. MONTGOMERY:** Well, may I just ask a
22 clarification? Did you see the presentation that EPA
23 made yesterday? I mean, I don't remember seeing your
24 faces in the audience, so you know the slides I'm...I'm
25 referring to, the bar graphs with the left and right?

1 **DR. SOLOMON:** Yeah...

2 **DR. MONTGOMERY:** For the preference
3 there?

4 **DR. SOLOMON:** Keith Solomon again. The
5 bar...the bar graphs probably refer to...well, some of
6 them consistently favored the right side, and there
7 were other animals that consistently favored the...the
8 left side, and those were the graphs you saw yesterday
9 which were the extreme ends of the...of the
10 distribution, and the others were in between, and there
11 was no apparent bias in...in a...in the study that
12 they...and then, when we switched the feeders or
13 we...when Larry's people switched the feeders every
14 second day or every day they switched them, the...even
15 though they preferred that feeder, they were then going
16 to a feeder that was different than the one they had
17 before.

18 So, we felt that controls...well, we believe
19 that that controls as far as we...which we couldn't
20 avoid, and Larry Brewer can probably give you a little
21 more explanation on that.

22 **DR. BREWER:** Larry Brewer. For...for
23 the purposes of this...of this slide, what this is, as
24 we repeated earlier, everything on...on the right side
25 shows...of the diagonal line shows birds that favored

1 the right side of the pen, and on the left side is the
2 birds that favored the left side of the pen. And so,
3 if you look at those, there's no real bias towards them
4 doing one or the other, and in the...in the...the
5 example given yesterday, the presenter said we picked
6 an...an extreme example, and this is what we're
7 hypothesizing about that extreme example.

8 And, again, because they would favor one side
9 of the pen or the other...and I have some ideas why
10 they do that. Some birds do. Some birds don't. I can
11 get into that if you want, but because, every day, we
12 switched the feeders from one side to the other
13 containing fresh food versus contaminated food, they
14 were getting the same exposure to...to the food in
15 total number of hours throughout this day.

16 **DR. MONTGOMERY:** Was it fresh
17 contaminated food?

18 **DR. BREWER:** No, it was fresh food,
19 uncontaminated.

20 **DR. MOORE:** Right, uncontam...but it was
21 fresh uncontaminated...

22 **DR. BREWER:** Every day.

23 **DR. MONTGOMERY:** And then, but you took
24 the contaminated feed and switched it side to side, or
25 did you put fresh contaminated feed?

1 **DR. BREWER:** They had fresh contaminated
2 feed every morning.

3 **DR. MONTGOMERY:** And fresh feed every
4 morning.

5 **DR. BREWER:** And fresh feed every
6 morning.

7 **DR. MONTGOMERY:** Okay.

8 **DR. BREWER:** And the next day, they had
9 the same thing in opposite positions.

10 **DR. MONTGOMERY:** Opposite sides, yes.

11 **DR. BREWER:** Yeah. And...and with
12 regard to what makes a duck lean to one side or the
13 other, we notice in mallards that they're
14 kept...they're kept sexes separate prior to the study.

15 **DR. MONTGOMERY:** Mm-hmm.

16 **DR. BREWER:** When you put them together,
17 even though they're in metal pens with metal dividers,
18 the female mallard is the vocal leader in the group,
19 and the males can hear the females next to them if
20 they're totally randomly assigned to their cages, and
21 then the treatments randomly assigned to that, but if
22 they happen to be next to a female and they can hear
23 her, they're going to spend more time on that side of
24 the cage or if its' on the other side of the cage, and
25 this does show a random propensity towards the sides of

1 the cage, and I really think that's the explanation.

2 **DR. MONTGOMERY:** Okay, thank you.

3 **DR. HEERINGA:** Just a...a note to
4 everybody. I would like to terminate this questioning
5 at about 2:15, because we...we have three other topics
6 this afternoon to get to. So, we have about 15 or 20
7 minutes.

8 Dr. Edler and then Dr. Portier.

9 **DR. EDLER:** Just for a while on
10 that...on that slide here. There is a time behind
11 that. We have day 1 to 5, so which time actually
12 this...does this figure belong to? Because I think we
13 have a little bit of a problem here. We have that
14 statements, we have the figures, and then we have the
15 real data, and always see these three...these three
16 fields very bounce...bounce around, and the figures, of
17 course, cannot show always the data. Sometimes we need
18 some more information.

19 **DR. SOLOMON:** Keith Solomon here, and
20 I'll just...the...the raw data is available in the...on
21 the CD that you've been supplied. We have all the
22 figure from that study all available if you want them,
23 and this...this is a mean value for the study that you
24 see here. To put all of the individual days on here
25 would have made it look somewhat uninterpretable.

1 I don't know if Dr. Brewer would

2 prefer...would like to add.

3 **DR. BREWER:** Just that that...these
4 values are the total feed consumed from both sides per
5 bird for the...for the full exposure period.

6 **DR. HEERINGA:** At this point, Dr. Lu and
7 then Dr. Portier. I know Dr. Portier has some detailed
8 questions, but Dr. Lu.

9 **DR. LU:** Alex Lu. I have two
10 fundamental questions regarding the Liquid PARAM model.
11 So, you mentioned that you...you found there is a dose
12 dependent half-life of recovery which struck me as a
13 very shocking finding, because for all the
14 pharmacokinetic o pharmacodynamics parameters that you
15 estimate, the half-life is one of the few...it's not
16 the only one...that's independent from the dose. The
17 half-life effect by the route of administration will
18 have an effect by which phase are you talking about,
19 proportionately for inhalation, but in terms of dose
20 dependence, it's very difficult for me to understand
21 that there is a possibility that these two things will
22 have relationship.

23 So, if you look at your slide 20 and 21,
24 especially 20, the curve actually look really
25 identical. I mean the previous one. Yes, the previous

1 one. This one. If you plot these three curves on the
2 semi log paper and estimate a slope, that should give
3 you the same number, and that slope will represent the
4 half-life. So, I don't know how you calculate the
5 half-life. There's no number that I can base this on.

6 So, that leads you to the problem on slide 21
7 which I don't know how you calculate that the half-life
8 will lead to this linear relationship. Again, if you
9 can comment on why the half-life is dose dependent.

10 And the second question or you can comment on
11 this is that you using the half-life derived from the
12 cholinesterase enzyme recovery in the model to estimate
13 dose...to estimate body burden. It seems to me that
14 you actually use the different and wrong parameter to
15 try to come up with a different measurement outcome
16 that has nothing to do with acetylcholinesterase
17 enzyme.

18 It seems to me like...I mean, if you are
19 going to use an estimate from the enzyme data, you are
20 using some sort of pharmacodynamic model, but they're
21 kind of like pairs, the...the parent compound and
22 metabolite relationship, but I think the Agency
23 presentation yesterday was talking about looking at the
24 chemical in the environment or in the bird and they
25 come up with the estimate half-life which...which I

1 think is reasonable, but in your approach, it struck me
2 as somewhat very novel. So, if you can comment on
3 this?

4 **DR. SOLOMON:** Dr. Lu, Keith Solomon. I
5 will initially talk to that, and then Dr. Moore may add
6 some comments to that. The...what we were looking at
7 in this particular relationship here is...is not just
8 cholinesterase. That's what they're measuring as an
9 endpoint in vivo. So, we take these birds. We've
10 gavage dosed them, and then we, at various times, we
11 sacrifice them and measure the brain
12 acetylcholinesterase.

13 So, what we're seeing is a combination of
14 recovery of inhibited enzyme over time, but in addition
15 to that, if there are any remnants of the initial dose
16 of carbofuran still circulated in the body, they could
17 inhibit newly released enzyme, and this would slow down
18 the recovery rate.

19 So, it's a combination of cholinesterase and
20 metabolism that we're seeing here, and I think that's
21 why we see a slow recovery at higher dose. If I took
22 this into a test tube, as I recall doing as a grad
23 student, the recovery rate was always the same. It
24 doesn't matter, because you're dealing with pure enzyme
25 and no...no metabolism going on.

1 The...in that sense, we believe that
2 this...because we're measuring the toxic
3 endpoint...this is what kills the birds, is inhibition
4 of cholinesterase. That is actually a very useful
5 endpoint from the point of view of a risk assessment,
6 because it is clearly related to mortality. It
7 integrates, in this case, metabolism once the chemical
8 is in the body and the recovery of the cholinesterase.

9 **DR. LU:** This is Alex Lu again. I think
10 I disagree with your interpretation of this slide. If
11 you look at...

12 **DR. HEERINGA:** Dr. Lu, we might want
13 to...

14 **DR. LU:** Okay.

15 **DR. HEERINGA:** Unless it gets to a point
16 of question. I mean, if it's really clarification on
17 this, then I'll permit it. Otherwise...please, if you
18 feel that you need clarification, but just for
19 discussion at this point, I think we'd prefer to save
20 that for later.

21 **DR. SOLOMON:** Well, I can pick this up,
22 if that's permissible, Mr. Chairman, later on.

23 **DR. HEERINGA:** Yes, you certainly may
24 talk with Dr. Lu and come back to us. Very quickly, to
25 Dr. Grue and then to Dr. Portier.

1 **DR. GRUE:** Chris Grue, University of
2 Washington. Was there a carrier used for...in the
3 mallard study, the avoidance study?

4 **DR. BREWER:** Larry Brewer. In the
5 avoidance, they were...were dosed in a...they were
6 not...there...there was no carrier with regard to in
7 the feed. They weren't dosed. They were, of
8 course...it was a dietary.

9 **DR. GRUE:** That's what I'm saying. Did
10 you use a carrier, though, in mixing the...the
11 pesticide into the water...I mean, into the feed?

12 **DR. BREWER:** No, it was put in neat.
13 It's a liquid. The product is liquid.

14 **DR. GRUE:** Okay. So, okay, so there's
15 no...there's no carrier involved. Okay.

16 Maybe I'll just ask a couple other points of
17 clarification?

18 **DR. HEERINGA:** Of course.

19 **DR. GRUE:** The time, the 1-hour time lag
20 for the avoidance work...both of these are directed to
21 Dr. Moore...and the 8-hour time step for the avoidance
22 results, could you just clarify those two for us?

23 **DR. MOORE:** I'll do my best. The 1-hour
24 time lag is the simple aspect of it. There
25 are...because the birds aren't able to, as far as we

1 can tell, at field relevant concentrations, sense the
2 compound in any way through taste or smell, there is
3 not an immediate avoidance. As...as Keith talked about
4 in his...his presentation, what happens is they feel
5 symptoms from the exposure. They feel those symptoms
6 within about half an hour. If you look at that graph,
7 you'll see at half an hour is when...when the levels
8 are lowest for acetylcholinesterase.

9 So, it's...I think it's our...our hypothesis
10 is that the birds feel sick, they reduce their feeding,
11 and then as the exposure is removed, they increase
12 their feeding accordingly. So, that feeling of
13 symptoms and reduction of food intake rate happens
14 around half an hour.

15 So, because we have a 1-hour time step that's
16 either zero or 1, we make it more conservative and said
17 there's a 1-hour lag in the avoidance. It's certainly
18 not immediate. If it was immediate, it would be a
19 lower risk.

20 And what was the second?

21 **DR. GRUE:** Maybe just make a comment on
22 this first point. I...I think it's important that you
23 make a distinction between testing repellancy and a
24 pesticide-induced anorexia, and what...what you're
25 suggesting is that this is a pesticide-induced

1 anorexia.

2 **DR. MOORE:** Yes.

3 **DR. GRUE:** And...and that...the
4 distinction is important, because it relates to the
5 potential hazard in the field.

6 **DR. MOORE:** Yes.

7 **DR. GRUE:** And we can...we can talk
8 about that more later.

9 The second clarification was the 8-hour time
10 step from the avoidance results, then, into...into the
11 model. I wasn't...I wasn't clear about that.

12 **DR. MOORE:** Sure. In the original
13 study, food consumption was measured on a daily basis.
14 As I understand it from talking with...with Larry
15 Brewer, it's just not feasible to go in and measure on
16 an hourly basis, because that amount of intervention
17 would...would seriously disturb the birds. So, we have
18 a daily consumption rate.

19 The model, however, has an hourly time step,
20 so we had to get from those values in reduced food
21 consumption expressed on a daily basis to the hourly
22 time step. In the protocol for that study, it's...it's
23 clear that they had an 8-hour daylight throughout the
24 duration of that study. So, for mallards, it's a
25 reasonable assumption that they fed over that 8-hour

1 period but not during the 16-hour dark period.

2 And so, basically what we did is we took the
3 results expressed as daily divided by 8 to convert it
4 to the hours that we have in the model. Is that an
5 assumption? Absolutely, it's an assumption.

6 **DR. GRUE:** Okay, thank you.

7 **DR. HEERINGA:** Let's go to Dr. Portier
8 now who, I think, has some questions on the model
9 structure.

10 **DR. PORTIER:** Thank you. Slide 32. I
11 have a few clarification on...on the methodology in the
12 model. So, starting on the left, the initial
13 concentrations in food and water, if I look at one
14 field, one of your 1000 fields in the simulation, all
15 20 birds are going to basically receive a time series
16 for food and a time series for water.

17 **DR. MOORE:** That's correct.

18 **DR. PORTIER:** In the slope of a K curve.

19 **DR. MOORE:** That's correct. Over time,
20 they'll receive that.

21 **DR. PORTIER:** Again, for that same
22 field, you've got one degradation rate for food and one
23 for water. Right?

24 **DR. MOORE:** Actually, we have separate
25 degradation rates for each of the parameters.

1 **DR. PORTIER:** Okay. So, for the...

2 **DR. MOORE:** For the grass, forage,
3 seeds, and insects.

4 **DR. PORTIER:** So, when...when you put
5 that together into concentrations in food and water
6 over time, essentially, you've got, for each field, a
7 time series.

8 **DR. MOORE:** That's correct.

9 **DR. PORTIER:** For each foray, a time
10 series for water.

11 **DR. MOORE:** Yes.

12 **DR. PORTIER:** All right? Okay. So,
13 you've got 1000 time series. So, that's that set. So,
14 there is...

15 **DR. MOORE:** You know what?

16 **DR. PORTIER:** ...there's no bumpiness
17 over time. They're pretty much...

18 **DR. MOORE:** Well, it's smooth and...

19 **DR. PORTIER:** Smooth curve. Okay.
20 Foraging behavior is the one where I start to...to lose
21 it right there.

22 **DR. MOORE:** Okay.

23 **DR. PORTIER:** In foraging behavior, it
24 seems that there's two parts here. There's the how you
25 take the total daily intake, the TDI, of a particular

1 bird, and distribute it over the 14 feeding hours of
2 the day.

3 **DR. MOORE:** That's correct.

4 **DR. PORTIER:** So, that can be either for
5 ducks, two on each side or...so, for a particular
6 bird...well, we'll skip the field that's on the left,
7 the bird's on the right. Right? For a particular
8 bird, do all of 20 birds in that field have the
9 same...of the same species have the same TDI
10 distribution to the day?

11 **DR. MOORE:** Yes, they would have the
12 exact same hourly intake rate per day.

13 **DR. PORTIER:** So, if we looked at your
14 slide 36 there, slide 36, there would just be one for
15 all 20 birds. Right?

16 **DR. MOORE:** That's correct.

17 **DR. PORTIER:** When I change to another
18 field, same species of bird, do I have the same...

19 **DR. MOORE:** Same intake rate.

20 **DR. PORTIER:** Okay, so that's fixed for
21 a bird.

22 **DR. MOORE:** That's correct.

23 **DR. PORTIER:** For a bird species.
24 Right?

25 **DR. MOORE:** Yes.



1 **DR. PORTIER:** Okay. The other
2 component, then, is the TDI for a bird. Is the TDI for
3 a bird distributed, or is that fixed to body weight?

4 **DR. MOORE:** The TDI is distributed, and
5 it's distributed based on the error term in the
6 allometric models that we used to estimate a food
7 metabolic rate.

8 **DR. PORTIER:** Okay. So, related to body
9 weight or body size...

10 **DR. MOORE:** Body weight, that's correct.

11 **DR. PORTIER:** ...and you're looking at a
12 distribution going in, and you distribute that. Okay.
13 So, where does this discussion on slides 40 and 42 come
14 in where you talk about field...

15 **DR. MOORE:** Ah, okay.

16 **DR. PORTIER:** ...distribution and
17 dietary residues distribution?

18 **DR. MOORE:** Okay. You...you are
19 completely clear in your understanding so far, so you
20 did...

21 **DR. PORTIER:** Well, that...I mean,
22 wasn't really sure.

23 **DR. MOORE:** That's great, and
24 this...this is a hard...this is the hardest part. So,
25 the birds get a certain portion of their daily diet

1 each hour of that distribution, but where they get it
2 from still has to be decided. Do they get it from on
3 the field, or do they get it from off the field?

4 And that's what this parameter does. This
5 proportion time foraging in the field...

6 **DR. PORTIER:** So, there's a binomial
7 proportion? Every hour, you flip a coin to decide if
8 it's on or off the field, depending on the bird?

9 **DR. MOORE:** No, we...that's...that's a
10 TIM Version 1 approach.

11 **DR. PORTIER:** Okay.

12 **DR. MOORE:** In our model, they can be on
13 the field and off the field in the same hour. So, what
14 we do is through this process of once we partition the
15 variation between fields and within fields, we come up
16 with a distribution that represents the range in
17 proportion of time that they...each individual spends
18 in the field, randomly draw that...from that
19 distribution.

20 And that's that bottom chart there on slide
21 40, and what we have is for that particular field, we
22 have a population for a group of 20 birds. Some will
23 have...only spend a small amount of time foraging in
24 the field, and those would be the bars right around
25 0.25, 0.35. Other birds in that group will spend a

1 large amount of time ever time step foraging in the
2 field, and that would be to the right. Most of them
3 seem to be around 0.65 to 0.75.

4 **DR. PORTIER:** So...so, the bird gets one
5 draw, and they're a 0.25 bird...

6 **DR. MOORE:** That's a...

7 **DR. PORTIER:** ...and every hour, they're
8 a 25 percent, then, in the field.

9 **DR. MOORE:** That's right. I mean, if we
10 had data to distribute those variables, we would. We
11 don't, but if you think about, particularly in the case
12 of...of nesting passerines, they're going to
13 have...they're going to make a lot of foraging trips
14 per hour, and so, there will be some consistency from
15 one time step to the next in where they spend their
16 time foraging, so it's not a perfect...

17 **DR. PORTIER:** But that...so that
18 fraction, the TDI, are going to be tied to the exposure
19 that the bird actually gets in any particular hour?

20 **DR. MOORE:** That...that's independent of
21 how much exposure they get.

22 **DR. PORTIER:** So, how does the exposure
23 come in?

24 **DR. MOORE:** Well, once you have a
25 concentration in all the dietary items...

1 **DR. PORTIER:** Right.

2 **DR. MOORE:** ...you know what the
3 rate...the in...their intake rate and how much they get
4 from the field. You have an hourly dose.

5 **DR. PORTIER:** Right.

6 **DR. MOORE:** The adjustment that's made
7 for preceding dose is the avoidance function. So, we
8 calculate an hourly dose, and then we look at how much
9 they've accumulated so far and figure out how much they
10 would reduce their food intake rate, and we reduce that
11 current time step exposure accordingly. And
12 that...that's how previous exposure factors into
13 current exposure.

14 **DR. PORTIER:** Okay. The...the
15 discussion on...what was it...figure 42 which talked
16 about...I wasn't quite sure what that slide had to do
17 with any of the other slides.

18 **DR. MOORE:** It was...it was really
19 addressing a comment from EPA. As you noted, the
20 concentrations, once we figure out the initial
21 concentration in the field, decay, and we assume no
22 intrafield variability. That...now, but EPA raised the
23 concern that there is, of course, intrafield
24 variability with dietary residues, and some of the
25 coefficients of variation are listed on that slide, but

1 what I wanted to make the point of is that it's not
2 that important once you account for bird foraging
3 behavior.

4 The birds spatially and temporally average
5 their exposures, because they are making multiple trips
6 into the field, and so, all I was trying to do with
7 this example, very simple example, is convey how the
8 importance of variability in dietary residue within a
9 field is reduced as a result of that spatial and
10 temporal average.

11 **DR. PORTIER:** I understand.
12 Slide...real quickly, please, slide 44 is your
13 avoidance behavior curve. Now, if I was a...if I gave
14 this to a student statistician, they would put a
15 straight line through zero that would actually be
16 sharper than your line and would have uncertainty of
17 about plus or minus 25 percent at every dose. Right?
18 In your...in your model, you're not using any of the
19 uncertainty...

20 **DR. MOORE:** No.

21 **DR. PORTIER:** ...and you're using a
22 curve which I don't believe fits the data.

23 **DR. MOORE:** That...that curve fits the
24 data. The statistics are discussed in our...our
25 report. It's a significant fit.

1 **DR. PORTIER:** Just not...

2 **DR. MOORE:** Yeah, is it messy?

3 Absolutely, it's messy. I would very much like to, in
4 a future iteration of the model, try to introduce the
5 uncertainty into that. Computationally, it's
6 difficult, because in each time step, you know, we have
7 to randomly figure out how much draws from that...so,
8 we figure out what the preceding dose was and then
9 randomly draw from the distribution to account for the
10 error and do that for each time step for each of 20,000
11 birds.

12 Even that is easy, but the problem here is
13 this noise represents variation between birds, not
14 between time steps within a bird. So, I would
15 actually...what I would suppose is that this curve is
16 different for every bird, and you would somehow have to
17 account for that in a model.

18 That...that's just an ordinary way of saying
19 computationally, it's a very difficult exercise.
20 Conceptually, I completely agree with you.

21 **DR. PORTIER:** And the...the last one is
22 45. And on this one, I understand how you've created
23 these three parallel lines, and...and I talked with my
24 statistician colleague, and neither one of us believe
25 that the...that the 05 or the 95 percent lines would be

1 exactly parallel if you...and then...and we're not
2 going to argue this, and we can talk about this on the
3 side, but I would have expected the line on the left to
4 be tilted more. The slope would change.

5 Because what you're assuming here is you're
6 just shifting the mean of the distribution. You're not
7 affecting the slope at all, and the slope...the slope
8 being the variants of the distribution. So, you're
9 saying the variants of the distribution of lower
10 percentiles is going to have the same variants as the
11 distribution of the median, and that's just not going
12 to be the case, but I understand how you did it.

13 **DR. MOORE:** Oh, I...I'm not sure I agree
14 with that. What the variants of any one of those
15 curves represents is variation in sensitivity of
16 individuals within a bird species, and I'm not sure why
17 I would expect variation in sensitivity to be different
18 from...in a systematic way from one species to the
19 next, but, you know, there's not enough data to answer
20 that.

21 **DR. PORTIER:** I was going to say if you
22 go back and you look at your slide 14, you actually see
23 that variability and sensitivity and how the slope
24 changes, especially when you shift it. So, I think
25 there's...even with the little bit of data we have

1 insight into, I see variants changes, slope changes.

2 **DR. MOORE:** But if you go to the next
3 slide...you have that? Oh, no, we don't have. You may
4 have to make the plots with mallards and...and bobwhite
5 quail, and actually, slopes don't look that different,
6 but, I mean, there are only a limited number of slopes
7 that have been reported in the literature. For
8 carbofuran for birds, they're all steep, and is there
9 variation in slope? Absolutely. Is it systematic
10 according to sensitivity of the birds? I'm not sure of
11 that. I'd have to look into the data.

12 But there is...they're all steep. They're
13 all fairly close together. So, that's why we made the
14 assumption of...of equal slopes for our three
15 hypothetical species.

16 And I would further note that this is the
17 exact same approach that's taken in TIM Version 1 and
18 2.

19 **DR. PORTIER:** I don't doubt that. The
20 other thing is if you shift those lines, you shift it
21 in 3.8x over, again, you have no data to show that the
22 slopes never vary, the slope of that line doesn't shift
23 as well.

24 **DR. MOORE:** You're right.

25 **DR. PORTIER:** Which means that you could

1 be sliding over, but some of the lower bound ones would
2 still be...so, anyway, the point made.

3 **DR. MOORE:** Yeah, I...I can comment on
4 that one. For a bobwhite quail which is one
5 with...where we have more treatments, we did do a...a
6 pointed curve for the aqueous bolus treatment and the
7 food matrix bolus treatment, and once you do that, you
8 can calculate, say, an LC5, an LC50, and an LC95. It
9 varies from 3.84 at the low end to 3.94 at the high
10 end.

11 **DR. PORTIER:** Oh, okay, that helps.

12 **DR. HEERINGA:** Okay, I'm going to have
13 to draw the question and answer period on this
14 particular presentation to a close simply because we
15 have three more presentations to finish, I think,
16 today. I want to thank Dr. Solomon and Dr. Moore and
17 the panelists.

18 I think, panelists, if there are critical
19 items, and I know several of you are raising your
20 hands, I think that we can get them answered at the
21 break. Obviously, if you have a conversation, you need
22 to report it back here publicly in terms of any
23 findings that would influence your recommendation.

24 So, at this point in time, we're going to
25 make an exception in the agenda. We're going...I'm

1 going to ask Mr. Ray Young...and this has been approved
2 by the relevant parties...who is a farmer and crop
3 consultant with Young & Young Consultants, I believe
4 with his son. He has a short public presentation, and
5 then we will return to the sequence of presentations by
6 FMC.

7 Mr. Young?

8 **MR. YOUNG:** My name is Ray Young, and
9 I'd like to thank Dr. Matten for giving me the
10 opportunity to speak to this distinguished panel here
11 today. I'm an independent crop consultant and a farmer
12 in northeast Louisiana.

13 By independent, I mean that we deal with
14 individual growers and that our business is in no way
15 concerning with crop sales.

16 I grew up in the '30s with my family, farming
17 cotton. We plowed the mules, chopped the cotton, and
18 picked the cotton. In 1931, my two older brothers went
19 to the Navy, and I was left to farm by myself at a
20 pretty young age, but during that time, I like to say
21 that we used nicotine sulfate to control aphids, and we
22 used Paris green to control leaf worms. Pretty bad
23 combination when you shook it out with a cloth flour
24 sack behind and you're through it.

25 In 1939, I began scouting cotton. That was

1 the very beginning of agricultural consulting as a
2 profession as...as we know it today. I received a
3 bachelor's degree from Louisiana Tech in agriculture in
4 1950. I served four years in the Navy as a carrier
5 pilot. I returned to civilian life, enrolled in LSU,
6 and received a master's degree in entomology in 1957.

7 I'm still actively involved in farming and
8 consulting with my son, Jesse. We give advice to
9 growers on every phase of crop production from seed
10 selection to harvest preparation. For the purpose of
11 my discussion today, I'll limit my remarks to our
12 dealing with insect control.

13 In our business, we're constantly on guard to
14 prevent insect resistance. This is a problem that
15 we've encountered through the years, and we...we deal
16 with this problem by alternating chemistry.

17 My first experience with insect resistance
18 was in 1955, cotton boll weevil that was living through
19 the chlorinated hydrocarbons. That was not a pretty
20 scene.

21 Since that time, we have seen resistance
22 develop in several classes of chemistry and several
23 insects, including the tobacco bollworm, the tobacco
24 bloodworm, tarnished plant bugs, and the cotton aphids.

25 There have been problems with aphids

1 sporadically throughout the cotton belt for many, many
2 years. It's sporadic occurrences, but you never know
3 when they'll show. Aphids develop resistance very
4 rapidly because of the frequency of generations. If
5 you look at figure 1, you'll...you'll see an
6 overlapping of generations.

7 Aphids develop through a process known as
8 parthenogenesis. That means that they give live birth
9 to fertilized females. Generations occur in 7 or less
10 days, depending upon temperatures.

11 So, you can see that these insects can very
12 quickly wrap up a whole plant, and when they do, they
13 damage that plant very quickly. These aphids excrete a
14 liquid called honeydew. That honeydew goes onto the
15 green leaves, setting on a fungus forms and grows and
16 interferes with photosynthesis. When that honeydew
17 gets on the lint as the lint begins to open, as the
18 bolls open, it causes a set of mold, and this
19 destroys...destroys quality and, hence, the price.

20 Over the years, many products have...aphids
21 have gotten resistant to many of the classes of...of
22 insecticides, the organochlorines, organophosphates,
23 synthetic pyrethroids, and some carbamates. Furidan is
24 a product that is effective. It has been effective
25 through the years. We've trusted it, and we return to

1 it for our worst case aphids.

2 For the past several years, we've had a new
3 type of chemistry called the neonicotinoids that have
4 worked quite well until the last couple of years, but
5 we are beginning to see a weakness, because they've
6 been applied to a good portion of the crop producing
7 area. As we lose these products, we'll lose control.

8 If you look at figures 5 and 6, look at
9 figure 5 first. That's in 205...2005. You'll see that
10 all products at 7 days gave excellent control of
11 aphids, 70, 84, 80 percent control. And that's at a
12 half rate for Intruder and Synthra.

13 Now, look at figure 6, and you'll see that in
14 2006, these products, at full label rates, were less
15 than adequate control. You will note, however, that
16 Furidan stands out among the bunch as still being very
17 effective.

18 We had one failure a couple of years ago, and
19 in that failure, furidan was granted on section 18, and
20 it cleaned the aphids up very nicely. If we lose
21 furidan, we lose a very important resistance management
22 tool.

23 Cotton is a vital part of the production of
24 agricultural products across the southern United
25 States. Furidan is a vital product for managing

1 insects in cotton. We don't need to lose this
2 important resistance management tool.

3 I feel very strongly about this testimony
4 because of my experience with insect resistance through
5 the years and my experience growing cotton for the past
6 67 years.

7 I thank you for your attention, and I
8 appreciate your working me into your busy schedule, Dr.
9 Matten. I would be happy to attempt to answer any
10 questions that you might have.

11 **DR. HEERINGA:** Thank you, Mr. Young.
12 Any questions for Mr. Young?

13 (No response.)

14 **DR. HEERINGA:** Thank you for that
15 presentation.

16 **MR. YOUNG:** Thank you very much.

17 **DR. HEERINGA:** An example of
18 conciseness.

19 I've been informed of the Designated
20 Federal...by the Designated Federal Official we need to
21 have a short administrative meeting of the panel in our
22 breakout room, so I'm going to call a break, and when
23 we return, we'll resume with the...the next of the
24 public presentations. Panel members, if you could just
25 join us here.

1 (WHEREUPON, a brief recess was taken.)

2 DR. HEERINGA: As soon as we have a
3 Designated Federal Official, we'll get underway. Okay,
4 we're ready. Okay, we're...we're going to be ready to
5 resume, and before we begin with the next presentation,
6 the Designated Federal Official, Sharlene Matten, has a
7 few clarifying comments.

8 DR. MATTEN: Yes, this is Sharlene
9 Matten. I...I just wanted to clarify a remark or a set
10 of remarks that were made this morning about the
11 Federal Advisory Committee Act and duplication of
12 efforts.

13 EPA has a longstanding policy of trying not
14 to do the exact same charge between two different
15 Federal Advisory Committees, one being the Human
16 Studies Review Board and the Scientific Advisory Panel.
17 After much discussion, a new light has been shed that
18 there...there may be some nuances in understanding of
19 different scientific questions that weren't addressed
20 specifically by the Human Studies Review Board that
21 could be available for some sort of discussion of those
22 very same studies that had a specific set of charge
23 questions related to them.

24 And so, the panel may have some discussion on
25 these studies related to those specific set of issues

1 that weren't previously addressed that wouldn't overlap
2 two dif...overlap charges between two different federal
3 advisory committees. And, hopefully, that makes some
4 sense.

5 I'm a little overwhelmed by the number of
6 attorneys that have been advising over the last several
7 hours, but I...I hope that clarifies things just a
8 little bit. It doesn't completely clarify it for me,
9 but...so, I think you can continue.

10 **DR. HEERINGA:** I think we will continue.
11 That's...that's probably the best...best step to take
12 at this point. And, again, just to reiterate, our
13 focus here is on full scientific exploration and
14 development of the issues at hand, and we're going to
15 do that, and we'll accommodate processes and legalities
16 and everything else as we go, and thank you very much.

17 And I apologize to the audience for the
18 abrupt recess there, but we're ready to move on now,
19 and we are, I think, to the next of the presentations,
20 and this is the worker risk presentation.

21 **DR. LAMB:** That's correct.

22 **DR. HEERINGA:** And Dr. James Lam of the
23 Weinberg Group, is going to be the leader.

24 **DR. LAMB:** That's me. I'm Jim Lam. I'm
25 with the Weinberg Group, and I was asked by FMC to

1 review the toxicology data, and in this presentation,
2 I'll talk for a very surprisingly short time about the
3 worker data on the toxicology relative to the worker
4 risk assessment, and then Dr. Jeffrey Driver will talk
5 about the exposure, occupational exposure assessment.

6 In the first slide is simply an outline of
7 the major issues that I will cover. The outline may
8 give you a sense this is longer than it really is. I
9 really think that this is going to be 15 minutes' worth
10 of touching on what to ask as the most important issue.

11 Ultimately, worker risk assessment is
12 evaluated by comparing the point of departure to
13 potential field exposures, and they look for margins of
14 exposure and...I hope everybody can hear me...the
15 margins of exposure generally need to be 100 or more.
16 The...the bottom line comes to that EPA's calculations
17 in the Notice of Intent to Cancel and the interim red
18 have scenarios for the selection of point of departure
19 and exposure assessment that gets you to less than 1 to
20 about 50, so they are considered by EPA to be
21 unacceptable.

22 FMC's worker risk assessment actually
23 demonstrates that the occupational exposures are
24 acceptable with margins of exposures between 110 and
25 3400, and I will explain that as we go through.

1 But there are really two major issues. One
2 is the issue I will talk about, and the other is the
3 issue that Dr. Driver will talk about. First, EPA's
4 assessment, I think as you already know, doesn't use
5 the guideline dermal toxicology study. Instead, they
6 have taken an oral toxicology study.

7 Both look at brain acetylcholinesterase, and
8 then they take the oral study and adjust using the
9 dermal absorption factor from the Shaw study.

10 My position is that you should be relying on
11 the der...21-day dermal study. No absorption factor is
12 necessary in this approach.

13 Dr. Driver will talk about that EPA's
14 position is relying more on older exposure assessment
15 tools, and he'll be talking about the new exposure
16 assessment methodology that is...that is being used by
17 EPA, but it's not being used yet by EPA in this
18 assessment.

19 There is...very quickly, because I know
20 you've heard all this stuff before...the margin of
21 exposure is, basically, take the point of departure for
22 the critical adverse effect and divide it by exposure,
23 and we're looking for margins of exposure greater than
24 100 for acceptable uses. The EPA approach and the FMC
25 approach basically end up with numbers that differ by

1 two orders of magnitude so that if you took the same
2 exposure number which, in this example, is 0.016
3 mg/kg/day, that the two different points of departure,
4 you would end up with very different margins of
5 exposure.

6 Bottom line as a toxicologist is that the
7 point of departure, the selection of the point of
8 departure, the study that you're using to select that
9 point of departure is critical. Typically, EPA will
10 use dermal toxicology studies for pesticide mixers,
11 loaders, and applicators.

12 Just to make this really clear, the interest
13 here is adults, and it is dermal exposure. It is
14 usually done that they use a 21 or 28-day rat or rabbit
15 dermal toxicology study, and there are testing
16 guidelines that exist that describe the testing methods
17 and the endpoints that need to be evaluated.

18 These are examples of studies, carbamates and
19 organophosphates, where that approach has been taken.
20 The...and we will get at..this is simply to give you a
21 sense that this is not a...an issue of first
22 impression.

23 EPA, though, in this particular case, has
24 used an oral point of departure of 0.02 mg/kg. It's
25 based on adult rat acetylcholinesterase inhibition, and

1 it has to be, since it's an oral study and our concern
2 is primarily dermal exposure, it has to be adjusted for
3 dermal penetration.

4 The study that they have and have relied upon
5 for that is the Shaw study, and I think Dr. Shaw was up
6 here earlier today. They, like us, are looking for
7 margins of exposure that are actually greater than or
8 equal to 100, but typically, they only take this
9 approach when they lack valid dermal toxicology
10 studies.

11 In...in this case, they basically classified
12 a valid study as unacceptable and leads them back to
13 this position. They've rejected the use of the dermal
14 study, and I believe that is, in fact, an error.

15 The studies are that...that the 21-day rat
16 dermal study was submitted. FMC has used this. Now,
17 this study was created in response to...there was
18 already a rabbit dermal study submitted to EPA. It's
19 my understanding that EPA was not satisfied with the
20 findings, that the...they didn't believe the no
21 observed adverse effect level could be that high, and
22 so that they asked for another study.

23 It's also my understanding that at that point
24 in time, they did not ask for pharmacokinetic data or
25 time to effect or time to peak response. They asked

1 for a dermal toxicology study.

2 There are also human dermal studies. I think
3 you've already heard a little bit about the issues in
4 these. I really don't see that the human studies play
5 much of a role in this case in any event.

6 But the review of the 21-day dermal study
7 does. In the EPA data evaluation record, basically,
8 they rejected the study specifically because the
9 information did not include time of onset, time of
10 peak, and time until recovery. That sort of
11 pharmacokinetic or pharmacodynamic information is not
12 in the guidelines for the dermal toxicology study, it
13 wasn't requested by EPA, and as far as I know, it
14 hasn't been used in a worker risk assessment.

15 I have an example where it was asked for, for
16 example, on carbaryl. It's not even clear it was used
17 even after they got those data, but I think, actually,
18 more important than...than the administrative aspects
19 of this is whether or not the data are really needed.

20 The most appropriate study is the one done by
21 the same route of exposure. The toxicology study to
22 evaluate dermal risk, the best one is the dermal
23 toxicology study. They have a good study in their
24 file. It's the same as has been used or very similar
25 to those used for other carbamates and other

1 organophosphates.

2 We need to talk a little bit about some of
3 the specifics, because I'm afraid there may have been
4 some confusion about the study this morning. It was a
5 6-hour exposure. Now, my understanding of what I heard
6 this morning from EPA was they want now time to effect.
7 At the end of the 6 hours, they would want sequential
8 evaluations. That's what I heard.

9 This study was done with a protocol specified
10 that no sacrifice should...should be later than 6 hours
11 after the exposure ending. I have to admit that we
12 went back and looked at the time to collection. The
13 average was 6 minutes. So, they clean...they dosed for
14 6 continuous hours.

15 Now, this is a product with a pretty fast
16 half-life. They dosed for 6 hours, and right at the
17 end of that, they cleaned the site, and within an
18 average of 6 minutes, 7 for females, 6.1 exactly for
19 males, they...the animals were killed, the samples were
20 collected.

21 The...the...there were 2 animals that were 12
22 minutes after sacrifice, 1 was 11. All the rest were
23 10 minutes or less.

24 There was not time...my opinion is that
25 it's...I have no data in the rat with carbofuran, but

1 if what they wanted was a 6-hour exposure and then we
2 start looking at response, it...it's nearly implausible
3 to me that the response is going to go up after we've
4 cleaned the application site. And so, the rapid
5 sacrifice was considered important, and that's the way
6 the study was done.

7 Out of that study, brain acetylcholinesterase
8 was evaluated. The no observed adverse effect level in
9 that study was 50 mg/kg/day. There was significant
10 suppression at 250, the next highest dose level. There
11 are a couple of dose levels below this which confirm
12 the lack of inhibition of brain or RBC cholinesterase.

13 In our opinion, and we hope the SAP will
14 consider this very seriously, that this study should be
15 accepted and used in the risk assessment. This is the
16 best model, the best science that's available at this
17 point in time.

18 Now, the other points, in addition to the 6-
19 hour exposure giving time for the peak to occur and
20 then, according to typical guidelines, and sacrifice
21 pretty quickly, the...the only value that I would say
22 the human study might provide...and I'm really not
23 going to push this very hard; I don't think it's that
24 important...is whether or not...is basically the human
25 study does show some...that the peak did come on. It

1 came on slowly.

2 There's also a carbaryl absorption
3 disposition metabolism and excretion study. It's a
4 different carbamate. It's at relatively high dose
5 levels, but it does show that dermal penetration
6 continued in that study pretty much throughout the
7 study.

8 And there's not a whole lot else I can offer
9 you in the science.

10 The RBC data they listed as part of the
11 reason this study was rejected as well. The real focus
12 was the lack of pharmacokinetic data, but I wanted to
13 address the point of variability in the RBC data in
14 this study.

15 As you can see from these coefficients of
16 variation...and you...I will say, too, that the FMC
17 reports that you've seen to date typically show
18 standard deviations. EPA's show standard errors. So,
19 with group sizes that are generally 10, our bars are
20 going to be three times bigger than everybody...than
21 the EPA ones, and that really is more the reason you
22 see this variation. These were not group sizes of 2 or
23 3 animals. I just want to be really clear on that.

24 But the coefficients of variation in this
25 study are not remarkable. They're not huge.

1 The weaknesses of the current approach
2 proposed by EPA is it's ignoring a valid study, a valid
3 dermal tox study. It calls for unnecessary
4 manipulation of the oral toxicology data. And they're
5 approach, in fact, does not address that very
6 pharmacokinetic information that they're asking that be
7 provided through the dermal study.

8 Also, the dermal study was not designed for
9 this purpose, so to be fair, it was done 20 years ago,
10 designed for a different purpose, and those data are
11 limited.

12 You don't have the raw data which, in our
13 case, of course, any FMC study goes to the Agency with
14 all the underlying raw data in considerable detail.

15 The approach that was taken was sampling
16 times of 2 hours and 24 hours and...and afterwards as
17 well meant that the exposure continued all the way out
18 to 24 hours. Acetone was used as a vehicle. That has
19 a high likelihood that it would enhance absorption of
20 the material because of the breakdown of the skin.

21 They didn't clean the application site, as I
22 mentioned, and also, they did not, in that study,
23 because it was not designed for this purpose, they
24 didn't measure acetylcholinesterase or its inhibition.

25 Their approach, the EPA approach, frankly,

1 does not improve the risk assessment. They don't model
2 the workday the way they developed it. The oral study
3 and the dermal penetration data together do not provide
4 information on dermal pharmacokinetics
5 The be...the preferred method is, frankly, the use of
6 the dermal toxicology study that's been provided.
7 These were 21 consecutive days of treatment. I think
8 you heard this morning it was 5 days a week, and that
9 really isn't correct, but I completely agree with
10 Ginger Moser that it...it doesn't matter. The 1st day
11 is probably going to be pretty much the same as the
12 21st. So, I'm...I don't think it makes any difference
13 whether it was 5 or 7. It was 7, and the sacrifice was
14 within minutes of the end of the treatment.

15 And bottom line is you should be using the
16 21-day dermal study. The point of departure should be
17 the BMDL of 50, that they should...EPA should not be
18 rejecting the study on the basis of this
19 pharmacokinetic data requirement.

20 And with that, I'm going to pass the
21 microphone to Dr. Driver to move on to worker exposure
22 and then you can ask...it's up to you, Dr. Heeringa.

23 **DR. HEERINGA:** That's what I was going
24 to suggest, and I want to thank you for conciseness and
25 the base of your presentation.

1 **DR. LAMB:** No problem. Thank you.

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

3 **DR. DRIVER:** Thank you very much. Thank
4 you, panel, for your continued endurance. I'd like to
5 briefly turn your attention to the carbaryl worker
6 exposure risk analysis.

7 **SPEAKER:** Carbofuran.

8 **DR. DRIVER:** Carbofuran. Sorry. Pardon
9 me. The...the purpose of the impact of...or the
10 purpose of my presentation is to demonstrate the impact
11 of using what we propose is the appropriate toxicology
12 benchmarks, route-specific benchmarks, as well as the
13 best available exposure monitoring data.

14 My outline includes a brief overview,
15 contrasting EPA's assessment with what we're proposing.
16 I'd then like to, by way of background, just discuss
17 the routes of exposure and the more simplistic exposure
18 assessment algorithm that's used for tier 1
19 deterministic calculations in contrast to relevant
20 stochastic modeling you saw earlier, so I'll bring you
21 back to elementary school math, the exposure reduction
22 via closed systems that are...that are used by
23 carbofuran, and I comment on those engineering
24 controls, and also the exposure monitoring data that
25 are available to inform the exposure analysis, and then

1 my results and conclusions.

2 So, with respect to an overview, as we heard,
3 EPA's assessment did address both dermal and inhalation
4 routes for workers, appropriately. In...in both cases,
5 the toxicology benchmark was based on oral routes,
6 BMDL10, necessitating, in the...in the case of the
7 dermal route, an absorption factor. As has been
8 pointed out, this inherently assumes, then, that the
9 dermal exposure results in...in essentially an
10 instantaneous bolus of pure dose, if you will, via the
11 dermal route as it's compared, then, to an oral
12 benchmark dose.

13 The exposure estimates were, appropriately
14 for a tier 1 assessment, based on standardized
15 scenarios in the Pesticide Handler's Exposure Database
16 and associated assumptions. The resulting MOEs are
17 listed here at the bottom of the slide. As..as has
18 been mentioned, they range from approximately 1 to 50.

19 On the right-hand side, we see FMC's refined
20 assessment. In this case, as Jim had mentioned, we're
21 looking at the dermal toxicology studies, the basis for
22 the dermal benchmark.

23 In the case of the inhalation route, as is
24 commonly done in the absence of an inhalation study for
25 this compound, carbofuran, it's based on an oral point

1 of departure. In this case, a value was selected
2 representing that derived by EPA for children which
3 would be protective for adults as well.

4 In this case, no dermal absorption factor
5 would be necessary, of course. We're using applied
6 dose dermal NOEL to compare to external dermal exposure
7 on the workers as you estimate it.

8 The exposure estimates, then, as the next
9 bullet indicates are based on data specifically
10 selected to represent exposures for workers involved in
11 using engineering controls that are used for carbofuran
12 in liquid applications.

13 In addition, we made some respiration rate
14 adjustments that I'll talk about for activity level
15 specific tasks that workers are undertaking. The
16 contrasting MOEs are listed there, ranging from 110 to
17 3400.

18 This difference in the MOEs, in part,
19 obviously, is due to the difference in the toxicology
20 benchmark associated with the dermal route. These are
21 total MOEs, by the way, across both the inhalation and
22 dermal routes. So, the difference, obviously, is
23 largely, in part, related to the difference in the tox
24 benchmark but also in...in terms of the exposure
25 estimates, as I will explain.

1 By way of background, the primary route of
2 exposure in...in most worker situations is the dermal
3 route, followed by inhalation. Engineering controls
4 can mitigate and, in both cases, reduce exposure
5 significantly. Carbofuran has very low vapor pressure,
6 so dermal route is...is typically the largest exposure
7 route of interest.

8 The exposure algorithm, very simply stated
9 here, is a function of the amount handled, as far as
10 what we refer to as the unit exposure metric divided by
11 body weight. The amount handled is typically expressed
12 as pounds of active ingredient handled. The amount
13 handled often is assumed to be a maximum application
14 rate, maximum acreage treated, so we're biasing that
15 towards an upper end of the distribution. We...we
16 intend to do that.

17 The unit exposure is typically expressed as
18 mg of exposure per lb of AI handled.

19 I'd like to...to briefly inform you about
20 closed system technologies. The worker protection
21 standard developed by EPA has defined the...these
22 technologies, properly functioning systems that enclose
23 the pesticide, of course, and prevent it from
24 contacting handlers or other persons, and studies have
25 been done and summarized that demonstrate, in this

1 case, the mean reduction in exposure relative to
2 conventional open mixing and loading, 96.8 percent.

3 This was from five studies that the California's EPA's
4 Department of Pesticide Regulations had reviewed.

5 The systems specifically used with carbofuran
6 include the micromatic drum valve system. I have some
7 examples here, and this would be fit to a 110-gallon
8 mini bulk container or a 15-gallon returnable
9 container. There's also a smaller container, 2.5
10 gallon, that utilizes a secure LG system.

11 Just for purposes of...of reminding us, this
12 is a picture of an open mixing and loading system,
13 obviously. This is not what's used with
14 carbaryl...carbofuran. Sorry. I'll get it right
15 eventually.

16 This diagram actually shows the micromatic
17 drum valve system, and it basically creates a dr...what
18 we refer to as a dry lock system that minimizes the
19 leakage. Technical specifications for this type of
20 system would be approximately 1 ml residue leaking or
21 less. Obviously, that's going to significantly reduce
22 operator exposure, and there are a variety of other
23 benefits that are mentioned here.

24 The schematic in the lower right-hand column,
25 if you can actually see that, just shows in black there

1 where these valves would be located at the top of the
2 container. We actually have a container here to your
3 right. Okay, I'll keep going.

4 So, what my friend, Dan O'Ryan, is now
5 picking up is the larger...this actually is the 25-
6 gallon container...or is that 15? 15, sorry, 15 gallon
7 container. The valve system is on the top, the
8 stainless steel valve system, so that...that's
9 obviously dry locks. The hose, then, would be
10 connected to the top of that valve system, creating a
11 sealed container for...these...these containers
12 actually can be returned and...and re-used after
13 appropriate rinsing.

14 There's a smaller container here at the
15 bottom here, too, that you can look at at your leisure.

16 Here's a picture of the secure NG closed
17 system for the 2.5-gallon. It's basically a...a valve,
18 a top, you see, that screws on the container, again,
19 creating a secure system. There's some pictures on the
20 graph here and some more that you can read about if
21 you're interested.

22 In addition to closed mixing and loading
23 systems, open cabs...or closed...I'm sorry...closed cab
24 systems are another engineering control that's used
25 with carbofuran. This is an example of the open cab,

1 in contrast, that a tractor operator obviously...and
2 this happens to be air blast in an apple orchard. In
3 contrast, here's a picture of an enclosed cab ground
4 boom application rig.

5 As indicated in EPA's guidance, enclosed cabs
6 can result in up to 98 percent reduction in both dermal
7 and inhalation exposure. So, in the case of
8 carbofuran, we have these engineering controls that are
9 being used.

10 And so, it's important to use exposure
11 monitoring data, then, that were developed with workers
12 using these controls. So, our proposal is to...to
13 consider those more relevant data. They include data
14 submitted to EPA by the Agricultural Handlers' Exposure
15 Task Force. There also are some data relevant within
16 the Pesticide Handlers' Exposure Database that can be
17 subset and used in addition to...to the AHTTF data.

18 And, finally, I'd also mention that the
19 inhalation exposure data can be and should be
20 adjusted...and this has been agreed upon through some
21 harmonized discussions with regulatory agencies...task
22 and activity level specific respiration rates. So,
23 persons, for example, piloting an aircraft or driving a
24 tractor would be breathing at a lower rate than someone
25 with a lot of physical exertion.

1 This, just quickly, gives you a map, if you
2 will, of the available exposure monitoring data that we
3 would propose for use. There are two studies from the
4 task force. They've been submitted to EPA, as
5 indicated by their...what are referred to as NRID
6 numbers. They provide a total of 22 monitoring units.
7 A monitoring unit can be thought of as a set of
8 measurements for each...for a unique worker.

9 In addition, two studies have been provided
10 for closed cockpit aerial applicator exposures of
11 liquids.

12 There are also 9 monitoring units completed
13 thus far for a closed cab ground boom application of
14 liquids. However, they haven't been submitted.

15 There are data within the Pesticide
16 Handlers' Exposure Database that can be used, adjusted
17 for an appropriate respiration rate.

18 The next slide just simply provides
19 comparisons of the central tendency values, the unit
20 exposure values expressed, in this case, as g of
21 exposure per pound AI. So, on the left-hand column,
22 you have these three scenarios I've been mentioning,
23 closed system mixing and loading of liquids, fixed wing
24 aerial aircraft applicator exposures, and then the
25 ground boom tractor drivers in enclosed cabs.

1 So, we have both the inhalation and dermal
2 routes and their respective unit exposures for either
3 the PHED data or a refined estimate that has been
4 adjusted based on respiration rate in the case of the
5 inhalation route, followed in the final column with the
6 AHTTF unit exposure values. I have bolded those values
7 that we're proposing for selection.

8 I've indicated the values shown here are
9 geometric means. The values listed here for PHED
10 depend on the best fit analysis within the database.
11 Typically, it's either a log normal or geometric mean,
12 a normal arithmetic mean, or an other categorization in
13 which a median value would be used.

14 The role of...of task force data and other
15 studies, too, that have been collected are going
16 forward and, in the recent past, have been, in fact,
17 the subject of...as well as the existing PHED data have
18 been a...a subject of discussion at a recent, January,
19 2007, science advisory panel. Some of the panel
20 members here were involved in that. It was an
21 excellent discussion. We...we all...there was
22 concurrence about the need to develop new data and a
23 lot of great discussion about how those data should be
24 collected, study design, sample size, and a variety of
25 other statistical considerations.

1 In general, agreement was that additional
2 data would significantly improve the assessments. In
3 fact, the primary purpose of the task force, as you can
4 imagine, is to address some of the deficiencies in the
5 existing data.

6 For example, the upper...upper left schematic
7 of the gingerbread man represents...the Os and Xs
8 represent locations of patches, patch dosimeters, small
9 square dosimeters that would be used at...at located
10 throughout...across the various body part areas of an
11 individual. This is sort of the historical method for
12 collecting dermal exposure monitoring data both for
13 outer and inner, outside being outside the clothing and
14 then underneath the clothing.

15 The lower right hand column represents the
16 preferred method which is a whole-body dosimeter. This
17 is an in...inner dosimeter that a person would wear
18 underneath their work clothing.

19 There are a number of advantages to the
20 der...that use of the dermal passive dosimeter, in
21 part, for example, as this bullet indicates, in looking
22 at some of the limitations of existing data, including
23 the patch type monitoring, for example, as the first
24 bullet indicates, you may often have an inadequate
25 number of measurements for one or more body areas, in

1 other words, missing patches, so that one would have to
2 extrapolate from another body part area to...to
3 estimate a value.

4 There were limitations, skipping down a few
5 bullets, of...of censored data, many values being below
6 the detection limit, particularly with inner
7 dosimeters, and there are some other limitations
8 mentioned here that you could read at your leisure.

9 So, the role of...of collecting data such as
10 those represented by AHTTF are probably obvious, but
11 let me just highlight a few things here for you. The
12 data, as I've mentioned, exist. The data, AHTTF data,
13 do exist for carbofuran representative of closed mixing
14 and loading systems and aerial application. There are
15 examples recently where EPA has also selected those
16 appropriate studies, aldicarb, carbaryl, and I think
17 they could be used here. Those studies were all
18 conducted under good laboratory practices. So many of
19 the historical data sets were not.

20 The limits of quantitation, as you can
21 imagine, analytical sensitivities were lower, so we
22 have a less...a lower proportion of censored data, the
23 use of full-body dosimeters, and, very importantly,
24 joint regulatory committees, EPA, PMRA, California EPA
25 have been involved, staff have been involved in the

1 design of these studies.

2 Another important aspect is that, from an
3 allometric standpoint, body surface areas are
4 proportionate to the subjects' body weights. I had
5 mentioned respiration rates that are task specific so
6 that non-physiological rates aren't used for low
7 activity tasks.

8 And the data represent full workdays in terms
9 of the monitoring period that they represent.

10 So, these studies can be used preferentially
11 for occupational assessments for liquid pesticides such
12 as carbofuran.

13 As Jim had mentioned, the toxicology endpoint
14 selection is critical. Preferentially, if route-
15 specific data are available that are considered valid,
16 they...they would be used. The dermal assessment can
17 be based, we think in this case, on the dermal 21-day
18 study, and as I had mentioned, the oral point of
19 departure can be used and has been routinely for the
20 inhalation risk assessment.

21 This just provides you with a sampling of
22 total margins of exposure across both routes for three
23 scenarios. The unit exposures used, the acres treated
24 assumed, and the resulting MOEs, corn...these are for
25 corn application scenarios which happens to be the

1 worst case scenario for carbofuran. The...the details
2 of our assessment are provided in written materials
3 submitted to the panel, to EPA.

4 And, finally, in conclusion, we would propose
5 consideration of the route-specific toxicology data,
6 the refined exposure monitoring data that would be
7 available, and using those data demonstrates acceptable
8 risks in the case of carbofuran occupational scenarios.

9 Thank you.

10 **DR. HEERINGA:** Thank you, Dr. Lamb and
11 Dr. Driver.

12 **DR. DRIVER:** I do have one last slide.
13 I'm sorry.

14 **DR. HEERINGA:** Sure.

15 **DR. DRIVER:** These...this is just
16 prompts, some questions for the panel to consider
17 which...which, I think, are obvious, but, you know, use
18 of the 21-day dermal study in contrast to an oral study
19 and the uncertainties that that may introduce, and,
20 secondly, use of the exposure monitoring data.

21 Thank you.

22 **DR. HEERINGA:** Thank you very much.
23 Questions for Dr. Lamb or Dr. Driver? Dr. Hattis,
24 okay.

25 **DR. HATTIS:** Yes, I have two questions.

1 You've got geometric means here. What are
2 the associated geometric standard deviations?

3 **DR. DRIVER:** I don't...I could provide
4 that to you. I don't have that with me.

5 **DR. HATTIS:** It's not in your written
6 materials or anything?

7 **DR. DRIVER:** I don't think it is, but I
8 can provide them to you.

9 **DR. HATTIS:** All right. And then,
10 second, do you have any surveys of actually uses of
11 carbofuran to see how...how often these wonderful new
12 procedures are actually employed?

13 **DR. LAMB:** Don, do you?

14 **DR. HEERINGA:** Be sure to introduce you,
15 I think, Dr. Carlson.

16 **DR. CARLSON:** Yes, my name is Dr. Donald
17 Carlson. I'm with FMC Corporation.

18 Actual surveys, we do not have actual
19 surveys. The equipment itself, as it's been
20 demonstrated, is the only equipment that is available.
21 It is sold only in these types of containers. In the
22 2.5 size, all of it is in 2.5 with the Sotera link G
23 with the exception of California. California requires
24 puncture box systems, and in that case, it goes into a
25 puncture box system.

1 We do have, obviously, data which is
2 collected by the 6A2 reporting in order to go and look
3 at whether there are affected work incidents of any
4 type, and that is available if you would like to look
5 at it.

6 **DR. HEERINGA:** Dr. Brimijoin and then
7 Dr. Edler.

8 **DR. BRIMIJOIN:** Just a quick one. So,
9 your assessment of the...which...which includes lines
10 on the 21-day rate dermal test study indicates that, in
11 some cases, there are large NOEs and, in other cases,
12 sort of in the...at the border of acceptable, on...on
13 the good side but close.

14 So, what happens to this effect if EPA were
15 to accept the 21-day dermal toxicology study, but given
16 that it has already determined that, in general, the
17 RBC is more sensitive than the brain and has already
18 determined that your RBC data from that study are
19 in...are not acceptable, what...what will that do to
20 your NOEs?

21 **DR. LAMB:** First, let me make it clear
22 that...and I do actually make it clear in the
23 discussion of the oral study. RBC in adults, EPA even
24 says, is not more sensitive, despite the chart they
25 keep throwing up. That...there's a data point that's

1 in error there, and they have concluded, and I think
2 it's even in the issue paper that you've received, that
3 RBC is not more sensitive than brain.

4 I'll also, in the next presentation...but I
5 can't miss the opportunity...will mention that,
6 obviously, it's very valuable for certain studies, but
7 EPA and...and I agree...EPA has said and I agree, it's
8 a surrogate measure. The adverse effect is brain
9 acetylcholinesterase activity, and the inhibition of
10 that activity is the adverse effect.

11 **DR. HEERINGA:** Dr. Lamb, you should
12 touch off that microphone right next to you.

13 **DR. LAMB:** I'm sorry.

14 **DR. HEERINGA:** Other questions? Dr.
15 Edler and then Dr. Lu.

16 **DR. EDLER:** Lutz Edler, German Cancer
17 Center. I have just a question, Dr. Lamb, about the
18 NOE calculation at 50 mg/kg. I think we have very nice
19 dose response data in this case, so I was wondering if
20 somebody has actually calculated a benchmark dose with
21 these data.

22 **DR. LAMB:** I don't know that anyone has
23 done...we have not done a benchmark dose calculation.
24 The data...the data, though, show clear inhibition at
25 the five-fold higher dose level of 250 and not

1 inhibition at the 50 for brain acetylcholinesterase
2 inhibition.

3 **DR. DRIVER:** And just a correction. In
4 our written report, we did provide a benchmark dose
5 calculation for the dermal route.

6 **DR. LAMB:** I don't think so.

7 **DR. DRIVER:** We didn't?

8 **DR. LAMB:** No.

9 **DR. DRIVER:** Okay. Sorry, okay, I...I
10 stand corrected.

11 **DR. LAMB:** I don't think it's there.

12 **DR. DRIVER:** 4.7.

13 **DR. LAMB:** He's just causing trouble. I
14 don't think it's there.

15 **DR. DRIVER:** That must have been for
16 carbaryl. I thought we did.

17 **DR. LAMB:** No, as far as I know, it
18 doesn't...it has not been calculated. So, I thought
19 the NOAEL worked pretty clearly, and, you know...

20 **DR. HEERINGA:** Dr. Lu and then Dr.
21 Morton.

22 **DR. LU:** I think you...your points are
23 well taken, and you have addressed most of the concern
24 that EPA raised in their presentation yesterday, but,
25 apparently, you omitted one point which I think is

1 critical. It's the performance of the contractor lab
2 on the samples. Can you comment on that?

3 Because what I'm getting by reading the...the
4 documentation and EPA's presentation is that there are
5 some issues associated with the analytical protocol
6 that actually introduce this continuing reactivation of
7 the enzyme activity. So, the resulting data look like
8 there's no inhibition at all, but the question is, is
9 that truly inhibition? The moment you collect the
10 sample from the...the rat, and then, is that
11 reactivated continuously?

12 And if that's the case, then, my opinion,
13 without how good the study was designed, the data is
14 not...cannot be used, and, you know, that's probably
15 the case. Or you can comment on this.

16 **DR. LAMB:** Thank you. The...it's really
17 important we separate these out. One is that the issue
18 is exclusively RBC cholinesterase inhibition or RBC
19 cholinesterase activity assays at a particular
20 laboratory. Brain acetylcholinesterase is really the
21 critical adverse effect that's being moni...modeled in
22 this 21-day dermal study. It's the correct point of
23 departure.

24 There are no questions about or issues that
25 I've heard about the brain acetylcholinesterase

1 activity. So, it's almost like...EPA has talked a lot
2 about the RBC issue, and...and my view is we should
3 basically...we can remove that from consideration in
4 this case.

5 And in this particular study, the brain
6 acetylcholinesterase activity responds very quickly.
7 It responds...it recovers quickly. It is certainly
8 a...an example of an effect on the central nervous
9 system. It, in fact...and I'll go into this in my next
10 talk as well...the brain appears to be, in adults, the
11 first endpoint that responds even in the EPA studies.

12 For example, the McDaniel study, I believe,
13 at 0.1 mg/kg/day, the brain responds in the
14 EPA...that's an EPA lab, different assay. It's not
15 until 0.3 mg/kg that RBC and motor activity start to
16 respond.

17 So, in the adult, the...if anything, the
18 brain appears to be not only the most relevant but also
19 the most sensitive endpoint and should be used...and
20 should be completely valid in...in this particular 21-
21 day dermal study.

22 I hope that answers your question.

23 **DR. LU:** This is Alex Lu again. I guess
24 my...my...let me put my question this way. Say you are
25 able to split the...the blood sample. Doesn't matter

1 if it's brain tissue or red blood cells. And you have
2 your contract lab analyze for cholinesterase enzyme
3 activity, and then you send it to EPA. Would you
4 expect this...the number from this blood sample will
5 come in agreement?

6 It look like that it won't, because, I mean,
7 there are many problems that I can...I can, you know,
8 envision associated with the protocol that your
9 contract lab used, and one of the most critical points
10 is that the sample was collected and sit on the ice for
11 an hour. So, if you think that the reactivation of the
12 enzyme activity inhibit by a carbamate or, in this
13 case, carbofuran was so dramatic, so rapid, then that
14 1-hour window of time will wipe out all information
15 resulting from dermal exposures.

16 Do you agree?

17 **DR. HEERINGA:** I was waiting for the
18 question mark, Dr. Lu.

19 **DR. LAMB:** I was, too. No, I don't
20 agree, because I don't believe you're really looking at
21 the correct critical effect. I think it really needs
22 to be the brain acetylcholinesterase inhibition where
23 you don't have the same issues.

24 **DR. HEERINGA:** Questions of
25 clarification? I'm going to go now to Dr. Bunge and

1 then to Dr. Chambers.

2 **DR. BUNGE:** On...

3 **SPEAKER:** Your mike went out.

4 **DR. BUNGE:** Thank you. I'm a specialist
5 in dermal absorption but not cholinesterase inhibition,
6 so I may be asking as naive question, but one of the
7 issue...the analysis method, the modified Elman's
8 reagent method, was used for both the red blood cell
9 and the brain tissue.

10 Is the problem that EPA has discussed
11 potentially occurring with the red blood cell, would it
12 not occur in the analysis of the brain tissue? In
13 other words, is...what's different about the two
14 tissues?

15 **DR. LAMB:** Right, right. I think that
16 the most significant issue with the red blood cell was
17 probably the dilution or rinsing of the red blood cells
18 which was not done with the brain. So, I do think that
19 the assays...there's a reason one is responding
20 and...and appears reliable and the reason the other
21 does not.

22 **DR. HEERINGA:** Thank you.

23 **DR. CHAMBERS:** Jan Chambers. The last
24 chart you had there with the NOEs that you calculated,
25 just clarify for me, did you use the AHTTF values for

1 that then?

2 **DR. LAMB:** Yes, right.

3 **DR. CHAMBERS:** All right.

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

5 **DR. BUNGE:** Annette Bunge again. Could
6 I have some clarification on how you establish the no
7 effect, no observable adverse effect level at 50? When
8 I look at the study report, at least in terms of the
9 means, and I did go through a statistical analysis, if
10 I look at the mean values of the cholinesterase levels
11 in the brain, I see they're reduced at lower doses than
12 the 50. Can you explain the decision to choose 50?

13 **DR. LAMB:** The...the selection of 50 was
14 the study authors' selection, but I really think it's
15 based on a combination of statistical significance and
16 the degree of cholinesterase inhibition. It...it's not
17 articulated in the report. I think it's...if it's not
18 50, it's real close.

19 **DR. BUNGE:** The report doesn't discuss
20 the NOAEL at all, and...and we have, at least as near
21 as I can tell...I think I've gone through all of my
22 piles of papers and electronic files...their report
23 describe how you took the data to determine the no
24 effect level. Maybe I'm mistaken. If we have a
25 document about that or if we can get one, it would be

1 helpful.

2 **DR. LAMB:** Okay, what we can do is look
3 at that and provide you something probably later today
4 or in the morning.

5 **DR. HEERINGA:** We'd like to have a
6 reference or if it requires a separate justification,
7 to provide it, that would be very helpful.

8 **DR. LAMB:** Sure.

9 **DR. BUNGE:** Actually, I had a few more,
10 but I'll ask one more and then let other people have a
11 chance. Now I've forgotten what I was going to ask.
12 Oh, yes, back to the issue of the...the timing and
13 maybe we should ask the EPA folks again, but I think
14 the issue wasn't a pharmacokinetic issue. It was the
15 issue of the sample handling. So, the samples were
16 collected more or less immediately, but then, they
17 could be held on ice for up to an hour, according to
18 the protocol.

19 And so, the question is, what about that one
20 hour on ice? What effect might that have had on the
21 measurement?

22 **DR. LAMB:** I had the impression from
23 what EPA has written and said that it...it was both in
24 that the problem, one, it...the understanding that EPA
25 had was that it sounded like they didn't think the

1 analysis was...even the sample collection was likely to
2 happen for an hour after the...after the cleaning of
3 the site. That's, as I mentioned in my talk, that's
4 not correct.

5 But it...it really sounded to me like they
6 were looking for data in a time course, much as you
7 have the data in the time course for the oral study
8 where they looked over a period of time and, as they
9 described it, from the time the dosing ends, they would
10 then look for whether the peak...when the peak comes,
11 what the time is to the peak, whether that changes.

12 So, it's my understanding, from what they've
13 written and said, that's what they want, but you might
14 be right, that we maybe need to ask them, because it's
15 not fair for me to say much about that.

16 **DR. BUNGE:** If I can follow up, then
17 let's assume that you...you did have the samples
18 collected almost immediately following the end of
19 exposure, but they could be held as long as an hour on
20 ice, according to the protocol. What effect would that
21 have on the data, the results?

22 **DR. LAMB:** Well, it's a...it's a fair
23 question that I don't have the answer to. It's...and
24 I...just as I have...just as I asked for how long did
25 we really have the animals there for an hour, the

1 answer was no, it was 6 minutes. I don't have the data
2 as to when they analyzed the samples compared to that
3 point in time, and I don't even know if they exist, but
4 we could check and see if they do.

5 That's the best I can do on that one, and I
6 really don't know that that's going to answer your
7 question, because that sort of time course was not
8 done. That's sort of...

9 **DR. HEERINGA:** Yes, Dr. Stinchcomb?

10 **DR. STINCHCOMB:** Audra Stinchcomb,
11 University of Kentucky. Could you describe the
12 application procedure in the dermal tox studies and how
13 it's better than or different from the acetone
14 deposition study?

15 **DR. LAMB:** I really think one of the
16 biggest differences in...is that the acetone deposition
17 study created a slurry with acetone as the vehicle, and
18 it...it's my understanding from people who worked in
19 this area that that is likely to degrade skin and
20 facilitate absorption beyond what you'd normally
21 expect, whereas the dermal toxicology study is not
22 using an acetone slurry. It's using the product either
23 as a formulation or diluted in water and then applied
24 to the skin.

25 **DR. STINCHCOMB:** It was applied in both

1 ways or...

2 **DR. LAMB:** I'm told it was...no, I'm
3 sorry. I'm told...I was hedging. I'm told it was
4 technical material in water, diluted in water, as a...

5 **DR. STINCHCOMB:** As a solution or a
6 slurry?

7 **DR. LAMB:** Slurry.

8 **DR. STINCHCOMB:** Is that typical of
9 other studies of this type, to put it in a slurry or
10 not?

11 **DR. LAMB:** Yes.

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

13 **DR. MONTGOMERY:** I thought this
14 compound...this is Cheryl Montgomery. I thought this
15 compound was insoluble in water?

16 **DR. LAMB:** That's why it was a slurry.

17 **DR. MONTGOMERY:** I understand that, but
18 if it's in a slurry and it's in water...oh, I guess I'm
19 ...I'm obviously confused. I understand it's a slurry
20 in water. You're saying that this...this is basically
21 an active ingredient...

22 **DR. LAMB:** That's essen...

23 **DR. MONTGOMERY:** It's insoluble in
24 water, so it's not in a...not.

25 **DR. LAMB:** And that is how it's used.

1 When it's entered...put in these tanks, water is added,
2 and Jeff knows more about this than me, but that's...it
3 ends up being used, actually, and the worker exposure
4 actually is to a slurry in water. So, that is a clear
5 reflection of the product as a worker is going to...if
6 a worker comes in contact with it, that's what they'll
7 come in contact with.

8 **DR. MONTGOMERY:** Is this part no-liquid
9 formulation?

10 **DR. LAMB:** Don Carlson will answer that
11 one.

12 **DR. MONTGOMERY:** And it comes in drums.
13 Typically...

14 **DR. HEERINGA:** Dr. Carlson?

15 **DR. MONTGOMERY:** ...chemicals that come
16 in drums are in liquid formulation, and if this
17 compound is insoluble in water, it must have
18 surfactants added to keep it suspended so that it can
19 stay in the solution.

20 **DR. CARLSON:** Don Carlson, FMC
21 Corporation again. First off, let me address the
22 question of the water solubility. The water solubility
23 of carbofuran varies anywhere, in the figures that have
24 been made available, from about 340 ppm to 600 ppm, so
25 it's not a...a relatively insoluble material.

1 In regard to the formulation, the technical
2 material for the furidan flowable was very finely
3 ground. It is put on a very finely ground clay
4 carrier, and then, that is suspended in water. The
5 water is about 40 percent of the formulation, and there
6 are suspending agents in the...the formulation that
7 help to keep it in suspension.

8 **DR. MONTGOMERY:** I'm going to think on
9 this.

10 **DR. HATTIS:** Was there suspending agents
11 also in the technical material that was used for the
12 experiments?

13 **DR. CARLSON:** The experiment was done on
14 technical material. There was a slurry of the
15 technical material which was pasted on or, you know,
16 applied to the skin, spread on the skin.

17 **DR. HATTIS:** It did have the suspending
18 agents. Is that right?

19 **DR. CARLSON:** No.

20 **DR. HEERINGA:** Dr. Carlson answered
21 that.

22 **DR. CARLSON:** The answer was no.

23 **DR. HATTIS:** Thank you.

24 **DR. CARLSON:** You're welcome.

25 **DR. CUMMINGS:** Dr. Heeringa, could I

1 just add?

2 **DR. HEERINGA:** Dr. Cummings, sure.

3 **DR. CUMMINGS:** Just for...just for
4 clarification, the...the guideline study from the USEPA
5 is to use...is to use technical material and not
6 formulated product.

7 **DR. CARLSON:** If I may, to further
8 clarify...

9 **DR. HEERINGA:** Sure, Don Carlson.

10 **DR. CARLSON:** ...in relation to Dr.
11 Hattis' question, what was used in the study was the
12 technical material in a slurry, and what the guidelines
13 specify is the technical material to be used in the
14 study.

15 **DR. HEERINGA:** Thank you. At this
16 point, we have, with the presentation by FMC and the
17 worker exposure assessment, there is supporting papers
18 and reports that we've received. Any additional
19 questions of clarification before we move on?

20 **(No response.)**

21 **DR. HEERINGA:** Not seeing any...one
22 more.

23 **DR. BUNGE:** Annette Bunge. One of the
24 issues that's been raised was that other 21 or 28-day
25 dermal tox studies for other carbamates or...or

1 organophosphates have been used, but what the Agency
2 has said about this pesticide is that it has this very
3 rapid recovery, and so, that's my question. On these
4 other pesticides that have...where studies have been
5 accepted, was the recovery as...as similarly rapid?

6 Because it's not just a combination...it's a
7 combination also of how quickly the body is able to
8 clear them.

9 **DR. LAMB:** I think it would not be true
10 for the organophosphates, because the binding is
11 typically irreversible, but for the carbamates, it
12 would be, but they typically have much shorter half-
13 lives, and, in fact, I think EPA talked about that
14 earlier this morning as far as the...the range of half-
15 lives for the N-methyl carbamates.

16 **DR. HEERINGA:** Okay. Well, thank you
17 very much, Dr. Lamb and Dr. Driver. Stick around. You
18 may be up here again shortly, I believe.

19 At this point, I'll turn back to Dr.
20 Cummings. I think we're up for the presentation on the
21 human health and dietary risk assessment.

22 **DR. CUMMINGS:** It will just be a moment
23 while we switch...

24 **DR. HEERINGA:** Absolutely. Before we
25 begin, I want to...just a small administrative matter.

1 Mr. Larry Kleingartner, if you would be willing to,
2 speak to Sharlene at some point.

3 Thank you very much for your patience, and at
4 this point, we'd like to begin, and, Dr. Lamb, if you
5 could begin and introduce your colleagues, as
6 appropriate.

7 **DR. LAMB:** You bet. With me
8 today...again, I'm Jim Lam of the Weinberg Group. I
9 have Dr. Robert Sielken who will be speaking after me,
10 and then I'll speak again, and then Dr. Morris from FMC
11 will speak on the dietary exposure model. So, you're
12 going to get four relatively short presentations.
13 We're trying to help you get through the lunch down and
14 keep things rolling along. How is that?

15 I will start with the oral risk assessment.
16 Some of these points we may have already covered. If
17 we have, I'll move along as quickly as possible to try
18 to help you get towards schedule.

19 The outline of our presentations, initially,
20 I'll talk about how FMC and EPA have done their risk
21 assessment generally and the selection of a point of
22 departure and past practice. Then, Dr. Sielken will
23 speak to the mathematical and statistical issues. I'll
24 talk again on some of the specific toxicological points
25 and conclude this section, and then Dr. Morris will

1 talk about the dietary exposure assessment that ties
2 the risk assessment together.

3 I think you all know that the Food Quality
4 Protection Act controls the presence of pesticides on
5 foods. Both EPA and FDA...FMC have carefully estimated
6 dietary exposure using various data and models.

7 But one of the key concepts in this is a
8 discussion of the risk cup, the method...and it was
9 mentioned yesterday. It's a...it's a model or a...a
10 target that was developed under the Food Quality
11 Protection Act that is a calculated allowable intake of
12 pesticide in food and...and other sources, food,
13 drinking water, for example.

14 One of the first steps and key steps in
15 determining the risk cup is the selection of the point
16 of departure. I am going to make your lives much
17 simpler today by not arguing much about the point of
18 departure.

19 You can do this from oral studies, whether
20 they're gavage or dietary. You can do it with one
21 study; you can do it with multiple studies.

22 Ultimately, you're trying to get a level that
23 represents no to a low response. And whether this is a
24 LOAEL or a NOAEL or some version of a benchmark dose,
25 as you heard yesterday, the EPA policy, when they use

1 the benchmark dose, is to use the BMDL10 which is the
2 95 percent lower confidence limit on the BMD10.

3 The risk cup is a calculated allowable
4 take...intake, because the calculation comes in once
5 you have the point of departure, you divide it by
6 various factors. There's the interspecies uncertainty
7 factor, the intraspecies uncertainty factor, and the
8 default values for those are 10. And there are the
9 regulatorily...the legislatively mandated FQPA factor
10 that begins at 10 and can be reduced if there's
11 sufficient data to protect children.

12 EPA, for carbofuran, has selected a point of
13 departure of 0.3 mg/kg based on postnatal day 11 rat
14 brain acetylcholinesterase. Those are the data upon
15 which they're relying on, but they have a concern
16 about, obviously, acetylcholinesterase inhibition.
17 That is one of the major issues that we will be talking
18 about, because that, in turn, leads to differences in
19 uncertainty factors.

20 They...the 10 and 10 standard interspecies
21 and intraspecies uncertainty factors are used, but they
22 drop the 10-fold FQPA to 5 instead of what we think
23 should be 1, and you'll hear me and EPA talk about the
24 risk cup. We're referring often to this acute
25 population-adjusted dose that Jack Housenger mentioned

1 yesterday or an adjusted reference dose, adjusted by
2 the FQPA factor.

3 What are the differences? Well, the
4 differences are, actually, substantial, and they really
5 come down to a couple of issues. There's no argument
6 about leaving the intraspecies factors at 10. There is
7 some...going to be some discussion about the
8 interspecies, whether it should remain at 10 or might
9 be dropped to 3. There is major issue about the Food
10 Quality Protection Act factor which, currently, EPA has
11 at 5 and we strongly believe should be at 1.

12 And in the end, that leads to differences
13 using exactly the same brain PND11 acetylcholinesterase
14 endpoint for us and for EPA. The...the risk cup for
15 EPA is 0.00006 mg/kg/day, and the way we do the
16 calculation with an uncertainty factor of 300, it would
17 be 0.001. If you used 100, it would be 0.003. I'm
18 sorry, 30 or 100 are the two uncertainty factors we
19 think are...are...it's going to be somewhere...it ought
20 to be somewhere in that range.

21 As I mentioned, to me, it takes a lot of
22 the...it should solve some of the discussion we've had
23 for this. For the purposes of this study, of this
24 evaluation, the brain acetylcholinesterase from PND11
25 of 0.03 is the number that FMC is using for the risk

1 assessment. It's the uncertainty factors that matter,
2 because it shrinks the risk cup down by to 5 to 16.7-
3 fold.

4 With EPA's factors, nearly every use of
5 carbofuran is precluded, and without them, the risk cup
6 allows the continued use of carbofuran with the
7 lab...adjusted label, as we've already discussed.

8 So, that additional risk factor or
9 uncertainty factor is very significant. If you use the
10 smallest uncertainty factor, you get the largest risk
11 cup. The 100-fold gets you another, and the 500
12 shrinks it down quite a bit, and I can't tell you
13 whether these are quantitatively correct cuts or not.
14 I'm sure they are, in fact, though.

15 We're using the pup brain
16 acetylcholinesterase endpoint, and EPA has expressed
17 the concern that I know you've heard that RBC
18 acetylcholinesterase is up to 5 times more sensitive
19 than brain. We...we...they've used the BMD50
20 calculations to make that comparison of sensitivity
21 rather than individual animal data.

22 The details on that calculation are not
23 apparent to us. The assumptions, the calculations, the
24 data, we can't find the in the Notice of Intent to
25 Cancel. We can't find them within other Agency

1 documents.

2 I know that you've already heard that the
3 number has changed a bit with a recalculation. We
4 don't know how that calculation was done, either, but I
5 think we're getting closer to understanding the
6 numbers.

7 Bottom line is we believe that the use of pup
8 brain acetylcholinesterase as the point of departure is
9 the appropriate. It is an...we are talking about an
10 acute effect. We are talking about a...an acute
11 response, not a chronic risk.

12 As EPA indicated yesterday, you don't have
13 issues of carcinogenicity, reproductive, developmental
14 and neurotox. The brain acetylcholinesterase, again as
15 mentioned yesterday, is the adverse effect. This is an
16 effect that's been measured in juvenile animals, and it
17 models nervous system responses.

18 The biological basis for some of these issues
19 I'm going to talk about after Dr. Sielken gets through,
20 but...but you should go into this knowing that we agree
21 on one uncertainty factor. We're closer on a second,
22 the interspecies factor being in the range of 3 to 10.
23 We completely disagree on the FQPA factor being 5 and
24 think it should be closer to 1, it...in fact, it should
25 be 1.

1 So, the uncertainty factor really belongs in
2 that range of 30 to 100, not 500, and we're going to
3 talk about each of these in more detail.

4 One point I want to make that I alluded to
5 earlier is this chart that we've seen several times in
6 this point as the origin of the 5-fold FQPA factor.
7 These are data from adults. These are data that were
8 shown in the MMC cumulative risk assessment, and this
9 particular data point that's circled is the one that,
10 actually, FMC had identified that as erroneous.

11 The way...we believe that number is low
12 simply because it's an artifact of a combination of
13 studies, and, ultimately, in the SAP issue paper,
14 basically, EPA says, and we agree, that the BMD10s for
15 adult RBC and brain acetylcholinesterase are similar,
16 and they don't support the 5x factor used for adults
17 that used...based on the adult data in the 2006 risk
18 assessment.

19 That is...that is how they say it started,
20 but we agree that then...it started with a concern that
21 adults were different, and it turns out they're not.
22 And this is the position with EPA is agreeing with in
23 the document.

24 So, I think it's important to clarify,
25 because I'm fearful you may have misunderstood

1 the...the point of that N-methyl carbamate slide and
2 comparing aldicarb to carbofuran and other N-methyl
3 carbamates.

4 So, now I'm going to move to the math. The
5 bottom line here, though, is that the 5-fold FQPA
6 factor is being applied because of the lack of RBC
7 acetylcholinesterase data in juvenile animals at the
8 low end of the dose response curve.

9 I'm going to put the pots aside for now and
10 let you listen to Dr. Sielken in the meantime and the
11 mathematical points.

12 Thank you. And, as usual, hold questions
13 till we're all done.

14 **DR. HEERINGA:** Yes. Dr. Sielken?

15 **DR. SIELKEN:** All right. This is Bob
16 Sielken, and I was asked to do a statistical comparison
17 of acetylcholinesterase inhibitions in RBC and brain in
18 rats exposed to carbofuran, and as Dr. Lamb has
19 indicated, we're going to be talking about the juvenile
20 rates, the PND11 in the EPA study, the PND17 in the
21 other EPA ORD study. So, we're going to be looking at
22 those juvenile rats, and we're going to be looking at
23 the relevancy of sensitivity of RBC to brain.

24 And when we come back, Dr. Lamb will go back
25 to the issue about well, we probably don't even need to

1 be looking at RBC, because brain is the relevant
2 endpoint. But because this issue of the 5x has come up
3 about the relative sensitivity, then let me try and
4 address that and really put that to bed, because there
5 really isn't a substantial difference in sensitivity
6 between RBC and brain in those juvenile rats.

7 EPA's methodology for comparing these
8 cholinesterase values is indicated in their issue paper
9 as being derived from table 5, and this is a
10 reproduction of table 5 shown here on this slide, and
11 in table 5, they actually tabled BMD50 values for PND11
12 in brain, 0.23; BMD...BMD50 in PND11 rats at 0.05 for
13 RBC.

14 Then they took the ratio of those two
15 numbers, 0.23 divided by 0.05, 4.6. Did the same thing
16 for PND17 animals, and said that on this basis, they're
17 going to conclude that RBC is...the juvenile rats are 3
18 to 5 times more sensitive to RBC inhibition than they
19 are to brain inhibition.

20 There are a couple of issues that I'd like to
21 talk about concerning their methodology. The first is
22 the derivation of the numerical values in that table 5.
23 It's not transparent. The numbers cannot be confirmed,
24 and in fact, yesterday, EPA said they've changed at the
25 last minute.

1 So, I...I do want to...to look at those
2 numbers. I think the more important issue, though,
3 is...is not where those PMD50s came from, although we
4 can't reproduce them in the table as it is. The more
5 important issue is that you have better data for
6 looking at relative sensitivity than those BMD50s.
7 BMD50s might be used if you didn't have better data,
8 but here, you really do have better data.

9 You, in fact, observed RBC and brain
10 inhibitions in the same animal at the same time. So, I
11 mean, you have individual animal data. That's being
12 ignored, the simultaneous availability of RBC and brain
13 in the same animal that's ignored in the BMD
14 calculation, and, really, you can use it directly to
15 get a better idea of relative inhibition.

16 And that would be in...sympathetic to the
17 comment we heard earlier from EPA that there is a high
18 degree of intra-animal correlation, that within an
19 animal brain and RBC are correlated. That correlation
20 is lost when you ig...ignore the individual animal and
21 you just spread the RBC values in one calculation and
22 the brain values in a different calculation. Okay.

23 Most of you, in fact, all of you probably
24 know what a BMD50 is. Here, since we're looking at a
25 continuous endpoint, cholinesterase inhibition, we're

1 starting with a curve where we've got 100 percent of
2 the acetylcholinesterase level in the controls, and
3 we're looking for how that level decreases as the dose
4 increases. And the point where the
5 acetylcholinesterase level is decreased 50 percent, the
6 dose corresponding to that is the BMD50. Simple idea.

7 If you look at the PND11 values from the EPA
8 ORD study, Moser, in 2007, and you plot that data as I
9 have done here, the diamonds, if you will, in this plot
10 indicate the sample means. I could have put on here
11 sample standard deviations as well, but for the
12 purposes of this talk, the means will be fine. They're
13 showing the mean inhibition at...at the experiment...at
14 the five experimental doses.

15 And you'll notice that...and this is for RBC.
16 And you'll notice that for RBC, the point where you
17 have a 50 percent inhibition happens to correspond to
18 that lowest experimental dose, 0.1 mg/kg/day. So,
19 regardless of the modeling or anything else that's done
20 with this data, if you're looking for the point where
21 there's 50 percent inhibition, you can go directly to
22 the experimental data, and it should be 0.1. Anything
23 else is, you know, not reflecting the experimental
24 data.

25 EPA got 0.05 initially. They got a different

1 number yesterday, but they got 0.05 in their report,
2 perhaps suggesting that you need to look at the data
3 itself, not just reported numbers supposedly related to
4 the data.

5 For PND17, the top curve here which is blue
6 but it's on top, is brain. The one underneath is RBC.
7 And this is, again, a plot of experimental data. You
8 can see, again, for RBC, that there's 50 percent
9 inhibition at the lowest experimental dose. So, again,
10 the BMD ought to be around 0.1. EPA got 0.07 in their
11 calculations initially.

12 You look at brain. Well, it's almost down to
13 50 percent at the second dose, 0.3, so maybe the BMD is
14 just a little bit bigger than 0.3. It's certainly not
15 0.2, as was in EPA's table 5.

16 This discrepancies between the data
17 and...between the experimental data and the numbers in
18 EPA's table 5 made it hard to reconcile what was EPA
19 doing to actually get those values and come to their
20 conclusion. Okay.

21 Again, with the idea of emphasizing looking
22 at the experimental data, if you just look at the two
23 lowest experimental doses in this study, EPA's study in
24 the PND11 pups, at the lowest dose, 0.1, the ratio
25 between the reduction in RBC and the reduction in brain

1 at that lowest dose is 1.3, not 5. It's 1.3.

2 You look also at the ratio of the percent
3 reductions at 0.3, the second lowest dose, and the
4 ratio is 1.2, again, not 5.

5 If you want to do dose response modeling
6 here...and I am a dose response modeler by trade, so
7 being...being a little disparaging about the dose
8 response modeling comes from one who does it all the
9 time, too, but I never do it without looking at the
10 data. Okay? So, if I go back to that PND11 data for
11 brain in the Moser study, the data points are here.

12 A fit of the exponential model with the power
13 in the model being 1 or a fit of the HAIR model which
14 is like a McCayliss-Menton model, those models, either
15 one of them, fit this data reasonably well. The same
16 thing could be said for the RBC data, particularly when
17 you're looking at the lower end.

18 I've done a piece-wise linear plot, but I'm
19 really trying to emphasize here that at the points
20 where you have data, these fitted curves go close to
21 the experimental data, and you can pick any of
22 the...either of those two models.

23 If you want to go with a BMD approach...and,
24 again, I don't think that that's the best
25 approach...you can take either one of these fitted

1 models, the fitted exponential or the fitted HAIR
2 model. both of which fit the data reasonably, and look
3 at BMD10s, BMD20s, BMD30s, BMD40s, just depending on
4 how far back towards zero you want to do your
5 extrapolation. Or you can do it linearly which is
6 probably the closest thing to the data.

7 And any of those numbers, comparisons of
8 BMD10s, 20s, 30s, 40s, using linear extrapolation
9 fitted exponential, fitted Hill models, those ratios of
10 relative sensitivity in doses...in the dose metric come
11 out to be all numbers less than 2. Certainly, well
12 less than 5.

13 Okay, I indicated in the beginning that there
14 was an issue with how EPA derived its numbers and it
15 was hard to replicate, et cetera. If you go ahead and
16 take their approach, you do show, if you enter it
17 correctly, that regardless of which model you take,
18 you're looking at relative sensitivity less than 2-
19 fold, more like 1.5-fold. All right?

20 And I also indicated at the start that there
21 was a better approach. You've got data on RBC and
22 brain in the same animal. So, why not use that data?

23 And that's true not only of the Moser
24 studies; it's true of the FMC studies as well. We
25 might debate about whether their RBC values are usable

1 or not in those FMC studies, but it's always there.

2 That's the protocol, is to observe both of these things
3 in the same animal.

4 Having this information in the same animal
5 allows for a direct comparison. You can do a...we can
6 take advantage of or not distort the analyses by the
7 fact that these observations on RBC and brain
8 inhibition in the same animal are highly correlated.

9 Use of the individual rats as unit of
10 analysis invoy...avoids issues of variability between
11 the animals in their response, differences in dose
12 administration, absorption, time from dose
13 administration to observation. So, all of those
14 differences between animals are kind of eliminated or,
15 at least, better taken account of by looking within the
16 same animal.

17 You don't have to make any unvalidated
18 assumptions about the shape of the dose response
19 models, and you don't have to dissociate the RBC data
20 from the brain data. You don't have to treat those
21 data sets as separate data sets.

22 And although this figure is a little hard to
23 read, as a statistician, I feel compelled to show how I
24 did my calculations, and this is an excerpt from the
25 Moser data on PND11 pups. We have the individual

1 animal data, as shown by the ID numbers down the left-
2 hand side, and for each animal at each dose level, I've
3 got a separate reading for brain and RBC cholinesterase
4 inhibition.

5 For the controls, I can take an average value
6 to give me a reference point when I look at inhibition
7 relative to controls.

8 For each of the animals, individual animals,
9 pups, at each of the doses, I get an observation on
10 both brain and RBC, and I can take these individual
11 values, compare them to the control average, and get a
12 percent reduction in, first of all, brain in that
13 animal. And we do the calculation again comparing the
14 animal's value to the average in controls to get a
15 percent reduction for RBC.

16 I can compare those 2 percent reductions and
17 get a relative sensitivity of RBC to brain. And I do
18 that calculation for each of the individual animals.
19 If I do that, I get the averages of these individual
20 animal measurements of relative sensitivity to be these
21 numbers at the four doses in that experiment, an
22 overall average of around 1.2.

23 The specific number doesn't really matter.
24 The numb...the important thing here is that it's really
25 close to 1. It's certainly not 5.

1 I did the same calculation for the PND17 rat
2 pups. Again, that's the other EPA pup study. And the
3 average there is around 1.56, again, certainly less
4 than 2, considerably less than 5.

5 Now, EPA raised the issue last night in the
6 waning hours of the day that...that I was...and they
7 knew from my advance submission that I was going to
8 talk about this, and they were trying to find an
9 argument against it or, at least, the scientific
10 critique, however you want to phrase that, and they
11 were...wanted to say that well, I'm looking at relative
12 acetylcholinesterase values and not relative doses.

13 Well, my contention would be...and we have
14 thought about this in the beginnings...is that as long
15 as the dose response relationships are linear...and
16 most non-threshold dose response relationships are at
17 least approximately linear, in general approximations
18 in the low dose region, that as long as you have
19 roughly linearity in the low dose region, the relative
20 reduction in the acetylcholinesterase values and the
21 relative magnitudes of BMDs are equal.

22 And I'm a mathematician, so I like to do it
23 one way, but I thought the easiest thing for my clients
24 and probably the panel was just to do a hypothetical
25 example that was some pictures. And so, I did.

1 Here's the acetylcholinesterase values for
2 brain in blue and in red is RBC. Other than the fact
3 that brain was usually bigger than RBC, the...that's a
4 hypothetical example. They have different slopes in
5 those linear relationships.

6 If I put that back and draw the picture in
7 terms of fractional reduction, you'll notice that when
8 I did my calculations, I did it not on fractional
9 reductions but acetylcholinesterase values, but if I
10 draw the pictures in terms of fractional reduction, I
11 get that picture.

12 And if I go ahead and do the comparison of
13 BMD50s, say, if I just, you know, come over from 50
14 percent and identify the two BMD50s, 2.3 and 3, take
15 the ratio of those, that ratio in this picture is about
16 1.3.

17 If I do the...if I look at it the other way,
18 that is, I look at a dose and look at the relative
19 acetylcholinesterase values, then that's what I get in
20 this picture. But if I take a dose of, say, 0.3...I
21 mean, 3...and these are an arbitrary dose scale...3 and
22 go up, the fractional reduction for RBC is about 0.65.
23 The fractional reduction for brain is about a half.
24 The ratio if those two reductions is 1.3.

25 So, whether you want to look at this in terms

1 of acetylcholinesterase values or BMDs in the low dose
2 region, the comparison is the same or equivalent.

3 For those of you who like algebra better than
4 pictures, your slide sets show that this equivalence
5 holds from an algebraic point of view as well as a
6 pictorial point of view, but I'll skip those slides for
7 everyone's benefit and just go right to my conclusions.

8 And the conclusions are that comparisons of
9 RBC and brain sensitivity to inhibition are
10 scientifically and statistically most valid when done
11 on an individual pup basis when that data is available,
12 and it is available here. EPA's approach of relying on
13 the BMD50s and basing the comparisons on these
14 artificial constructs requires unnecessary assumptions
15 about the dose response, and it loses the commonality
16 of RBC and brain within the same animal.

17 The average ratio of RBC to brain in the
18 PND11 pups which is our target, PND11 pups, is 1.22
19 which really is not a biologically significant
20 difference, as being told to me by my biological
21 colleagues. So, you're really looking at 1.22. You're
22 not looking at 5. You're not even looking at 2. The
23 FQPA safety factor really should be 1, and that's the
24 bottom line.

25 **DR. LAMB:** As promised, I'll...this is

1 Jim Lam of the Weinberg Group. I'll move on to
2 the...immediately to the toxicological issues and...and
3 then pass over to Dr. Robert Morris.

4 First of all, we need to make the point that
5 brain acetylcholinesterase is, in fact, the more
6 relevant endpoint. It is more reliable statistically.
7 The levels are higher in brain by, typically, an order
8 of magnitude compared to red blood cells. It's more
9 relevant toxicologically.

10 The brain has basically been used as the
11 point of departure in numerous other risk assessments,
12 and the comparison of a value of brain
13 acetylcholinesterase to red blood cell
14 acetylcholinesterase has been reviewed by the science
15 advisory panel in the past.

16 I'm not going to read this whole slide, but
17 the...the bottom line in the review with respect to the
18 cumulative risk assessment was brain provide a health
19 protective endpoint for central and peripheral nervous
20 system and represents a direct measure of a common
21 mechanism of toxicity as opposed to using surrogate
22 measures which is a term that I think we've all used in
23 describing red blood cell. It is an absolute necessity
24 in a human study; it is not such a necessity in the
25 rodent studies as they've been designed.

1 Also, within the N-methyl carbamate
2 cumulative risk assessment, EPA's position was that
3 brain cholinesterase is equally sensitive or more
4 sensitive compared to RBC, and it is a health
5 protective endpoint for both the CNS and peripheral
6 nervous system.

7 It is representative of the adverse effect.
8 It is...it is a sign of neurotoxicity. It's not a
9 biomarker which is really what RBC may serve for. It
10 is a functional response. RBC may or may not be a...a
11 synch as far as a function, but it certainly is not a
12 direct measure of neurotoxicity.

13 Another point made in the McDaniel study
14 which is an ORD study published in Toxicological
15 Sciences...and I know all these studies may be running
16 together in your head, and I know, by now, they're
17 actually running together in my head, but in this
18 study, she had reviewed a number of different
19 compounds, and in the ultimate sentence, final sentence
20 of the document, indicated that current data
21 supported...this is a 3007 paper...support the use of
22 brain cholinesterase over RBC when evaluating
23 neurotoxicity for these chemicals, and carbofuran was
24 one of these chemicals.

25 RBC is variable. It's variable in EPA's

1 studies. It's variable in FMC studies, and this is
2 putting aside the issue of the quality of the assay.
3 It is much more variable than brain
4 cholinesterase...acetylcholinesterase.

5 And it's less reliable. You're talking, as I
6 said, at lower levels in red blood cells than brain.
7 Brain acetylcholinesterase activity represents the CNS
8 directly, and I think it better represents the
9 peripheral nervous system than red blood cell values
10 do.

11 It's...toxicologically, it is relevant. It
12 is, in the case of carbofuran, you get a rapid
13 response. We are talking peak responses beginning at
14 15 to 30 minutes. The blood-brain barrier does not
15 seem to slow this compound down a lot once it's
16 absorbed in the body.

17 The peripheral and central nervous system
18 responses are both in nerve cell endings. They're not
19 in circulating RBCs. As I say, one of the best uses
20 for red blood cell is in human studies where brain is
21 not an accessible endpoint or peripheral nervous system
22 to map accessible endpoints.

23 So, in our hands, with animal toxicology
24 studies especially, this is the best model for
25 potential neurotoxicity. And if it is used, if RBC is

1 used in the risk assessment, you really need to
2 consider the potential response at the low end of the
3 dose response curve where you have a BMD50 comparison,
4 but that involves unnecessary data manipulation, and
5 it's really valid if those dose response curves are, in
6 fact, parallel from the BMD50 to the BMD10.

7 The responses at the lowest levels are really
8 the ones that are most important, and we have valid
9 brain pup acetylcholinesterase data available at the
10 low end of the dose response curve which is why we
11 agree on the critical effect and point of departure.

12 So, in the...that same McDaniel study, the
13 lowest dose of carbofuran...the low dose first
14 inhibited brain acetylcholinesterase. The 0.1 mg/kg
15 dose level, that was the one endpoint that responded.
16 This is in adult rats.

17 Red blood cell and motor activity responded
18 later. I've heard discussions of the correlation of
19 these endpoints, but the fact is that red blood cell
20 motor activity, brain, all tend to move together, but
21 in these studies on carbofuran, brain moved first.

22 Now, we talked some already about aldicarb.
23 You guys talked yesterday a little bit about aldicarb
24 and urban legends. This particular example...and
25 there's a chart over here to the...to the side

1 that...that is actually, it's the next slide in the
2 package. So...so, you've got this slide, all this
3 thing up here, but initi...comparing aldicarb in the
4 lab to carbofuran in the rat, what you see are BMDL10s
5 that are somewhat different, showing that there is a
6 couple of fold, two or three-fold difference in potency
7 based on the BMDL10s for brain, rat brain
8 acetylcholinesterase. And I'm leaving the human and
9 the oxamyl out at this point.

10 So, the potency factors for the cumulative
11 risk assessment were in that range with a little less
12 than a two-fold difference between aldicarb and
13 acetylcholinesterase, but when you count the zeros, you
14 can see that aldicarbs, APAD or risk cup is actually
15 much larger than carbofurans.

16 And this chart over to the side or the one I
17 can show up here on the top, if you put various
18 elements at unity for carbofuran...and this is purely
19 for the comparison...and look at adult rat brain, human
20 RBC, BMD10, and juvenile rat brain BMD10 and compare
21 these, aldicarb is more toxic, relative toxicity,
22 greater toxicity, not dose. Toxicologists like me have
23 trouble with these charts, but the toxicity of aldicarb
24 was higher than carbofuran in every case. Oxamyl was
25 lower, but the carbofuran's APAD is, in fact, higher

1 than the other two.

2 Another important point, talking about the
3 uncertainty factors. If you were to take the 10 for
4 interspecies and 10 for intraspecies, they are 100-fold
5 results in a very conservative dietary risk assessment.

6 We believe that for certain purposes, you
7 actually should consider the human study, and I realize
8 that I may have folks throw rocks at me about this one,
9 but the fact is the HSRB did not...you are not
10 repeating the task that the HRB undertook. They never
11 considered the full weight of the scientific evidence.
12 They basically received a limited weight of evidence
13 that has been substantially updated since the time it
14 was presented to them.

15 I really believe you need to be looking at
16 the full weight of the evidence and the human studies
17 in context. The dermal study can be set aside, but the
18 oral study was not excluded by the HSRB based on
19 ethical issues. They had concerns about it
20 scientifically which I've talked about.

21 The...they did BMDL...actually, EPA, I guess,
22 did BMDL10 calculations for the human study. They are
23 very close to...in risk assessment, close to means
24 within an order of magnitude. They are very close to,
25 in fact, a lot closer than that, to the 0.03 point of

1 departure we're talking about or effect level we're
2 talking about for brain cholinesterase. This is a
3 human study. Of course, this is based on the RBC
4 cholinesterase.

5 Peak response was at an hour. The study was
6 peer reviewed by several scientists who felt it was
7 appropriate to use it to develop a reference dose.

8 And, in fact, EPA proposed using the human
9 BMDL10 with uncertainty factor of 1 for interspecies
10 and 10 for intraspecies, and that's what was presented
11 to the HSRB, but the design of this study was limited.
12 It was a single oral dose. It had a small sample size.
13 There were 9 people, 2 per group. Really, the math
14 does work.

15 It's...there are three dose levels. There
16 was one control person, but each individual served also
17 as their own control, because there was a pre-dosing
18 evaluation was well. And the top dose was treated
19 twice.

20 And then there are multiple time pre and
21 post-dosing assessments. Bottom line is RBC
22 cholinesterase was decreased in...in the control, oddly
23 enough, but it was...it was decreased 11 and 22 percent
24 at 1 hour and back to normal within 3 hours. 0.05
25 mg/kg did not show symptoms. And these are the data

1 that EPA used to develop the BMDL10.

2 I've already mentioned that the HSRB did not
3 que...they were concerned about the study sample sizes
4 especially, and I see that. That's...but, in fact, the
5 response was very similar to the animals. You are
6 seeing a lot of animal data, and these extensive animal
7 studies should increase confidence in the human
8 findings or vice versa. They, if nothing else, they
9 reinforce that we are in the correct range for
10 response.

11 You're seeing all of the data. We don't
12 believe these human studies should be used to select a
13 point of departure, but we do believe they can support
14 a reduction in the interspecies uncertainty factor from
15 10 to 3.

16 Now, if you look at the dietary risk
17 assessments, these are three different versions. The
18 first column is the version that EPA is presenting in
19 the Notice of Intent to Cancel. The bottom line is the
20 acute population adjusted dose is four zeros and a 6,
21 0.00006, with an FQPA factor of 5 and an interspecies
22 factor of 10.

23 If you did the human study, the EPA did...was
24 silent on whether or not they would stick with 5, go to
25 1, or use 10, so I...but I put 1 for comparative

1 purposes. That's my number, to be clear.

2 The number for the acute POD, though, would
3 be 0.0026. The approach that we're presenting is the
4 same point of departure, 0.03, based on rat brain
5 acetylcholinesterase inhibition. Same intraspecies
6 uncertainty factor. Different interspecies uncertainty
7 factor which has, often in this talk, been expressed as
8 a range of 3 to 10, but the FQPA safety factor of 1 for
9 a number of 0.001 mg/kg/day.

10 So, conclusions, the data converge on the
11 BMDL10 of 0.03. Pup brain acetylcholinesterase data
12 are reliable and, actually, in these first two bullets,
13 I think, are entirely consistent with EPA's position.
14 Where, I guess, we really disagree on is the additional
15 5x uncertainty factor based on purported sensitivity of
16 RBC which is a surrogate measure, not an endpoint of
17 toxicity. The brain acetylcholinesterase is the
18 endpoint that reflects an adverse effect.

19 The 3x uncertainty factor based on the human
20 data, and that the total uncertainty factors basically
21 should be in the range of 30 to 100, not 500 as
22 proposed by EPA, and that, basically, that...that risk
23 assessment is much more conservative than for other
24 carbamates or than it needs to be for carbofuran.

25 These are some charge questions that we have

1 in the toxicology. Is brain the preferred endpoint
2 over RBC toxicologically? Do the available data
3 support the conclusion or not that RBC
4 acetylcholinesterase in PND11 pups is 3 to 5 times or
5 that there's this uncertainty that it's 3 to 5 times
6 more sensitive than brain acetylcholinesterase?

7 Do they support the imposition or failure to
8 reduce the 5x FQPA factor? This is a juvenile
9 endpoint, not an adult endpoint, and do the data
10 support reducing the interspecies uncertainty factor to
11 3?

12 With that, we now move on to the diet, the
13 last of this series, the dietary exposure assessment,
14 Dr. Robert Morris from FMC.

15 **DR. HEERINGA:** Thank you, Dr. Lamb.

16 **DR. LAMB:** Thank you.

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

18 **DR. MORRIS:** Thank you, Dr. Lamb. Good
19 afternoon. I'm Robert Morris. I'm a risk assessment
20 specialist with FMC Corporation, and I'll be discussing
21 the exposure portion of the dietary risk analysis.

22 I...I will not bore you with what a risk cup
23 is, because I think you've heard it more than enough.
24 So, I'm going to move on to the exposure level and how
25 it's calculated using the dietary eval...dietary

1 evaluation exposure model, the DEEM model and what that
2 means to the actual percent of food within the dietary
3 risk cup.

4 There are three critical differences between
5 EPA and FMC's APAD calculations. This is a depiction
6 of the two dietary risk analyses that you've been
7 reviewing. The EPA's dietary risk analysis is a
8 refined tier 3 analysis very similar to FMC's. The
9 drastic difference is on the hazard side which is what
10 you'll be determining on whether the 5x is appropriate
11 in the FQPA side or if it should be removed and whether
12 the 3x that Dr. Lamb is proposing is appropriate to
13 result in an uncertainty factor of anywhere between 30
14 and 100.

15 In addition, there are a few exposure
16 elements that would result in slight decreases in APAD
17 that I would like to discuss. Some of them include the
18 crops that are considered in the dietary risk analysis,
19 and, also, there's a rather major difference between
20 the way EPA has performed the dietary risk analysis for
21 potatoes and residues associated with that from the PDP
22 program and the way FMC has done it, and I will go into
23 more detail on that.

24 As you've already seen, EPA considers with
25 their dietary risk cup for their...the foods to fill

1 the cup over...basically overfills the risk cup, and
2 this demonstration shows that with around 300 percent
3 of the APAD taken up.

4 However, just doing one simple correction by
5 removing the 5x uncertainty factor which has been
6 supported by Dr. Lamb and Dr. Sielken, now the risk cup
7 itself has plenty of room to consider not just the food
8 but also consider rattle. So, this is an important
9 decision that you will have to make on what is the
10 appropriate uncertainty factor to apply.

11 This makes the...the decision that's facing
12 you a very, very difficult one, and we...we really hope
13 you get good consideration of this.

14 If you take only the EPA's assumptions...and
15 this does not include any of FMC's dietary risk
16 assumptions...and make this change, you now notice that
17 the risk cup, which is overfilled with the EPA's
18 assumptions, now is around 50 to 60 percent of the
19 APAD.

20 As I mentioned to you earlier, the
21 exposure...the...the crops that were actually
22 considered in the exposure assessment for the Notice of
23 Intent to Cancel document by EPA has additional crops
24 that we didn't consider and for...we just considered
25 the amended label. The amended label includes the

1 following crops, many of which are the exact same
2 assumptions for residues that the EPA has. There are a
3 couple of exceptions. Potato I'll go into in more
4 detail, but there are a few other small slight
5 differences between the 4F application to melons and
6 the 15G application to cucurbit vegetables which is the
7 way we calculate it.

8 The milk itself that was discussed in detail
9 yesterday, we have the exact same assumptions that EPA
10 has.

11 For potatoes, FMC has looked at a large
12 amount of the PDP data that's available. There's
13 nearly 3000 samples that have been collected since
14 1995. This is in the...this is USDA's PDP program.
15 The...the...it's only until you get to the recent data,
16 which is the 2006 data, though, that you see a lower
17 detection limit.

18 If this lower detection limit is applied to
19 the potato residues, it makes a drastic difference in
20 the...the actual APAD predictions. In EPA's dietary
21 assessment, they relied on the 2002 to 2003 LOD which
22 is nearly an order of magnitude higher. So, when you
23 use the EPA's practice of half the LOD, it makes a
24 major difference in the risk assessment.

25 The fact that no residues have been detected

1 and the observation that there...there has...there are
2 valid new samples of over 700 that have been collected
3 makes FMC believe you should be using the most current
4 LOD in your calculations and you shouldn't be impacting
5 your APAD calculations on, basically, no...no residues
6 detected.

7 So, if you do these corrections, you'll now
8 see that the APAD predictions in the risk cup...and
9 this is just 100x illustration for uncertainty
10 factors...is in the...about a third of the cup now has
11 been taken up by...by food contributions. This
12 includes the most sensitive populations, similar to
13 what EPA has considered.

14 If one were to take the food and then add
15 water to it, you can see that there's room. About two-
16 thirds of the cup is available for drinking water, and
17 we think that once you start considering drinking
18 water, this is...this is an area that needs a lot of
19 consideration, because it doesn't seem like EPA put a
20 whole lot of thought into what...what would happen if
21 the risk cup was open and what is the relevant
22 concentrations that should be in drinking water.

23 This shows, as Dr. Lamb has presented, the
24 300x uncertainty factor assumption, and there's even
25 more room available for water, in this case, around 90

1 percent for all the dietary sensitive populations.

2 So, when one looks at those 100x uncertainty
3 factor assumptions and the 30x uncertainty assumptions,
4 one can do a drinking water level of comparison
5 approach and see what that translates to in drinking
6 water concentrations. This...these values that have
7 been calculated come to between 1 and 4.4 ppb if you
8 consider either then 100x uncertainty factor or the 30x
9 uncertainty factor in the risk cup.

10 So, in conclusion, the dietary contributions
11 from the amended label are the crops considered on the
12 amended label, the NPORE tolerances, and the mini
13 gran...minimal granular use all fit within the FQPA
14 risk cup. Remaining risk cup space was then allotted
15 for drinking water and calculated using the DWLOC
16 approach, resulting in estimated drinking water
17 concentrations that I mentioned that were approximately
18 1 to 4.4 ppb.

19 These numbers are actually higher than what
20 you'll see in true concentrations found in water
21 samples, and that will be talked about by the water
22 panel, you know, just following this presentation.

23 And I have one question to pose to the panel
24 for your consideration, and that's about when you have
25 an ND situation like we do for potatoes and the ND has

1 changed because of new analytical capabilities, should
2 the EPA be applying the new detection limit for our
3 potato commodities, or should be...should they be using
4 the older data?

5 Thank you.

6 **DR. HEERINGA:** Thank you very much. And
7 at this point, I'd like to open it up for questions
8 from the panel for Dr. Lamb and Dr. Sielken or Dr.
9 Moore. Yes, I'll start with Dr. Edler.

10 **DR. EDLER:** Lutz Edler, German Cancer
11 Center. I think...with problems with the time, but
12 only two short questions, I think.

13 One question to...to Dr. Sielken. The
14 calculations you showed of the original data where you
15 got these factors, 1.2, 1.3 and so on, did you also
16 consider the variability of the controls which is
17 actually used for normalizing these data? Did
18 you...did you do some calculations? Because if you
19 calculate these ratios, they get a lot of variability
20 which are not in...in...in the point figure actually.

21 **DR. MORRIS:** The individual animal data
22 is there, of course, for the controls. I did not look
23 at percent inhibitions relative to the control mean
24 minus the standard deviation. I could have done that.

25 That would have affected...would have

1 affected both the percent inhibition for brain as well
2 as the percent inhibition for RBC. I don't know how
3 much of an effect that would have for the ratio.

4 **DR. EDLER:** May I just follow up?
5 That's a totally different question which I have in
6 mind for a while. Are there specific reasons that in
7 these newer studies, the radiometric..radiometric
8 method for the RBC and the brain con...concentrations
9 were not used? Because I...I'm asking this also
10 because in the 2005 SAP, there had been a discussion
11 about that usage of these methods, and my question is
12 simply what's the reason that one stayed with a
13 modified Elman method?

14 **DR. SIELKEN:** This is Bob Sielken,
15 again, to respond. The...the calculations that I
16 showed for relative inhibition of LDC in brain being
17 less than two-fold was all based on EPA's...EPA ORD
18 studies, and it's my understanding that they used the
19 radiometric method, but there was no problem in
20 their..their analysis. That was all EPA...

21 **DR. HEERINGA:** Dr. Lamb? Sorry, Dr.
22 Sielken.

23 **DR. LAMB:** Yeah, with regard to the
24 Elman assay that is the one that typically is done in
25 these guideline studies. The...I don't know that I

1 want to go out on a limb as to whether...you guys would
2 probably know better than I...as to whether that is the
3 method that...the method, only method required or
4 mentioned.

5 **DR. HEERINGA:** We maybe could have
6 your...Jane to respond. Have her come up and say what
7 she said to you.

8 **DR. MCCARTY:** My name is Jane McCarty.
9 I'm a toxicologist with FMC Corporation and was
10 responsible for monitoring the studies that were done
11 by FMC.

12 The reason that the contract laboratories
13 that most industry goes to to do these kinds of studies
14 aren't done using the radiometric method is that most
15 of these laboratories do not have licenses for handling
16 the radio-labeled material that's required in that
17 process, so they don't have that method available to do
18 these large studies.

19 **DR. HEERINGA:** Thank you. Dr.
20 Handwerger?

21 **DR. HANDWERGER:** I'm just a small town
22 pediatrician, and I...I...I'm really very surprised
23 that neither you or the EPA have mentioned pregnancy,
24 fetuses, or risk of pesticides to pregnant women.

25 You know, I think of the paper last year on

1 diabetes care from NIEHS, another part of the
2 government, where Seldona and his colleagues showing an
3 increased incidence of gestational diabetes in women
4 exposed to a number of pesticides, including
5 carbofuran, circumstantial evidence of an increased
6 risk in some studies of breast cancer to women who've
7 been exposed to carbofuran, and so forth, but we've not
8 talked about any of...of these kinds of issues.

9 You know, I love birds, and I love rats and
10 mice, but, you know, I...I...I happen to work more with
11 people, and...and I...I really am somewhat surprised
12 that we haven't really talked about that. We've talked
13 about atrazine and, you know, its potential dangers for
14 prostate cancer and so forth, but I'm also concerned
15 about things like gestational diabetes, because, you
16 know, it...it's said that these pesticides are not
17 teratogens, but diabetes in pregnancy is a teratogen,
18 and...and, clearly, women with gestational diabetes
19 have a...a marked increased risk of having infants with
20 congenital abnormalities and so forth.

21 And I know that we're not here to discuss
22 this issue, but I just wish, when we talk about the
23 health effects, that we...we go and look at the
24 literature and think about what is there about...about
25 humans and about pregnancy and about fetuses and with

1 possible effects of...of carbofuran on sperm counts in
2 workers. There have been reports about decreased sperm
3 counts on workers, but we're not talking about that
4 here today.

5 I mean, of course, I don't know why we're not
6 talking about this today, but I'd just like to...for us
7 just to keep that in perspective.

8 **DR. HEERINGA:** I think, Dr. Lamb, if you
9 want to address that question, you may. Otherwise, I
10 think it's one appropriately put to the EPA, too,
11 because I think the statements have been made to
12 essentially set aside some of these other effects that
13 Dr. Handwerger is really alluding to.

14 **DR. LAMB:** I think...I think it's the
15 disadvantage of where you are in this process which is
16 the process that involves hundreds of other
17 toxicological and exposure studies and...and these
18 issues have...are not ignored. They are addressed at
19 other studies along the way, both in the initial
20 registration, re-registration, and as other questions
21 come up.

22 And what's happened is we're to the point
23 that we're...we're at what is...what is typically
24 referred in risk assessment as the critical effect.
25 And so, these other endpoints have been addressed

1 either through animal toxicology studies...I mean, if
2 something comes up in the literature, I can tell you
3 that if it's problematic regarding a pesticide, EPA is
4 aware of it, and we, if...if it's a product for which
5 we're responsible, the companies respond, and I think
6 EPA would say the same thing.

7 But this is...we're to the point that this is
8 the most sensitive effect, most sensitive species.
9 This is what we think should be used for risk
10 assessment, and if you protect from this, you should,
11 at the same time, be protecting from the other concerns
12 that you...you're raising.

13 At the same time, I can't respond to every
14 epidemiological observation that may be raised without
15 some specifics. So, I'd stop there.

16 **DR. HEERINGA:** Thank you, Dr. Lamb. Dr.
17 Portier and Dr. Chambers.

18 **DR. PORTIER:** Dr. Sielken, you fit an
19 exponential model to your data, and if I remember
20 correctly, EPA fit an exponential power model to the
21 same data. Did you fit the power models, and is the
22 power different than 1?

23 **DR. SIELKEN:** Yes, I did hear that
24 comment from EPA yesterday. I did hear Dr. Setzer say
25 that for the brain data, when he fit the power, it was

1 1 or close to 1, so...which is the same power that I
2 was using.

3 My experience with the power model which ends
4 up being four parameters and five data points is that
5 that power is very volatile, variable...pick one...and
6 hence, the results are very problematical for
7 interpretation.

8 The ones that I used were...was simple
9 exponential as well as the simple 1 model.

10 **DR. PORTIER:** But you get great fit.
11 Right?

12 **DR. SIELKEN:** Sufficient for BMD
13 calculations, yes.

14 **SPEAKER:** Well, I guess I have a similar
15 question...

16 **DR. HEERINGA:** Whoa, whoa.

17 **SPEAKER:** Oh, I'm sorry.

18 **DR. HEERINGA:** Dr. Lu?

19 **DR. LU:** Alex Lu. I had a similar
20 question. If we can go back to slide 21, okay, so try
21 to make sense of this graph. When there's no dose,
22 there's no inhibition, but when there's a dose 1 which
23 is highest dose, inhibition is actually the lowest.

24 So, there's some sort of...am I interpreting
25 this graph differently than you? I look at this...

1 **DR. SIELKEN:** Well, okay, maybe
2 your...the label up there is percent inhibition
3 relative to controls is a slightly misleading. It's a
4 scale from zero to 1. At zero, there is no
5 inhibition...there is not 100 percent inhibition, so
6 you might want to label that as 100 minus the percent
7 inhibition.

8 So, yes, clearly, at dose 0, there's no
9 inhibition relative to controls, and at the highest
10 dose which is the right-hand side of the figure,
11 there's...

12 **DR. HEERINGA:** You want to fit the y
13 label on there.

14 **DR. SIELKEN:** Yeah.

15 **DR. LU:** I've got a second question
16 that's kind of related to what Dr. Portier just asked,
17 is if we try hard to do a semi log plot, it's similar
18 to one of the plot that EPA gave yesterday, the
19 relationship between dose and response become very
20 linear which sort of like you agree that the dose and
21 response in this case should be linear. So, if you
22 calculate BMD10 or 50 places on the curve that you
23 present here, so my question is that, will that
24 be...will the outcome of the calculation be the same
25 when you convert a graph to some more linear scale and

1 then you can do the comparison?

2 So, I mean, you don't have to answer the
3 question right now, but I suspect that there is going
4 to be some differences, and the differences will
5 probably be in between your calculation and the
6 Agency's calculation.

7 **DR. SIELKEN:** I don't think so. I think
8 you're point is...is a good one about...about scales
9 and models, but I get the same relative sensitivity
10 whether I'm doing...directly looking at the
11 experimental data at the doses that were observed of
12 1.3, for example, as a relative sensitivity at 0.1, the
13 experimental dose, no modeling involved versus if I do
14 extrapolations to the low dose region and whether I go
15 down to a BMD10, 20, 30, 40...you know, obviously, 40
16 is less extrapolation, but over that whole range of 40,
17 30, 20, 10, I'm still getting the same ratios of BMDs
18 in the neighborhood of 1.5.

19 **DR. HEERINGA:** Dr. Ed...oh, Dr. Lu, a
20 follow-up?

21 **DR. LU:** I do have a follow-up. I guess
22 based on my experience with acetylcholinesterase
23 inhibition is you don't need to get a linear response,
24 because you always see...especially for a carbamate is
25 that you always see a quick inhibition and then you pot

1 belly, and that's...that's sort of the data that kind
2 of common out there.

3 If you don't put it in a somewhat, a semi-log
4 scale, then you never get the linear range that you got
5 to forward, and the...I think that the down side of not
6 using the semi-log is that you ignore the effect if the
7 dose is very low, and I think EPA has approached it
8 sort of like a method by the area and do the
9 calculation of the ratio, but I think my suggestion is
10 that for you to go back and come up...do the semi
11 calculation that EPA used and see whether there are
12 some differences in terms of a numerical value, and
13 you'll be surprised that...now, we're talking about
14 ratio between 1.5 to somewhere, that 4 point something
15 that EPA used, but I think the ratio will be very...

16 **DR. SIELKEN:** I disagree that I would
17 get any number close to the number that 5 per EPA. I
18 mean, I'm running the same models that they're running,
19 and...and I just don't get anything like their ratio.
20 And the data itself aren't suggesting that ratio.

21 Your other point about the quick recovery and
22 how long it takes, that relates to the time course, and
23 here we're looking at a fixed time which is mainly 40
24 minutes in the ORD. So, I don't have that time issue,
25 because it's a fixed time.

1 **DR. LU:** Thank you.

2 **DR. HEERINGA:** Thank you, Dr. Sielken.

3 Dr. Edler?

4 **DR. EDLER:** No, thank you.

5 **DR. HEERINGA:** Okay. Dr. MacDonald and
6 then Dr. Chambers.

7 **DR. MACDONALD:** Yeah, I have been
8 puzzling over these same graphs as Dr. Lu has been, and
9 just one further question. You had together a
10 hypothetical example that you got linearity on linear-
11 linear scales, yet most of the graphs like this I think
12 we have seen of the experimental data, we've got a log
13 linear plot. So, how do you justify getting the
14 straight line on linear-linear?

15 **DR. SIELKEN:** This is Dr. Sielken in
16 response. I did the...I did the approach both ways.
17 In other words, I did it on the dose scale by...by
18 looking at the Hill models, the exponential models, and
19 looking at it on that scale. On the relative values of
20 the acetylcholinesterase inhibition, the inhibition
21 scale, if you will, then those two are equivalent when
22 I have linearity. They're not equivalent when I don't
23 have linearity.

24 My contention was that line...and...and
25 that's all that these pictures were, was to show that

1 when you have linearity, looking at it on the dose axis
2 or on the response axis, you get the same ratio. That
3 was the only purpose of these pictures. So, I mean,
4 that's why these pictures were put up there this way.

5 I also made the comment that if we had
6 approximately low dose linearity...and we are dealing
7 with low doses in the risk assessment, not these doses.
8 We're dealing with much lower doses....that at those
9 low doses, the changes are going to be roughly linear.

10 And so, I'm talking about the right units for
11 that type of dose scale.

12 Thank you.

13 **DR. HEERINGA:** Dr. Chambers?

14 **DR. CHAMBERS:** Clarification for Dr.
15 Morris, please. This is Jan Chambers.

16 When you're talking about the LODs changing
17 because of the newer technology, and you talked about
18 the number of samples, were you just looking at the
19 more recent samples since the technology got more
20 precise?

21 **DR. MORRIS:** Robert Morris in response.
22 I was looking at all the data, but I was applying the
23 limit of detection from the new analytical
24 capabilities, the 2006 data.

25 **DR. CHAMBERS:** But applying that to even

1 the older data that might have used the older
2 technology?

3 **DR. MORRIS:** That's right, because
4 you...you can't...when you do the residue definition
5 files, you can't have mixed amounts in your...in the
6 file.. You have to have one or the other for LOD.

7 **DR. HEERINGA:** Yes, Dr. Stinchcomb?

8 **DR. STINCHCOMB:** If it's not
9 inappropriate, can I ask one more question about the
10 dermal study or not?

11 **DR. HEERINGA:** Why don't you...because
12 we're going to turn to water next and...

13 **DR. STINCHCOMB:** Okay.

14 **DR. HEERINGA:** ...I think let's go ahead
15 and get your question in.

16 **DR. STINCHCOMB:** So, when the slurry was
17 applied to the skin in the dermal tox study, is there
18 significant water that's still remaining, or is the
19 water all rubbed in and there was just dried particles
20 on the skin? And then, what happens at 6 hours when
21 the occlusion covering was removed?

22 **DR. LAMB:** I think that originally, it's
23 there as a slurry. It's...it's placed there and that,
24 over time, I think, with most of these studies...I am
25 not familiar with this...what they saw in this

1 particular case, but in most of these studies, the
2 application site dries, and that at the end of the
3 application period, this is why you then clean out that
4 site, and I think they used Ivory soap and water,
5 basically, to clean the site and then immediately
6 sacrificed the animals.

7 So, it's put on wet, but it has access to
8 air, so my expectation is it would dry over time.

9 **DR. CHAMBERS:** This states that there
10 was occlusion. Is that not true?

11 **DR. LAMB:** I thought it was semi-
12 occlusion. Let me check with Dr. McLean. Semi
13 occlusion, meaning it has access to air, but the animal
14 can't reach it.

15 **DR. CHAMBERS:** So the water evaporates
16 and you have dried particles?

17 **DR. LAMB:** That's my guess, yes.

18 **DR. CHAMBERS:** Do we know the particle
19 size of the chemical?

20 **DR. LAMB:** I don't. Somebody might, but
21 I don't.

22 **DR. HEERINGA:** We can probably get that
23 for you.

24 **DR. LAMB:** Yeah.

25 **DR. HEERINGA:** Yes, Dr. Bunge?

1 **DR. BUNGE:** Can I just make one follow-
2 up question?

3 **DR. HEERINGA:** Sure.

4 **DR. BUNGE:** So, the tape that's used, is
5 it non-occlusive? That's the two 3M tapes that are
6 talked about, are they...can water go through them?

7 **DR. MCCARTY:** Jane McCarty from FMC.
8 The tape that they used to cover the site, first they
9 put, I think, gauze on, and then they put vet wrap
10 which is a...a semi-elastic, semi-occlusive wrap. It
11 was not a totally occlusive wrap.

12 Even though I think the EPA DER described it
13 as an occlusive covering, it was not totally occlusive.
14 It was always semi-occlusive.

15 **DR. HEERINGA:** Dr. Reed?

16 **DR. REED:** With...excuse me. With all
17 the questions that, the follow-up questions that we
18 have, I guess we're, at least we are, curious about the
19 concept of...of the entire amount that is applied to
20 the skin in terms of...of how much is...is...is it in
21 contact with the skin. Is it the entire amount whether
22 it's in...in a solid form or...or wettable? I think
23 there was mention about solubility.

24 So, can you give us an estimate in terms of
25 how much was in contact with the skin that was in the

1 wet stuff?

2 **DR. LAMB:** What I can do is provide for
3 you the area that was treated on the back of the animal
4 that...that will answer that question. It is in the
5 report, and we can pull it out so that you know, and
6 the, basically, the volume of the material so we can
7 calculate that.

8 So, is that in respon...does that answer your
9 question?

10 **DR. MCCARTY:** I can answer the area.
11 The area is...

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

13 **DR. MCCARTY:** Dr. Jane McCarty. The
14 area that the material is applied to 5 by 8 cm, and the
15 material was prepared. It was a slurry. The water was
16 added to the weighed material, and that slurry was
17 applied and spread over that 5 by 8 cm area.

18 **DR. REED:** As a follow-up...this is Ruby
19 Reed again. And so, I guess the curious question
20 is...is how much is taken up by the gauze and then, you
21 know, dry up at what point so that how much of the
22 chemical is in contact with the skin after 6 hours.
23 Does that make sense in terms of...

24 **DR. MCCARTY:** Yeah, I don't...I don't
25 have any way of measuring that. I don't know.

1 **DR. HEERINGA:** Okay. What I'd like to
2 do at this point, here is my proposal which I'm going
3 to follow. It's...chance to vote was yesterday, I
4 guess, and I'm sorry about this, but I feel it's very
5 important to finish this series of presentations this
6 evening.

7 What I'd like to do is I'd like to call for a
8 10-minute break, and then, as a service, we're going to
9 have Larry Kleingartner from the Sunflower Growers is
10 going to do a short presentation, and then we will move
11 to a full consideration of the...the water presentation
12 by SM...FMC. So, is that okay?

13 I anticipate wrapping up by 7:00. The only
14 thing that we have to make sure of is that I'm told at
15 6:00 p.m., these doors lock out here, so if you...if
16 you want to use the facilities, you're going to need
17 a...a hall monitor to let you back in.

18 **(WHEREUPON,** Session C was concluded and a brief recess
19 was taken.)

20 **DR. FAWCETT:** My name is Richard
21 Fawcett, and I am one of the panel of 3 that FMC
22 convened to conduct a refined risk assessment for
23 Carbofuran in drinking water, and to also recommend
24 mitigation measures to protect ground and surface
25 water. The other members of the panel are Burnie Engel

1 and Dr. Engel, and Martin Williams. Robert Morris is
2 also with us here from FMC, and may be able to answer
3 some questions.

4 I want to start with just a little cheat-
5 sheet here with some acronym definitions. We may use
6 these, and hopefully we'll define them the first time
7 that time that we get to them, but if not, you'll have
8 this in the materials you can refer back to. I want
9 to introduce this topic by very briefly summarizing
10 EPA's methods and conclusions on drinking water
11 exposure, and contrast those with those from the panel
12 that we have here, that will be speaking to you this
13 afternoon. In their tier 2 modeling process EPA used
14 their typical procedure of the index reservoir modeling,
15 using Prism's exams.

16 But some important assumptions that were made
17 is that 100 % of the crop or in some cases all of the
18 agricultural land was treated with Carbofuran. So that
19 meant that up to 87 % of the watershed received
20 Carbofuran. Using those modeling techniques, they
21 calculated acute estimated drinking water at
22 concentrations of from 19 to 49 part per billion. In
23 their ground water assessments the estimated exposure
24 by scaling results from a shallow ground water
25 perspective study in Maryland to reflect all crops

1 specific application rates in all uses across the
2 country.

3 Using that technique, their 90 day average
4 estimated drinking water concentrations were from 1.4
5 to as much as 110 part per billion. Now I am sure you
6 are all familiar with the EPA's tiered approach in risk
7 assessment. Where they begin with a screening level,
8 and then may go to higher tier, more detailed
9 assessments, if that's deemed appropriate or necessary.
10 EPA stopped at the tier 2, and one of the reasons they
11 did is because as you've seen in EPA's calculations,
12 the risk cup was full with their dietary assessment.

13 There was not room for drinking water, so it
14 was deemed not necessary to carry forward with some
15 higher-tier assessments. However, they do in their
16 procedures allow for this, and the quote on the bottom
17 of the screen simply says, "failing a tier however,
18 does not necessarily mean that the chemical is likely
19 to cause health or environmental problems, but rather
20 there is a need to move to a higher tier, and conduct a
21 more refined assessment."

22 And because, with the material you have seen
23 presented by FMC would indicate that there is room in
24 that risk cup, then we think it is very appropriate
25 that we need to have the best assessment possible to

1 know what that drinking water contribution would be, to
2 see if there is room in that risk cup. And we would
3 argue that there is room, as you'll see from our
4 calculations. So we will be giving you the results
5 from that higher tier, a some refined assessment, this
6 afternoon.

7 We have already heard - and I am going to try
8 to be as brief as I can - You have heard how the use of
9 Carbofuran has changed over the years, due to market
10 forces and changes in label directions and eliminations
11 of some crops. The slide on the left shows 1992 us of
12 Carbofuran going from the lighter colors through green
13 to blue is the highest use. In 2005, you can see how
14 the use has declined considerably. And because alfalfa
15 is no longer on the label, the 2005 data has been
16 adjusted for that. If you were to consider a pre-
17 emergent herbicide such as Atrogene, which is used on
18 80% of corn acres, or may a post-emergent herbicide
19 like Glyphocate that is used on over 90% of the soy
20 beans, then it is very appropriate to assume that 100 %
21 of the crop is treated with that product. But for
22 something like Carbofuran, when less than 1 % of the
23 crop area is treated, that really is not appropriate.
24 And it's an important concept that we're going to be
25 talking about, considering that percent of crop

1 treated. Just to very quickly summarize what you'll
2 hear about our surface water assessments, FMC in their
3 tier 3 modeling, a higher tier modeling, considered the
4 actual percent treated for Carbofuran from sales
5 figures. And for the watersheds a model that was
6 anywhere that was form 0.41 percent of the crop area
7 treated.

8 And that translated into from 0 to 0.7 % of
9 the watershed treated with Carbofuran. In that
10 modeling you'll see the results that presented later,
11 that shows that the estimated drinking water
12 concentrations were less than 1 part per billion.
13 EPA, as it turns out, has also used that tier 3
14 approach and they have used the percent crop treated
15 approach, in the cumulative methyl carbonate
16 assessment, using that procedure they came out with as
17 well with concentrations below one part per billion.

18 For ground water, the FMC's tier 3 modeling
19 analysis also showed that Carbofuran's concentrations
20 would be expected to be below 1 part per billion.
21 And the monitoring data that we'll be showing are also
22 supportive of that tier 3 modeling estimate. I would
23 like to turn the slides over to Dr. Engel, who will be
24 reporting on some of the surface water assessments
25 we've conducted.

1 **DR. ENGEL:** Hi, I am Doctor Engel, I
2 have extensive research experience with hydro logic
3 water quality modeling, and large spacial data sets to
4 support those analysis. I'll spend about 10 minutes
5 talking about a portion of the surface water
6 assessment, initially looking at some of the work that
7 we did with resovoir based systems, and then pass the
8 slides to Marty Williams, who will talk about the
9 flowing water assessment.

10 For the surface water assessment, we looked
11 as resovoires within Indiana, used the Prism Exams
12 Model - for which I'll provide a couple of more details
13 in a couple of moments - and a key point that here is
14 that we used actual Carbofuran use within those
15 watersheds and those assessments, and you'll see the
16 impact that has. We then looked at a national
17 resovoir assessment to understand what the potential
18 vulnerability may be for resovoires nationally to
19 Carbofuran use, and considered the community water
20 system characteristics in that analysis. And finally,
21 as I said, Marty Williams will talk about the flowing
22 water assessment, the rivers that may be used for
23 community water systems, and used, monitoring data used
24 the warp model that he'll describe briefly and some
25 statistical analysis in that exploration.

1 First, let me do a quick overview of a couple
2 of key concepts in setting up this reservoir modeling
3 approach that we have used, and that EPA has used as
4 well. As you are probably aware, there is some
5 watershed area that would contribute run-off to a
6 reservoir, so that might be depicted here, and would be
7 called the drainage area. So this is going to be the
8 area on which materials may be applied, so therefore
9 this represents a potential capacity to deliver
10 materials to a reservoir.

11 Run off from that area might enter a reservoir
12 so that would have some capacity. So depending on the
13 size of that capacity, larger would be more potential
14 for dilution. So sizes on these are going to matter.
15 Not all this watershed is likely to be treated. As
16 many of you flew across the country to get here, you
17 probably noticed that even within the corn belt not
18 everything is low cropped agriculture, that there are
19 non-agricultural land uses in the watershed. So the
20 green here depicts some percentage crop area within
21 this watershed, and not all that area is likely to be
22 treated with a particular product, especially a product
23 like Carbofuran.

24 So some percentage of that crop may be
25 treated, and that would ultimately provide some percent

1 area treated for the overall watershed. An important
2 concept as we look at an analysis within Indiana and
3 then scaled this nationally, was to examine this ratio
4 of percentage area treated with Carbofuran multiplied
5 by the drainage area of the watershed, divided by the
6 normal capacity of the reservoir. So this combination
7 identifies areas that would have potential for high
8 exposure to Carbofuran or applied to other products,
9 could be used in a similar fashion. So we'll see this
10 again in a couple of moments.

11 Within Indiana, we looked at 15 actual
12 reservoir based systems. Indiana being in the corn belt
13 is fairly typical of land uses, soils, management
14 practices, Carbofuran use, but importantly to us, the
15 community water system data was available in a very
16 timely fashion, so that we could take advantage, and
17 use that in the Prism Exams modeling. Using the same
18 model that EPA used in their tier 2 assessment, here
19 though we took advantage again of actual data within
20 Indiana, with the actual community water system and
21 watershed data to conduct those analyses. Another
22 important distinction here is that we used actual
23 Carbofuran use that was experienced within this area on
24 a county by county basis, between 2002, 2004.

25 What did we find? Interestingly, only 3 of

1 the 15 community water systems experienced Carbofuran
2 use in that period. The percentage of application of
3 crop areas within that was quite low, as you've heard
4 about already, and the range of expected Carbofuran
5 concentrations in those resovoirs ranged from .01 to
6 0.13 parts per billion. Contrast that to what EPA
7 would predict with their tier 2 approach, in that same
8 location one would get 19 to 49 parts per billion,
9 quite a stark contrast.

10 I know this is a little bit complicated,
11 so let me slow down and put some of these ratios in
12 perspective then and explain and hopefully help you
13 understand that some Indiana resovoirs were more
14 potentially vulnerable to Carbofuran than the index
15 resovoir. But at the end of the day, when we consider
16 the percentage crop treated, that that vulnerability
17 goes away. So let me step through this: So if we look
18 at this top line, this is the ratio of drainage area to
19 normal capacity for all the resovoirs within Indiana,
20 and it ranges from about 236 as depicted here in the
21 table, to about 2.

22 In contrast, the Shipman Index Resovoir that
23 EPA has used for tier 2 assessments is about 12. So we
24 have about half the Indiana systems being potentially
25 more vulnerable and about half less vulnerable. If we

1 now modify that, and consider the percentage cropped
2 area within those, that's going to be the second line
3 here, we see that values reduced correspondingly and
4 where does the index reservoir fall? It falls more at
5 the upper end now.

6 If we take that one step further, and
7 consider Carbofuran use in the watersheds now, for
8 Indiana, since the percentages were quite low, this
9 relationship hugs this bottom line, whereas the index
10 reservoir remains at a value of 5.5 or 10.4, depending
11 on the particular run that EPA was making with that.
12 So to summarize the slide, so within Indiana, many
13 reservoirs potentially more vulnerable, but when one
14 considers the actual use of the Carbofuran product,
15 they become much less vulnerable.

16 Again, as Doctor Williams pointed out, the
17 EPA has in the past, in the NMC Cumulative Assessment,
18 used a comparable sort of a concept. A watershed,
19 some of that watershed agricultural land uses. Some of
20 that watershed treated, some of those crop uses treated
21 with Carbonates, and yet a smaller subset treated with
22 Carbofuran. And in fact, Carbofuran percentages on the
23 order of magnitude that we were using for our
24 assessments within Indiana. When EPA did that, they
25 found that their estimates with the index reservoir sort

1 of approach for Carbofuran in reservoir based systems
2 range from .002 parts per billion, to about .82 parts
3 per billion, that upper end being in Florida. FMC has
4 proposed that that be removed from the label, so it we
5 adjust that, concentrations would be actually quite
6 close to what we found for Indiana, .002 to .35 parts
7 per billion. And just quickly, EPA has used that
8 concept as percent crop treated approach on other
9 occasions.

10 Moving to the national assessment to
11 understand the vulnerability or potential vulnerability
12 of community water systems, we took the Carbofuran use
13 between 1998 and 2003, actually we took the maximum use
14 experienced in any county in any of those years, used
15 the natural break method to divide this into 4 use
16 classes, and then we go to the next slide, we use this
17 to identify every single reservoir based systems within
18 these class one to class four use tiers , or use
19 categories.

20 We identified the potentially vulnerable
21 community water systems in these, based on the use
22 intensity of Carbofuran, so based on our experience in
23 Indiana , if use intensity was more than 2.1 pounds of
24 active ingredient per acre we put that in the
25 potentially vulnerable category, we also looked at the

1 resovoir watershed property, this drainage area by
2 percentage area treated divided by normal capacity
3 ratio, and again based on Indiana sensitivity analysis,
4 if that value exceeded .037, that was a good indicator
5 that there was potential to have Carbofuran in the
6 resovoir, above .5 parts per billion.

7 So we put those in the potentially vulnerable
8 category as well, and then as one might expect,
9 following some concerns about security of drinking
10 water systems, we were unable to get data for
11 Pennsylvania, and parts of North Carolina in a timely
12 fashion. So systems for which we lacked information,
13 we put those in the potentially vulnerable category as
14 well.

15 So what are the results of that? So we found
16 that 20 or the 30 states that we examined didn't have
17 community water systems that were resovoir-based that
18 were..that met any of these vulnerability criteria's,
19 so those could be assumed to be quite safe. In the 10
20 remaining states we found 65 reservoir-based systems
21 that could potentially be vulnerable, 15 based on the
22 characteristics of Carbofuran use, or the ratio that I
23 talked about. And again, 50 of those we were unable to
24 obtain data. So to be conservative we placed those in
25 this vulnerability category. You heard earlier in the

1 morning that FMC has proposed mitigation measures, we
2 would propose mitigation measures for these counties in
3 which these 65 systems would be located. At this point
4 let me pass the slides to Marty Williams to continue
5 the flowing water assessment.

6 **MR. WILLIAMS:** Good afternoon, or I
7 should say good evening, at this point. My name is
8 Marty Williams, I am with Waterborne Environmental Inc.
9 My background is in hydrology and water quality and for
10 the past 20 years my work has focused on the patent
11 transport of pesticides in the environment. To address
12 flowing water systems, we kind of took a stab at it in
13 three different areas.

14 The first one was looking at the U.S.G.S.
15 N.W.Q.A. database. N.W.Q.A. stands for the National
16 Water Quality Analysis. It's a monitoring program
17 developed by the U.S. Geological Survey to assess the
18 status of waters in the country. N.W.Q.A. includes
19 ground water and surface water data, there are study
20 units that are not primarily agriculture, there are
21 others that are more urban. The frequency of sampling
22 varies. Some states cites are sampled extremely
23 frequently, on the order of several day intervals for
24 periods. Others are more relaxed.

25 That always brings people - including the

1 EPA- to say "was the peak concentration missed in that
2 kind of study?". But when you look at it all together,
3 we've got over 20,000 Carbofuran records, and that
4 encompasses many many many site years, equivalence of
5 data. So it is a very large data set to work with.
6 Carbofuran, being an agriculture pesticide, you know
7 the monitoring and analysis for that is geared mostly
8 towards the ag type environments and the sample
9 frequency is more geared more towards the spring and
10 summer. So one would argue that the data on Carbofuran
11 is bias toward where you would find Carbofuran
12 detections. In that data there are over 20,000 records
13 for Carbofuran, but only 71 of those samples have
14 concentrations exceeding 0.5 ppb.

15 That's only 0.2 percent out of the data. The
16 maximum concentration in that data set was 32.2 part
17 per billion. EPA is aware of that sampling location,
18 but it also is a very, very unique condition, it was a
19 nursery environment with somewhere on the order of 10
20 pounds per acre application. That type of application
21 is no longer labeled and allowed, and the receiving
22 water was a very small ditch, which is not
23 representative of a community water supply. Since
24 community water supplies by nature have to supply
25 sufficient water to service their population, you don't

1 see it on small streams, they are geared toward larger
2 river systems.

3 To try to make a more, drinking water type of
4 assessment, we took a subset of that data where we
5 removed ditches, streams, impoundments in order to try
6 to come up with a representative data set that was more
7 applicable to a farm water community, water supply, and
8 that's shown in this bottom box here. From that we
9 still had a large number of Carbofuran records, because
10 the N.W.Q.A. program was mostly geared towards water
11 systems, but we only saw 29 samples greater than 0.5
12 ppb, and the max concentration in there was 5.82 ppb
13 which was the Trinity River Basin in Texas, and there
14 were only 2 or three other samples above 1 ppb, and
15 they range from 1.0 to 2.0. This Trinity River Basin
16 data set has been investigated by FMC in the past and,
17 you know, if you have questions on that, Donald
18 Carlson from FMC can come in to address it, but it also
19 is a very unique situation.

20 This map shows you in the lower left the 2005
21 usage patterns for Carbofuran, just so you can kind of
22 put that into context. This is the data, those are our
23 detections. I can't see the colors from here because
24 of my eyesight...but...it's still hard to see the
25 colors in there. You'll find that there is very very

1 few points greater than 1.0 part per billion in that
2 data set. This overlay is the non-detects, just to
3 give you an idea of where that sampling has occurred.

4 The second analysis we performed was to use
5 the U.S. Geological W.A.R.P. model, which was a
6 watershed regression profess, which is what that
7 acronym stands for. EPA has been looking at that as a
8 kind of a candidate tool for addressing drinking
9 water's exposure for pesticides And what W.A.R.P. is,
10 is a series of regression equations developed initially
11 for Atrazine, they later adapted it to be used for
12 other chemicals by allowing chemical specific use
13 intensities, half lives, and soil absorption
14 coefficients to be used in that model, for it to be
15 used for other chemicals.

16 It involves a number of spatial parameters.
17 I'm not going to go over them in detail here, but they
18 are using the equations because they were found them to
19 be sensitive during their analysis in regression
20 development. The most important one is Carbofuran use,
21 and when you integrate those together, you get the
22 prediction of concentrations spatially within a
23 watershed. This shows the results of our analysis
24 using warp.

25 We focused on the 4 states in the corn belt,

1 because they represented high areas of Carbofuran use.
2 We did the analysis at what is called the Hot Twelve
3 Scale watershed, which is a relatively small watershed
4 classification is USGS's hierarchy scheme, and it's on
5 the order of 2,500 acres in size generally. For
6 example in Illinois there is thousands of hot twelves.
7 So these are really, really small basins that we did
8 the analysis on, so we are probably predicting
9 concentrations on the high end. The colors range again
10 from yellow low concentrations to dark blue higher
11 concentrations.

12 You can see the variability in that area.
13 The highest concentration was predicted for Illinois,
14 and that was 0.68 parts per billion. In the past few
15 weeks we did another analysis because EPA has expressed
16 concern - not just for this product, but for other
17 situations - that monitoring data does not capture a
18 peak, and that W.A.R.P. is then giving you the range of
19 high exposure concentrations that you might see in the
20 typical year, rather than after some extreme events.

21 So we wanted to try to determine if there was
22 a way to better estimate when an extreme event
23 concentration could be, and to do that we did a
24 statistical extrapolation. We took those 13,000 data
25 points that I showed you for the river/bay systems,

1 filtered, they were filtered to remove the ditches and
2 you know small streams, and canals and those sorts of
3 systems, and we also removed all concentrations less
4 than 0.5 ppb in order to get us that upper range of the
5 curve of detections to fit a regression line.

6 We developed a best-fit distribution, and
7 used that to extrapolate, to understand the probability
8 of high exposure events. The red points in here are
9 the individual detections of Carbofuran from that data
10 set. The middle blue lines flowing from the lower left
11 to the upper right is "best bet" line.

12 The outer blue lines are the 95th percentile
13 confidence intervals. The probabilities associated
14 with this tip were then re-adjusted to bring in the
15 data set of interest, which is you know the 13,000
16 points ...the whole... the river system, and the
17 results of that analysis is provided here. So we are
18 showing concentrations from the table of 0.5 ppb all
19 the way up to 20 ppb, the probability of occurrence.

20 The probability of one PPB was up there at
21 the 99.93 percentile, and that equates to really the
22 equivalent of being equal to or exceeded .07 percent of
23 the time. That's 7 out of 10,000 chance of occurring.
24 If you look at the...our W.A.R.P. prediction of 0.68
25 that's a 0.2 % probability of occurring, and maximum in

1 the N.W.Q.A. data set of 5.82 was 2 in 100,000. So we
2 feel that the probability analysis confirmed that we
3 are getting high probability exposure values from, you
4 know, out of the N.W.Q.A. data, and the W.A.R.P.
5 monitoring.

6 In summary, from all of our surface water
7 studies, with the same crop treated, the P.C.Y. is
8 critically important for an accurate prediction of
9 exposure for niche products like Carbofuran, and the
10 weight of evidence of our analysis has really shown.
11 Estimated drinking water concentrations in the subpart
12 per billion level and more toward an upper end level of
13 one part per billion. At this point Dr. Fawcett will
14 take over and provide an overview of the ground water
15 assessment.

16 **DR. FAWCETT:** When I was first
17 contacted by FMC to see if I had interest in
18 participating in a project to try to define the risk of
19 Carbofuran reaching ground and surface water I was at
20 first a little surprised by the concern. Because to my
21 knowledge of the monitoring literature Carbofuran had
22 been really a very rare detect, in either ground or
23 surface water, especially in the major areas of its
24 use. I was of course aware that back in the late 70's
25 early 80's that Carbofuran was detected in wells on

1 Long Island New York, along with some other pesticides,
2 where it had been used at relatively high rates on the
3 sandy soils in potato production. And for that reason,
4 use on Long Island was then prohibited on a label.

5 So there were some localities where
6 detections had occurred, but there were other
7 localities where detections were very rare. So it was
8 an interesting discrepancy to try to understand and
9 explain, but it's a very important discrepancy, because
10 as you have seen, EPA used a perspective study
11 conducted in Maryland to calculate their estimated
12 drinking water concentrations for all localities and
13 cropping systems. And that site in Maryland was chosen
14 to try to replicate the Long Island conditions.

15 So why might we have more detections in some
16 areas than others? Or maybe fewer detections today
17 than in some older historical monitoring studies? One
18 of the factors is the reduced use. We've seen how it's
19 become a niche use product, used on less than one
20 percent often of the acres.

21 So when we look at some of the older
22 monitoring studies, maybe done in the 80's, it was
23 used on at least ten times as many acres. So if we are
24 going to use those older studies to interpret for
25 today, we can of have a ten-fold safety margin there.

1 But also there are specific vulnerability factors. We
2 really need to have all these together: Sandy soils,
3 coarse soil, shallow groundwater, but also have acidic
4 soils and acidic groundwater. We need all of those
5 factors together to get that vulnerability. And we
6 also need to keep in mind that there have been a number
7 of previous label changes.

8 Some of it you have heard about already; that
9 have reduced or prohibited use in vulnerable areas.
10 Use was prohibited in Long Island, New York, in 1984.
11 A groundwater advisory was added to the label in 1985,
12 advising against use where soils were coarse and
13 groundwater was shallow. And then there were some
14 specific changes addressing the more vulnerable
15 regions, due to soil type or groundwater depth.

16 Sequential treatments were not allowed on
17 those vulnerable soils in 1997. So you could only
18 apply the product once, not twice. And significantly,
19 the potato rate was reduced from 6 pound per acre -
20 which is probably what they were using on Long Island
21 when they got into trouble - from 6 pound down to one
22 pound per acre in those vulnerable soil areas. Again
23 EPA's tier 2 assessment, they based it the perspective
24 groundwater study in Maryland. And that site is very
25 unique, again selected to try to mimic Long Island.

1 It has a sand soil texture, not a loamy sand
2 or sandy loam, but a true sand with greater than 90%
3 sand particles. This soil was very acidic, with a pH
4 of less than 5.8 for all measurements, and often far
5 below that. The ground water is also acidic, all
6 measurements were less than 6 and many below that, and
7 of course being a monitoring study, it had a relatively
8 shallow well depth of 13 to 14 feet.

9 Why is pH important? pH is very important to
10 Carbofuran persistence, and therefore the leaching
11 potential. The longer it lasts in the soil, the
12 greater the chance that it might move through the soil
13 to reach wells, and once it reaches water, the lower
14 the pH, the longer it will last and the greater the
15 chance that it may show up in that well.

16 We have seen some earlier numbers, the half
17 life depends upon the experimental conditions, but here
18 is a study that looked at soil half life, at pH 7 the
19 half life was 23 days, reducing the PH to 6.6 increased
20 that persistence to 43 days. Similarly in water, at a
21 pH of 9 Carbofuran has a half life of 12 hours. We
22 don't want to mix Carbofuran in alkaline water in the
23 spray tank, because it breaks down in the sprayer too
24 quickly to get the activity. If we look at pH 7, the
25 half life is 28 days and down to pH 5 it becomes

1 stable. So low pH's make Carbofuran more persistent,
2 and more likely to reach ground water.

3 We began our analysis, and really we did it
4 in 2 stages, we first concentrated on those green
5 states, essentially the corn belt, the higher use areas
6 for Carbofuran. Corn belt and 3 specific states in the
7 Pacific Northwest where it is used on potatoes.

8 We then conducted a separate analysis
9 essentially of all the states east of the Mississippi
10 that we had not previously analyzed. This included
11 areas that we assumed to be more vulnerable. Where we
12 had more sandy soils and where that Maryland site of
13 course is. But they were lower use areas. The first
14 thing we did was to try to find all of the monitoring
15 studies that we could find in the literature. And EPA
16 did identify many of these areas and they summarized
17 them in their document, but we were able to find some
18 additional monitoring studies, and partly some large
19 ones in the heart of the corn belt.

20 Those studies were done anywhere from 1983 to
21 2005, and an important source of data for us was that
22 National Water Quality Assessment. And those studies
23 were done anywhere from 1993 to about the present. So
24 it gives us a little more recent data set, and a very
25 high quality extensive study. Soil texture, we wanted

1 to identify those high sand soils and used the Statsco
2 Database to get at that. Water pH, we got from either
3 published studies, or surveys in states or databases or
4 in some cases we used the N.W.Q.A. data set for water
5 pH. Soil pH, rather than use a database, to try to
6 eliminate the complication of non-agricultural soils,
7 we contacted state soil specialists in each state, and
8 got their professional opinion of the typical ranges of
9 surface soil pH's as well as subsoil pH's.

10 Vulnerability, including aspects such as
11 groundwater depth, we ended up using EPA's County
12 Drastic Database, and I'll say a little bit about
13 drastic in a minute. And we also tried to get
14 Carbofuran use survey's to try to match the time
15 periods that these monitoring studies were done. For
16 many of the earliest studies we used state pesticide
17 surveys, kind of the mid ranges, we used the mass of
18 the National Agriculture Statistics service numbers,
19 and for recent use we accessed FMC's sales figures.

20 Many of you may be familiar with or heard of
21 Drastic before. It's a tool to measure the relative
22 vulnerability of groundwater. I won't read through
23 what all of what the acronym stands for, but you can
24 see the many factors that go into that, into that
25 calculation. When you apply Drastic you end up with a

1 score or a number. The higher the score, the more
2 vulnerable that site. For example, Wicomico Maryland,
3 that's the county in which the perspective study was
4 done, the score for that county is 185.

5 Undoubtedly if you calculated a score for the
6 study site, it would be a higher number, because it was
7 selected for it's vulnerability. But the county
8 average score for that county is 185. That's an
9 important number, because we'll use that as a benchmark
10 later.

11 To look at some other vulnerable areas,
12 Suffolk County, New York on Long Island, the score for
13 that county is 195. For comparison purposes, to look
14 at some higher use areas to the west, just to see what
15 the numbers would be. Cedar County, Iowa, that's where
16 my home farm is, the score for that county is 137.
17 Washington County, Mississippi, down in the Delta, the
18 score for that county is 144. Polk County, Oregon, is
19 out in the Willamette Valley, the score there was 122.

20 We chose to use Drastic as a tool, in a
21 tiered approach to try to identify potentially
22 vulnerable areas. And we use that 185 as a benchmark,
23 that Wicomico County, Maryland. This map shows all the
24 counties in the United States that had a score of 185
25 or more. And you can see that its almost all centered

1 over here on the eastern seaboard and down through
2 Florida, with very few other counties scattered across
3 the country.

4 We then took an overlaid Carbofuran use data
5 on those high grassy scored counties to see if we had
6 both vulnerability and use. This shows for 1992, the
7 highest use is in red, but even there, that's 5 pounds
8 per square mile, even there, low use compared to other
9 pesticides. This shows use in 2005. What we did then,
10 was by using this, even those we'll see in a minute;
11 the detections of Carbofuran in that region have been
12 very low in the N.W.Q.A. data since 1993. But to make
13 sure that there was really no question about, worries
14 about contamination. We recommended..the amended label
15 has a number of geographical prohibitions. Florida,
16 North and South Carolina, the DELMARVA Peninsula, are
17 all prohibited from use. And those other scattered
18 counties are addressed, as well set backs, which I
19 think you heard about earlier.

20 Let's look at the monitoring results. We've
21 got this divided into 2 sides, a left hand side of the
22 slide are the major use areas, the kind of corn belt
23 and potato states. On the right side and slide, are
24 those states on the east of the Mississippi. Looking
25 first on the left, there were 9,431 private, public and

1 monitoring wells in that universe of data. It's
2 important that there were private wells, because EPA is
3 rightly concerned, that if you for example simply look
4 at safe drinking water monitoring data that you'll miss
5 the private wells. There were many private wells in
6 the surveys.

7 There were also a lot of monitoring wells.
8 An important part of the N.W.Q.A. data set are shallow
9 monitoring wells on the edge of agricultural fields.
10 So we should have some of those worst case scenarios in
11 the data set. Looking at those western wells, I think
12 there were a total of 18 detects for a .19 % detection
13 rate. So really very rarely detected. And whenever we
14 talk about detection rates we need to consider
15 detection limits. N.W.Q.A. has very low detection
16 limits of .028 or .003, depending on the method used.
17 And while there were a few studies in the 80's that had
18 higher detection limits, most all the other studies had
19 detection limits of about .5 or less.

20 Looking at the highest concentration found in
21 those western states, that was one part per billion.
22 Found a well in Iowa. So there were no wells that came
23 anywhere close to approaching EPA's estimate of 17 part
24 per billion for their corn scenario. That well in
25 Iowa, I am very familiar with, because I made a

1 personal investigation back in the 80's. And it did
2 have a commercial mixing, loading, disposal site very
3 close to that well without any documented containment
4 in those years. At least it was my opinion it was
5 probably effected by that point source.

6 We shift to the right side of the slide, we
7 contrast to the states to the east. About 7,000 wells
8 in that data, and you can see the detection data was
9 higher; 2.56 % detection rate. Important, if we look
10 at the N.W.Q.A. data, and again that's 1993 onward.
11 It was about half the detection rate, despite the very
12 low detection limit, detections were lower in those
13 more recent years. Maximum detection it that was 36.6
14 part per billion back in '85, in a Massachusetts well,
15 we really don't have the details to say whether it was
16 a point source or something else, but that was the
17 highest number in the data set. But it's important to
18 consider that most of the detections, in fact all of
19 the detections above 1 part per billion occurred in the
20 1980's.

21 Before those label changes that reduced use
22 or prohibited use in vulnerable areas. Since 1993, in
23 that N.W.Q.A. data set there was only one N.W.Q.A. well
24 that had a concentration above 1 part per billion, and
25 that was 1.3 part per billion in a Connecticut well.

1 Just to give you an idea of where the monitoring is
2 done, these are the N.W.Q.A. watersheds we don't report
3 on in those far southwest states, this shows where all
4 the N.W.Q.A. watersheds are. And here we have overlain
5 the locations of those additional studies we've
6 located. Often times they were just a few counties and
7 states that were aimed at vulnerable areas, but you can
8 see there in the heart of the corn belt they were
9 statistically designed statewide surveys for Nebraska,
10 Minnesota, Iowa and Illinois; an important use area.
11 Let's look at where we have the N.W.Q.A. detects,
12 because we have geo-referencing for all of those wells,
13 we can show you where the detections were, and where
14 the non-detects were.

15 These are the detections for Carbofuran in
16 the N.W.Q.A. wells. This just shows detection remember
17 all those except one were below one part per billion,
18 and about 99 % of them were at a tenth of a part per
19 billion or less, so usually very low concentrations.
20 That shows you where the detections were. This shows
21 you where the non-detects were. So you can see exactly
22 where the monitoring was conducted. And I have here on
23 the lower left, we show that the Carbofuran use map.

24 It's very important, because if you look
25 this, this is kind of one of the higher of use. It

1 just matches very closely, this area of higher
2 monitoring. Also in the Northwest we have monitoring
3 going on where there is the highest level of use. Also
4 important to note; here along the Eastern Seaboard,
5 very intensive monitoring in those vulnerable areas.
6 So the N.W.Q.A. gives us intensive monitoring both
7 where Carbofuran is used and in the more vulnerable
8 areas.

9 What are the factors that may explain the
10 discrepancy of the more detections in the East? At
11 least in those early years of monitoring in particular.
12 Again, looking here on the left side of the slide we
13 are looking at those more vulnerable eastern states.
14 Sand texture was greater than 5% of the surface soils
15 for 12 states. If we go over and look on the right for
16 the corn belt and the Northwest, it was less than 5 %
17 for all states except for Michigan and Nebraska. And
18 talking to soil specialists, those sandy soils in
19 Michigan and Nebraska were not real crop soils. Look
20 at Drastic.

21 For the states to the east the Drastic scores
22 above 185, the county scores range from 0 to 88 %, but
23 there were 7 states that had greater than 10% of soils,
24 or counties having a Drastic score of 185. To the
25 west, there was only a single county in Minnesota that

1 had a Drastic score of 185 or more. Far, it's rare to
2 find those vulnerable counties in those major use
3 states. Water pH's, in the east, generally low, they
4 were below 7. The mean pH for all the wells in the
5 data we analyzed, below 7 for 14 states. In the west,
6 they are above seven for all states, the mean pH.

7 In fact, there are only a few wells, single
8 wells in Texas, that had a pH as low as that Maryland
9 site. Soil pH's are a similar story, much lower in the
10 East. In particular the sandy soils and humid areas,
11 it's not uncommon to find low pH soils, often as low as
12 5.5, and in the subsoils as low as 4.5. It's kind of
13 the opposite as you go west, the farther west you go,
14 the higher the pH soils are. Often 6 to 7 for many
15 corn belt states, 7 to 8 as you get to Nebraska, west.
16 And in contrast with the East, subsoils tend to be
17 higher in pH, because of the presence of calcareous
18 parent materials or other reasons, so we have in the
19 East, lower pH's, and in the West, higher pH's.

20 So from that monitoring analysis, we are
21 confident that present use of Carbofuran results in a
22 very low risk of groundwater contamination. And in
23 fact in 99.9 percent of those N.W.Q.A. wells analyzed
24 since 1993; 99.9 percent were equal to or less than .17
25 part per billion, so far below one part per billion.

1 But we wanted to carry the analysis farther,
2 and look really at a more national scale. EPA agrees
3 that Drastic is a useful tool to find vulnerable areas,
4 but there may be other tools that are also concerned
5 that the monitoring might have missed vulnerable sites.
6 So Waterborne conducted a national Carbofuran leaching
7 assessment, where they uses Prism, the Prism model to
8 simulate all agricultural soils, the entire U.S.,
9 64,000 soils. Assumed 30 years of consecutive use of
10 Carbofuran, in that model, and to measure the leaching
11 concentration at 5 meters below the soil's surface.

12 It was then loaded into an Aquifer model to
13 predict concentrations of Carbofuran in shallow ground
14 water. Both simulations were conducted either with or
15 without the geographic and soil restrictions that you
16 have heard about. And calculating maximum daily
17 concentrations, 95th percentile, or 90th percentile for
18 each of those runs. I am going to very briefly in the
19 interest of time just show you a snap shot of the
20 results of that nationwide analysis. Again, assuming
21 Carbofuran was used on every acre in the United States.
22 Again, this is the results from the amended label, that
23 has those geographical and soil type restrictions.
24 Across the top you have the spatial, less than 1
25 percent of acreage, less than 5 percent, and less than

1 10 percent of acreage.

2 Over on the left you have either the maximum
3 concentration that was predicted, or the 95th
4 percentile predicted. And you see that those are all
5 low numbers, nearly all except for that one maximum
6 value, less than a part per billion. To kind of put it
7 in words for the non-statisticians like myself, if all
8 eligible were treated at the one pound rate per acre
9 for every year for 30 years, and all the acreage had a
10 ground water depth of 5 meters, or about 15 feet, and
11 of course many areas don't have that shallow ground
12 water.

13 Then a concentration of .22 part per billion
14 would be expected to be equal or exceeded 5 % of the
15 time on less than 1 % of the acres. So it does confirm
16 that the expected concentrations really are low. Less
17 than the 1 part per billion that we have been talking
18 about.

19 In conclusion, on the ground water, expect
20 drinking water concentrations in ground water due to
21 Carbofuran use are expected to be less than a part per
22 billion. Or there is room in that risk cup for that
23 amount. This is shown by the modeling in the National
24 Prism Assessment, as well as that monitoring data.
25 Ninety nine point nine percent of the almost 9,000

1 N.W.Q.A. wells since 1993 had a concentration of equal
2 to or less than .17 part per billion.

3 We also believe that the potential for ground
4 water contamination can be mitigated through labels
5 changes, and being conservative to remove some of those
6 worries about potential contamination. The amended
7 label that went in has use...all the old prohibitions
8 are still there...things like Long Island, the things
9 you have heard about earlier.

10 But new prohibitions include all of Florida,
11 all of North Carolina, all of South Carolina, and all
12 the DELMARVA peninsula are prohibited from Carbofuran
13 applications. For some of those few other scattered
14 counties in other states, there is a well set back of
15 feet 50 feet required in those specified counties.
16 There is a new prohibit, a new label addition that
17 prohibits the mixing and loading and disposal
18 activities within 50 feet of a well, unless you have an
19 impervious pad.

20 To address the surface water concerns for
21 some of those counties you heard about, identified in
22 Illinois, Louisiana, and New Mexico, and all of Texas
23 and Pennsylvania, the label now calls for 66 foot
24 buffers adjacent to streams. I'm sure where many of
25 the panel members wonder where that 66 feet comes from.

1 It's of course to both to be protected and compatible
2 with government farm programs. In order to get paid,
3 farmer to be paid, to seed down those buffers with a
4 conservation reserve program, they need to be at least
5 66 feet. On my farm, we have several miles of buffers,
6 along all the streams and many of these buffers were
7 already there, with help, with things like the
8 conservation reserve program.

9 I want to end with some quick acknowledgments
10 of some of the other scientists involved in these
11 studies, particularly monitoring and modeling. And we
12 have a few key questions like some of the other
13 speakers have had, that really relate to what we have
14 talked about here, I'll just leave them on the screen
15 for a minute.

16 I want to turn it over now to Keith Solomon,
17 and I know he'll be brief. I know he has a plane to
18 catch, but I think he has 3 slides on aquatic
19 toxicology, we have of course been dealing with the
20 drinking water aspects.

21 **DR. HEERINGA:** Dr. Solomon, then
22 we'll take questions.

23 **DR. SOLOMON:** Mr. Chairman, panel
24 members, I just had actually 3 data slides, and 1 title
25 slide, and it covers a large area. In terms of aquatic

1 risks, this was not a charge question to the SAP, and
2 it was mentioned yesterday by EPA. There are 2
3 documents that are being provided to the panel that
4 overview both the aquatic and the mammalian risks. And
5 just to briefly cover the aquatic, we obtained toxicity
6 values for aquatic organisms from the US EPA's ecotox
7 data base.

8 We also used microcosm based, this is
9 experimental ecosystem based no observed effect
10 concentrations from Theo Broxworth in the Netherlands,
11 and Bartoningen and then we looked and compared these
12 two exposures, calculated by EPA in the IRED, also
13 using the N.W.Q.A. data that has been discussed
14 previously, although we did test a hypothesis that
15 there were changes in the pre 2000 and the post 2000
16 data, and we also used the one part per billion maximum
17 concentration that was talked about in the presentation
18 just given. So this starts off with a quick species
19 sensitivity distribution survey.

20 In the hollow points, the fish data the fish
21 are less sensitive to Carbofuran that the arthropods
22 and the solid points, and this just indicates the range
23 of susceptibility to Carbofuran in these organisms.
24 Now if you overlay on top of this the estimated
25 concentrations from the IRED, you will see that fish

1 are still above the maximum concentration that they
2 estimated, but obviously there is some overlap with the
3 arthropod concentration.

4 However if you look at this in the context of
5 the Brock microcosm studies, which really show the low
6 observed adverse effect concentrations for microcosms,
7 which integrate many different species and interactions
8 between them. What you see is, this actually is very
9 close to the lower limit of the concentrations
10 estimated by EPA, and it still obviously exceeds some
11 of the toxicity values for the arthropods.

12 The reason for this is that the LC 50 testing
13 in the laboratory probably maximizes exposure which
14 does not occur in the real world. If you then place on
15 top of that the water concentration for the
16 presentation you just heard, you will see that somewhat
17 lower risks would be even less, lower from the Brock
18 microcosm reviews. I took the N.W.Q.A. data. I can't
19 show the individual data points, there are too many of
20 them, and it ceases the system up. These are the
21 regression lines, and you can see here that the
22 intercepts that some of these values on the basis of
23 some fairly high concentrations from places like Zonner
24 Creek, that we talked about earlier, in excess of 99 to
25 99.9 percent, so a very small probability that these

1 very high concentrations will occur and that adverse,
2 threshold adverse effects would be seen.

3 In terms of mammals, one slide. Mammals are
4 less sensitive than birds. And I am going to rely on
5 Dwayne Moore's modeling here. The mouse is the most
6 sensitive of the mammals, from the IRED 2 mg per kg and
7 the least sensitive mammal that I saw was the dog at
8 15. But in many instances these, in situations outside
9 of misuse and baiting, there would be similar exposure
10 reductions that we talked about in the avian risk
11 assessment, and in all likelihood they would have a
12 lower risk than for birds. And this I think is
13 consistent with the incident data, which excludes
14 misuse. If you look at the data, flowable uses are
15 only a very few incidences associated with mammalian
16 mortalities. There were more on the granular material,
17 but of course that's no longer in use, so thank you
18 very much Mr. Chairman.

19 **DR. HEERINGA:** Dr. Solomon, Dr
20 Fawcett, Dr O'Neil. Questions from the panel? With
21 regard to the presentations on water. Dr Sparling.

22 **DR. SPARLING:** Don Sparling for
23 Southern Illinois University. With the, I'm not
24 familiar with the Drastic score system. Why was 185
25 chosen? And how high do values go for Drastic?

1 **DR. FAWCETT:** One eighty five was
2 chosen because it was the value that was associated
3 with that Maryland prospective ground water monitoring
4 study, and I think values generally ranged maybe up as
5 high as 240. That would be like up in Broward County
6 Maryland, I mean Florida is in that sort of ballpark.
7 Maybe higher than that, 247, or something like that,
8 it's a relative index in its approach to relative
9 vulnerability. Mr Williams.

10 **DR. HEERINGA:** Other questions on the
11 presentation on the ground water or flowing water?
12 Okay, I want to thank you very much, again, for your
13 concise clear presentation. We have final, Mr.
14 Kleingartener, we have one more presentation left to go
15 before, I think. Mr. We have one more presentation
16 from FMC, just a wrap up that Dr. Cummings will do. We
17 are going to finish out after Dr. Cummings' summary
18 presentation. We are going to go to Mr. Kleingartner
19 and Mr. Engel from, representing the National Sunflower
20 Association, the sunflower growers. But let's continue
21 with the final presentation from FMC.

22 **DR. CUMMINGS:** Thank you Dr.
23 Heeringa. I only have about 3 or 4 slides, it
24 shouldn't take much more than an hour and a half. So
25 we should be in pretty good shape. I am pretty sure I

1 am not going to get questions, so... . Real briefly, I
2 just wanted to summarize after, I was going to save my
3 thanks for the end, but I think I do want to thank the
4 chair as well as the entire panel for their patience,
5 endurance, level of participation. Certainly their
6 attention throughout the... it's been a long day, and
7 we certainly appreciate the registrant having the
8 opportunity to present our scientific position to the
9 panel, and for their consideration.

10 Just real quickly, what I would like to do is
11 just summarize from a risk perspective what you've
12 heard in these scientific presentations today. And
13 hopefully what you've heard is that a reasonable set of
14 assumptions have been presented, scientifically
15 justified, and they support the conclusion that from an
16 F.Q.P.A. risk perspective, all of the crops that F.M.S.
17 is proposing to move forward with, that is the import
18 tolerances, the phase out crops, which will be phased
19 out over the next 3 to 4 years, as well as the 5
20 critically important crops, do meet the F.T.P.A.
21 standard, and fit within the risk cup. Now just to
22 reiterate this one slide very quickly, you saw it
23 earlier, it's not quite as neat and clean, I think it
24 is actually shown up on the side over here in a little
25 bit different form, but essentially if the F.T.P.A.

1 safety factor is reduced to 1 - as is our position - as
2 well as reducing the inner species safety factor from,
3 well either maintaining it at 10, or reducing it to 3,
4 and maintaining the intra species safety factor.

5 There is, the food exposures do fit within
6 the risk cup and leave ample room for water
7 contributions. Basically to conclude there, is that
8 also we hope you've heard in the water segment of the
9 discussions is that there really is negligible
10 contribution to surface, from surface and ground water
11 to the risk cup.

12 Generally low to minimal avian risk. There
13 have been mitigation measures to alleviate any
14 concerns of avian risks, of higher risk, and that there
15 are acceptable margins of safety for workers. And in
16 addition, what you have heard along these critical and
17 important uses is that the benefits essentially do
18 outweigh the risks associated with the use of the
19 product. And I am not going to go through this, but
20 just, it's in your packet and these are the, just kind
21 of a re-cap of the scientific questions that the
22 registrant would feel that the SAP. should consider, if
23 they feel appropriate. So I'll go through those
24 quickly. Finally, I think to reiterate my comments,
25 earlier today, I guess much earlier today now, we do

1 feel based on sound science that the science does
2 support continued registration of Carbofuran in the
3 United States, based on the amended label. I would
4 like to thank the panel again for their attention.

5 **DR. HEERINGA:** Thank you Dr.
6 Cummings. Questions for Dr. Cummings in the wrap up
7 from the panel members? Okay, Dr. Cummings and your
8 team, thank you very much for your all of your
9 presentations; and panel members, thank you for your
10 questions and your patience. In case anybody is
11 wondering, this is not the latest a science advisory
12 panel has ever gone. I understand that genetically
13 modified corn went on almost until midnight on one of
14 it's days. Charlene was there, so we will . . . no
15 pizzas.

16 Okay, returning to the program, we are going
17 to have 2 public commenters this evening, to do them
18 the favor of allowing them to get out. The first Mr.
19 Larry Kleingartner, who is representing the National
20 Sunflower Association, Mr Kleingartner.

21 **MR. KLEINGARTNER:** Thank you, Mr.
22 Chairman and members of the committee, for
23 accommodating us and I appreciate your work on this
24 subject. We just want to give you a little background.
25 You have heard obviously lots of laboratory kinds of

1 things, and we want to take you to the actual
2 production field and talk about one crop that would be
3 impacted in the absence of Carbofuran. Just some quick
4 sunflower basics. Sunflower is really a fairly minor
5 crop in the United States, several million acres, but
6 the product is very important in terms of demand, in
7 terms of nutrition.

8 It has, it is a naturally stable oil;
9 sunflower oil is. So it doesn't have to go through the
10 hydrogenation process, which results in trans-fatty
11 acids. So the potatochip companies in the United
12 States, a lot of snack food companies see this oil as a
13 very, very primary oil in the production of their
14 products. And it is also very low in saturated fats.
15 So it really is a preferred oil. We also produce
16 confection sunflower seeds, and if you are a baseball
17 fan, you'll notice that a number of baseball players
18 love to chew and spit sunflowers in absence of chewing
19 tobacco.

20 So I'm hitting all the health events here.
21 And it's also very high in folic acid and vitamin E,
22 and we can go on and on, 'cause you are going to hear
23 this from the potato people tomorrow. Here are just a
24 few of the products you know that, Frito Lay has
25 really become a major, major customer, they are the

1 largest snack food company in the U.S., and they
2 switched a majority of their products to sunflower oil,
3 to eliminate trans, and to lower saturates. I found a
4 Jim Beam up there.

5 Even though it's more Miller time right now,
6 for you Jim Beam people, there are sunflower seeds that
7 are soaked in Jim Beam, and you can get a little, you
8 can get just a little kick from that as well. I didn't
9 bring any samples, I didn't think I could get them
10 through the process out front. But let me get on to
11 serious stuff here.

12 The sunflower plant is a native species plant
13 in North America, and with that we've got some fairly
14 significant and native insects, and they've been here
15 for centuries, and once we throw up a 200 acre
16 sunflower field with nice big juicy heads and stalks
17 these native insects just have an absolute field day,
18 like kids in a candy shop. Because we are a native
19 species crop, the G.M.O., the Genetically Modified
20 Option is not possible for us at this point in time in
21 the regulatory phase, because of the potential of
22 outflow of the genes to the wild species. So, as far
23 as "quick fixes" for some of these production issues,
24 the G.M.O. is not an option. This is just kind of a
25 "look-see" of where the production is at.

1 Let me get my laser here, this is where we
2 really have more of our insect problems, related to the
3 insect that we are talking about here, that we need
4 Carbofuran for. It's really in the Colorado, Kansas
5 area, and you see it's a fairly concentrated production
6 region. And again, it's a native insect that has been
7 with us, and this is it, the Adult Stem Weevil, it's a
8 very difficult insect to scout for, and I have a
9 producer, Mr. Unruh, who is sitting beside me and he'll
10 talk about that in just a minute.

11 It's a very cyclical population, as most
12 insects are, and Carbofuran really is the only
13 effective control. We're not using a lot of this
14 problem, I mean a lot of this product. But in this
15 particular area of the United States this insect is
16 rampant, and is there every year. And to produce this
17 crop successfully this is really the only product we
18 can use. In this area of Eastern Colorado, Western
19 Kansas, there is about \$ 200,000,000 worth of
20 infrastructure in place for processing this crop, so it
21 is a center of production.

22 The Stem Weevil basically impacts the stem,
23 it lays eggs, the larvae burrow into the stem, they
24 float up and down that stem all season long. We've
25 counted as many as 100 larvae in a stem, the stem is

1 weakened when there is that kind of pressure. You've
2 got a heavy head on the top side, with a weak stem on
3 the bottom side. You get a little breeze, which we
4 have quite a bit of, in Eastern Colorado and Kansas,
5 and you can see what happens when in that bottom photo.

6 They just basically tip over at the base. We
7 also have some secondary diseases that the Stem Weevil
8 is a vector for, and in essence, the hole in the stem
9 creates the pathway for these pathogens. And that's
10 the Charcoal Stem rot, and the Phoma Black Stem. And
11 those are fairly significant diseases when we get this
12 kind of pressure. Our response, we have been testing
13 genetic material in Western Kansas for the last 5
14 years. When I say "we", it's a combination of state
15 universities, and the U.S.D.A.'s Agricultural Research
16 Service.

17 We have found good segregation in populations
18 of wild species, and other you know, further refined
19 stocks of genetics. We have recently as an
20 organization, funded a poll stock, to take this
21 research and move it to the next level and try to get
22 this resistant material into hybrids as soon as
23 possible. We look at that as a 6 year process before
24 we really get into commercialization, so we need this
25 lead time. And as you can well recognize, insect

1 resistant research is a fairly high risk kind of
2 research.

3 In summary, Furodan is an important product
4 for the production of sunflowers in this key region of
5 Eastern Colorado, and Western Kansas. We don't have
6 any alternatives. I'm not aware of any pesticide
7 alternatives in the pipeline. We are working on hybrid
8 resistance, and Furodan really becomes an important
9 product for us with this kind of demand that we have in
10 place.

11 We really can't afford to lose any acreage.
12 Again, our demand is so strong we are importing
13 sunflower oil to make up for the lack of domestic
14 production, so an insect driving production out of this
15 country would certainly impact domestic users, and
16 certainly producers as well. So with that Mr. Chairman
17 I will give the chair to Bruce, and we'll be happy to
18 answer your questions.

19 **DR. HEERINGA:** Thank you very much Mr.
20 Kleingartner. Before we turn to Mr. Unruh, I will ask
21 if there are any questions from the panel. Yes, Dr.
22 Hattis.

23 **DR. HATTIS:** What is the basis for your
24 assessment that it is a unique product, that other
25 pesticides, either Carbonates or phosphates, or from

1 other insect classes would not do the job?

2 **MR. KLEINGARTNER:** Yeah, the uniqueness
3 of the product is that it translocates into the stem,
4 and so the larvae then, as they are chewing the
5 material, die. Other insecticides would all be contact
6 insecticides to kill the adult, and the adult is laying
7 eggs over a significant, I mean a fairly long period of
8 time. And that's what makes it unique.

9 **DR. HEERINGA:** Dr. Lu.

10 **DR. LU:** Quick question, this is sort
11 of a personal education question. So how do sunflower
12 farmers apply pesticides like Carbofuran to such an
13 enormous land?

14 **MR. KLEINGARTNER:** If I could let Mr.
15 Unruh answer that question, because he actually does
16 the, does the-

17 **DR. LU:** Okay, second question is, has
18 the trade group ever measured say, Carbofuran residue
19 in sunflower seed oil?

20 **MR. KLEINGARTNER:** Yes, all of that is
21 in place since early in the process of the plant
22 development. To my knowledge residue is not an issue
23 at all. If it were, we would be out of, we would not
24 be using this product.

25 **DR. CARLSON:** Mr. Chairman.

1 **DR. HEERINGA:** I have to stay with, Mr.
2 Carlson, I have to stay with, if you have some
3 clarification that can be passed with the other public
4 speakers, I have to stay with this at this point.
5 Bruce Unruh, I guess we have answered the question
6 about application, and-

7 **MR. UNRUH:** I'll touch on that in mine
8 in a little bit. We're pretty much over that. My name
9 is Bruce Unruh, and I farm at Burnett Colorado. That's
10 East/Central Colorado, about 14 miles from the Kansas
11 border, and I raise wheat, corn and sunflowers. Our
12 average rainfall is 17 inches, so water to us is a
13 precious commodity. I use Furodan on the sunflowers
14 for Stem Weevil and on corn for Root Worm control.

15 Without the use, sunflowers I have had up to
16 a 30% loss. Because of the Stem Weevil, I have seen
17 neighbors that have had losses even greater than that.
18 When this thing hits and the wind blows, we have had
19 straight line winds before harvest at 60 miles per hour
20 and it blows everything over.

21 If Furodan were banned I would no longer be
22 able to grow sunflowers, because Furodan is the only
23 labeled product right now on the market for use with
24 Stem Weevils. So It's like, if we can't put that on we
25 would be off label and where I grow confectionary

1 flowers, they are very critical with the residue,
2 because you eat them, and so there are only certain
3 periods. As far as putting it on, I use a half pound
4 of actual ingredient at planting with the seeds, so it
5 is put approximately 2 inches in the ground and covered
6 up.

7 The other stage, if it doesn't go on then,
8 would be at approximately a B7, 8 stage, which would be
9 a little bit under knee high, and it be over the top,
10 and still at the same half pound of active ingredient,
11 so it's not a heavy rate we're using, just enough to
12 knock this thing down, and keep it held down.

13 On my farm, like I say, 2,200 pound flowers,
14 248 acres, 30 cents a pound, 30% loss, would be \$
15 47,000, which you only stand that about one or two
16 years, and then you are looking for another occupation.
17 On the next page is pictures that Larry showed, and he
18 talked about the Stem Weevil bores into the stalk.
19 When the wind blows at harvest that's why it falls
20 over. The other thing is to go down low, we go down
21 low with like snouts on the combine. As you start
22 picking things up, you pick up a lot more stalks. You
23 get docked at the elevator, they don't want all the
24 trash, so you can't separate it with the combine. Like
25 Larry said, when you've got a heavy and a short stalk

1 the stalk sticks up, and you get the stalk for free.
2 Because of the increased loss of sunflower heads there
3 is also another problem that develops, it's volunteer
4 sunflowers the next year, and if hybrid sunflowers get
5 tough to grow, volunteers will grow fantastically, and
6 they'll come up 2 or 3 times a year, which causes us
7 another chemical operation, plus a loss of moisture the
8 next year.

9 So, it kind of, as the ball rolls, you start
10 creating more problems because of this. On the next
11 page there it talks about Kansas State University's .
12 . what their estimated cost of raising flowers is, and
13 where I arrived at my numbers. For lack of time I
14 won't go through that.

15 Basically without this, I am looking at a
16 \$96, at least, loss per acre. So why am I going to
17 continue to raise the crop? With the direct cost of
18 losing Furodan would be over 52,000 on the total acres,
19 the total cost to operate my farm would be much
20 greater. More importantly, sunflowers are an integral
21 part of my crop rotation, so it's not like I put
22 Furodan on every acre every year. This would be like a
23 3 or 4 year, so it gives time for the soil and
24 everything to digest it, and it wouldn't be like the
25 water issue, or anything of that nature. Integrated

1 pest management; I have observed neighbors who have
2 been in flowers for 4 years, not used Furodan and have
3 had some major losses.

4 Last year I watched a neighbor lose, I know
5 he was at 30%, I didn't go out and look much closer,
6 but you could tell it was bad. Later planting dates,
7 where we're at, doesn't seem to help. Also we start
8 losing yield at that stage of the game. Other
9 chemicals, like I say, there is nothing else labeled.
10 So there is no other product. You grow them and hope
11 for the best, which that doesn't always work.

12 The lower annual rain fall in my area limits
13 the alternate crops that we can go to, so it takes my
14 rotation and changes that picture completely. Like I
15 say, without Furodan, I don't think I'll be able to
16 grow sunflowers, so I just appreciate your studying
17 into it, looking at everything with a very open mind,
18 and I just thank you for your time and effort.

19 **DR. HEERINGA:** Thank you very much, Mr.
20 Unruh. Questions from the panel? Yes, Dr. Kehrer.

21 **DR. KEHRER:** Jim Kehrer. Mr.
22 Kleingartner said that the weevil problem was cyclical,
23 but it sounds like you treat the sunflowers every year
24 with Furodan, is that true?

25 **MR. UNRUH:** When I grow sunflowers I

1 treat them every year, because to scout them, when you
2 walk out there in that period they drop to the ground,
3 and because of the color they look like the ground.
4 All the consultants that I know will not even scout for
5 them. They just say at a certain stage you have just
6 got to put it on, or you are going to lose them, so
7 they come up every year.

8 **MR. KLEINGARTNER:** If I could clarify,
9 they are cyclical in other parts of the country, but in
10 that region where Mr. Unruh lives they are consistent,
11 yeah. But up in the Dakotas and Minnesota we may see
12 them every 6 years or so, but not to the volume that we
13 see consistently in this area of Eastern Colorado,
14 Western Kansas, and that's why we are doing all the
15 resistance testing there. Because we have a continuous
16 cycle or a continuous population of the insect.

17 **DR. LU:** So you forgot to tell us how
18 you apply the Carbofuran on the sunflowers.

19 **MR. UNRUH:** I apply it at planting, at
20 the half pound of active ingredient with the seed, with
21 the starter fertilizer at the time. So it is put in,
22 in the furrow. The other time is approximately like a
23 B7, B8, about knee high, and then we come over the top
24 of the ground grade.

25 **DR. LU:** So it's like an aerial spray,

1 or-

2 **MR. UNRUH:** No, it's for the ground
3 grade. Like just a close sprayer.

4 **DR. LU:** Okay.

5 **DR. HEERINGA:** Dr. Sparling.

6 **DR. SPARLING:** Don Sparling, Southern
7 Illinois University. I know the sample says there is
8 only one farm, but after application of Carbofuran,
9 have you ever found dead birds in your sunflowers?

10 **MR. UNRUH:** I have not found dead birds
11 around Furodan since granules have been gone.

12 **DR. SPARLING:** Have you looked?

13 **MR. UNRUH:** Yes, yes, I walked the
14 fields and looked for other pests because a little bit
15 after this we are going to come into head moth, and
16 other pests start showing up. And these are on
17 sprinklers, which we have to go out and check everyday,
18 so I have driven around and walked and have not found
19 any birds.

20 **MR. KLEINGARTNER:** Mr. Chairman, if I
21 might, on the back of my presentation there is a copy
22 of a news release from the Department of Justice, which
23 deals with the issue of the Colorado producer who was
24 found to mis-apply. If you notice in the second
25 paragraph, the second sentence, he relates to the mis-

1 application of the chemical. To our knowledge in the
2 sunflower industry, this is only time we have heard of
3 any bird kill related to this product.

4 **DR. HEERINGA:** Since I have opened it
5 up for you, Dr Carlson, did you have something related
6 to the detection of sunflower oil?

7 **DR. CARLSON:** Yes. Don Carlson, with
8 FMC Corporation. There was a question raised relative
9 to, would there be residues in sunflower oil?
10 Virtually all oils, whether they come from sunflower or
11 any other oil seed crops go through a process for
12 processing the oil. In the stage going from raw oil to
13 refined oil it is usually treated with a very alkaline
14 treatment, and in that step as a result of a the highly
15 alkaline treatment, all residues of Carbofuran, either
16 Carbofuran or 3 Hydroxy Carbofuran would be completely
17 destroyed. And the EPA has verified that, and agreed
18 to that conclusion. Thank you.

19 **DR. HEERINGA:** Thank you Dr. Carlson.
20 You answered my question about why these bugs don't
21 show up in the Dakotas. Because that's where my
22 mother's family is from.

23 **MR. UNRUH:** Fortunately we have
24 different bugs there. But we have alternatives to
25 Furodan.

1 **DR. HEERINGA:** But the wind never
2 blows.

3 **MR. UNRUH:** The wind never blows.

4 **DR. HEERINGA:** Okay, with that, I think
5 I would like to draw today's proceedings to a close.
6 Before I do close, I want to thank everybody for their
7 patience today. We will resume first thing tomorrow
8 morning at 8:30 with a continuation of the public
9 speakers who have registered to speak. Again, if you
10 are in the audience and have not had an opportunity to
11 speak but wish to speak, please see Dr. Matten, to
12 register for a 5 minute presentation, and Dr. Matten
13 has a few closing comments before we break.

14 **DR. MATTEN:** Right, I think it was this
15 morning still, the health effects divisions personnel,
16 they gave a number of clarification slides in the
17 morning in they have made printouts of those slides,
18 plus they answered Dr. MacDonald, maybe, about the
19 sourcing of various materials, data in the matrix table
20 and so that is also provided. And then after that meet
21 next door.

22 **DR. HEERINGA:** Panel members if we can
23 meet briefly in the break out room, thank you everybody
24 for your participation today. See you tomorrow.

25 **(WHEREUPON,** the session was concluded at 6:33 p.m.

CAPTION

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Further, as relates to depositions, it was agreed by and between counsel and the parties that the reading and signing of the transcript, be and the same is hereby waived.



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12 constitutes a true record of the transcript as
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14 I further certify that the inspection, reading
15 and signing of said deposition were waived by
16 counsel for the respective parties and by the
17 witness.

18 I certify that I am not a relative or employee
19 of either counsel, and that I am in no way
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21 this action.

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25 SUBMITTED ON FEBRUARY 6, 2008



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