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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

CONFERENCE CENTER- LOBBY LEVEL

ONE POTOMAC YARD (SOUTH BUILDING)

2777 SOUTH CRYSTAL DRIVE

ARLINGTON, VIRGINIA 22202

FEBRUARY 5, 2008

8:38 A.M.

1 U.S. ENVIRONMENTAL PROTECTION AGENCY
2 FIFRA SCIENTIFIC ADVISORY PANEL (SAP)
3 OPEN MEETING
4 February 5, 2008
5 **DR. MATTEN:** Good morning. I think we
6 ought to get started now. Everyone can do their last-
7 minute stretches or...or whatever you need to do. It's
8 not an opera, so if you need to cough, just go ahead.
9 We're fine with that. Bathrooms are, if you didn't see
10 them, are out this door on the left side of the hall.
11 We'll try to have periodic breaks so that everyone can
12 stretch your legs, et cetera, and if you have the
13 agenda, we...the agenda is floating.
14 My name is Sharlene Matten. I'm the
15 Designated Federal Official for the FIFRA Advisory
16 Panel meeting. As you know, this is a...the first day
17 of a planned four-day meeting on the scientific issues
18 associated with the Agency's proposed action under
19 FIFRA 6(b), notice of intent to cancel carbofuran.
20 As the Designated Federal Official, DFO, for
21 this meeting, I serve as a liaison between the panel
22 and the Agency and am responsible for assuring that
23 provisions of the Federal Advisory Committee Act, FACA,
24 are met. I want to thank Dr. Steve Heeringa on my left
25 for serving as the chair of this meeting, and I also

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1 want to thank the members of the panel and the public
2 for attending this meeting, as well as the people from
3 EPA who will be giving presentations during the meeting
4 as well as the entire EPA team.
5 The function of the Scientific Advisory Panel
6 and the panel composition, by way of background, the
7 Federal Insecticide, Fungicide, Rodenticide Act, FIFRA,
8 Scientific Advisory Panel, often called SAP, is a
9 Federal advisory committee under FACA that provides
10 independent scientific peer review and advice to the
11 Agency on pesticides and pesticide-related issues
12 regarding impact of proposed regulatory actions on
13 human health and the environment.
14 The FIFRA Scientific Advisory Panel only
15 provides advice and recommendants...recommendations to
16 EPA. All of the decision making and implementation
17 authority remains within the Agency.
18 As the Designated Federal Official for this
19 meeting, a critical responsibility is to work with
20 appropriate Agency officials to ensure that all
21 appropriate ethics regulations are satisfied. In that
22 capacity, panel members are briefed on provisions of
23 the Federal conflict of interest laws. In addition,
24 each participant has filed a standard government
25 financial disclosure form.

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1 I, along with our deputy ethics officer from
2 the Office of Prevention, Pesticides, and Toxic
3 Substances, and in consultation with the Office of
4 General Counsel, have reviewed these reports to ensure
5 all ethics requirements are met.
6 The members of the public requesting time to
7 make a public comment, please limit your comments to 5
8 to 10 minutes unless you have previously discussed
9 additional time with myself. For those that have not
10 pre-registered, you still may make public comments.
11 Please see me at your earliest convenience, and we can
12 add you to the list of those who wish to present oral
13 comments.
14 There is a public docket for this meeting.
15 It...we refer to as EPAHQOPP20071088, and in case you
16 don't remember that, that's fine. You can always see
17 me, and it's published...put into all of our reference
18 materials. You can still provide public comment.
19 All background materials, questions posed to
20 the Agency by the panel, proposed to the panel by the
21 Agency, and other documents related to the scientific
22 advisory panel meeting are available in the docket, so
23 as of today's presentations will also being made
24 available in a few days. The background documents are
25 also available on the EPA web site, the scientific

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1 advisory panel web site, as well as all written public
2 comments are available.
3 The Agency has prepared an agenda for this
4 meeting that lists contact information for this docket.
5 After this meeting is concluded, the
6 scientific advisory panel will prepare a report
7 consisting of responses to the questions posed by the
8 Agency, considering all the background materials,
9 presentations, and public comments. The report serves
10 as meeting minutes, and they will be completed within
11 30 days after the close of this meeting.
12 Again, I wish to thank the panel for their
13 participation, members of the EPA, as well as the
14 audience for their participation in this very valuable
15 meeting. I am looking forward, as well as I can speak
16 for the panel, to the challenging and interesting
17 discussions that will be held over the next four days.
18 Thank you.
19 And now I will turn the next stage of the
20 agenda over to Dr. Steven Heeringa who will act as the
21 scientific advisory panel chair for this meeting.
22 **DR. HEERINGA:** Good morning, everyone,
23 and welcome to the first day of our multiple-day
24 session on the topic of the notice of intent to cancel
25 carbofuran. We have a very serious matter before us.

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1 We have a tremendous amount of information that's been
2 provided to us, and an expert panel assembled here this
3 morning.
4 I will be serving as the chair of the
5 meeting. I am the current chair of the FIFRA Science
6 Advisory Panel...Advisory Panel. I am a statistician
7 from the University of Michigan Institute for Social
8 Research where I am engaged primarily in population-
9 based research. I have no specific expertise on these
10 matters other than my biostatistical background, but
11 we've assembled, obviously, a large and very competent
12 group of experts to address the science issue.
13 I'd like the members of the panel at this
14 time to introduce themselves to the audience. I'll
15 begin on my left with Dr. Jan Chambers.
16 **DR. CHAMBERS:** I'm Jan Chambers with the
17 College of Veterinary Medicine at Mississippi State
18 University. My area of expertise is pesticide
19 toxicology, primarily neurotoxicology metabolism, and
20 I'm a member of the permanent panel.
21 **DR. HANDWERGER:** I'm Stuart Handwerger.
22 I'm from the Departments of Pediatrics and Cell and
23 Cancer Biology in the College of Medicine at the
24 University of Cincinnati. My clinical expertise is in
25 endocrinology, and my research is in molecular and

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1 developmental biology, and I'm a member of the
2 permanent panel.
3 **DR. PORTIER:** Good morning. I'm Ken
4 Portier. I'm a biostatistician with the American
5 Cancer Society, and my expertise is as an applied
6 statistician, and I've done some work in probabilistic
7 risk assessment. I'm also a member of the permanent
8 panel.
9 **DR. SCHLENK:** My name is Dan Schlenk.
10 I'm a professor in the Department of Environmental
11 Sciences at the University of California at Riverside.
12 My research expertise is in fate and effects of
13 xenobiotics in aquatic organisms, and I'm also a member
14 of the permanent panel.
15 **DR. CLARK:** I'm Larry Clark. I'm
16 assistant director of the USDA's National Wildlife
17 Research Center. My areas of expertise are wildlife
18 ecology, wildlife disease, and especially biology of
19 animals.
20 **DR. DELORME:** Good morning. I'm Peter
21 Delorme. I'm currently acting director of the
22 Environmental Assessment Directorate at Health Canada's
23 Pest Management Regulatory Agency. I have expertise in
24 both fate and effects of pesticides.
25 **DR. GRUE:** Hi, I'm Chris Grue. I lead

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1 the Washington Cooperative Fish and Wildlife Research
2 Unit at the University of Washington. My area of
3 expertise is fish and wildlife toxicology with an
4 emphasis on cholinesterase inhibitors.
5 **DR. HILL:** Hello, I'm Woody Hill.
6 I...I'm a wildlife toxicologist, and my area has mostly
7 been with organophosphorous and cholinate pesticides.
8 **DR. MCCARTY:** John McCarty with...with
9 the Department of Biology at University of Nebraska at
10 Omaha. I'm an ecologist, and my primary expertise is
11 working with field studies on birds, most recently in
12 agricultural ecosystems.
13 **DR. MONTGOMERY:** Good morning. I'm
14 Cheryl Montgomery. I'm a consultant with Montgomery
15 Associates. I am a risk assessor, and my academic
16 background is in chemistry.
17 **DR. SAMPLE:** I'm Brad Sample. I'm a
18 consultant with CH2M HILL, and I...my background is in
19 ecological risk assessment and wildlife toxicology.
20 **DR. SPARLING:** I'm Don Sparling with the
21 Cooperative Wildlife Research Laboratory, Department of
22 Zoology at Southern Illinois University, and my area of
23 expertise is wildlife toxicology.
24 **DR. STINCHCOMB:** Audra Stinchcomb,
25 College of Pharmacy, University of Kentucky. My

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1 expertise is in dermal absorption, and I'm a ad hoc
2 member.
3 **DR. REED:** Mu-may Ruby Reed from
4 California Environmental Protection Agency. I'm a
5 toxicologist doing pesticide risk assessment. Also
6 address health risks at the HS factor.
7 **DR. MACDONALD:** Peter MacDonald,
8 professor of mathematics and statistics at McMaster
9 University in Canada, and I have general expertise in
10 applied statistics.
11 **DR. LU:** I'm Alex Lu. I'm on the
12 faculty of Rollins School of Public Health at Emory
13 University. I do research in relation to human
14 exposure to pesticides and using biomarkers for the
15 assessing the health effects.
16 **DR. HATTIS:** I'm Dale Hattis, originally
17 a geneticist at Clark University in Massachusetts. I
18 specialize in issues of mechanistic modeling of
19 variability and uncertainty.
20 **DR. EDLER:** I'm Lutz Edler from the
21 Biostatistics Department from the German Cancer
22 Research Center. My expertise is in statistical
23 methods in experimental as well as clinical cancer
24 research methodology, also experimental design and risk
25 assessment.

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1 **DR. BUNGE:** I'm Annette Bunge from the
2 Department of Chemical Engineering, Colorado School of
3 Mines, and my expertise is dermal absorption of
4 chemicals.
5 **DR. BRIMIJOIN:** I'm Steve Brimijoin.
6 I'm from Mayo Clinic, Department of Pharmacology. My
7 research interest is in the pharmacology and toxicology
8 of cholinesterases.
9 **DR. BAILEY:** Ted Bailey from Iowa State
10 University. My main interest is in design of
11 experiments.
12 **DR. HEERINGA:** Thank you very much,
13 panel, and I believe one panel member, Jim Kehrer, from
14 Washington State University, Dean of Pharmacy there,
15 will be joining us later this morning or early this
16 afternoon.
17 At this point in time...oh, Gary Isom also.
18 Gary is a member of the permanent panel and, I believe,
19 a pharmacologist from the Purdue University, Lafayette,
20 Indiana.
21 Okay, I think we're set to get underway this
22 morning. I want to reiterate my pleasure at the panel
23 that the SAP staff has again assembled. Some of them
24 are old acquaintances and colleagues from prior SAP
25 panels. I'm very, very pleased at the quality and the

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1 coverage of the scientific content that we have
2 represented here.
3 So, with that, let's get underway, and I'd
4 like to introduce for some opening remarks Dr. Debbie
5 Edwards who is the director of the Office of Pesticide
6 Programs at the EPA. Dr. Edwards?
7 **DR. EDWARDS:** Thank you. Welcome and
8 good morning. This meeting is being held as part of a
9 process that began when we published our re-
10 registration and tolerance reassessment decisions for
11 the insecticide, carbofuran, in August of 2006.
12 We reached these decisions after many years
13 of deliberation by scientific experts within the
14 Agency, numerous stakeholder meetings, and two formal
15 public comment periods. Our scientific assessments led
16 us to the decision that carbofuran products are not
17 eligible for re-registration under the Federal
18 Insecticide, Fungicide, and Rodenticide Act and that
19 the tolerances currently in place for residues of
20 carbofuran in or on food commodities do not meet the
21 standard for safety that is set forth in Section 408 of
22 the Federal Food, Drug, and Cosmetic Act.
23 In most cases when the Agency reaches similar
24 conclusions, we are able to work with the pesticide
25 registrants and other stakeholders to arrive at a

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1 voluntary cancellation. In 2006, however, we were
2 unable to reach voluntary agreement with the carbofuran
3 registrants for cancellation of their product
4 registrations.
5 Thus, the Agency proceeded to the next legal
6 option which was to draft a notice of intent to cancel
7 and to present it to this independent scientific
8 advisory panel and to the U.S. Department of
9 Agriculture for their review. A requirement for
10 scientific advisory panel comment on the health and the
11 environment of the action proposed in the notice of
12 intent to cancel is clearly articulated in Section 25
13 of the Federal Insecticide, Fungicide, and Rodenticide
14 Act.
15 Today's meeting is unique and somewhat
16 historic in that it has been nearly two decades since
17 EPA was unable to reach a voluntary cancellation
18 agreement in the circumstances in which we find
19 ourselves here today.
20 It is relevant to point out that subsequent
21 to the Agency's 2006 decision, the registrant proposed
22 to conduct some additional studies that they believed
23 would for refinement of the risk assessments, and we
24 agreed to review and consider those data if they were
25 submitted in a timely manner.

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1 Now, more than 18 months after our original
2 decision, we have reviewed a number of recently
3 submitted studies, and while they allow us to refine
4 our assessments somewhat, they have not substantively
5 changed our original conclusions regarding carbofuran
6 safety and eligibility for re-registration. Therefore,
7 we are continuing to pursue a cancellation process for
8 all carbofuran products registered in the United
9 States.
10 All of the new studies and our reviews have
11 been provided to this panel along with charge questions
12 on which we are asking the panel to focus. The role of
13 the panel is to advise the Agency on whether our risk
14 assessments are reasonable based on currently available
15 information.
16 The next speakers on today's agenda will go
17 into greater detail on carbofuran's history, our
18 regulatory process, and the challenge to this expert
19 panel. After that, Agency scientists will provide
20 summaries of our ecological and, in particular, our
21 avian risk assessment as well as our human health risk
22 assessment. We will begin the public comment period
23 this afternoon.
24 I expect that this will be an interesting and
25 challenging meeting. The importance and the complexity

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1 of the issues to be addressed will require considerable
2 hard work on the part of the panel, and I want to thank
3 each of you, each panel member, in advance, for your
4 efforts and for your service to the people of this
5 country.
6 Thank you.
7 **DR. HEERINGA:** Thank you, Dr. Edwards.
8 At this point, I'd like to introduce Dr.
9 Steve Bradbury who is director of the Special Review
10 and Re-registration Division of the Office of Pesticide
11 Programs. Steve?
12 **DR. BRADBURY:** Thank you. I'd like to
13 follow up on Dr. Edwards' comments and thank all of you
14 for your time and hard work before the meeting and
15 during the next four days and as you prepare your
16 deliberations. We realize that there's a lot of
17 information that you've been reviewing, and we greatly
18 appreciate your efforts.
19 Just to follow up a little bit on...on what
20 Dr. Edwards provided in her opening comments, as...as
21 Dr. Edwards indicated, the Federal Insecticide,
22 Fungicide, and Rodenticide Act requires EPA to
23 determine whether uses of a pesticide generally present
24 unreasonable adverse effects on the environment. In
25 addition, other statutes that EPA operates under also

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1 require us to take a look at the safety standards
2 associated with human health.
3 In the context of implementing our...our
4 regulations, the Agency is under a process of a 15-year
5 cycle where it had to...it has to re-register
6 pesticides or reevaluate pesticides that were
7 registered prior to 1984, and part of our history with
8 carbofuran relates to this time cycle and the deadlines
9 associated with making our decisions.
10 As you all know, carbofuran is a N-methyl
11 carbamate insecticide that's used on a number of plant
12 products, including a number of food crops and feed
13 crops. And the reevaluation of carbofuran in that 15-
14 year cycle that I mentioned previously began in the
15 late 1990s, and over the time that the reviews are
16 going on, extensive reviews, EPA determined that
17 products containing carbofuran were not eligible for
18 re-registration based, in part, on ecological effects
19 as well as effects to human health in terms of our
20 dietary exposure as well as occupational risks.
21 And during this extensive review process,
22 there were a series of public comment periods as well
23 as SAP reviews on various components of the
24 methodologies that revolved...evolved from the late
25 '90s through 2006 when the Agency published the interim

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1 re-registration eligibility decision which synthesized
2 its analyses over the last several years.
3 As Dr. Edwards indicated, after the IRED and
4 in discussions with the registrant, the registrant
5 proposed to submit additional data and information to
6 the Agency, and the Agency agreed to review the new
7 studies and data if they were submitted in a timely
8 manner. Within a period of March to November, 2007,
9 the studies were submitted to the Agency, and in
10 subsequent talks, the...the specifics of those studies
11 will be described.
12 The Agency reviewed these new studies and
13 data and evaluated the extent to which the information
14 provided by the registrant could alter the ecological
15 and human health risk assessments that were published
16 in the 2006 decision. After these analyses, the Agency
17 determined that the new data did not significantly
18 change the risk conclusions and, therefore, published
19 the draft notice for intent to cancel on January 8th,
20 2008.
21 Under FIFRA, there are certain steps that we
22 need to go through when we...when we propose a notice
23 for intent to cancel. One aspect of the process is to
24 get feedback on review from the U.S. Department of
25 Agriculture in terms of the impact of our decision on

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1 the agricultural economy. In addition, the meeting
2 we're having today and during this week deals with
3 another aspect of the NOIC process which is...involves
4 EPA asking the official science advisory panel for
5 comment on the scientific bases of the human health and
6 environmental assessments that underlie any action
7 associated with the NOIC.
8 Of course, EPA will take the input from USDA
9 and from the panel, evaluate these comments, and
10 publish our response to the...to the comments provided
11 as part of our deliberative process.
12 To clarify a bit of how we work through the
13 USDA's rule and SAP's rule, I just wanted to touch on a
14 couple of comments, some of which were already
15 mentioned at the opening of our meeting. So, while the
16 SAP is charged with commenting on the scientific issues
17 associated, in this case, with the carbofuran risk
18 assessments, there are certain topics that the SAP
19 isn't authorized to comment on.
20 One topic area has to do with the benefits of
21 carbofuran with potential impact of this decision on
22 the agricultural economy, and as Dr. Heeringa mentioned
23 and the DFO mentioned, the...the regulatory decision
24 itself is the business of the Agency, and the focus of
25 today's meeting, this week's meeting, is focused on the

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1 science underlying the decision.
2 With regard to the benefits analysis or the
3 potential impact on the agricultural economy, at the
4 same time that the NOIC was published, it was also made
5 available to the U.S. Department of Agriculture along
6 with associated background information on the benefits
7 analyses and the..and the details behind the Agency's
8 interpretation, and the USDA is reviewing that
9 information concurrently with the process that the SAP
10 is going through so that both the benefits analysis and
11 your review of the underlying science will be occurring
12 in a parallel fashion.
13 So, let's turn to the...the goals and
14 objectives for this week's meeting. And as I was
15 indicating before, the EPA is requesting the SAP to
16 provide comments on whether the Agency has reasonably
17 assessed the nature and magnitude of risks to public
18 health and the environment posed by the use of
19 carbofuran based on currently available information and
20 accepted scientific methods.
21 As I indicated earlier, the focus of...of
22 this decision for carbofuran is based, in part, on a
23 time line set out in our statutes in terms of deadlines
24 that we have to meet in order to reach our decisions,
25 and there's also a process and set of time line

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1 decision of the NOIC process. So, one concept or
2 important points of today's...this week's meeting is
3 that our decision concerning the NO...NOIC is focused
4 on currently available data and currently accepted
5 scientific methods.
6 And there's a...somewhat of a distinction
7 between other SAPs that we've had over the years on a
8 variety of topics in which other SAPs were typically in
9 the process of developing methods or looking at an
10 evolutionary process in which sometimes we're asking
11 for advice on next steps or other kinds of information
12 that may be helpful. In this case, unlike previous
13 SAPs, the EPA is not asking for advice on whether the
14 scientific bases of the carbofuran risk assessments and
15 the regulatory decision could benefit from development
16 of new scientific methods or new scientific data. So,
17 the decision that EPA has to make is based on currently
18 available information and currently accepted scientific
19 methods.
20 As we've indicated in our opening statements,
21 the...the methodologies used to assess carbofuran's
22 ecological and human health risks have been the subject
23 of several previous SAPs, and, therefore, EPA is
24 primarily requesting review of the scientific issues
25 that have merg...have emerged since 2006 rather than

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1 asking the panel to provide additional comments on
2 previously peer reviewed aspects of the carbofuran risk
3 assessments.
4 To provide the...the adequate scientific peer
5 review that the Agency needs, the SAP is responsive to
6 the charge questions that are really required by the
7 Agency to help us get feedback and insights on the
8 analyses we've done and...and the charge questions that
9 follow. While these charge questions need to be
10 addressed, certainly, the panel is not precluded from
11 commenting on other additional scientific as...aspects
12 of the carbofuran risk assessments that are associated
13 with the NOIC.
14 During public comment, there may be issues
15 raised that you wish to explore, and, of course,
16 members of the panel may raise issues that...that you
17 wish to explore as well. The key is that we...the
18 Agency truly needs responses to the charge questions
19 that we have in addition to any other...any other
20 insights on the scientific issues you wish to...to
21 bring to our attention.
22 So, as I indicated before, the Agency has
23 identified scientific issues that it feels is most
24 critical to its ecological and human health risk
25 assessments. These issues primarily concern topics

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1 that have been...not been previously addressed by the
2 scientific advisory panel.
3 In general, the issues associated with the
4 charge questions involve the new studies and new data
5 that the registrant submitted to EPA since the 2006
6 decision was published, and the questions also then
7 explore how these data may affect the carbofuran human
8 health and ecological risk assessments.
9 So, just to...to wrap up the...the overview
10 of...of the next couple of days, involve presentation
11 of the carbofuran decision and some of the processes
12 EPA followed in preparing the draft NOIC, and Jude
13 Andreasen, on my left, will provide that summary.
14 There will then be presentations by scientists in the
15 offices of Environmental Fate and Effects Division and
16 Human Health Effects Division in which they'll
17 summarize some of the key...quote, key issues
18 associated with the ecological risk assessments and the
19 human health risk assessments. There will then be
20 presentations by the public, and then we'll move into
21 the charge questions as we move through the end of the
22 week.
23 And with that, I'd like to thank all of you
24 again for your hard work and contributions to this very
25 important effort, and I turn the mike to the chair.

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1 **DR. HEERINGA:** Thank you very much, Dr.
2 Bradbury, for those opening remarks, and at this point,
3 I would like to introduce Jude Andreasen who's with the
4 Special Review and Re-registration Division of the
5 Office of Pesticide Programs. Good morning.
6 **DR. ANDREASEN:** Good morning. I'm just
7 going to cover a bit of carbofuran's regulatory history
8 and add a few more details to Dr. Bradbury's summary of
9 the NOIC process.
10 Carbofuran was first registered in 1969.
11 It's marketed in both granular and liquid formulations,
12 and it's a restricted use pesticide. It controls a
13 variety of insect pests on food and non-food crops, and
14 about 1 million pounds a year are marketed, and 99
15 percent of that is the flowable liquid formulation.
16 As Dr. Bradbury said, we focused on the
17 reevaluation of carbofuran, because our statutes
18 require any active ingredient registered prior to 1984
19 be reevalued...reevaluated periodically to make sure it
20 still meets our safety standards, especially with the
21 constantly evolving assessment methodologies.
22 Because of the acute avian risk problem of
23 the granular formulations of carbofuran, it was subject
24 to what we call our special review process in the late
25 '80s, and in 1991, we reached a negotiated agreement

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1 with the registrant which imposed a production cap of
2 the granular formulation of 2500 pounds of active
3 ingredient per year. In addition, the granular product
4 was only to be a...applied on four crops. Since then,
5 one of those crops has been canceled.
6 In the 1990s, the registrant recognized that
7 additional measures needed to be implemented to reduce
8 worker, water, and ecological risks and voluntarily
9 implemented some changes, including reduced application
10 rates and number of applications, limited applications
11 on sandy soils because of the propensity of carbofuran
12 to leach, and the use of engineering controls such as
13 packaging changes.
14 And as already stated, our re-registration
15 process requires us to make a finding of no
16 unreasonable adverse effects and also to seek public
17 comment aggressively during our reevaluation. That
18 public comment period began in June of 2005, and there
19 are several other public comment periods, as you can
20 see, until the final comment period which opened in
21 August when we published our...what we call our IRED,
22 the Interim Re-Registration Eligibility Decision,
23 that's already been discussed.
24 And as we stated, the...our 2006 re-
25 registration decision found unacceptable risks and that

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1 all products of carbofuran were not eligible for re-
2 registration due to ecological, dietary, and
3 occupational risks.
4 Now, this chart which is based on our 2006
5 decision lists the crops for which carbofuran is
6 registered, and it's actually on two slides, this slide
7 and the following slide. The food risk column does not
8 include water which is at food only, and there's a
9 check mark in any column there we found unacceptable
10 risks.
11 Since the 2006 assessment, we have had
12 additional monitoring data and some refinements of
13 percent crop treated, but, basically, our assessment is
14 the same as this chart.
15 When we published the IRED, the...we stated
16 not only were all products ineligible for re-
17 registration, but we allowed for a four-year phase-out
18 for some crops for which we felt there were moderate
19 benefits and limited alternative pesticides that could
20 be used. In addition, those uses also had acceptable
21 dietary risks, so we felt a four-year phase-out would
22 be consistent with our safety standard.
23 At the same time, we proposed to allow import
24 tolerances, that is, carbofuran could not be used
25 domestically on those four crops, bananas, coffee,

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1 rice, and sugar cane, but we would allow residues on
2 imported commodities if they were within our safety
3 tolerance levels.
4 This is a time line of the NOIC process. As
5 Dr. Bradbury said, from March through November, we had
6 new submissions, and in November, by November, we
7 realized that we were not going to change...the new
8 assess...new submissions which had all been assessed on
9 an expedited basis had not changed our bottom line
10 decision. So, we announced this meeting of this panel
11 on November 20th.
12 We then opened a public docket on January
13 8th, and a month from now, we expect that the panel
14 will provide us the report. We will then
15 review...through March and April, we'll review not only
16 the panel's report but all of the public comments that
17 are submitted, and we expect by April or May to have a
18 decision.
19 If our decision remains unchanged, we will be
20 issuing a Notice of Intent to Cancel Carbofuran.
21 After...if and when we issue that Notice of Intent to
22 Cancel, the registrant will have 30 days to request a
23 hearing.
24 This is just to give you an idea of the types
25 of studies that were submitted between March and

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1 November. All of these studies have been provided to
2 the panel, and these are toxicity studies, both avian
3 and rat toxicity studies, and they have all been
4 reviewed by our scientists.
5 We also received water studies on
6 drinking...sorry...with surface water and groundwater.
7 These have also been provided to the panel, but we have
8 not included a charge question to the panel on drinking
9 water. However, the panel, as Dr. Bradbury said, is
10 not constrained from commenting on the assessments that
11 bear on our drinking water assessment. All these
12 materials have been provided to the panel and reviewed
13 by us.
14 Between March and November of 2007, we not
15 only provided expedited review to the FMC submissions,
16 we also had review completed of our own EPA lab which
17 did cholinesterase studies, and all of those studies
18 had to...were subject to internal peer review, and we
19 did a meta analysis for the cholinesterase studies,
20 both the FMC and the EPA studies, and then all our
21 studies had to be reviewed by manage...management
22 before finalization and then cleared for confidential
23 business information.
24 As you can see, the Agency has been on a very
25 tight scheduled in 2007.

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1 We also received from the registrant benefits
2 analyses, assessments on certain crops, and those were
3 reviewed. They were not provided to the panel, but
4 they were reviewed.
5 And now, our ecological risk assessment
6 scientists will give you an overview of the ecological
7 effects and...and the review of all the studies that
8 were submitted in 2007.
9 Thank you.
10 **DR. HEERINGA:** Thank you very much.
11 Before we begin with Dr. Brady's presentation, I'd like
12 to turn to the panel quickly to see if there are any
13 questions for either Dr. Bradbury or Dr. Andreasen.
14 Dale?
15 **DR. HATTIS:** Yes, I...I didn't notice in
16 the package that...and maybe I just o...overlooked it,
17 whether we got the actual IRED document from 2006. Is
18 that...is that intentional, or did we get it?
19 **DR. ANDREASEN:** I believe it was in the
20 package, and if it wasn't, we will certainly get it to
21 you.
22 **DR. HEERINGA:** Dr. Matten says it was,
23 so we'll...we'll find it for you, Dale. Any other
24 questions of clarification?
25 If I might, I might ask one of Dr. Bradbury

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1 and Ms. Andreasen. The...in reviewing the materials,
2 there have been several proposed label changes by the
3 registrant. Your decision at this point relates to the
4 current registration, and how does that relate to these
5 label changes? I notice, for example, that alfalfa is
6 still on your risk table.
7 **DR. BRADBURY:** The reg...excuse me. The
8 registrant submitted proposed labels in December of
9 2007, and we're in the process of discussing some of
10 the complexities associated with that submission,
11 because included in that submission is...is use on four
12 year cotton which isn't a currently registered use, and
13 everything's connected together.
14 But having said that, as you know, the charge
15 questions on focusing on some, I would say, some
16 fundamental issues in terms of cholinesterase
17 inhibition and how that is interpreted in terms of
18 benchmark dosing and then feeds into the human health
19 risk assessment, as an example, and there are other
20 charge questions that are focusing on issues associated
21 with evaluating risk to birds at the...at the scale of
22 a field that's being treated.
23 So, I think, if I could offer, in...in many
24 ways, I think the charge questions will be...give us
25 insights regardless of what pattern of uses or cropping

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1 patterns may or may not exist in the future, because
2 the questions, I think, are really focusing on
3 fundamental underlying issues associated with how to
4 interpret human health endpoints or how to interpret
5 risk at the scale...scale of a field.
6 So, if that's helpful...we'd be happy to
7 follow up some more.
8 **DR. HEERINGA:** Thank you. That
9 help...that's very helpful for me, at least.
10 Okay, at this point in time, let's move on
11 and...with Dr. Donald Brady who is director of the
12 Environmental Fate and Effects Division of the Office
13 of Pesticide Programs who's going to give us an
14 overview of the ecological science issues. Dr. Brady?
15 **DR. BRADY:** Thanks very much, Dr.
16 Heeringa. I'd like to add my welcome and appreciation
17 for the members of the panel here today as we embark
18 upon our discussions. I'd also like to acknowledge the
19 scientists in EPA who participated in the analysis and
20 will make some of the presentations that you'll see on
21 the ecological risk assessment this morning.
22 By...by way of background, the Environmental
23 Fate and Effects Division, EFED, responsibility is to
24 assess risk to the environment from pesticide exposure
25 to non-tar...non-target aquatic organisms, non-target

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1 terrestrial organisms, and endangered species. EFED
2 developed the ecological risk assessment for
3 carbofuran.
4 As the EFED presentations proceed, you'll see
5 that the carbofuran risk assessment is based on three
6 lines of evidence. First is a deterministic screening
7 assessment, second is a probabilistic risk assessment,
8 and the third is field data, including incident reports
9 and field studies, including monitoring studies.
10 EPA's decision to cancel carbofuran is based,
11 in part, on the risks to terrestrial and aquatic non-
12 target species. Risks to birds are
13 partic...particularly significant and exist for all
14 currently registered uses.
15 The...my presentation describes the
16 development of the ecological risk assessment, the peer
17 review of the underlying methodologies and tools, and
18 describes the focus of the issues for today's science
19 advisory panel.
20 By way of background and as you heard some of
21 this a little earlier, carbofuran was registered in
22 1969. The development of the ecological risk
23 assessment began in 1989. EPA's assessment was subject
24 to three comment periods. The IRED was signed in
25 August, 2006, and new avian information was provided in

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1 2007.

2 There have been a number of science advisory

3 panels on the Agency's risk assessment methods. The

4 first two that are shown on this slide focused on

5 deterministic methodologies. The panels in 1997 and

6 2000 focused on probabilistic risk assessment methods

7 in general, and the two panels listed here in 2001 and

8 2004 focused specifically on the terrestrial model that

9 EPA uses.

10 Did I jump? Ah, sorry.

11 EPA completed the risk assessment in August,

12 2006. Subsequently, new data, including a new model,

13 some as recently as October, 2007, was submitted to

14 EPA. EPA evaluated all the data.

15 In the first study, number 1, EPA reviewed

16 the quality of the individual avian studies. In the

17 second study, number 2, EPA evaluated the impact of the

18 studies, individually and collectively, on the avian

19 risk inclusions. The third document listed there

20 summarizes some of the major issues relevant to

21 carbofuran, but these are...have not been addressed

22 specifically in the charge questions, because we have

23 previously sought input from the science advisory panel

24 on these questions.

25 In terms of the aquatic ecological risk

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1 assessment, this was a refined product assessment. The
2 deterministic assessment used...employed representative
3 uses and a range of application rates. The
4 probabilistic risk assessment employed uses identified
5 as highest risk in the deterministic and maximum
6 application rates. We looked at aquatic incidents.
7 And our conclusions are, for freshwater fish,
8 low risk for acute exposure, risk from chronic exposure
9 for corn and sorghum uses. For estuarine and marine
10 fish, risks from corn and sorghum uses. For freshwater
11 invertebrates, acute and chronic risks for nearly all
12 uses. And estuarine and marine invetebrate risks from
13 nearly all uses.
14 Regarding the terrestrial risk assessment,
15 ecological risk assessment, this was a refined
16 terrestrial assessment. The deterministic looked at
17 representative uses and application rates spanning the
18 range for all currently registered uses. The
19 probabilistic looked at birds, application rates
20 spanning the range for all currently registered uses,
21 incidents, and field studies.
22 The conclusion for birds, acute risks to
23 birds from all uses; chronic risks from most uses. No
24 NOIC was available.
25 Mammals, acute risks for all uses and chronic

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1 risks for most uses.
2 The presentations we've prepared for you
3 today provide more detailed discussions on these topics
4 and are addressed in the charge questions.
5 Issues not addressed in the charge questions
6 incloud...include flowable versus granular uses. The
7 flowable uses represent approximately 99 percent of the
8 carb...current carbofuran use in the U.S. Since 1994,
9 due to high avian risks, granular...granular use has
10 been limited to the sale of 2500 pounds of active
11 ingrediment...ingredient per year.
12 The deterministic methods were peer reviewed
13 in science advisory panels. No new data was available
14 or submitted to refine exposure or toxicity to aquatic
15 organisms. The process used by EPA to estimate aquatic
16 ecological risk has been reviewed by science advisory
17 panels and deemed appropriate for both screening level
18 assessments and probabilistic assessments.
19 No new tools or data were available or
20 submitted to refine exposure or toxicity to mammals.
21 Deterministic methods have been peer reviewed by
22 previous science advisory panels.
23 TIM, the Agency's terrestrial model, has been
24 reviewed in previous science advisory panels. Thus,
25 EPA is not posing specific questions to the panel

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1 regarding the software. One charge question does
2 address the effect the model version has on the
3 carbofuran risk conclusion.
4 The focus of the science advisory panel
5 ecological risk charge questions is on the lines of
6 evidence supporting risks of carbofuran to birds.
7 These include the probable...probabilistic risk
8 assessment model version used in the assessment, the
9 impact of new data or alternative assumptions on
10 estimating risks to birds, conclusions that can
11 reasonably be drawn from a...available incident
12 reports, conclusions that can be drawn from the results
13 from field and monitoring studies.
14 Overall, are our conclusions reasonable,
15 giving information currently available for carbofuran?
16 I'd like to just close by describing the
17 presentations that will follow. The first is the
18 overview of carbofuran ecological risk assessment by
19 Dr. Edward Odenkirgen...Odenkirchen...sorry, Ed;
20 overview of field data and incident reports by Dr.
21 Melissa Panger; and the avian probabilistic risk
22 assessment by Dr. Christopher Salice. So, these
23 presentations will provide an overview of EPA's
24 ecological risk assessment and the impact of new data
25 or tools provided to EPA throughout the past year on

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1 our ecological risk assessment conclusions.
2 Thank you.
3 **DR. HEERINGA:** Thank you, Dr. Brady.
4 Panel members, any questions for Dr. Brady before we
5 begin the three major presentations?
6 **(No response.)**
7 **DR. HEERINGA:** Okay. I guess at this
8 point, Dr. Odenkirchen.
9 **DR. ODENKIRCHEN:** Well, good morning,
10 everyone. Thank you very much for this opportunity to
11 present a body of work that has taken several years,
12 and as you saw from the earlier presentations, quite a
13 number of individuals have worked on this risk
14 assessment.
15 If you have any questions over the course of
16 this that I can't answer, there's...we have a number of
17 folks that are...that are in the audience that worked
18 on this assessment, particularly the aquatic side, so
19 if there's any questions with regards to that, maybe we
20 can get those answered. Most of my experience with the
21 assessment is primarily focused on the avian side.
22 **DR. HEERINGA:** When we get to those
23 questions, Dr. Odenkirchen, we'll address them to you,
24 and you can call up the individuals who...
25 **DR. ODENKIRCHEN:** Fantastic. I'll call

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1 for help when needed. That's for sure.
2 Well, my presentation today is basically an
3 overview of the carbofuran ecological risk assessment,
4 an overview. As you've probably seen the assessment at
5 this point in time, there's quite a few hundred pages
6 involved in there, so it's a little bit of a challenge
7 to do this in...in 45 minutes or less. So, it's going
8 to go pretty fast, and it's going to be fairly cursory,
9 and if we have any more in-depth questions, please fire
10 them off to me.
11 After I give a presentation, there will also
12 be that overview of field data and incident reports by
13 Dr. Panger, and she's gone back and looked at the
14 incident data, that other leg of the triad of things
15 that we evaluated, the three lines of evidence, to see
16 what can be teased out of...out of that information or
17 what use we make of it, whether or not there's any
18 critical questions with regards to temporal aspects and
19 interpretation of individual studies.
20 And then, last by not least, Dr. Salice is
21 going to look at our probabilistic risk assessment in
22 terms of...in light of the new data that's been
23 presented to the Agency for evaluation. We want to
24 make sure we give that a fair hearing. We want to make
25 sure we incorporate it into our existing tools where

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1 appropriate and looking at our new versions of our own
2 software and how that impacts the...the risk
3 assessment, the conclusions of the risk assessment,
4 and, indeed, some of the assumptions and background
5 information provided by FMC for their new liquid PARAM
6 model and how that affects our conclusions.
7 Again, I think it's important to realize that
8 this assessment went through a number of internal and
9 external peer review steps. Back from June through
10 August of 2005, we had an internal branch review that
11 involved senior scientists and branch management. Then
12 we had an internal division review which involved
13 the...the division's own risk assessment review panel
14 which is all of our senior scientists and some senior
15 branch management. Then an external error correction
16 phase before it ever went out to the general public.
17 The external error correction phase involved
18 members of industry looking at our...our risk
19 assessment to look at things like mathematical errors,
20 errors...factual errors associated with capturing, you
21 know, did we move a decimal point in the wrong place,
22 did we add and subtract correctly, et cetera.
23 And then, beyond that, there's a...after it
24 went public, there...in the revised combined risk
25 assessment from March to May, there was a public

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1 comment period where...where the general public was
2 invited to comment on our assessment. We went back and
3 reevaluated our assessment in light of those comments
4 and came out with the interim RED, and, again, that
5 went out for another external peer review for public
6 comment.
7 Well, the objective of our risk assessment,
8 as has been said earlier...Steve touched on it...was to
9 estimate the risks to non-target organisms associated
10 with the current registered uses of carbofuran. Our
11 non-target taxa that we assessed included freshwater
12 and estuarine and marine vertebrates and invertebrates
13 and terrestrial vertebrates, primarily terrestrial
14 vertebrates as they consist of birds and mammals and,
15 by analogy, to herbivore.
16 Our assessment was done consistent with a
17 number of ecological risk assessment guidelines
18 and...and our peer reviewed methodologies. I'm not
19 going to discuss these in depth, but much of this was
20 covered in the package of information that you guys
21 received to support this...this SAP, but we've been
22 very mindful of going through and incorporating
23 additional modifications to our existing methods as
24 were suggested by the SAP both in version analysis and
25 inclusion of our alternative assumptions, and you'll

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1 see those in Dr. Salice's presentations later.
2 Again, carbofuran, it's an N-methyl carbamate
3 used primarily as an insecticide and hermaticide. It
4 is a cholinesterase inhibiting mode of action, and one
5 of the important things here, and you're going to see
6 this throughout the...the rest of the assessment,
7 whenever you see a red asterisk or something in red
8 text, it's probably going to be an issue that's going
9 to be discussed further today.
10 And one to open up right away is this
11 potential for reversibility of the inhibition of
12 cholinesterase. We go back and we look at different
13 methodologies in a probabilistic assessment on how to
14 account for that, there's some new data that's been
15 provided by the registrant with regards to that. So,
16 that's part of our charge questions to you.
17 The risk assessment considered 26
18 agricultural uses and 5 non-agricultural uses of the
19 pesticide. Primarily, it was...it dealt with the
20 flowable formulations. It dealt with aerial and ground
21 applications, both foliar and broadcast as well as
22 banded in furrow and, in certain circumstances such as
23 grapes, drip irrigation uses.
24 The risk assessment considered application
25 ranges that...that went from the lowest effective

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1 application rate all the way up to the maximum labeled
2 rate. The uses were usually grouped under common
3 categories of agronomic practice, under application
4 method, and by rate and surrogate use, and as a
5 consequence, we assessed our risk by a surrogate
6 process.
7 So, what we would do is we would group those
8 crops, those uses, that were common in terms of
9 application rate or in geographical area and
10 meteorological area for the aquatic side, and we...we'd
11 group those together and run one assessment on...on a
12 representative use, and that way, we...we...we get a
13 better in-depth analysis of that use and alternative
14 assumptions, but we don't bog ourselves down with
15 repetitive computations that do very little to change
16 the outcome of the...of the risk conclusions.
17 On the aquatic side, we dealt primarily with
18 exposure from carbofuran in the water column as it's
19 introduced into aquatic systems through surface runoff,
20 erosion, and spray drift. And on the terrestrial side,
21 we dealt with primarily exposure to residues in food
22 items with the deterministic assessment and for food
23 items and drinking water for the probabilistic
24 assessment, and that dealt with directly...primarily
25 with direct deposition of spray and spray drift and,

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1 for the drinking water, a little bit about surface
2 runoff and erosion.
3 Our assessment endpoints are typical for our
4 approach, dealing primarily with survival, growth, and
5 reproduction, and they're based on an individual
6 organism level.
7 Our measures of effects. In the...in the
8 risk question process that we employed in our
9 deterministic assessment, we dealt primarily with an
10 acute endpoint and a chronic endpoint or a reproduction
11 endpoint for both birds, mammals, and as well as
12 freshwater and estuarine or marine vertebrates,
13 primarily fish, and estuarine and marine invertebrates.
14 Those were limited to acute measures of lethality,
15 medium dose lethality, and on the reproduction end
16 primarily dealing with no observed effect levels.
17 You'll see a no observed effect level as the
18 desired endpoint for birds on the 21-week reproduction
19 study. However, for the case of carbofuran, no no
20 observed effect level was ever reached. There were
21 bird mortalities at all dose levels in that study.
22 Our problem formulation deals with a risk
23 hypothesis, what we're going to test for, through the
24 application of our three lines of evidence. In this
25 case, I've combined them, both the terrestrial and the

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1 aquatic, together on one slide, so I apologize that it
2 looks a little long, but it's that terrestrial and
3 aquatic vertebrates and invertebrates are subject to
4 adverse effects, reduced survival or reproduction, when
5 exposed to carbofuran residues following application of
6 the pesticide and at labeled use rates. And in our
7 case, labeled rates extends everything from what could
8 be minimally effectival...effective through a typical
9 use rate that would be allowable under the label and a
10 maximum rate allowable under the label.
11 Again, we looked at three lines of evidence
12 in our analysis plan, a deterministic screen that uses
13 primarily our risk quotient model which is a point
14 estimate of exposure divided by a point estimate of
15 effects; a refined risk assessment which we'll call the
16 probabilistic assessment for the rest of these
17 presentations which is probabilistic techniques
18 primarily establishing variables for
19 key...distributions for key variables throughout the
20 risk equations, and then using Monte Carlo sampling to
21 analyze the variability within those outcomes; and then
22 field studies which looked at incident reports and
23 field monitoring programs.
24 On the aquatic side, we again, we dealt with
25 primarily with exposure in the water compartment.

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1 Didn't concern ourselves, because of the physical-
2 chemical properties of the compounds, with
3 look...at...with concerns with regards to dietary
4 exposure or exposure in sediments. We examined our
5 surface water estimates of exposure, looking at small
6 volume of aquatic surface water bodies. We used our
7 PRZM exams model which is our standard process.
8 We did not look at all labeled uses directly,
9 but, again, we used a surrogate approach where we
10 grouped uses and...and labels by methodology,
11 application rate, geographical area, agronomic
12 practice, as well as meteorological information to come
13 up with a series of surrogate scenarios.
14 The results of our deterministic assessment,
15 they've been touched on earlier by Dr. Brady. We...the
16 acute and chronic risks to freshwater fish are not an
17 issue for most uses except for corn and sorghum. All
18 uses exceed acute and chronic levels of concern for
19 invertebrates, and those risk questions range from 1.6
20 to 16 on the acute side and from 6 to 36 on the chronic
21 side.
22 And the only things that did not raise a
23 concern were drip irrigation use on grapes, the lowest
24 foliar rate...this would be the lowest minimally
25 effective rate...on alfalfa, and applications to small

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1 grains, soybeans, and sunflowers.
2 Some of the results with regards to estuarine
3 and marine fish and invertebrates, except for that
4 because the estuarine and marine fish are more
5 sensitive to carbofuran than the freshwater group, all
6 uses had acute and chronic concerns for fish except
7 for, again, grapes, lowest foliar rate on potatoes and
8 alfalfa, and the small grains, soybeans, and
9 sunflowers. And all uses exceeded acute and restricted
10 and chronic levels of concerns for invertebrates.
11 When we went to a probabilistic assessment on
12 the freshwater fish and invertebrates, it generally
13 supported the deterministic screen that acute risk is
14 unlikely to be a concern for freshwater fish. Chronic
15 risk concerns for the highest foliar rates to corn and
16 sorghum at the...resulted in the no observed effect
17 concentration being seen in over 60 percent of
18 application years. We did a sort of a...looked at the
19 full suite of application years rather than just a
20 point estimate of a...of a single peak year.
21 The use on potatoes would be infrequently
22 exceeded, so it's much less than 60 percent of the
23 application years, and it supported the deterministic
24 screen for both acute and chronic adverse effects to
25 invertebrates at a high degree of mortality and a high

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1 frequency of that mortality occurring over the time
2 series of data...time series of exposures that were
3 modeled.
4 And, similarly, for reproduction effects
5 levels, there...we exceeded for nearly all uses in
6 greater than...almost approaching 50 percent of the
7 years modeled.
8 On the estuarine and marine side, again, we
9 supported primarily the re...the results of the
10 deterministic assessment. Corn and sorghum, on
11 average, resulted in greater than 18 percent mortality.
12 We had potential for frequent disruptions in the
13 function and quality of all estuarine and marine sites.
14 For instance, in corn and sorghum, under the highest
15 use rates, we frequently had over 100 percent mortality
16 in the taxa that we...we assessed.
17 For coastal potatoes, because of the high
18 rainfall introductions into that crop and
19 broad...broadcast applications on grapes, we frequently
20 resulted in greater than 60 percent...67 percent
21 mortality, and in foliar applications to cotton at
22 plant and soil incorporation, looking at that potential
23 new use, resulted in greater than 53 percent and
24 greater than 23 percent mortality respectively. And
25 those occurred quite frequently, greater than 50

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1 percent of the modeled daily exposures of which there
2 are about 15,000 daily exposures in the model run.
3 Now, on to the terrestrial assessment which
4 is primarily what we're going to be talking about for
5 the majority of the next few days, at least on the
6 ecological side. We had an emphasis in the
7 deterministic approach on dietary route of exposure.
8 Our point estimates of peak residue concentrations are
9 derived primarily from our standard Fletcher nomagram
10 which uses the uptake translocation, accumulation, and
11 bioconcentration database that we rely on for
12 distributions of exp...of residues, pesticide residues
13 in food items.
14 It uses the most sensitive tested animal
15 endpoints for effects. In this case, an avian acute
16 LD50 is based on the fulvous whistling duck. A 21-week
17 reproduction lowest observed effect concentration for
18 reproduction effects which is actually mortality in
19 the...in the...in the birds, the adult birds that were
20 dosed, and, consequently, no observed...there was no no
21 observed effect level, no threshold effect level for
22 reproductive effects from that study.
23 We looked at a mouse acute lethal study
24 of...in terms of a single lower dose for mammals and
25 then used a rat three-generation reproduction NOAC for

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1 our reproduction endpoint. We used the risk quotient
2 calculation method, again, at point estimate of
3 exposure divided by point estimate for effects.
4 The levels of concern, when we compare those
5 risk quotients to, the acute lethal dose concern is
6 whenever a risk quotient equals or exceeds 0.5, and a
7 reproduction risk concern is whenever a risk quotient
8 equals or exceeds a value of 1.
9 We assessed a number of crops under this
10 representative uses by application method and rate.
11 Again, we looked at alfalfa, corn, cotton, grapes,
12 potatoes, small grains, sorghum, soybeans, sugar cane,
13 sunflowers, and tobacco.
14 The model is mostly sensitive to application
15 rate in...and application method. Sorry. These crops
16 provided us with the greatest variety of application
17 rates and...and methods.
18 Application rates, as you can see, ranged
19 from a minimally effective rate of 0.125 lb/acre all
20 the way up, for most of the crops, to 2 lb/acre and,
21 then again, up to 6 lb/acre for the special case with
22 tobacco.
23 The mammalian risk quotient results, we
24 divide our acute effects to deal with herbivores,
25 granivores, and insectivores, and three body sizes, 15,

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1 35, and 1000 grams. As you can see, for the
2 herbivores, the risk quotients for acute effects ranged
3 from 3.9 all the way up to 684, driven primarily by
4 application rate and body weight size of the...of the
5 animal considered.
6 For granivores, they were somewhat lower,
7 ranging from 0.11 to 9.5. That's primarily driven by
8 the fact that the...the residue assumptions with
9 regards to small grains and seeds that are...that is
10 used in our deterministic assessment, those residues
11 are much lower than...than other vegetative matter.
12 And then, the insectivores which use
13 primarily the...the vegetative matter values for broad-
14 leaf foliage and fruits, et cetera, as a surrogate for
15 large and small insects, the insectivores also had very
16 similar risk quotients to the herbivores, ranging from
17 4.7 to 365.
18 The chronic effects ranged...RQs ranged from
19 0.1 to 72, and, again, as you can see, comparing to our
20 lethal risk concerns, we reached conclusions with
21 regards to the deterministic assessment that the
22 dietary pathway is sufficient to cause concerns for
23 mortality and reproduction effects.
24 Very similar results for birds. Again, we
25 divided into herbivores, granivores, and insectivores.

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1 You can see the range of risk quotients there goes from
2 17...or 0.6 for the lowest for granivores all the way
3 up to several thousand for the herbivores.
4 The chronic concerns are greater than 1 to
5 greater than 690. Why are there greater values there?
6 Because we don't have a no observed effect threshold.
7 We only have a lowest observed. So, therefore, when we
8 calculate our risk quotients, the...the risk will be
9 somewhat higher than if we just assume that was a no-
10 eff.
11 The major take home there is regardless of
12 whether it was a greater than value present before
13 those numbers is that all of them were below our
14 chronic risk concern values for the deterministic
15 assessment.
16 And our conclusions with regard to the
17 deterministic was...is that exposures via the dietary
18 pathway are sufficient to cause mortality and
19 reproduction effects. Again, that's based on
20 assumptions of complete exposure pathways. No
21 variability associated with those pathways, and also
22 based on the assumption of the most sensitive tested
23 species in the laboratory.
24 So, we moved on. Any questions? Yeah?
25 **DR. MONTGOMERY:** Did you have the same

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1 assumptions for granivores for avian as you did for
2 mammals...
3 **DR. ODENKIRCHEN:** That's correct.
4 **DR. MONTGOMERY:** ...for the residue
5 levels?
6 **DR. ODENKIRCHEN:** Yeah, same thing with
7 residue levels. The...the seed values are somewhat
8 lower than...than the foliage levels, short grass, tall
9 grass, broad-leaf foliage. Seed values are lower.
10 **DR. HEERINGA:** Just a second. I'd like
11 to hold the questions unless you feel, Dr. Odenkirchen,
12 that this is an appropriate point, but there will be a
13 lot of questions, and I'd like to organize them, I
14 think, at the end of your presentation.
15 **DR. ODENKIRCHEN:** Right, yeah,
16 we're...we're about halfway through the slides, so
17 we've got a lot of ground to cover.
18 **DR. HEERINGA:** Why don't you go...please
19 go ahead and finish your presentation, just for
20 consistency, and then we'll turn to the questions.
21 Thanks very much.
22 **DR. ODENKIRCHEN:** Thank you. When we go
23 to the probabilistic assessment, we add a number of
24 variables for the bird probabilistic assessment. The
25 first was to define the probability of magnitude of

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1 avian effects. The risk question provides us with a
2 unit-less number which really doesn't tell you a lot
3 with regards to how often those effects may occur or
4 how big those effects might be.
5 We wanted also to explore key areas of
6 variability and uncertainty in the data sets that
7 underlie the deterministic approach to...to find out
8 whether or not, when we incorporate that variability
9 and uncertainty, are we going to get drastically
10 different results than we would have predicted on the
11 basis of our risk quotient analysis. And, finally, to
12 consider the potential for exposure routes other than
13 merely food as they might be potential for risk drivers
14 in the assess...in...in...in the field.
15 In our problem formulation, again, recall
16 that the deterministic assessment identified acute
17 lethal effects as an area of concern for birds. Our
18 risk managers expressed a desire to have more
19 information on these potential effects.
20 All of our registered uses were des...were
21 identified as being of concern within the screening
22 process, so we had to figure out a way to focus those
23 down, and what we did was we focused our refinements on
24 a selected subset of uses. We selected those uses
25 which had a large range of application rates, and the

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1 reason be...for that was so that we could bracket the
2 application rates that are evident for some of the
3 other uses.
4 So, therefore, we get a risk picture
5 associated with very, very low rates and very, very
6 high rates and more typical rates, and that encompassed
7 our other ones that we dealt with the risk questions.
8 It gave us more information on how to interpret the
9 risk quotient results for the un...for the other
10 applications.
11 We looked at those uses which had a large
12 potential land area that were treated. We felt that
13 that gave us a greater opportunity for surrogacy in
14 terms of what organisms were on those fields, how
15 representative they might be for other crops,
16 and...and, last but not least, is probably the most
17 important aspect was where there was additional
18 biological information to support refinements, where
19 there were actual field information, field studies, to
20 allow us to interpret the results against those, field
21 data that allowed us to look at how well...how often
22 and how intensely bioorganisms might use these agro
23 environments, more information on what bird species are
24 present and what their behavior might be like in these
25 agro environments.

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1 So, we...we settled on focusing on corn and
2 alfalfa crops. And to do a probabilistic assessment,
3 we used the terrestrial investigation model version 1.0
4 as the assessment tool. All the way back in early
5 2000, 2001, that went to the SAP. There were a number
6 of refinements that were offered by the SAP to improve
7 that. This model was the one that was present and
8 available to us at the time we conducted the risk
9 assessment.
10 We have gone back subsequent, and you'll see
11 in Dr. Salice's presentations later that we've looked
12 at our subsequent versions of the model after another
13 SAP go-around. We now have version 2.1 of the model,
14 and we'll be incorporating some of the results today in
15 our presentations as that to sort of test how the model
16 versions have changed and improvements may or may not
17 have altered our risk conclusions.
18 And now we focused on species shown to use
19 these crops, as evidenced by incidents in field
20 studies. When we move the TIM 2.1 model that you'll
21 see later, we focus on more generic birds as a...as a
22 recommendation from the SAP to consider generic birds
23 as well as actual species known to occur in
24 cert...in...in certain agro environments..
25 For...to come up with those focal species, we

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1 considered census data from field studies for use...for
2 the pesticide actually used on corn and alfalfa. We
3 considered species that were found dead in such field
4 studies. We also looked at the open literature surveys
5 of birds in and around corn and alfalfa fields.
6 And our selection criteria were a high
7 frequency of current...of occurrence in Midwestern corn
8 and alfalfa areas, a high frequency of observation
9 within the actual fields, and either observed
10 mortalities or close to them in terms of size, nesting,
11 and feeding characteristics. So, if we had birds that
12 were not well covered by biological information but we
13 had other...other species that were really well
14 characterized in terms of that information, we would
15 seek to use those as a surrogate for a species found in
16 a particular system.
17 The focal species on corn ranged everywhere
18 from the meadowlark on down to the killdeer. As you
19 can see, there are a variety of dietary preferences,
20 insectivores, granivores, and the omnivores. Most of
21 our birds were primarily ground feeders, but they did
22 occupy a different series of nesting sites, the ground,
23 within a shrub layer, and within a tree layer. So,
24 that...we expected that that would give us a variety of
25 expected uses in the field and along the field margins.

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1 Similarly for alfalfa, we had the dickcissel
2 through to the vesper sparrow. You'll see that the
3 meadowlark and the dove, et cetera, have overlap with
4 the...with the corn use, and that was
5 primarily...primarily to allow us to compare the
6 results of different varying use patterns of the
7 species on a given crop to see whether or not we've
8 established an adequate bracketing for that...for
9 those...for that data.
10 Again, a variety of dietary preferences, and,
11 again, because of the nesting sites, we feel we have a
12 variety of expected uses of field and field margins.
13 The approach to the analysis, we used a full
14 suite of carbofuran and acute lethal effects data for
15 birds. We relied primarily on the LD50 data.
16 Rather than relying on a simple point
17 estimate of the most sensitive species tested, we
18 normalized all the data to a single body weight and
19 used an approach by Aldenberg and Slope to come up with
20 a distribution of effects and then picked a series of
21 points along that distribution, a 5th percentile, 50th
22 percentile, and 95th percentile, those distributions
23 for a low, medium, and high sensitivity assumption for
24 each bird species, because our data is incomplete for
25 the majority of species that are on the fields and only

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1 a few species have been tested and there's very little
2 overlap between what's on...on the field and what's
3 actually been tested in the laboratory, so we had to
4 account for that uncertainty.
5 We considered minimum, typical, and labeled
6 maximum application rates, and we allowed for the
7 dis...distribution...distribution of carbofuran in the
8 diet and drinking water and, indeed, in the feeding
9 bird, as you'll see some discussions later about this,
10 in the feeding bird to...to make sure that when we do a
11 time series of exposures, we're mot merely adding up
12 all the exposures and then taking the worst case
13 picture.
14 A little bit about this TIM 1 model. The
15 model can be characterized as a species-specific model.
16 It addresses acute mortality over a defined exposure
17 window. In the case of carbofuran, it's a 14-day
18 window with two 12-hour time steps per day.
19 And then, in subsequent versions of the
20 model, we actually go down to an hourly time step per
21 day, and the feeding properties are actually
22 distributed over a bimodal feeding pattern in our
23 subsequent models, as the SAP has recommended. But for
24 the TIM 1 model, two time steps per day with an equal
25 amount of feeding in the morning and in the afternoon.

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1 The spatial scales at the field level such
2 that the field and surrounding areas are assumed to
3 meet the requirements for each focal species, and,
4 indeed, looking at our field data, our incident data,
5 and some of the field data from the...from the...from
6 the literature, we did try and select species that
7 actually did use the fields or at least were present on
8 the fields, the temporal scale for the exposure is
9 immediate to and following a single application.
10 When we ran TIM 1 early on, we were...we were
11 limited by computational abilities. I mean, it was
12 rather clunky. We were running it in an Excel
13 spreadsheet with some fairly flow computers at the
14 time, and we...we limited it to one single application.
15 Today, with TIM 2.1, we have the ability to run several
16 application methods, but to be...or several subsequent
17 applications.
18 But to be fair here and make sure that all
19 our presentations are even in that you see, we'll limit
20 our TIM 2 models in...in subsequent presentations to
21 also a single application.
22 The major parameters addressed in the model,
23 food habits, daily ingestion rates, frequency on
24 the...of feeding and drinking on sprayed fields, the
25 residues on focal species' food and water sources, what

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1 they use, degradation rates on those food and water
2 sources, and inter and intra species toxicity
3 estimates.
4 For each of the major vailable...variables,
5 we devel...we...we constructed a distribution, and then
6 we sample by Monte Carlo sampling techniques,
7 integrated exposure, the distributions for ultimate
8 exposure, and the dose response curve and came up with
9 a probability and magnitude of afute...of acute lethal
10 effects.
11 Little comparison of the risk quotient
12 process with the probabilistic process, again, a point
13 estimate for exposure, select...expected to be fairly
14 conservative. It's a...a high end or reasonable upper
15 bound type of assessment. We had some controversy over
16 whether it represents as 90th or a 95th percentile
17 value or an extreme value, but it is on the upper end
18 of the curve.
19 On the probabilistic approach, we...we strike
20 to use a distribution of all the exposure values.
21 There is some controversy. You'll see an asterisk
22 beside that in terms of whether or not the...the
23 available data sets are robust enough to allow for
24 distributions across fields and within a field. We
25 explore some of the additional data to allow us to

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1 determine how...how all...how close we are on the mark
2 in our TIM 1 model assessment. You'll see that later
3 in Dr. Salice's presentations.
4 The effects endpoint is the LD50 for the RQ
5 process, and on the probabilistic process, we used the
6 full dose response curve. We use the lowest LD50 in
7 the RQ process. We use a species sensitivity
8 distribution in the probabilistic approach.
9 We just merely have a simple division of an
10 exposure estimate by effects endpoint. In the RQ
11 process, we have a full integration of a
12 distribution...two distributions, both for the dose
13 response and the exposure, to come up with probability
14 and magnitude. So, one gives us a single number, and
15 one gives us a variety of numbers that is the full
16 distribution of probability and magnitude of adverse
17 effects.
18 This slide's kind of small, kind of far away,
19 but this is our conceptual flow diagram. You'll see
20 some things in red which, again, are areas where
21 we...where we'll more fully...fully explore later
22 today. We start out with picking our focal species,
23 what does it eat, what its food habits are, what its
24 food...what its food requirements are in terms of how
25 much does it eat and how much does it drink. That's

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1 primarily based on allometric relationships related to
2 body weight and the dietary type.
3 Frequency of eating and drinking on the
4 contaminated field, how often is it on the field versus
5 off the field. If we look at contaminated water
6 sources and degradation rates on food items, we come up
7 with residues on and in food and water. You'll see a
8 little bit more discussion today about that. That's
9 primarily related to application rate in our...in our
10 model, although for the contaminated water source, it
11 relies on some of the PRZM outputs, those surface
12 runoff values. We used those in the TIM 1 model to
13 look at drinking water exposures.
14 We look at elimination rates from
15 the...because we're doing two time steps each day in 14
16 straight days of potential exposure on the field, we
17 want to make sure we account for elimination of
18 carbofuran from the bird. We do that in one
19 methodology in our...in our risk assessment as it...as
20 you'll see it today.
21 And we've explored alternative methodologies
22 to use, instead of elimination rate, to use recovery
23 rate from acetylcholinesterase inhibition as a...as a
24 surrogate for that. And that was a recommendation by
25 the SAP to consider the site of toxic action, to...and

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1 look at some dose response and time series information
2 with regards to that. So, we have...we've looked at
3 additional data provided by the registrant to allow us
4 to modify our model in that way.
5 We come up with a dose estimate for each
6 time...each time point. We compare that dose estimate
7 to the dose response distribution, and we come up with
8 an individual average risk. We come up with a
9 calculation of individual mortality for a series of
10 birds and then a percent mortality for either a group
11 of birds or cohorts of individuals within a given
12 species.
13 So, the variables we explicitly consider in
14 TIM 1, well, on the chemical side, we look at the
15 stability of the compound in various environmental
16 media, primarily here, water, soil, and vegetative
17 items. What is the toxicity of the pesticide in terms
18 of its LD50 slope and...and the slope of the dose
19 response. You'll see issues there related to how we
20 look at the LD50, and you'll see some discussion later
21 of new data with regards to the effects of dietary
22 matrix on that.
23 We look at pesticide residue variables in the
24 exposure model, primarily, what are the residue
25 concentrations in food items. We'll have a little bit

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1 of discussion about variability within fields and
2 across fields today. I'm sure you'll see some from
3 other presentations from the public today as well.
4 And we also look at what the sources of
5 residues in drinking water are. Primarily, we're
6 looking at dew and puddle formation on the field.
7 For bird variables, what does the bird weigh?
8 How much does it eat? What does it eat? You'll notice
9 that there's an asterisk beside how much does the bird
10 eat. We're going to ask ourselves, in light of
11 additional data, whether or not the presence of
12 carbofuran in the diet affects how much a bird eats and
13 what implications that has on the risk assessment. Dr.
14 Salice will cover that later.
15 We ask, where does the bird eat? In this
16 case, is it on the field or is it off the field? And
17 what data can...can shed more light on that. How much
18 does the bird drink, and where does it drink?
19 And then, on the application variables,
20 what's the application rate? As you...as I've said
21 before, we use a scenario approach, lowest, typical,
22 and maximum applications. And how is the application
23 made? Is it by air? Is it on...is it on...from ground
24 equipment, or is it in the furrow?
25 If we follow a bird in the TIM model, the

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1 model could be run in two different ways. One way is X
2 iterations of Y birds in a cohort. So, we could run
3 1000 iterations of 20 birds on a given field. We group
4 20 birds. We'll track the number of dead in each
5 cohort with the probability of death in each cohort,
6 and we'll take the average across all of those out
7 of...out of 1000 groups of those.
8 The alternative way is just to put 10,000
9 birds into the...into the assessment and follow each
10 bird for 14 days, look at its predicted risk of...of
11 mortality, and then take the average value of those.
12 And in both cases, in the SAP in 2000, what
13 you'll see is that the central tendencies for both of
14 those distributions, which is what we base the rest of
15 our assessment on, the most robust portion of that
16 curve, that central tendency is almost exactly
17 computationally exactly the same. Some little bit
18 difference with regards to rounding and the...the math
19 that's run through in terms of the spread sheet, but it
20 comes up almost exactly the same.
21 So, in...in either case, that central
22 tendency which is then post-processed in a binomial
23 distribution for probability and magnitude of effects
24 where we sit there and use that as the probability of a
25 positive event, in the case of the probability of

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1 mortality, and we use that into a...a cohort of Y
2 birds. And in the case of the...of the TIM 1 model
3 that was run for carbofuran, it was 20 birds on a given
4 field.
5 So, you always start with X iterations of 20
6 birds on a field. You get an average and plug it back
7 through. Or 10,000 birds, take an average and plug it
8 back though. And what's the probability and magnitude
9 of 20 birds on a given field?
10 We could do 1000 birds on a given field or 10
11 birds on a field, and what would just do is provide us
12 more resolution in terms of the...of the extremes of
13 the...of the distributions. We get lots more points
14 and get a better idea where the defection points are in
15 terms of the distributions, but, really, the central
16 tendency outcomes in most of the picture isn't going to
17 change by a great deal.
18 So, let's follow a bird. We pick a species.
19 We randomly pick an individual bird from a distribution
20 of body weights for that bird. We calculate its free
21 living metabolic rate from an...from an allometric
22 equation that's provided in the wildlife exposure
23 factors handbook.
24 To be fair, we didn't look at the
25 distribution of outcomes of that algorithm. We used

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1 the...the most robust version of that algorithm,
2 the...the mean curve, if you will, rather than looking
3 at extremes of the 5th and 95th percentile predictions
4 of that...of that energy requirement. So, we used the
5 on average value for that body weight.
6 For each food group, we randomly pick a gross
7 energy from a distribution of gross energies from that
8 food item from the wildlife exposure factors handbook.
9 We look at how well it's assimilated into...from that
10 dietary item, that energy is assimilated into the bird.
11 We come up with how much...what's the
12 metabolizable energy, then, from the gross energy. We
13 look at...excuse me...what the intake rate would be
14 based on the energy requirement of the bird on a given
15 daily basis and its metabolizable energy.
16 Then, for each one, we look at the daily
17 uptake rate from each food item, and, again, what
18 you'll see is there's an asterisk there, because we're
19 look...going to look further at what the presence of
20 carbofuran might mean in terms of uptake of food.
21 For each food group, we randomly generate a
22 residue. We'll have a little bit more discussion on
23 residue in each of those food items. For each food
24 group, we calculate a residue ingestion rate which
25 would be a function of both the uptake and the residue

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1 value. We calculate a total daily intake of the
2 pesticide.
3 We ask ourselves now, is that...this is a
4 hypothetical daily intake, but the next question is, is
5 the bird on the field or off the field? If the bird is
6 assumed to be off the field, then the intake is zero,
7 because we didn't carry residues off the field in this
8 particular case. We could in subsequent versions, but
9 here, it's a fairly generous assumption that there is
10 no drift off the field.
11 If it is on the field, we assume that the
12 intake rate is related...the intake of the pesticide is
13 related to that total intake rate of the pesticide in
14 that given time step, and then we calculate a total
15 residue for that time step that was ingested by the
16 bird from the treated field.
17 And then, subsequent to that, we allow some
18 of that residue to be dissipated from the bird as we
19 move from one time step to the next. There will be
20 some more discussion...thank you very much...there will
21 be some more discussion with regards to that later on
22 in Dr. Salice's presentations, and then we compare each
23 of those data...those time step estimates of residue to
24 the dose response and ask ourselves a question, where
25 is that bird on the dose response?

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1 We take the peak value of all those residue
2 and those dose responses, and that's the peak risk of
3 individual...peak individual risk for that bird.
4 So, 14 days of exposure, 2 time steps per
5 day, so you're talking about 21 comparisons to the dose
6 response curve.
7 Subsequent versions of the model actually, up
8 front, pick a random tolerance from the dose response
9 for a given bird, and we ask ourselves, is the exposure
10 at the peak value above or below? And then we decide
11 whether or not the bird dies.
12 But here, we looked at where it was on the
13 distribution of possible outcomes, the risk of
14 mortality for the individual.
15 When we look at frequency in a treated field
16 which determines whether or not a bird is on the field
17 in any given time step, the available data are limited
18 to counts of birds inside and out of a particular crop,
19 at least those related to corn and alfalfa within the
20 United States.
21 There are some radiotelemetry data for bird
22 use, time budget information with regards to birds in
23 Europe. We'll talk a little bit about that later and
24 what the authors concluded in two bird...in two
25 publications with regards to their studies, but right

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1 now, we're looking at basically data that's related to
2 census information on the bird. So, it doesn't
3 represent time budgets of individuals. It represents,
4 at best, the probability of birds being on a field at a
5 given time, and even then, are rather loose.
6 Both EFED, the Agency, and the science
7 advisory panel, in evaluating that data, believe that
8 there were basically quite important limitations to
9 that data to use that to look at time budgets, and
10 recognizing those limitations, at the time, was the
11 best thing that we had.
12 What's important to realize that is that
13 while we come up with a probability of being on or off
14 a field, we don't use that probability to multiply by
15 the exposure value. That's critical, because there's a
16 number of risk assessments that we've seen that
17 actually take an exposure value and say the bird is
18 expo...theoretically exposed to 1 mg/kg of a body
19 weight in a given time step, but it's only going to be
20 on the field 50 percent of the time, so the exposure
21 can only be 0.5 mg/kg.
22 We don't use it dilute the exposure. We use
23 the data to decide whether the bird is on the field or
24 off the field in a given time step. If you're on the
25 field, we're assuming you're feeding on the field. If

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1 you're off the field, we assume you're not. Okay?
2 In subsequent versions of the model, we have
3 some modifications to that. We consider the time of
4 the day on how intently you might be feeding, and,
5 also, we consider how likely you are to repeat that
6 behavior over time. We have a fidelity factor we
7 applied to our model.
8 But for the TIM 1 model, it's rather simple
9 in...in its application. We'll look at the effects of
10 the other model on the risk conclusions later on in Dr.
11 Salice's presentations.
12 So, the retention of the chemical-in birds.
13 The purpose is to account for the pesticide body burden
14 from one exposure time step to another. We relied on
15 metabolism data in chickens. We had a lot of
16 discussion about this in...in the first SAP using the
17 exact same data set that was related to, basically,
18 based on carbofuran.
19 We adjust a single L dose 24 it...retention
20 factor which was the result of the chicken data to an
21 appropriate time step. In other words, we look at the
22 rate constant. We solve for a...a...a half-life value.
23 We consider, you know, a first order equation.
24 We had some discussion over whether it's
25 truly first order, and that's probably...if we had

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1 additional data with regards to carbofuran, that might
2 be incorporated in, but we don't at this point in time.
3 We do have some other surrogates for
4 recovery, and we'll discuss those later in Dr. Salice's
5 presentations, but right now, 24-hour retention period
6 led to 17 percent of carbofuran retained from one 24-
7 hour period to the next, and a 12-hour retention set,
8 in other words, our time steps are one each 12 hours,
9 and we set it a constant of 41 percent retained.
10 So, if you solved for 24 hours with a rate
11 constant of 41 percent, you'd end up with 17 percent.
12 So, you can see that they're based on the same
13 endpoint.
14 And, remember, that's based on chickens. So,
15 it's not based on red-winged blackbirds or meadowlarks,
16 et cetera, so I'm sure there are differences there, and
17 that will remain a, for want of a better term, a known
18 unknown, if I can be excused for...for borrowing a
19 quote from someone.
20 EFED relied on summary statistical
21 information for our vegetative food items. We looked
22 at...we...Fletcher provides us with distribution data,
23 central tendencies, means, extremes, and 95 and 5th
24 percentile values, and we constructed log normal
25 distributions for food items for vegetative foot items,

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1 broad leaf foliage, short and tall grass, fruits,
2 seeds, pods, et cetera.
3 There are limited data for field studies on
4 carbofuran, but we did look at that data in terms of
5 the report. You can see it in the...in the report for
6 carbofuran. It was also looked at in terms of the data
7 for the SAP when they evaluated Chemex which was
8 essentially the same data set.
9 The SAP cautioned us, don't rely on
10 individual data for a limited number of studies for any
11 given pesticide unless it's real robust and there's a
12 lot of them. You're probably better off looking at the
13 distribution of information from a variety of studies.
14 And so we, to give it fair hearing, have looked at it
15 both ways.
16 We constructed log normal distributions for
17 those residues for each food item, and we normalized
18 them to application rate. Those distributions are
19 based on the total set of data in Fletcher, et.al. and
20 not parsed out between field...across field data and
21 within field data.
22 And, actually, you can pretty much expect
23 that there might be differences in that variation, and
24 Dr. Salice will talk a little bit about that later on
25 in light of some of the field data we have, some of the

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1 assumptions...alternative assumptions that one could
2 take.
3 Maybe assume that there's no variance on the
4 given field. That would be a convenient calculation to
5 do if we assume that the variability was zero on a
6 given field, and we'll explore whether or not the data
7 would support that and what other al...alternative
8 assumptions could be.
9 For insects, we relied on data from
10 publication by Fisher and Bowers. There's been
11 considerable discussion of the differences between
12 deterministic and probabilistic. The deterministic
13 approach uses vegetative items as a surrogate for
14 insect data.
15 We decided to go one step further and use the
16 actual insect data. There are some questions with
17 regards to that...those distributions, whether there's
18 effects on the basis of size, whether there's effects
19 on the basis of collection method, are we biasing data
20 with regards to having some of that data based on
21 insecticides, in other words, if we're using pitfall
22 traps, if we're looking at residues for insecticides,
23 would we be biasing that data in terms of what was left
24 mobile and running around, or flying, as opposed to
25 things that might be moribund or...or...and...and still

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1 potential food items for birds that might have high
2 residues.
3 But we won't get into that data too much
4 today. We'll just discuss a little bit about
5 variability within fields with regards to that data.
6 So, right now, we're going to take it at face value.
7 The data cov...data cover a variety of
8 application methods, pesticides, and crop areas, and I
9 think that...that we, by using the data right now, we
10 get a pretty good broad, overall picture. We're in the
11 process right now within the Agency of...of tearing
12 that data apart and looking whether we can parse it out
13 into different distributions.
14 That, right now, is not ready for prime time.
15 We still have a considerable amount of peer review to
16 do. I would imagine that some of you might be involved
17 in a subsequent peer review much later on when we
18 finally get those distributions better ironed out.
19 So, for our tox endpoint, we use the acute
20 lethal effects. We primarily rely on the LD50 study.
21 We don't use the dietary studies, and...and the SAP
22 basically said for Chemex, which essentially was the
23 data set for carbofuran, for a compound like that, the
24 LD50 was probably the...the most appropriate to use.
25 It allowed us to have a nice clear dose

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1 response relationship. It allowed us to extrapolate
2 across a variety of pathways, not perfectly, but it's a
3 lot better than looking at a...trying to relate a
4 dietary matrix to drinking water, for instance, or a
5 dietary matrix to a dermal or inhalation exposure, for
6 instance.
7 It is a robust data set for the species. A
8 lot of species have been tested by this method. It
9 does not account for that dietary matrix. You'll see
10 an asterisk where there's additional data that the
11 registrant has provided to us so we can make some more
12 confident assessments and test for those assumptions of
13 whether or not dietary matrix makes a difference.
14 And it provides us with a nice short exposure
15 window rather than something that's stretched out over
16 several days, so we can look at short time steps.
17 The acute dietary exposure studies, they
18 weren't selected primarily because the dose response
19 relationships are rather obscure. They're well related
20 to the concentration in the diet but poorly related to
21 what the concentration is in any given bird. There's a
22 lot of noise in those studies.
23 Primarily, we don't..we don't follow each
24 individual bird to find out exactly what it eats. We
25 don't really account for spillage, et cetera, which

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1 could potentially be important.
2 So, a number of people on the SAP back in
3 2000 said, you know, for the data set you have, let's
4 go with the LD50. And then, there...because that more
5 protracted exposure window, it gets a little difficult
6 to have a relevance to the field where the birds may be
7 on the field one day and off the field the next or
8 even, indeed, on and off the field on subsequent
9 multiple time steps within a given day.
10 The results of our probabilistic assessment.
11 We ran 360 different scenarios just for corn and
12 alfalfa uses. For broadcast application of corn and
13 alfalfa and for each focal species, there were 27
14 separate scenarios that...that involved drinking water
15 present on the field, drinking water not on the field,
16 low, medium and high applications, and low, medium, and
17 high assertions of sensitivity.
18 Here's the output for a single application
19 of...of carbofuran at 0.75. That was the typical
20 application to Midwestern corn. A lot of numbers
21 there.
22 I'd like to draw your attention to how that
23 data is presented. I've got some errors already.
24 Thanks, Jude.
25 There are three assumptions for sensitivity

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1 to the pesticide reflecting our overall uncertainty for
2 a specific species. Okay? We don't test killdeer, for
3 instance. We don't have any data that tested killdeer
4 for actually how sensitive they are to carbofuran.
5 So, we have a high sensitivity assumption, a
6 medium sensitivity assumption, and a low sensitivity
7 assumption pulled from the distribution of possible
8 assump...of...of sensitivities for that given body
9 weight of bird.
10 Then we have three different outputs. These
11 are...these are 1000 runs of 20 bird cohorts on the
12 field. That's the first way we run the model. So, we
13 come up with a central tendency value for the
14 distribution of possible 20-bird results. We come up
15 with a maximum and minimum, in this case, a 5th and 9th
16 percentile.
17 But I...let's go back one more. What I want
18 you to also look at is that you'll see that there's one
19 called RWB which is red-winged blackbird, and you will
20 only see a medium sensitivity assumption there. We
21 don't know exactly where red-winged blackbirds are in
22 terms of sensitivity, whether it's high, medium, or
23 low.
24 We could go back and look at the
25 distribution, but what's important to know is that red-

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1 winged blackbirds were actually tested. They were a
2 tested species. So, we're not going to mess with
3 how...how high or low sensitive it was. We relied on
4 the laboratory data for that particular species.
5 That's why you don't see three different scenarios in
6 terms of sensitivity for that bird.
7 So, what I'd like to call your attention to
8 is those mean values of sensitivity assumption. Those
9 are the things that get plugged into our binomial
10 assumption of 20 birds on a given field.
11 And they range all the way from, for
12 low...birds with very low sensitivity assumptions,
13 regardless of what they eat and how often they spend on
14 the field...how much time they spend on the field,
15 those are largely insensitive birds, and they largely
16 don't have mortality...all the way up to birds with
17 high sensitivity, assumed sensitivity, where mortality
18 ranges anywhere from about 25 percent all the way up to
19 87 percent.
20 Now, if you look at this result, this is for
21 the minimumly effective application, 0.25
22 lb/acre/single application. The values in gray, again,
23 are those 5th and 95th percentiles of those
24 distribution of...of 1000 bird...1000 run cohorts of 20
25 birds. So, what this is, is these are the...the mean

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1 central tendency values.
2 Again, you'll see this on the more typical
3 application rate of 0.7 lb/acre where mortality, again,
4 for very low sensitivities, obviously, is...is zero,
5 and it ranges all the way up to risk of mortality about
6 98 percent for killdeers if they're assumed to be a
7 high sensitivity.
8 What I'd like you to take home from
9 this...this information, at the very least, is is that
10 you'll see that sensitivity matters a great deal.
11 There's a lot of uncertainty in predicting effects for
12 a given species because of the uncertainty surrounding
13 the sensitivity of that species to carbofuran. It's
14 probably one of our biggest drivers.
15 Again, for the highest application rate, this
16 would be the highest maximum application allowable on
17 the label, again, you'll see if you're very low in
18 sensitivity, you don't have much, little or no
19 mortality, and as you get to a high sensitivity, you
20 get quite a bit.
21 What I'd also like you to look at is you
22 start to look for...at the different birds in terms of
23 their sensitivity, that...that range in sensitivity
24 within any given column is a function of primarily two
25 things. More than...the two things are that it's

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1 eating which determines how much it eats and the
2 residues it gets from those values, and the other thing
3 that determines those ranges is how often that species
4 is on the field. So, how often it has the opportunity
5 to be exposed at the rates assumed to occur on a given
6 field.
7 If we take those central...those values and
8 we create those distributions of 20 birds in the
9 binomial, you get three curves, and those three curves
10 reflect the sensitivity. So, I would like you to look
11 at these curves.
12 These are reverse cumulatives which represent
13 the likelihood of mortality greater than or equal to X.
14 Mortality is on the bottom, zero through 20 dead birds
15 out of 20, and the probability being zero to 100
16 percent.
17 What you also see is for untested species,
18 there are three curves which represent the mortality
19 for low, medium, and high sensitivity assumptions, and
20 what you'll see is for low sensitivity assumptions,
21 you're pretty much down near the origin, not a lot of
22 mortality, not often. And as you get up to the high
23 sensitivity assumptions, we bump up close to 100
24 percent mortality, and we bump up to it quite
25 frequently.

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1 And here is our tested species, in this case,
2 red-winged blackbird, and you'll see there is only a
3 single curve, because we're relying primarily on the
4 data set for that single bird species.
5 If we look at all those...those birds, we
6 look at all 27 runs, combinations of sensitivity, and
7 we look at all the different species, we can construct
8 a representative distribution of a...of all outcomes of
9 the median lethal...the median risk assessment. If we
10 go back, go all the way back to these tables, and we
11 take each of these combinations of sensitivity and mean
12 mortality of species, and we treat it as if it was a
13 different...as an individual species.
14 So, obviously, killdeer can't be a medium,
15 and high, and a low sensitivity species at once, but
16 its propensity to be on the field and its dietary
17 matrix may indi...may represent a variety of species
18 and...and the sensitivity range may also represent the
19 potential outcome of a variety of species in terms of
20 their sensitivity.
21 So, if we go back and we look at those...each
22 one of those point estimates and we plot them on a
23 curve, so for all species and sensitivity assumptions
24 modeled, we can come up with mean predicted
25 mortalities, and we can rank and graph it.

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1 Now, it's not a perfect fit, and I haven't
2 fit a curve to this, so it's going to...it's got
3 some...some noise into it, but if you look at this,
4 you'll see that the mean mortality is the fraction of
5 dead birds in 20-bird cohorts at the bottom, and it's a
6 cumulative...reverse cumulative probability, and what
7 you'll see in this case is that about 65 percent of the
8 species sensitivity combinations had at least 10
9 percent mortality with mortality as severe as 98
10 percent.
11 So, what would we conclude from that? Well,
12 we ran through this on all the alfalfa species. What
13 we found was that between 55...alfalfa and corn.
14 Between 55 and 95 percent of the bird species modeled
15 exhibited some mortality, depending on the crop and
16 depending on the assumptions of application rate.
17 The results were dependent on application
18 rate, as I just said, with the greater the rate, the
19 greater the mortality, frequency and magnitude, while
20 on method, banded in furrow applications had less
21 mortality, less frequently, than aerial broadcast.
22 Primarily a function of the residue assumptions and the
23 distribution of those residues across the field.
24 The target crop likely a result of...was
25 likely a result of differing extent of bird use on the

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1 fields. In other words, we have meadowlarks and
2 mourning doves on alfalfa fields and corn fields, and
3 the field data gave us some differing values in terms
4 of the probability of being on a field at a given time
5 step, and the assumption of sensitivity to the
6 pesticide. Obviously, the greater the sensitivity, the
7 greater level of mortality.
8 And those are pretty much our conclusions
9 from our probabilistic assessment. We don't have a lot
10 of time to go into each and every individual result,
11 but that's pretty much what we had.
12 We had one special case which we looked at
13 waterfowl on alfalfa. We have a lot of incidents of
14 waterfowl landing in alfalfa, and we concluded that
15 anywhere up to a few days after application, the
16 mortality events from waterfowl, using mallard duck
17 toxicity data as a surrogate, we...we could get
18 some...some fairly high mortality rates as...as flocks
19 of mallards might arrive on a field after application.
20 And the half-life of carbofuran is relatively
21 short for food items, so as you get farther and farther
22 away from the time of application, the risks become
23 lower and lower there.
24 So, looking at incident in field studies,
25 that third triad of our assessment, we asked ourselves

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1 some questions. We want to first realize that field
2 studies are...are, at best, an imperfect construct.
3 They're very difficult to run, very expensive to run
4 well, there's a lot of noise in them, there's a lot of
5 environmental variability. It's rather difficult to
6 control for things when you start talking about
7 hundreds of acres of application. You might have to
8 deal with confounding factors of other pesticides being
9 present and drifting. You might have even problems
10 with your own pesticide, your test pesticide, drifting
11 onto fields. It's hard to count up birds. It's hard
12 to find all the birds. All of those things.
13 So, the question is, can we really use those
14 for the...the numbers that they present? Are they hard
15 and fast representative values of mortality, for
16 instance?
17 But what we want to look at those val...those
18 field studies for is the first question, are one or
19 more exposure routes complete? So, I want you to
20 remember that. Do the field studies and the incident
21 studies tell us whether or not there are exposure
22 routes that are potentially complete?
23 And are our laboratory-based predictions of
24 effect...remember, we used laboratory data for our feed
25 toxicity...the question is, are those effects

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1 manifested in the field?
2 Our conclusions for incident reports...and
3 Dr. Panger is going to go into some depth on this after
4 I get through boring you guys to tears...our...our
5 conclusion was when carbofuran used as currently
6 registered, wildlife mortalities can and do occur.
7 When we looked at avian field studies, our conclusions
8 were carbofuran is measurable in the avian diet. So,
9 again, we're asking ourselves, do we have a complete
10 exposure pathway? And, again, carbofuran used at
11 current application rates, can it adversely
12 affect...impact wildlife, both on a mortality and
13 incapacitation basis, all the way through reproductive
14 impairment?
15 So, Dr. Panger, again I say, will...will
16 discuss this more fully in...in a subsequent
17 presentation.
18 So, our overall conclusions, let's wrap those
19 up as you might see it in the assessment. The
20 deterministic model, one or more exposure pathways are
21 assumed complete. Those exposure levels meet or exceed
22 levels shown to cause adverse effects in the
23 laboratory, mortality and reproduction.
24 On the probabilistic basis, those exposures
25 are variable, but one or more pathways are complete.

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1 Exposure levels are sufficient to cause mortality based
2 on laboratory effects data. Mortality is frequent and,
3 under some situations, it can be severe.
4 Incident monitoring and field data suggest
5 that one or more exposure pathways are complete, and
6 exposure levels are sufficient to result in some field
7 observable effects, not...not to be limited to
8 mortality, incapacitation, and reproductive effects.
9 So, there were some key scientific issues
10 from the SAP review of TIM, and we talk about that,
11 because a lot of our data today is going to be
12 evaluated using that model. There were...there were
13 issues related to focal species selection, the
14 frequency of birds treat...on treated fields, frequency
15 of birds on treated fields and how we set those
16 parameters, the consideration of drinking water source
17 selection, puddle persistence, concentrations in
18 drinking water, residues in food items, residue
19 clearance from focal species, selection of exposure
20 time steps...remember we used two time
21 steps...selection of acute toxicity standard, defining
22 the distribution of species sensitivity, and other
23 factors affecting sensitivity.
24 We looked at some new data, and what do they
25 tell us about some of those issues related to the

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1 science advisory panel's approach? Well, they gave us
2 some...we have some new data on...on...in terms of
3 looking at residues in food items. We looked at
4 residue clearance in focal species. We have new data
5 with regards to possibly changing residue clearance and
6 substituting some acetylcholinesterase recovery as a
7 surrogate for residue clearance.
8 The selection of acute toxicity standard, in
9 this case, how dietary matrix might affect the acute
10 toxicity standard, and then some other factors
11 affecting sensitivity.
12 Also, when we start talking about residues in
13 food items, we also would talk about the dosages, and
14 we have some additional data with regards to whether or
15 not a bird will actually use treated food from
16 carbofuran-contaminated food items, and, if so, is that
17 avoidance or is that some other...manifested in some
18 other way?
19 So, all that we'll talk about a little later.
20 Dr. Salice will present some of his analysis using the
21 TIM 1 model and, indeed, as appropriate, whenever new
22 data is appropriate, how it might fit into the TIM 2.1
23 model and how that might change our...our
24 interpretations.
25 Now, the 2.1 model also looked at focal

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1 species selection. We went from actual species to
2 generic species, so you'll see how the TIM 2.1 model
3 affects results when we incorporate that recommendation
4 from the SAP. Frequency of birds in treated fields and
5 setting those parameters, there's some subtle
6 differences in 2.1 versus 1.0.
7 In terms of fidelity factor where we can
8 actually incorporate assumptions of how strongly does a
9 bird adhere to its initial choices of being on the
10 field or off the field. We could, in that way, deal
11 with data with regards to avoidance, for instance, if
12 the data was robust enough for us to include into the
13 assessment. Or, indeed, whether or not we could deal
14 with other things such as prey availability and whether
15 or not the presence of a pesticide, if we did have
16 data, would suggest whether a bird might use a...a
17 field more intently than on average.
18 Then, we could also consider drinking water
19 sources and how those source selections were instead of
20 just using PRZM EXAMS results or PRZM results. We
21 actually constructed actual model puddles in TIM 2.1.
22 Got a lot of talk about that and a lot of favorable
23 response, and that's actually something that we've
24 incorporated into version 2.1.
25 Puddle persistence, how long the puddles

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1 last, we had some questions with regards to...in...in
2 evaluation of TIM 1 on puddles being on the field
3 before applications are made, whether or not there
4 would be direct application of those. We actually can
5 consider that in 2.1.
6 Concentrations in drinking water and
7 selection of exposure time steps. Our TIM version 2.0
8 and 2.1, as it's finally gone through the SAP, that 2.1
9 has hourly time steps. So, you'll see the effects of
10 hourly time step assumptions and how that affects the
11 results of the risk assessment at...in contrast to what
12 was done in 1.0 which was just basically two 12-hour
13 time steps.
14 We also look at alternative input
15 assumptions. It's very important to realize that I
16 don't think anybody has a lot on frequency of birds on
17 treated fields. So, we're going to look at some
18 alternative assumptions in setting parameters there and
19 how that results in changes to our assessment.
20 We look at residues in food items, variance
21 across fields and within fields, and whether or not
22 there are data that are available to allow us to make
23 in-depth and...and highly specific assumptions of
24 variance between and among fields and within fields,
25 and what those assumptions might look like if you take

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1 the val...the data at face value today.
2 And then, selection of exposure time steps.
3 Again, we go from 12-hour time steps to 1-hour times
4 steps. How does that result in changes to our risk
5 assessment?
6 And I, at this point in time, I'll open it up
7 to questions.
8 **DR. HEERINGA:** Actually, what I'd like
9 to recommend, Dr. Odenkirchen, is that we take a 15-
10 minutes break and then return for a considered set of
11 questions to you on this presentation.
12 To the panel, a few administrative issues.
13 Dr. Hattis, Dale, in response to your question on the
14 IRED, you did not get the actual document. Copies are
15 being made.
16 **DR. HATTIS:** Okay.
17 **DR. HEERINGA:** You'll have that
18 available to you. Reminder to panel members, too, as
19 we enter our question session, be sure to introduce
20 yourself by stating your name before you ask the
21 question, so that way you'll get on the recording.
22 So, let's return here at about 10:41, 10:42,
23 15 minutes from now. Thank you, everyone.
24 **(WHEREUPON, a brief recess was taken.)**
25 **DR. HEERINGA:** Good morning, everyone,

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1 again. Welcome back to the second half of our first
2 morning session on the topic of the scientific issues
3 associated with the Agency's proposed action under
4 FIFRA 6(b), Notice of Intent to Cancel Carbofuran.
5 At this point in the process, we have begun
6 the series of scientific presentations by the EPA
7 Environmental Fates and Effects Division scientific
8 staff, and Dr. Odenkirchen has given his presentation,
9 and we are at a period where I would like to open it up
10 to our panel members for questions of clarification on
11 the presentation or on the materials that were
12 submitted related to this presentation.
13 Just a...a general comment for everyone's
14 sake at this point. This process of presentation and
15 question and answer is going to probably delay our
16 schedule a bit through the course of this day and, I
17 suspect, tomorrow morning as well and the public
18 comment period. So, again, it is a floating agenda,
19 and I'll try to keep you apprized of where I think we
20 are with respect to the overall agenda and timing, but
21 at this point, let's dig into these issues here.
22 Questions from the panel for Dr. Odenkirchen
23 on this presentation? Dr. Hattis, I know you had one
24 before. Are you ready there, or are you going to wait
25 and...Dr. Edler?

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1 **DR. EDLER:** Well, I think it's two
2 questions. I think a simp...one simple question. One
3 thing is just if you...if we have these two models now,
4 the TIM 1.2 and the TIM 2.1. Is it actually that the
5 2.1 is...the first one, the 1.0, is that really a
6 subset of the 2.1 so that you could actually check in
7 some sense by the 2.1 the earlier one, or are they in
8 some way not so that you can just say well, we can do
9 simple things with the first one but the more
10 complicated things with the second one?
11 **DR. ODENKIRCHEN:** All of the above. No,
12 the TIM...first off, the TIM 1.0 and 2.1 differ in one
13 very fundamental way. One is done in a spreadsheet
14 crystal ball type of environment, and TIM 2.1 is done
15 in a...in a...in a C program environment. It's
16 actually a stand-alone program.
17 Essentially, TIM 2.1 represents an iterative
18 step of...of refinement beyond TIM 1.0. So, if you
19 wanted to run...if you wanted to run TIM 2.1 exactly
20 like TIM 1.0, it's entirely possible to do so. It's
21 impossible to run 1.0 like TIM 2.1, however. There's a
22 lot of other functionality that's been built in.
23 The big differences between the models are
24 TIM 1.0 deals entirely with dietary exposure and
25 drinking water exposure, drinking water as a function

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1 of contamination in on-field dew and on-field puddles.
2 TIM 2.1 deals with dietary drinking water, dermal, and
3 inhalation, and the algorithms that are used to
4 calculate concentrations in drinking water are
5 different, quite fundamentally, and represent a much
6 more advanced procedure at the instructions of the SAP.
7 And then the inhalation and dermal sort of represent
8 what...what we would like to think is about as far as
9 you can go with the existing data sets that you have in
10 terms of dermal and inhalation.
11 So, you can turn those on and off. You
12 can...you can actually change the puddle
13 characteristics to be much closer to TIM 1.0. They
14 won't be perfect. You can adjust everything even in
15 terms of the bimodal feeding pattern and time steps to
16 mimic what happens in TIM 1.0.
17 But they do remain fundamentally different
18 models. They do have some of the same underlying
19 distributions in them in terms of variability of
20 residues, et cetera, et cetera, but they are two
21 fundamentally different models in terms of their
22 construct.
23 **DR. HEERINGA:** Sure, Dr. Edler, a second
24 question?
25 **DR. EDLER:** That was about the earlier

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1 part of your talk about when you showed the
2 deterministic model, where you had the deterministic
3 model and the probabilistic model. In the
4 deterministic model, actually, you come up with...with
5 single figures like the RQ value or the...the NOEL or
6 NOAC value and so on. My question is when you do the
7 deterministic approach, you still have, I think, from
8 time to time, you have dose response data, so you could
9 actually analyze then a dose response curve and then
10 actually get some...also some variability estimates
11 from the...in the deterministic framework.
12 So, my question was, was that done also in
13 the deterministic framework, or did you then just
14 switch over with the whole thing to the probabilistic
15 model?
16 **DR. ODENKIRCHEN:** Switched over to the
17 whole thing. Rather than pick and choose distributions
18 from there, we tried to take the whole thing over.
19 One thing that we did do in the...that you'll
20 see in the report for TIM 1 is we did not vary the
21 slope. We picked just...we picked a constant slope for
22 the dose response. It's the mean slope of all the
23 species tested, so we didn't park it on either end of
24 the...of the...of the distribution of possible outcomes
25 there, but yes, for the deterministic, we just do an

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1 archeal LD50 divided into...
2 **DR. HEERINGA:** Dr. Sparling?
3 **DR. SPARLING:** Don Sparling from
4 Southern Illinois University.
5 In the materials that we were given ahead of
6 time for review...and I might not have the terminology
7 correct in a regulatory context...but it seemed to me
8 it was alleged that TIM 1 and 2...TIM 2 were, for lack
9 of a better term, not approved for risk assessment
10 officially, and I...that may be an inappropriate term,
11 but there was some question as to whether TIM 1 and TIM
12 2 were...had gone through all the ratification
13 necessary for a risk assessment.
14 **DR. ODENKIRCHEN:** I'll pass that off to
15 one of our policy people, because that's not a science
16 issue at this point.
17 **DR. HEERINGA:** Dr. Bradbury?
18 **DR. BRADBURY:** Thanks. The...as Dr.
19 Odenkirchen described, the deterministic methods as
20 well as the probabilistic methods have gone through
21 various peer reviews by the science advisory panel,
22 public process, public response in terms of development
23 of the model, and so, in the context of doing the risk
24 assessments that were undertaken, yes, they have gone
25 through the process that...that the Agency requires in

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1 terms of documentation, in terms of document and peer
2 review, and being transparent on how the model is
3 worked.
4 And, again, as we'll...subsequent speakers
5 will talk about the...the risk assessment process as
6 one that tries to bring together multiple lines of
7 evidence to see if there is concordance among different
8 approaches and...and that is in the context of how
9 these tools were used, but the...the bottom line is
10 yes, the models have been through the peer review
11 process and the Agency's review process in terms of how
12 it's being used in a risk assessment.
13 **DR. HEERINGA:** Dr. Grue and then Dr.
14 Clark.
15 **DR. GRUE:** Chris Grue, University of
16 Washington.
17 You noted that sensitivity is a big driver in
18 your results, in your modeling. How...how did you
19 decide or how does the model decide what sensitivities
20 to assign to different species in terms of the category
21 of high, medium, and low? I don't understand.
22 **DR. ODENKIRCHEN:** The
23 sensity...sensitivity is done outside of the model.
24 It's external to the model. So, what we do is we take
25 the data, all the endpoint data. We take a

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1 representative body weight for the species tested, and
2 we normalize all the data to a standardized body
3 weight, eliminating the variability associated with
4 body size as it may relate to sensitivity.
5 So, then we have an underlying sensitivity
6 associated with species differences, other biochemical
7 differences, et cetera. We take those, and we
8 construct a distribution. It's a Eilenberg slope
9 procedure. I think it's a modified T distribution
10 which is...which is done, and then we take a point at
11 the 5th, 50th, and 95th percentile, and they are the
12 mean estimates at the 5th, 50th, and 95th.
13 There are some approaches that are done that
14 take the lower bound of the 5th percentile and the
15 upper bound of the 95th percentile and, you know,
16 expand the...the range out. We just took the mean
17 values of each of those.
18 It's a process that we've discussed at some
19 length even with the Canadian government. They do it a
20 little bit differently. They, rather than construct a
21 distribution that way and normalize out for body
22 weight, they treat body weight as a covariant. I'm not
23 a statistician, so the actual nuances of how that
24 changes the 5th and 95th percentile, you'd have to talk
25 to somebody else about.

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1 But the process that we do is external to the
2 model. There's a separate spreadsheet that allows us
3 to...to construct that distribution. And it would be,
4 you know, naturally, the smaller number of tested
5 species that you have, the bigger and wider that
6 distribution becomes.
7 **DR. HEERINGA:** Dr. Clark?
8 **DR. CLARK:** Larry Clark, Department of
9 Agriculture, National Wildlife Research Center.
10 As a bit of a follow-up to that
11 question...thank you for that...relative to the
12 allometric relationship between, you know, LD50, for
13 example, and...and the response and the concentration,
14 what correction factors or did...would the sensitivity
15 analysis look at taxonomic differences? You said you
16 looked at species differences, but there might be, for
17 example, ordinal fat family influences on the...
18 **DR. ODENKIRCHEN:** Right. What we do is
19 we used a...we use a allometric fat correction factor
20 that was done for acute toxicity values for...to
21 normalize for. In other words, there's a...a document
22 that was done by...oh, the name escapes me right
23 now...up in...up in Wildlife Canada...
24 **SPEAKER:** Pierre.
25 **DR. ODENKIRCHEN:** Pierre, thank you.

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1 Pierre actually went through and...and cor...and
2 generated body weight allometric sensitivity
3 relationships for a variety of different chemicals.
4 So, we used the one specific for carbofuran from that
5 data set to allow us to normalize that.
6 **DR. HEERINGA:** Dr. Clark, follow-up
7 question?
8 **DR. CLARK:** But I guess what I was
9 getting at is that even though there might be
10 allometric relationships for a particular pesticide,
11 there still might be taxonomic influences that
12 influence the parameter of weight.
13 **DR. ODENKIRCHEN:** Absolutely, yeah. We
14 don't divide out, you know...you know, for anise or
15 some other, you know, taxonomic grouping. They're
16 still lumped together. There's probably about
17 every...I think when you start talking about a compound
18 like carbofuran, while it's the most robust acute
19 toxicity data set we have for birds, there's still not
20 a whole lot of birds in there. And so, you start
21 parsing out the different, you know, taxonomic groups,
22 and your N sizes get really, really small, and your
23 distributions start really blowing up. So, we kind of
24 worry a little bit about, you know, doing some sort of
25 artificial precision in terms of what we're, you know,

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1 we're really polishing.

2 **DR. HEERINGA:** Dr. Delorme?

3 **DR. DELORME:** Peter Delorme, Health

4 Canada. In your probabilistic risk assessment, you

5 chose a time period of 14 days for your aid in

6 assessment. Can you just share with us how you arrived

7 at 14 days? Is it based on the chemical, or is it just

8 based on computational power or other considerations?

9 **DR. ODENKIRCHEN:** Both. We felt that 14

10 days is pretty reasonable for a compound with such a

11 short half-life like carbofuran. Residue

12 it...residence times were fairly short. So, we

13 probably captured the majority of what's happening in

14 terms of we've captured, over 14 days, several half-

15 lives. So, we're rapidly getting into diminishing

16 returns in terms of exposure.

17 Would I choose that same kind of exposure

18 window for a compound that hung around forever and a

19 day? No, probably...that would probably be an

20 underestimation of potential exposure, but for

21 carbofuran, in fact, that was reasonable.

22 But the other part of that coin is that

23 running it in a spreadsheet environment with 10,000

24 equations done 10,000 times, you had to cut it off at

25 some point in time, and that seemed to be a reasonable,

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1 two weeks.
2 It also reflects sort of the intervals
3 between one application to the next, 7 to 10 days. We
4 figure we're probably pretty well covering an outward
5 bound of the interval.
6 **DR. DELORME:** Just as another question,
7 in...you said that in your documents, you...when you
8 used TIM 1 and TIM 2.1, that you only did single
9 applications. Have you done the analysis with multiple
10 applications, or are even multiple applications allowed
11 at this point?
12 **DR. ODENKIRCHEN:** I don't recall whether
13 multiple applications are...are allowed at this point
14 in time, but no, we have not run them. So, everything
15 that you'll see over the course of today and tomorrow,
16 probably, are single applications.
17 **DR. HEERINGA:** Dr. McCarty and Dr.
18 Sample and then Dr....
19 **DR. MCCARTY:** John McCarty, University
20 of Nebraska at Omaha.
21 The field metabolic rate that was input in
22 the model is...first, is that done the same for both
23 models? And does the equation take into account in any
24 way the...the variation in field metabolic rate with
25 stage and life history?

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1 **DR. ODENKIRCHEN:** First one is yes, and
2 the second one is no. It uses the field metabolic rate
3 associated with adult measurements. It doesn't deal
4 with, you know, nestlings or...or fledglings or
5 anything.
6 **DR. MCCARTY:** But to clarify, so,
7 essentially, non-breeding adults, adults not...
8 **DR. ODENKIRCHEN:** Right, I think they're
9 all non-breeding adults. I don't think there's much in
10 terms of the...the data set. I don't...I haven't
11 pulled apart the entire data set that's used for that
12 field metabolic rate equation that's in the Wildlife
13 Exposure Factors Handbook. To the best of my
14 knowledge, it's...it's non-breeding adults. It's
15 primarily derived from...from lab data ramped up, I
16 think.
17 **DR. HEERINGA:** Dr. Sample?
18 **DR. SAMPLE:** Brad Sample from CH2M Hill.
19 I have two questions right now. One is just
20 to clarify the toxicity values that you included from
21 the high, medium, and low are entered into the
22 probabilistic models as point estimates. Correct?
23 **DR. ODENKIRCHEN:** That is correct. What
24 we do for ea...we do a scenario, a high, medium, and
25 low scenario.

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1 We could do a distribution of those,
2 probably, in an outer loop type thing, but at this
3 point in time, it would mull up the computations in
4 the...in the model. There are so many computations to
5 run, it would probably take 14 hours to run.
6 So, what we did is we felt that we would
7 bracket it and...with scenarios and find out what the
8 role of that area of uncertainty would be in terms of
9 the overall predictions of the model, and then, how
10 might we look at that interpretation to give us some
11 greater light in terms of, you know, what might be the
12 responses across a variety of species.
13 But, yeah, we did...you know, it could be run
14 the other way but just not in this environment.
15 **DR. SAMPLE:** Okay. The other question I
16 had really relates to both TIM 1 and TIM 2.1, and
17 do...do either of these models take into account
18 dependencies amongst the variables, correlations, so
19 that when you do...are selecting the...the R values
20 from the distributions in the Monte Carlo that you're
21 actually having the correlations taking...taken into
22 account?
23 **DR. ODENKIRCHEN:** Let me see. I'm
24 trying to think what tests were conducted. It's been
25 some...quite some time since we did this. I could

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1 prob...I could probably give you a more accurate thing
2 if I go back and review with some of the other people,
3 but most of our value...variables were dealt with
4 primarily as independent variables. I don't think we
5 have any tests for dependency built into the model, so
6 we haven't, you know, done any correla...there's no,
7 you know, correlation time that's put into the model
8 for most things.
9 The only thing I would say is in TIM 2, there
10 is a...a high degree of correlation between times put
11 on the field and the fidelity factor, because that is a
12 mathematical function. It's a marked up chain model,
13 so there's a high degree of correlation there.
14 **DR. HEERINGA:** Dr. Sparling and then Dr.
15 Montgomery.
16 **DR. SPARLING:** Don Sparling from
17 Southern Illinois University.
18 It may be argued that looking at LD50 based
19 in the laboratory studies could be possibly
20 conservative when you're looking at field situations.
21 Has there ever been an attempt to try to model
22 secondary effects, indirect effects such as predation
23 on moribund birds?
24 **DR. ODENKIRCHEN:** No, not in the
25 assessment that you've seen. We considered, for

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1 endangered species assessments in the future, potential
2 secondary exposures, but we...what we term biologically
3 vectored exposures, but that's not incorporated in this
4 assessment, since this is not dealing with endangered
5 species.
6 What we have included, though, is the effects
7 of dietary matrix into the overall conclusions of the
8 risk assessment, and, of course, Salice will present
9 the results of that for you later today.
10 **DR. HEERINGA:** Dr. Montgomery?
11 **DR. MONTGOMERY:** Could you clarify for
12 me, please, the frequency determination? It says on
13 one of your slides that it was...you had a selection,
14 selection criteria. It says the model uses census
15 data.
16 **DR. ODENKIRCHEN:** Yeah.
17 **DR. MONTGOMERY:** Could you clarify what
18 you mean by census data, what its sources are?
19 **DR. ODENKIRCHEN:** Basically, the census
20 data comes from two big sets of data. One is the data
21 that's submitted in support of...of carbofuran
22 registration, field study data from the late '80s.
23 **DR. MONTGOMERY:** From FMC?
24 **DR. ODENKIRCHEN:** From...I can't recall,
25 but I think it is from FMC. And then the other data

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1 is data that's available from the literature, and the
2 census data primarily is counts, simple counts at given
3 points in...in time.
4 We'll have some discussion in terms of how
5 field studies were set up in terms of how birds were
6 monitored, et cetera, but in short, most of the census
7 data is limited to certain site...sections of the
8 fields. It's limited to certain...you don't know
9 whether you're counting the same bird over and over and
10 over again, so it's entirely bi...it could be entirely
11 biased one way or the other, but it's the best data we
12 have. You know, you could be counting the same bird
13 over and over and over again on the field and treat
14 them as separate birds. So, there's that.
15 The problem is that that's probably the best
16 data we have. What we would like to have for improving
17 the assessments overall for a variety of chemicals is
18 additional data on time budget analysis, because then
19 we could actually determine, but right now, the...the
20 status of the science is...is that where we do have
21 time budget analysis, it's not for native species and
22 not even in native systems.
23 So, we're relying on that census data,
24 knowing its limitations, and trying to use it in ways
25 where we can test a variety of outcomes from it. So,

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1 we have different species that range anywhere from, you
2 know, a few percent poten...potential to be on the
3 field to up to 80 percent potential to be on the field,
4 and when you start evaluating everything, you realize
5 yeah, that is a big driver. More...additional data
6 could be useful there, but right now, I don't think
7 anyone's got...done a study that they can give us on
8 that.
9 But, again, it's just simple counts, so we're
10 using it as a surrogate for whether the bird is on the
11 field or off the field, not the percent of diet that
12 it's getting when it's on the field, et cetera.
13 **DR. MONTGOMERY:** May I ask a follow-up?
14 **DR. HEERINGA:** Go ahead.
15 **DR. MONTGOMERY:** Do you...you had said
16 that you had some literature in addition to data that
17 had been submitted by the registrant. What was your
18 process for selecting which studies or census studies
19 you would incorporate?
20 **DR. ODENKIRCHEN:** Gather all of the few
21 studies that are there...
22 **DR. MONTGOMERY:** I'm interested
23 more...more of the quality.
24 **DR. ODENKIRCHEN:** The quality studies...
25 **DR. MONTGOMERY:** What were the criteria

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1 for deciding was the study worthwhile to keep or not?
2 Because, as we know, there's a wide range of science
3 quality.
4 **DR. ODENKIRCHEN:** Well, I think that the
5 majority of the stu...the majority of the issues with
6 regards to evaluation of those data were much like we
7 would evaluate most laboratory data, was we had...if
8 there was a methodology that we can understand, first
9 and foremost, and number two is are the data
10 being...are the data generated being used to answer a
11 specific hypothesis that meets our...that matches up
12 with what we're doing.
13 What we don't want to do is
14 find...change...you know, use data that's not suitable
15 for a particular question that we're answering. So, we
16 try and use data that's...that was meant to come up
17 with counts and...and use information.
18 Did we...did we apply a specific review
19 criteria, you know, like a standard evaluation
20 procedure or something like that? No. So, it was
21 primarily can we understand what was done and did it
22 match up with the types of crops that we're...we're
23 dealing with, and when there are important differences,
24 can we understand how those differences might matter.
25 One of the major differences in some of the

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1 information that was used and brought up in the SAP was
2 the issues with regards to Conservation Reserve
3 Program, the CRP fields versus fields in crop versus
4 edge fields, and there are some confounding factors
5 there, but I think the data sets are kind of small for
6 us to really parse out the influence of CRP from other
7 things. There may be some differing opinions on that,
8 but we have not explored that at any rate.
9 **DR. HEERINGA:** Dr. Bailey and Dr.
10 Sample.
11 **DR. BAILEY:** Ted Bailey from Iowa State.
12 I believe you talked about use of covariants,
13 uses of covariants. Is that fair?
14 **DR. ODENKIRCHEN:** That's what the
15 Canadians have done with regards to sensitivity
16 distributions. That's not in our...
17 **DR. BAILEY:** Okay. My question is, what
18 would have been the purpose of the covariants in the
19 context of what we're talking about here?
20 **DR. ODENKIRCHEN:** You'd have to ask
21 Peter.
22 **DR. DELORME:** Covariant of weight.
23 Peter Delorme, Health Canada. Covariant of weight,
24 because weight can influence toxicity, apparently.
25 There are...there is paper out there. I could provide

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1 you with the references tomorrow.

2 **DR. BAILEY:** Okay.

3 **DR. HEERINGA:** Dr. Sample?

4 **DR. SAMPLE:** Thank you. I had another

5 couple of questions. The first relates to your diet

6 preference identification. When you incorporated this

7 in the model, did you have the species consuming a

8 single food type, or was it a...a composite of multiple

9 food types and their differing proportions?

10 **DR. ODENKIRCHEN:** For the omnivores,

11 it's a composite, and that's based on literature data.

12 We did not vary the composites. In other words, you

13 know, for one bird, 60 versus, you know, 40 percent, et

14 cetera. We...we left them as a fixed, but we have a

15 range of everything from 100 percent seed eaters to 100

16 percent insect eaters and then things in between,

17 different composites.

18 **DR. SAMPLE:** Okay. The second question

19 has to do with sort of the implementation of the model,

20 and it's...I think you said earlier it's focused on a

21 single field?

22 **DR. ODENKIRCHEN:** Yeah.

23 **DR. SAMPLE:** And a question I have is

24 probably more rhetorical than sort of application of

25 the model is this pesticide is not applied as a single

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1 field. It's frequently in a landscape context with
2 multiple fields, and has EPA, in their analysis,
3 considered looking at what are the implications
4 of...because we're looking at when the birds are off
5 site that they're...you know, the assumption is that
6 they're not exposed to anything, and that assumption
7 has some serious concerns to me, particularly if we're
8 talking about these large agro ecosystems that, when
9 they're off site, you know, they may be being exposed
10 to additional carbofuran or to another cholinesterase
11 inhibiting compound so that their exposures on site are
12 going to be exacerbated by whatever they've experienced
13 elsewhere.
14 Has that been considered as being a part
15 of...as part of the model?
16 **DR. ODENKIRCHEN:** It has been considered
17 and discussed, and it has not been modeled to date.
18 **DR. HEERINGA:** Dr. McCarty?
19 **DR. MCCARTY:** John McCarty. This is a
20 follow-up to something you responded to Dr. Montgomery.
21 You're...in the translating those field studies into
22 field use and consumption, you mentioned the possible
23 uncertainty about how to deal with things like CRP, and
24 I guess I'd like some clarification how...how those
25 uses are considered, a CRP field adjacent, a buffer

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1 strip versus even habitat within a field like grassy
2 terraces, waterways, things like that, and perhaps even
3 a more general clarification of the spatial scale used
4 in the model in general.
5 **DR. ODENKIRCHEN:** Okay. First and
6 foremost, the...the study only...the model only treats
7 fields and buffers as two distinct compartments, so it
8 doesn't evaluate any transition zones between edge and
9 farther afield, et cetera. You're either on the field,
10 or you're off the field. And if you're on the field,
11 you get exposure; if you're off the field, you get zero
12 exposure.
13 With regards to the quality of edge habitat,
14 the quality of edge habitat is not built into the
15 model. The model is assumed that whatever values that
16 we saw from the literature represented a reasonable
17 sweep of habitat types in those edge environments,
18 those edge...areas adjacent to the cultivated field,
19 and, therefore, we relied on that information in
20 general.
21 So, the question is, did we consider whether
22 or not if there was a presence of a waterway or a...or
23 a...or a windbreak or something of very high quality
24 and very highly attractive or of high resource versus
25 low resource and make determinations in how that would

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1 affect the model? That has not been built into the
2 model.
3 So, you'll get a range of values from the
4 utilization of the crop versus non-crop areas. How CRP
5 has affected that is the interpretation of what's crop
6 and what's not...non-crop. That...that can result in
7 some changes in the distri...in the interpretation
8 there. And we have not, to date, explored all that
9 information.
10 I think it's important, though, to realize
11 that we still end up with a suite of...of ranges of
12 wildlife utilization that go from very low to quite
13 high. So, we run from anywhere from about 12 percent,
14 I think, time spent on field to...or possibility for 12
15 percent potential to be on the field at any given time
16 up to 80 percent. So, we have a pretty good wide
17 range.
18 **DR. HEERINGA:** Dr. Grue?
19 **DR. GRUE:** Chris Grue, University of
20 Washington.
21 Just to follow up on that and the earlier
22 comments related to the application of census data,
23 could you clarify how you take...how you took the
24 census data and then translated that to 12-hour
25 on...your 12-hour time?

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1 **DR. ODENKIRCHEN:** Yeah, all we do is we
2 take the...the...the counts on and off the field from
3 the census data. That gives us a proportion of birds
4 on and off the field, and we use that as a surrogate
5 for the probability that a bird at any given time will
6 be on or off the field.
7 We take that, and we assemble a distribution
8 from the range of results from those counts. We
9 assign...we assign a distribution to that species, and
10 then we randomly sample for each individual bird and an
11 initial probability to be on the field in TIM 1.
12 So, you may be 12 percent likely to be on the
13 field at any given time step or 50 percent or 100
14 percent, and so, that...that probability stays with the
15 bird throughout the entire run of the model in TIM 1.
16 In TIM 2, it's a mark-off chain, so whatever
17 the decisions were made for the bird to be on the field
18 the first time, it's influenced by the overall mean
19 value for all birds within that species, and then, the
20 fidelity factor or the propensity to adhere to that
21 behavior. So, the...basically, they're all driven from
22 the counts which are just simple ratio, and then that's
23 translated into time spent on the field...or not time
24 spent on field, the potential to be on the field. It's
25 very important to make that distinction.

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1 **DR. HEERINGA:** Additional questions from
2 the panel? Obviously, if something occurs to you
3 during the course of the other presentations, you
4 reserve the right to revisit that.
5 **(No response.)**
6 **DR. HEERINGA:** Not seeing any additional
7 questions at this point in time, I think that we're
8 ready to move on to the second of the presentations,
9 and I think this is Dr. Melissa Panger.
10 **DR. PANGER:** So, good morning, everyone.
11 So, as mentioned in some of the earlier talks, one of
12 the lines of evidence that the Agency used in its
13 ecological risk assessment for carbofuran were field
14 data which included reported ecological incidents and
15 field studies which also included some monitoring
16 studies that were submitted by the registrant, FMC.
17 Now, due to serious shortcomings of these
18 lines of evidence, of these data which I'll be
19 discussing throughout this talk, the...they do not
20 allow for the quantification of the level of wildlife
21 mortality that's associated with carbofuran. However,
22 taken together, what they do demonstrate is that when
23 carbofuran is used as currently registered or at
24 currently registered application rates, then wildlife
25 mortality, especially in birds, can and does occur.

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1 And I'll be starting with the ecological
2 incident reports, and this is a standard line of
3 evidence that the Agency uses in its ecological risk
4 assessments, and when we're looking at the incidents
5 related to a specific chemical, in the case here of
6 carbofuran, it's important to understand or look at the
7 incidents in the context of the Ecological Incident
8 Information System, or the EIIS, which is the
9 Environmental Fate and Effects Division's...that's the
10 database that we use to explore wildlife pesticide
11 incidents associated with particular chemicals.
12 Also, it's important to understand that this
13 database contains reports submitted primarily from
14 state agencies and from toxicology laboratories, and
15 the submission of the reports by these entities is
16 completely voluntary. And we also do get some reports
17 from the registrants which are under some reporting
18 requirements which I'll discuss later on in the talk
19 briefly.
20 Now, another important thing to consider is
21 that there is no national level systematic program for
22 the monitoring of pesticide ecological incidents, so
23 the data that...that populate the database, the EIIS,
24 were not collected systematically. Also, we know that
25 the ecological incidents in our database likely

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1 represent a very small fraction of the actual incidents
2 that occur, and the question is why.
3 Well, there are several reasons. One is that
4 carcasses can be very difficult to see. Anybody who's
5 ever tried to go out and do a monitoring study or look
6 for dead...dead animals in an area, especially with a
7 lot of groundcover, understand the difficulty of this,
8 especially when you consider that most animals, when
9 they're sick and are dying, will try to hide
10 themselves, conceal themselves as a defensive mechanism
11 against predation.
12 And just to illustrate the difficulty in
13 finding carcasses, when people are trained to go out
14 and do carcass searching, the carcass efficiency rates
15 which are normally based on some...sometimes a carcass
16 randomly placed in search areas are almost always below
17 100 percent. So, even trained individuals going out
18 and looking for randomly placed objects, things that
19 aren't hiding, rarely find all of the...the objects in
20 a search area, especially if there's a lot of
21 groundcover.
22 Also, incidents involving agricultural
23 pesticides typically occur in agricultural areas which
24 tend to be rural, so there may not be a lot of people
25 around to witness a carcass. And then, carcasses can

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1 be removed from sites of application or sites of the
2 incident through mechanisms such as scavenging or
3 decay.
4 Also, even if the carcass is seen, that
5 doesn't mean somebody's going to report it. Somebody
6 who sees some carcasses, especially if it's just a
7 couple of birds or mammals lying around scattered, may
8 not realize the importance of...of reporting the
9 incident, or they simply do not know who to report the
10 incident to, and this does vary by state and, actually,
11 within regions of states, so it can be fairly confusing
12 in terms of who to actually contact.
13 Even if the incident is reported, an incident
14 may not be linked to a specific cause, and this is
15 because things like affected animals may move off site,
16 and the further you get from a site of application, the
17 less likely that carcass is going to be correlated with
18 a site of application.
19 And there are some examples from carbofuran
20 incidents, an incident involving some duck and geese.
21 1200 duck and geese were killed in...from exposure to
22 carbofuran that was applied to a...a alfalfa field in
23 2000 in New Mexico, and some of the carcasses were
24 found up to a half a mile from the site of application.
25 So, again, the greater distance you move from the site

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1 of application, the less likely you are to match...to
2 link it to a cause.
3 Now, also, if the incidents aren't
4 investigated promptly, tissues and residues may
5 deteriorate, limiting, again, the ability to link an
6 incident to the pesticide, because if we don't have
7 residues, it's...we can't link it to the pesticide.
8 And an incident may not get investigated due
9 to limited resources. And, in fact, when we contacted
10 one of the agencies, state agencies that's responsible
11 for a substantial number of the terrestrial incidents
12 that we have in the EIIS, which is the New York State
13 Department of Environmental Conservation, we were
14 contacting them about an overall drop in incidents that
15 we see which I'll be discussing a just a second, but
16 their response was the reason for the decrease in
17 incident reporting is largely due a lack of resources
18 to conduct the work needed to identify, investigate,
19 and track incidents of poisonings. We have been unable
20 to fund the analytical costs associated with these
21 investigations, and thus, there have been few incidents
22 reported.
23 So, the...the...kind of the underlying
24 message here is if states don't have the money, then
25 incidents often don't get investigated.

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1 And even if an incident is investigated,
2 reports may not get to the Agency. We may not receive
3 them. And, again, this is because incidents by state
4 agencies and toxicology laboratories is completely
5 voluntary, the submission, and sometimes the inc...the
6 information may not be complete enough that we get
7 from investigations, and we can't enter it into the
8 EIIS or we simply don't get the report.
9 Also, only acute toxic effects are reported
10 in our incident database, so anything, any potential
11 effects of a pesticide on things like reproduction or
12 growth, we simply don't have any information of what's
13 occurring regarding incidents for those types of
14 chronic endpoints.
15 So, as you can see, there's a lot of things
16 that have to go right for an incident to end up in our
17 database, and if people are out there looking, they're
18 motivated, they're repor...they're investigating, then
19 it tends to...can impact the number of incidents that
20 the Agency actually re...receives.
21 And an example of this is if we take, again,
22 from the carbofuran incidents, there was a grape
23 monitoring study conducted, a program conducted in the
24 early '90s in California that looked at flowable uses
25 of carbofuran on grapes, and what we find is that 27 or

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1 the 28 reported grape incidents for carbofuran came in
2 from those monitorings, during the monitoring program.
3 So, again, it suggests that we're more likely to get
4 incident reports when people are actually specifically
5 looking at them and have the funds to actually
6 investigate them.
7 So, taken together, we know that the EIIS is
8 a very incomplete database and that the reported
9 incidents in the EIIS likely represent a very small
10 fraction of the non-target animals killed or
11 incapacitated by pesticides.
12 Now, because of these shortcomings, a lack of
13 reported evidence for a pesticide cannot be used as
14 evidence that incidents involving that pesticide don't
15 occur. It's a classic case of absence of evidence
16 can't be used as evidence of absence.
17 Also, information in the database cannot be
18 used to quantify the level of effect associated with a
19 certain pesticide. It's just simply not that kind of
20 database. It's not...the data aren't systematic.
21 Even with these limitations, however,
22 the...the Agency feels that the EIIS is still a very
23 important tool, because what it does, for example, and
24 how we use it is that if...if an incident report shows
25 that the registered use of a specific pesticide

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1 resulted in adverse impacts to the environment, then we
2 can assume that that pesticide, as used, can result in
3 an impact to the environment.
4 And it demonstrates, following up on Dr.
5 Edenkir...Odenkirchen's talk, is that under actual
6 field conditions and using pesticides as registered and
7 labeled, that there is a complete path of exposure that
8 has occurred that has resulted in impacts to non-target
9 organisms.
10 Now, regarding the carbofuran incidents
11 specifically, the EIIS contains 399 reported incidents
12 from 1972. So, from '72 to 2007, we have 399 incidents
13 for carbofuran. 84 of these are from registered uses,
14 and these are uses where the applicator actually
15 followed label directions, and so, it's
16 considered...the legality of use is considered
17 registered.
18 129 involved misuse, and this can be either
19 intentional misuse such as baiting or unintentional
20 misuse, somebody used the wrong application rate on
21 accident or applied at the wrong time of year or...or
22 whatever. For carbofuran, most of the cases are
23 baiting situations in our database.
24 And then, 186 of the carbofuran incidents,
25 the legality is undetermined, and these represent uses

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1 that were either misuses or registered uses. We just
2 simply don't have enough information to classify the
3 legality of use.
4 And so, this really does kind of demonstrate
5 that the lack of information we often get with
6 the...the incidents and the difficulty in terms of
7 trying to categorize it based on legality of use.
8 Now, the...the...considering only registered
9 uses of carbofuran, we see that the effects primarily
10 involve mortality in birds, but it's not limited to
11 mortality in birds. We also see mortality in mammals,
12 mortality in fish, mortality in vertebrates, both
13 terrestrial and aquatic, and also incapacitation in
14 birds.
15 The number of individuals per incident, again
16 only considered...considering registered uses, ranged
17 from 1 to about 2500, and in the cases where...for
18 terrestrial incidents where we have in the hundreds or
19 into the thousands, those...those are bird kills.
20 So, it's important to consider, although I'm
21 going to be focusing on mortality in the talk, the
22 effects aren't limited to mortality but also include
23 some sub-lethal effects.
24 Now, again, only considering currently
25 registered uses, there have been incidents associated

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1 with the following use sites as...as noted on the
2 incident report, and that is agricultural area,
3 alfalfa, corn, soybean, and spinach.
4 Now, when we look at the number of incidents
5 that...this is considering all carbofuran
6 incidents...when we look at the number the Agency has
7 received through time, we do see that there's been
8 fluctuation, depending on the year, in terms of how
9 many that we've received, and we do see what looks like
10 an actual clear drop or a clear drop in the number of
11 carbofuran incidents we've received over the last
12 several years. Because of the shortcomings of the
13 database, however, it's...it's difficult to make a
14 conclusion regarding what might be causing this
15 decrease.
16 And some of the reasons that we
17 explored...and this is not an exhaustive list for
18 trying to explain what might be causing this drop in
19 carbofuran incidents...one is that the actual decrease
20 or the decrease may be due to actual decreases in
21 carbofuran incidents through time. And FMC, in their
22 public comments recently to the RED, has suggested that
23 they believe that this drop in carbofuran incidents
24 over the last several years is the result of changes in
25 labels and stewardship programs that they've been

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1 conducting.
2 Now, there is some support for this. And,
3 again, if we go back to that grape use example, the
4 monitoring program that was conducted in California in
5 early 1990s, we see as a result...as...they found
6 several incidents in that monitoring program related to
7 flowable use of...of carbofuran on grapes, and so,
8 there were some label mitigations made, put on the
9 label in 1994 which involved things like when applying
10 carbofuran through irrigation system, it has to be at
11 night. You have to stop it two hours before sunrise.
12 And this was to basically limit the number of puddles,
13 contaminated puddles that were available for drinking
14 water.
15 And we see after those mitigations were put
16 on the label, we don't see a single carbofuran incident
17 involving grapes in the EIIS, but we also know that we
18 only have one other grape incident that falls outside
19 of the monitoring program, and that was an incident
20 from 1986. So, the lack of incidents after the label
21 mitigation could be explained by the label mitigation,
22 but the paucity of incidents before that can't be
23 explained by any label mitigation.
24 And we don't find any evidence for any other
25 uses that kind of fit this pattern.

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1 So, the fact that we see so many incidents
2 during the monitored...monitoring program also brings
3 us to our second potential reason for a drop in
4 incidents that we report...re...or explored, and these
5 were changes in monitoring efforts. So, in the grape
6 case, again, when people were monitoring, more
7 incidents were reported.
8 Also, when we compared carbofuran incidents
9 to non-carbofuran terrestrial incidents, we see that
10 there's a very similar pattern through time. So, the
11 graph...let's see if I can get this pointer working.
12 So, this graph here represents all carbofuran
13 incidents. These are carbofur...these are non-
14 carbofuran terrestrial incidents. And you can't see
15 the dates. I apologize for that, but that starts at
16 1967, goes to 2007 on both graphs, so that's 40 years
17 represented. Each blip is a...is a year. The scales
18 are the same.
19 And so, what you see is a very similar
20 pattern with the carbofuran incidents and then also
21 when you take away the carbofuran incidents which
22 indicates that there's maybe something across the board
23 occurring here in terms of reporting and that this drop
24 isn't necessarily due to a drop or the efforts of
25 a...of a single company.

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1 Also, when we look at the total number of
2 terrestrial animal incidents...and this is all
3 carbofuran and all other chemicals...when we look at
4 the total number of terrestrial animal incidents per
5 state, we see that 40 percent of them are from
6 California, primarily from the California Department of
7 Fish and Game, and New York which a lot of...most of
8 them from the New York Department of Environmental
9 Conservation. And unless we assume that all
10 terrestrial animal incidents actually occurred in these
11 two states, in California, and New York, then we have
12 to assume that there might be some differences in the
13 state monitoring efforts and that monitoring efforts
14 can play a role in the number of incidents that the
15 Agency receives.
16 Now, as mentioned earlier, we did contact the
17 New York State Department of Environmental Conservation
18 regarding what they thought was their drop in
19 incidents, and, again, they stated that it was due to a
20 lack of funding.
21 Now, and since the majority of carbofuran
22 incidents are reported from non-registrants...86
23 percent of them come from non-registrants and only 14
24 percent come from the registrants...a lack of funding
25 for state agencies could have a dramatic impact on the

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1 number of incidents that the Agency receives.
2 Now, another factor that we considered or
3 explored a little bit was...that might have played a
4 role in decline in carbofuran incidents and incident
5 reports overall has to do with change in...in
6 registrant reporting requirements. In 1998, there was
7 a change in the incident reporting requirements for
8 registrants, requiring them to report the details of
9 only those incidents that were considered major.
10 And for an example, for an incident to be
11 considered major for birds, it has to be...involve more
12 than 200 of a flo...individuals of a flocking species,
13 more than 50 individuals of a songbird species, or more
14 than 5 individuals of a predatory species.
15 Now, incidents considered minor that don't
16 fit this...this classification as...of major only need
17 to be reported aggregately by the registrant, so they
18 just have to tell us there were two incidents in 2005
19 involving chemical whatever. So...and we...we normally
20 don't get any other details at all on the incidents,
21 and because we don't get the...the information
22 associated with those incidents, we can't determine
23 legality of use, we can't determine a use site, we
24 can't determine a magnitude of the incident. So, those
25 incidents are normally not included in our EIIS

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1 database.
2 Now, because the EIIS is heavily dependent on
3 getting reports from state agencies and from the
4 registrants themselves, any fluctuation in state
5 funding for pesticide monitoring and investigations
6 and/or changes in reporting regulations for registrants
7 have the potential to influence the number of wildlife
8 incidents that the Agency receives.
9 Now, because the drop in incidents appears to
10 correlate with a general decrease in state funding and
11 the CFR changes in reporting requirements...and I just
12 highlighted 1998 here, because this is when the new
13 reporting requirements were put in place...it suggests
14 that the drop in incidents might be due to a drop in
15 reporting and not necessarily a drop in actual
16 incidents.
17 Unfortunately, at this time, we don't have
18 enough information to relate the drop to any one
19 specific cause. It could be a result of one of these,
20 a combination of these, or some other factor that we
21 simply didn't explore, but what we can conclude is we
22 simply don't have enough information at this time to
23 conclude that the drop in carbofuran incidents is due
24 to stewardship programs or label mitigations.
25 Now, going back to the carbofuran incidents

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1 specifically and considered...considering only
2 registered or currently registered uses and limiting
3 the analysis to flowable carbofuran, since that was the
4 focus of our risk assessment, the last risk assessment
5 that we did, and is the focus of our SAP's charge
6 questions, we see the following. And this is just
7 directly...taken directly from the EFED science chapter
8 for the RED in 2006, and we did not include the grape
9 incidents here because of the potential for the
10 mitigation that occurred in the...in the mid '90s.
11 So, from 1972 to 2000, there were a total of
12 31 incidents involving currently registered uses of
13 flowable carbofuran, and they were from...21 were from
14 alfalfa, 7 were from corn, and 3 were from other crops,
15 and the number of affected birds was greater than 7400.
16 Again, if you include grapes, all of those numbers go
17 up.
18 Now, since the incidents prior to 2000
19 are...were analyzed and discussed at length in the RED
20 chapter, we decided to focus some of...some of our
21 attention on the carbofuran incident reports the Agency
22 has received since 2000. And the Agency has received a
23 total of 37 incidents...and this is all formulations,
24 all legalities of uses...37 incidents since 2000. 24
25 of them are currently in the EIIS database. 8 were

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1 aggregately reported from FMC and from the National
2 Wildlife Health Center, USGS's NWHC, and then 5 we
3 received but haven't yet been entered into the EIIS.
4 Now, of these 37, 19 likely represent
5 intentional misuses or baiting situations. 2 involve
6 registered uses. One was an incident in 2000 on
7 alfalfa in New Mexico which killed up to 1200 ducks and
8 geese, and this incident was discussed in the RED
9 chapter. And then, we also have a 2000 incident on
10 alfalfa in California that affected 4 beehives.
11 Now, the remainder of the incidents that
12 we've received since 2000, most of them we don't have
13 enough information to really say too much more about
14 them. They've been listed as undetermined.
15 Three of them are likely mistakes based on
16 the profiles that they...they have, and then there's a
17 couple that we have quite a bit of information on, but
18 they're fairly complex. And one incident that fits
19 that complex category is a 2006 incident on sunflowers
20 that killed 2200 birds in Colorado.
21 Now, in this case, a farmer planted...no-till
22 planted some sunflowers. He only got a third of the
23 stand come up because of worm damage, so he had
24 wireworm and cutworm damage, and there apparently was a
25 lot of weeds in the...in the field, so he basically

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1 wanted to start over. So, he applied a tank mixture of
2 2,4-D lysophate and carbofuran, basically, as a burn
3 down to get rid of the sunflower stand, the weeds in
4 the field, and then also added carbofuran to get rid of
5 the...the pests, and then he no-till planted another
6 crop of sunflowers.
7 Now, the complexity here is that on the
8 federal label Furan 4F, there is both an at-plant
9 application allowed, but this has to be in furrow, and
10 then a foliar application that's also allowed pre-
11 bloom. Now, the complexity is here is because he was
12 not treating the current stand of sunflowers, it
13 was...could be considered an at-plant application. He
14 applied a...the same amount or a legal amount for a
15 fol...foliar application which is 0.5 lb/acre. So,
16 there's a complexity here in terms of the legality.
17 But one thing that we can take away from this
18 incident is since that the farmer used a registered
19 rate and that the application would have been no
20 different than allowed for a foliar application. It
21 does demonstrate that application of carbofuran to
22 sunflowers at labeled rates can result in bird
23 mortality.
24 Now, there was some...in this incident for
25 this, there was evidence that there might have been a

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1 lot of wheat seeds in the field from a previous...the
2 farmer had a wheat field in 2005 that was heavily
3 damaged by hail, and so there...a lot of the heads were
4 shattered, so there was a lot of wheat, presumably,
5 still in the field a year after that, and it...if that
6 was the case, then that probably did contribute to the
7 magnitude of...of this event of killing 2...killing 200
8 birds.
9 So, if we take all the information together
10 on the incidents, basically, the...the incidents that
11 we see for registered uses and we take them as a whole,
12 what we can conclude when we put this information
13 together is that the reported inc...incidents
14 demonstrate that when flowable carbofuran is used as
15 currently registered and at currently registered
16 application rates, mortality in animals, especially in
17 birds, can and does occur.
18 Now, because the recent drop in reported
19 carbofuran incidents does appear to parallel and
20 overall drop in incident reports, indicating that
21 something across the board in reporting is occurring,
22 such as a loss in state funding or changes in reporting
23 requirements and/or some other factor, we simply don't
24 have enough information at this time to conclude that
25 the drop in carbofuran incidents is due to stewardship

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1 programs or label mitigation.
2 Incident reports do show that under field
3 conditions and for registered uses of carbofuran, there
4 is at least one complete pathway of exposure that can
5 result in wildlife mortality and incapacitation. And,
6 also, because of these...the potential changes through
7 time, the lack...the lack of systematic data collection
8 for the EIIS, and the difficulty in...in all the steps
9 that have to occur for an incident to actually occur in
10 our database, the incidents that we have record of in
11 our EIA database likely rep...represent a small
12 fraction of the actual incidents that actually occur,
13 and incident data cannot be used quantitatively.
14 Okay, so moving on to some of the carbofuran
15 field studies, I'm going to focus here on studies that
16 were conducted using flowable carbofuran. Again, I'm
17 not going to talk about all the granular studies that
18 have been conducted. I'm going to focus it on
19 of...flowable since that was the focus of our risk
20 assessment and is the focus of our charge questions.
21 And the...the field studies that were
22 discussed in EFED's RED science chapter primarily
23 involve studies that were conducted in Canada using
24 flowable carbofuran for grasshopper control which has a
25 lower application rate than all U.S. uses. It has a

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1 0.12 lb/acre application rate. And then, we also have
2 some studies that were submitted by FMC using flowable
3 carbofuran in the...in the U.S.
4 Now, for the Canadian studies, some of these
5 studies found some effects of carbofuran; some didn't
6 find any. The several of them had issues with them,
7 making conclusions regarding...or their conclusions
8 tentatively...tentative. Several of them had fairly
9 small sample sizes.
10 Some of them relied on sampling of live,
11 mobile individuals which would not include
12 incapacitated or dead individuals, and thus, the
13 samples may be biased toward underestimating exposures.
14 And some focused on mammals which, in itself, it not a
15 shortcoming of the study. It's just that we are
16 focusing on birds here.
17 Now, one additional Canadian study that was
18 discussed in the RED chapter was by Fox, et.al. from
19 1989, and, again, this was a Canadian study involving
20 the flowable use for grasshopper control, and what they
21 found in this study was that flowable carbofuran had a
22 significant impact on the survival and reproductive
23 success of burrowing owls in this...in their study.
24 They found that direct overspray of burrowing
25 owl burrows resulted in an 83 percent reduction in

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1 brood size and an 82 percent reduction in nest success
2 from their 1986 data, and when they...when they
3 compar...combined their '86 and '87 data, of the 12
4 pairs of birds that were directly exposed to carbofuran
5 overspray, 8 of the nests failed completely.
6 So, this study and all of the previous
7 Canadian studies are discussed in more detail in the
8 RED chapter.
9 Now, again, there were awful...also several
10 studies that were submitted by FMC on flowable
11 carbofuran, and they include a 1983 alfalfa study from
12 Utah, two studies from 1989, one on corn and one on
13 alfalfa, and state monitoring reports from 1995 and '96
14 on cotton use in several.
15 Now, I'm going to focus here on the two 1989
16 studies here, because they both represent currently
17 registered uses for carbofuran, and they were really
18 the most rigorous in terms of their methodology for
19 carcass monitoring, of finding carcasses.
20 Now, the 1983 alfalfa study from Utah relied
21 primarily on bird surveys to determine if carbofuran
22 had an effect on bird density, so it did not really
23 address potential wildlife mortality directly.
24 All of the state monitoring reports that were
25 conducted by state agencies and submitted by FMC from

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1995 and '96...they were conducted as part of the Section 18 requirement...had insufficient methodology to show that negative results meant that mortality from carbofuran was not occurring, and, in fact, very few of the studies found any evidence at all of...of mortality, but some of the deficiencies, serious deficiencies in these monitoring studies included and weren't limited to some of the programs didn't conduct carcass searches at all.

Some conducted carcass searches on all-terrain vehicles, and with the difficulty we talked about previously about trying to locate carcasses...and these involved using searches on foot, walking slowly through a field...the difficulty would be compounded, you can imagine, if you're driving through on an ATV.

Several of the studies didn't conduct or didn't report results from carcass search efficiency tests, so we have no idea what the success rates were for finding carcasses in the search areas. Some of the carcass searches were conducted more than two days post-application and, in some cases, up to 15 days post-application.

And then, on all of the studies, they conducted their carcass searches on less than the Agency-recommended search area. We provide guidance

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1 for these monitoring programs, and they...none of them
2 even came close to the...the search areas that we
3 suggested.
4 Now, regarding the 1989 field studies on corn
5 and alfalfa, I'm just going to briefly go through some
6 of the methodologies, because they were similar for
7 both studies, and you're also going to see these
8 studies again in...in Dr. Salice's talk, so just when
9 he mentioned the '89 studies, he's talking about these.
10 The...the Nebraska corn study, there
11 were...in the corn study, there were 15 plots and 15
12 plot...or 16 plots in Texas at the New Mexico border.
13 Alfalfa, there were 16 plots in Kans...Kansas and 16
14 plots in Oklahoma. Roughly half of these were
15 controls; half were treated with carbofuran.
16 The control chemical used for the control
17 fields in the corn study were pyrethroids, and the
18 control chemical used in the alfalfa study was
19 chlorpyriphos, so the...the control fields were treated
20 with these chemicals, and the treated fields were
21 treated with carbofuran.
22 The search teams consisted of five
23 individuals that were walking 5 to 10 feet apart,
24 walking slowly through search areas, and it also
25 included some dog searches. The pretreatment searches

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1 occurred within 10 days of treatment, and the post-
2 treatment searches occurred within 7 days of treatment.
3 The search efficiency rates that were based
4 on randomly placed dead chicks in the search areas
5 ranged anywhere from 100...or 0 percent to 100 percent,
6 depending on the actual search area being searched.
7 Now, here's schematic drawing of the search
8 area. The search are is...this is a field. This is
9 from the corn study, but the...it was similar in the
10 alfalfa study. The gray area represents areas that
11 were searched, the search area. Roughly 5 acres were
12 included in the field and 5 acres of edge habitat, so
13 each plot was about 10 acres in size, and...but they
14 didn't go beyond 50 feet of the edge in...in either
15 direction, so they didn't go past 50 feet in the field
16 or past 50 feet from the edge into the edge habitat.
17 So, it was really a perimeter search.
18 So, here are the results for the number of
19 bird carcasses and feather spots found during this
20 study. We see in the corn studies, there was a total
21 of 15 bird carcasses recovered in the pretreatment
22 searches and a total of 48 in the post-treatment. 7 of
23 those came from controls and 31 came from the treated
24 plots.
25 In the alfalfa study, there were 9 dead birds

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1 found pretreatment, and 46 were found post-treatment,
2 24 in the control...again, this was the chlorpyriphos
3 control...and then 22 in the carbofuran fields.
4 Now, in the study report, the authors used
5 pretreatment mortality or the...the mortality from
6 pretreatment and the mortality from the control plots
7 as meaningful covariants for...for...as measures of
8 natural mortality, and so, they found very little
9 statistical difference between when they compared
10 treated plots to controls or to pretreatment plots.
11 However, the mortality from...from
12 pretreatment...from pretreatment or from control fields
13 probably does not represent natural mortality, so post-
14 treatment comparisons in this case and comparisons
15 between controls and treated fields are essentially
16 meaningless, because in both studies, other chemicals
17 known to be toxic to animals, including birds, were
18 used on or near some of the control and treated fields,
19 including chlorpyriphos, dimethoate and methomyl, and
20 some of the control fields were adjacent to fields
21 treated with carbofuran that weren't in the study. So,
22 if you had a control field here, another field here
23 that wasn't in the...in the study, carbofuran was used,
24 in some cases, on this field, and they...they collected
25 carcasses on the edge in between the two fields.

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1 And, in fact, in the corn study, carbofuran
2 residues were found on edge vegetation from all fields
3 where carcasses were found, including both the controls
4 and the treated fields.
5 However, we can perhaps get some useful
6 information from this. Because of the pretreatment
7 searches, we can assume that most of the carcasses, if
8 not all, but most of the carcasses were removed prior
9 to treatment, that all of the mortalities that we find
10 post-treatment weren't there before the treatment. We
11 can assume that they...they died after the treatment.
12 And, also, the fact that we have residues for
13 the carcasses, both carcasses on the treated fields
14 that were...that had enough tissue to be...to have
15 residues tested on them, most of them did find
16 carbofuran residues.
17 So, we have this incident where we have kind
18 of a clean sweep of the area before the treatment, and
19 then, all the mortalities afterwards, and most of those
20 did show some residues of carbofuran. We can assume
21 that probably most of those mortalities on the treated
22 fields were likely due to carbofuran exposure.
23 It's important to keep in mind that these
24 numbers don't take into account several factors that
25 may actually mean that the number of mortalities

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1 associated with these fields are actually higher
2 than...that what's reported. They didn't...most of the
3 search areas had search efficiently...efficiency rates
4 of less than 100 percent, so in most cases, they
5 weren't able even to find randomly placed chicks that
6 weren't hiding themselves in the search areas.
7 Scavengers had plenty of opportunity and likely removed
8 some of the carcasses from these search areas, and
9 they, again, had a very limited search area.
10 In a study by Stinson, et.al. from 1994 that
11 looked at granular carbofuran use on corn...it was
12 granularly used, but it was on corn in Virginia...they
13 found carbofuran related mortality in birds associated
14 with 10 of the 11 farms that they looked at. They
15 recovered a total of 113 bird carcasses, and 74 percent
16 of those carcasses recovered were in the corn fields.
17 And, again, this is just...in these alfalfa
18 and corn studies, it was just a perimeter search.
19 So, the actual numbers of mortality listed
20 here are probably...the actual numbers were probably
21 higher. That's...I just want to make that point. And
22 at the very least, they show that mortality associated
23 with registered uses of carbofuran on corn and alfalfa.
24 So, when we take all the field studies
25 together, we have some shortcomings in the available

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1 field studies on flowable carbofuran, and adverse
2 effects were found in all the studies when we include
3 the...the...the Canadian studies, and taken together,
4 they do demonstrate that carbofuran use at application
5 rates equal to or lower than recommended on current use
6 labels, as in the Canadian grasshopper cases, can
7 result in impacts to wildlife.
8 So, when we take the incident data together
9 with the field data, incident reports and field studies
10 on flowable carbofuran, taken singularly or as a whole
11 as a line of evidence, do not allow for quantification
12 of level of wildlife effects, including mortality,
13 associated with carbofuran. Taken together, however,
14 these lines of evidence do demonstrate that when
15 carbofuran is used as currently registered or at
16 currently registered application rates, then wildlife
17 mortality, notably in birds, can end and does occur.
18 And the effects aren't limited to mordal...mortality.
19 We do...or to mortality in birds. We have mortality in
20 other taxa, and also, we see sublethal effects when we
21 include both the incident and the field studies of
22 incapacitation and reproductive effects.
23 And so, that's it. So, if there's any
24 questions...
25 **DR. HEERINGA:** Thank you very much, Dr.

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1 Panger, and I'll turn to the panelists, beginning with
2 Dr. Hill.
3 **DR. HILL:** Yeah, Elwood Hill. I...I'm
4 curious as to how you did your off-site monitoring and
5 how you accounted for the fact that carbofuran induced
6 cholinesterase activity in brains can be re...reversed,
7 and did you then look for residues in carcasses or...
8 **DR. PANGER:** From the '89 studies?
9 **DR. HILL:** I'm just talking conceptually
10 about any of these kinds of studies and the way you did
11 things, because at one point, you did mention the off-
12 site comparison versus the on-site. It's been
13 mentioned by yourself and Ed, both. I was just curious
14 as to how you...how you did that and how you define
15 mortality when it's off site versus on site.
16 **DR. PANGER:** Well, the...well, it
17 differs depending on the incident reports and the field
18 studies, so do you have a...do you want to hear both?
19 Because if it's the incident data, what we typically do
20 if it's a...of there's mortality found and somebody
21 calls it in and there's an investigation conducted by a
22 state agency, for it to be included as a registered use
23 for a particular pesticide, the pesticide has to be
24 linked to the carcass. And so, they typically do
25 residue analyses.

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1 And so, if we...if we have a carcass found
2 near a field or associated in the case with the 1200
3 ducks, apparently, from the necropsies, the incident
4 that reported or from New Mexico that affected the
5 dozen ducks and geese that were found a half-mile from
6 the application site, apparently, from the necropsies,
7 these birds were falling from the air. And so, there
8 was almost a trail for that...in that case and so, from
9 the field...and so, but we do still have residues from
10 those carcasses.
11 So, for it to be linked to a pesticide in
12 the...in the database, we typically have to have a
13 residue sample.
14 Now, for the studies that were conducted, the
15 field studies, for like the '89 studies,
16 they...the...they did a lot of analyses of residues,
17 and they collected residues on the...on the edge
18 habitat within their search area which was within 50
19 feet of the edge of the field. They had residues
20 within the fields of application, residues on the
21 carcasses, those that had enough tissue to actually do
22 a residue analysis on. And so, we have residue
23 analyses from both the in field and off field for the
24 edge habitat for the...some of them tested the
25 vegetation and the carcasses and on the in field where

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1 they checked the...the carcasses and the vegetation.
2 So, is that...is that kind of what you're
3 getting at or...
4 **DR. HILL:** Well, yes, yeah, that
5 strengthens it up.
6 **DR. PANGER:** It varies depending on the
7 study.
8 **DR. HILL:** What...what tissues did you
9 use?
10 **DR. PANGER:** It varies, too. A lot of
11 them use gastrointestinal contents. Some actually
12 measured residues in...in, I believe, on surface areas,
13 residues, so it varied depending on...on the study.
14 **DR. HILL:** Essentially, everything was
15 external of the animal? I mean...
16 **DR. PANGER:** Well, not the
17 gastrointestinal, yeah.
18 **DR. HILL:** Yeah, if there was no bird
19 left.
20 **DR. PANGER:** Right, right, exactly.
21 **DR. HILL:** So, therefore, it's not
22 poisoned until such time as...
23 **DR. PANGER:** All as we're doing is
24 demonstrating that there was an exposure, and that's
25 what we're trying to demonstrate.

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1 **DR. HILL:** Thank you.

2 **DR. HEERINGA:** Dr. Kehrer?

3 **DR. KEHRER:** Jim Kehrer, Washington

4 State University.

5 This might have been covered, since I had a

6 conflict and missed the first half of this morning, so

7 I apologize if I'm repeating something or something you

8 can't actually answer. Throughout this, you qualified

9 it by saying repeatedly that this was with currently

10 registered uses of carbofuran, but FMC, if my

11 understanding is right, is proposing some significant

12 changes to the registered uses, and if those are taken

13 into account, does it change any of your assessment?

14 **DR. PANGER:** Yeah, that was talked about

15 earlier.

16 **DR. HEERINGA:** Dr. Bradbury answered

17 that question, but why don't we...you can answer it?

18 **DR. BRADBURY:** Snapshot of a previous

19 comment was that as we look at the deterministic risk

20 assessment, the probabilistic risk assessment, and the

21 incidents reported here, it's thinking about issues of

22 application rate, is the habitat associated with the

23 model or an observation, and thinking through to what

24 extent are those observations, be they field

25 observations or observations from a model unique to

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1 that specific scenario, to what extent did they broadly
2 represent other kinds of cropping patterns or other
3 kinds of application rates or other kinds of
4 application.
5 Then, the basic follow-up comment to your
6 question was that as we take a look at most of the
7 charge questions, essentially all the charge questions
8 for ecological and human health, from the Agency's
9 perspective, they're sort of getting at some underlying
10 issues in terms of the risk base inhibition, what's the
11 shape of the dose-response curve. So, in mammalian
12 systems, too, to what extent do the scenarios that Dr.
13 Odenkirchen's releasing anywhere describing unique, or
14 are they representative of broader applications? And
15 the Agency's conclusions is for the most part, these
16 issues, we think, are broadly applicable to different
17 types of uses. In the case of ecological risk
18 assessment, we're looking at effects on field as
19 opposed to looking at sort of effects across the
20 western corn belt very carefully.
21 **DR. HEERINGA:** Dr. Chambers, Dr.
22 Delorme, and then Dr. Grue.
23 **DR. CHAMBERS:** Jan Chambers. I gather
24 from what you just said that you would link a
25 carbofuran residue to the bird before it would be

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1 characterized as a carbofuran death?
2 **DR. PANGER:** In most cases, yes, that's
3 true.
4 **DR. CHAMBERS:** So, you also indicated
5 earlier that there were fields adjacent with other
6 pesticides, and also, were these residue analyses
7 targeted specifically to carbofuran and nothing else,
8 or were...was there a broad-spectrum residue analysis?
9 **DR. PANGER:** Yeah, for the '89 studies,
10 I'll have to look back, but I...if I recall correctly,
11 in the alfalfa study that used chlorpyriphos as a
12 control, they also did look at some chlorpyriphos
13 residues, I believe, in some of the carcasses.
14 **DR. CHAMBERS:** Are...are the analyses
15 done to look for anything that might be there or...
16 **DR. PANGER:** Oh, for these cases? No,
17 they were...for these studies? They were specifically
18 for carbofuran in most of the cases.
19 **DR. CHAMBERS:** What about your incident
20 reports though?
21 **DR. PANGER:** In incident reports, they
22 do a broad...sometimes a broad study, but a lot times,
23 we're...we...we...you know, because of the use that
24 occurred near the field or if an incident is
25 involved...associated with a field, we know what was

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1 used on that field, and sometimes, they're targeted
2 towards the chemicals on those fields.
3 **DR. HEERINGA:** Dr. Delorme?
4 **DR. DELORME:** Peter Delorme from Health
5 Canada.
6 Have you had the opportunity to analyze your
7 incident report data either for carbofuran or for other
8 chemicals to see whether or not there's a bias in terms
9 of the size of the birds that are reported?
10 **DR. PANGER:** In terms of the size?
11 **DR. DELORME:** Yeah.
12 **DR. PANGER:** The actual birds were? You
13 mean ducks versus...
14 **DR. DELORME:** Yeah, smaller birds. For
15 example, if you...if you look at being able to recover
16 things in the field and being able to see them, what we
17 notice, is it...is it biased so that the larger species
18 are more represented in your data set compared to the
19 smaller ones?
20 **DR. PANGER:** We definitely do have
21 a...it's not limited to large waterfowl, but...but a
22 lot of...most of our incidents do involve...that we
23 have do have large waterfowl associated with them. So,
24 yeah, you're talking about a larger critter.
25 **DR. DELORME:** Yeah.

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1 **DR. HEERINGA:** Dr. Grue?

2 **DR. GRUE:** Chris Grue, University of

3 Washington.

4 You make a comment about the comment about

5 the New York reporting...

6 **DR. PANGER:** Mm-hmm.

7 **DR. GRUE:** ...and the potential change

8 there because of a lack of funding, but you didn't say

9 anything about California and California's over 800

10 incidents. What's the situation in California?

11 **DR. PANGER:** Yeah, we were just...we

12 just contacted the one with the highest number just to

13 see...just to...we haven't done an exhaustive analysis,

14 and we can go back and look, but we just basically

15 looked at the one with the highest number of...of

16 terrestrial incidents, if we go back there, so you can

17 see that New York had a substantial number of

18 terrestrial incidents. So did California, but we just

19 went with the highest just to kind of see what their

20 thought were...was.

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

22 **DR. HILL:** Yes, why did you...Elwood

23 Hill. Why did you choose chlorpyriphos as your

24 control?

25 **DR. PANGER:** Oh, these were not studies

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1 conducted by EPA. These...the '89 studies were
2 submitted by the registrant as part of their
3 requirements for registration. So, these studies were
4 not conducted by the EPA. I...I know that there was
5 some going back and forth in terms of...of protocols,
6 but I don't know exactly what the final...these were
7 conducted back in the '80s, so I'm not sure what the
8 reasons were that they used chlorpyriphos as a control
9 in those studies.
10 **DR. HILL:** Well, perhaps that will be
11 discussed later on when they make their presentation.
12 **DR. PANGER:** Yeah, maybe.
13 **DR. HILL:** But the other issue, of
14 course, to follow up on that is that...is whether or
15 not they administered an exposure level that would be
16 likely to assure some mortality or if the exposure
17 level was within the registered...
18 **DR. PANGER:** They were all registered...
19 **DR. HILL:** ...chemical protocol.
20 **DR. PANGER:** They were all registered
21 uses, because these were studies that were...these were
22 actual fields that people were applying chemicals to.
23 They weren't...they were...these were real-world
24 fields, so they...they collected the fields from
25 talking with local farmers. And so, the...the...the

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1 people, of course, on the controls didn't want to not
2 use anything on their fields, and so, they did you use
3 a control chemical, and...and so, they were all
4 registered uses.
5 **DR. HEERINGA:** Dr. McCarty?
6 **DR. MCCARTY:** John McCarty, University
7 of Nebraska.
8 One is just a point of clarification. Are
9 these the same studies that FMC sites as Booth and
10 Jorgensen?
11 **DR. PANGER:** Yes, that is. That's
12 correct.
13 **DR. MCCARTY:** I had assumed so.
14 **DR. PANGER:** Yeah, and Dr. Salice will
15 be talking about them a little bit more.
16 **DR. MCCARTY:** Okay. Second, is there
17 any information on either bird density in these fields
18 prior to application and the types of birds that were
19 recovered?
20 **DR. PANGER:** Yeah, they did some
21 exhaustive...they did some very detailed...these
22 studies, actually, there was a lot of work put into
23 these '89 studies, and they did surveys in addition. I
24 couldn't get into all the details, because they
25 were...they're fairly big...big studies, but they did

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1 do surveys of live birds in...in the fields, limited to
2 these...the areas that they were searching, so they did
3 surveys in terms of number of birds and then types of
4 birds, what species were found.
5 **DR. ODENKIRCHEN:** And just to connect
6 the dots on that, the...the data that was used from
7 those surveys was incorporated into the probabilistic
8 assessment.
9 **DR. MCCARTY:** And I guess just to follow
10 up on that just a little bit, first, then, do you
11 recall at all what density these were?
12 **DR. PANGER:** Yeah.
13 **DR. MCCARTY:** And, second, how the...is
14 the...is there a bias...somebody mentioned size bias.
15 Is there a bias in the birds recovered in these fields
16 versus those actually observed?
17 **DR. PANGER:** Yeah, they...they had...I
18 do recall they have...I think it was in the corn study,
19 a lot of difficulty, because there was a lot of
20 variation in terms of number of birds per site and
21 there were some timing issues because of the...the
22 study because of the pretreatments and the post-
23 treatments were conducted over, I think, about a month
24 period.
25 There...there were some times in the study

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1 where birds were flocking through pre-migratory
2 behavior and so on, so they had a lot of confounding
3 factors going on in terms...so they...they kind of, you
4 know, it made it really hard to kind of look at those
5 data in any meaningful ways, because they were so
6 confounded by timing issues in terms of where the birds
7 were in their annual stage or cycle.
8 **DR. HEERINGA:** Dr. Clark, Dr. McLean.
9 **DR. CLARK:** Larry Clark, USDA. Relative
10 to the incident reporting database...and it's similar
11 to the question on size bias...is there a distribution
12 pattern for the number of birds that were reported per
13 incident? So, for example, if there are more birds in
14 an event, are they likely to be seeing more than you
15 would expect by chance alone?
16 **DR. PANGER:** Well, we have...I haven't
17 done that analysis, but it...you know, most of our
18 incidents for carbofuran involve more than one
19 individual. So, I mean, but it's not limited. We do
20 have some incidents with one individual and carbofuran
21 incidents.
22 So, in terms of a bias, I would...I would
23 have to say it probably is biased towards a larger size
24 in terms of magnitude of individuals affected, but I
25 haven't done...I have not done that analysis.

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1 **DR. CLARK:** Okay. And you also
2 mentioned that several of the confounding factors in
3 terms of the related variables relative to the use of
4 the compound in field applications and all the caveats
5 that...and you said that there were not enough data in
6 terms of to do a quantitative analysis along these
7 lines, but I guess my question speaks to you make those
8 sorts of comments, but then there are other
9 interpretations of it that can be put onto the other
10 side of the ledger in terms of causality. So, how do
11 you weight those sorts of...of attributions that you're
12 making in a non-quantitative sense?
13 **DR. PANGER:** Well, the...the...the value
14 of the incident data, because it isn't systematically
15 collected, we don't...and there's all these other
16 caveats I could go into, what's actually...when an
17 incident actually comes in, what steps have to be gone
18 through to get that, but what it does show us, as Dr.
19 Odenkirchen has suggested in his talk, is that it shows
20 us that in an actual field condition, we have cases
21 where carbofuran has been used as currently registered
22 at currently registered application rates, and we have
23 had mortality associated with those that have residue
24 analysis showing that they have been exposed to
25 carbofuran.

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1 And so, that's what we feel the value of
2 these database...this database and the data from the
3 field studies is. So, I mean, we can't quantify the
4 level of risk associated with these data, but we
5 can...it does show us that there's been an exposure and
6 it has resulted in mortality.
7 **DR. HEERINGA:** Dr. Montgomery, Dr.
8 Sample, and then Dr. Grue.
9 **DR. MONTGOMERY:** I'm Cheryl Montgomery.
10 I have a question. I was hoping you could clarify it.
11 You had some numbers up showing treated and controlled.
12 **DR. PANGER:** Mm-hmm.
13 **DR. MONTGOMERY:** And I believe FMC felt
14 that there was not a...I'm not sure I should use the
15 term statistically significant difference between
16 treated and controlled. I'm wondering, when you...when
17 you ran and did, I assume it was carcass analysis done
18 on these for exposure to carbofuran...
19 **DR. PANGER:** Mm-hmm.
20 **DR. MONTGOMERY:** ...were the controls
21 also tested for carbofuran residues?
22 **DR. PANGER:** I...I...I'll have to go
23 back and look. I know...I just remember from...and
24 these studies we have available if anybody would like
25 copies of these studies, but I know that the vegetation

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1 from all of the...the edges and the fields were tested
2 for carbofuran. I'm not positive about the controls or
3 the carcasses that were found off-site of treated
4 areas.
5 **DR. MONTGOMERY:** And, of course, range
6 would impact whether they...they may have been in a...
7 **DR. PANGER:** Yeah.
8 **DR. MONTGOMERY:** ...treated plot and
9 then migrated to a control area in the time that it
10 took the team to migrate along the perimeter of the
11 site.
12 **DR. PANGER:** I'll have to get
13 back...I'll...I'll look at that and get back with you
14 on that issue.
15 **DR. MONTGOMERY:** Okay. And could you
16 just, if I could tap one more little question...
17 **DR. PANGER:** Yeah, sure.
18 **DR. MONTGOMERY:** ...at the risk of being
19 a microphone hog, I'm wondering if you could give me
20 some feel for the area that was looked at in the study
21 versus what might typically be...you might be
22 considering in a treated field. You said it was a 50-
23 foot perimeter.
24 **DR. PANGER:** Yeah.
25 **DR. MONTGOMERY:** What would be

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1 the...what would be the approximate ratio between the
2 area that was looked at...because you would assume when
3 you're further in the field that you're not going to
4 be...you would not get maybe overlap between the
5 treated and the untreated bird migrating. So, I just
6 want to get a feel for what the...
7 **DR. PANGER:** Yeah.
8 **DR. MONTGOMERY:** ...what the area is
9 they looked at versus what area might be representing a
10 typical application field.
11 **DR. PANGER:** I guess I
12 don't...certainly, I understand your question, but, I
13 mean, in terms of application, the application would
14 have been to the entire field. Right?
15 **DR. MONTGOMERY:** Right.
16 **DR. PANGER:** And they made a point in
17 these studies...they couldn't do...they really
18 didn't...weren't able to do within field searches,
19 because the corn was 6 to 8 feet high. The alfalfa was
20 something like 6 feet high...
21 **DR. MONTGOMERY:** Right.
22 **DR. PANGER:** ...during the study, so
23 they weren't able to get into the fields to do the
24 searches, and so, we could exp...you know, expect the
25 residues or exposure could occur throughout the field

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1 if it's treated, and they only searched the perimeter
2 within 50 feet of the edge on both sides of the edge.
3 So, I guess I'm not quite clear...
4 **DR. MONTGOMERY:** But the search is like
5 half an acre and the whole field is 4 acres?
6 **DR. PANGER:** On, no, I'm sorry. Yeah,
7 the search area was...was...each plot was about 10
8 acres.
9 **DR. MONTGOMERY:** Each search plot?
10 **DR. PANGER:** Each search plot, so it was
11 5 acres within the field and 5 acres on the edge
12 habitat.
13 **DR. MONTGOMERY:** Okay.
14 **DR. PANGER:** Yeah, I'm sorry, I
15 didn't...didn't understand that.
16 **DR. MONTGOMERY:** Well, I probably didn't
17 state it very well, either. Thank you.
18 **DR. ODENKIRCHEN:** But just to clarify
19 it, what you're getting at is the question of whether
20 or not we might be missing birds in terms of mortality
21 events in the interior of the fields? Is that what
22 you're sort of...
23 **DR. MONTGOMERY:** I'm...I'm trying to
24 look at the, you know, at the data set and ask myself
25 the representativeness of it...

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1 **DR. ODENKIRCHEN:** Right.
2 **DR. MONTGOMERY:** ...what the sample area
3 was versus what the impact area would be.
4 **DR. ODENKIRCHEN:** Right. I think one of
5 our concerns has been, with regards to these studies,
6 is that while one might anticipate there's a high
7 degree of exchange back and forth across an
8 edge...there's a lot of activity on the edges...
9 **DR. MONTGOMERY:** Right.
10 **DR. ODENKIRCHEN:** ...there's...there's
11 very little data to preclude that the birds will not
12 actually use the interiors of the fields. In fact, the
13 observations, if you go to fields, you'll see that
14 birds are in the interiors of the fields. And, indeed,
15 one of the...the studies that we looked at, one of the
16 literature studies, showed that some species are
17 actually quite often in the interior of the fields, the
18 Stinson study. I guess, what is it, 114 of those part?
19 Those birds are within the...74 percent of them were
20 recovered from the interior.
21 So, yes, one of our concerns has been how
22 representative is the edge from what's happening in the
23 interiors, and there, you know, there may be as equal
24 or maybe slightly lower representation inside the field
25 than there is on the edge.

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1 **DR. MONTGOMERY:** That's why I was
2 interested in whether the control carcasses had been
3 tested for exposure, because it seems that just
4 from...based on home range and...and short-term
5 migration that you might get some exchange over a
6 perimeter assessment area as opposed to an area that
7 was assessed in the same...
8 **DR. PANGER:** Yeah, what I'll do is I'll
9 go back and I'll look at that issue, and then I'll look
10 at the distribution of the fields in the study relative
11 to each other.
12 **DR. MONTGOMERY:** Okay.
13 **DR. PANGER:** If that would...might be
14 helpful to you.
15 **DR. ODENKIRCHEN:** And I think the other
16 thing, too, is that you have to remember that
17 it's...the utility of the interior of the field is
18 probably highly species specific. So, you're going to
19 have species that are, you know, really biased to shrub
20 scrub layers and such, and they're probably going to
21 spend a lot more time in that edge environment. Then
22 you're going to have species like red-winged blackbirds
23 and stuff, and you'll watch them flock up and fly out
24 of...out of the field at all places across the field
25 and, indeed, there's probably other species that will

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1 use those interiors quite readily as well.
2 So, yeah, you know, we can probably come up
3 with a species that represents anywhere...any number of
4 a range of utilities in the fields, and we pretty well
5 covered much of that with our probabilistic assessment.
6 And our field studies, I think, we...we probably biased
7 our species selection on the field studies, because we
8 did use the field data to select our focal species for
9 the probabilistic. We probably biased the ones...the
10 ones most frequently found. Those were probably the
11 ones that were in the edge.
12 **DR. HEERINGA:** Dr. Sample?
13 **DR. SAMPLE:** Brad Sample. Cheryl
14 actually asked most of my questions right there. Some
15 follow-ups, though, I just wanted to get clarity. It
16 was asked earlier about the residue analysis for both
17 on site...on field birds and on the controls, and was
18 carbofuran the only pesticide that was looked at? Were
19 other...
20 **DR. PANGER:** No. Again, I think in at
21 least the alfalfa study, they also looked at
22 chlorpyriphos.
23 **DR. SAMPLE:** On...
24 **DR. PANGER:** I'll have to...I'll have to
25 double check that, but...

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1 **DR. SAMPLE:** Okay. And the next thing
2 and relating to that and sort of talks about with
3 the...the movements of the birds is given the context
4 of these fields and knowing that there's other fields
5 around that were sprayed...I think you said that some
6 of the adjacent...
7 **DR. PANGER:** Mm-hmm.
8 **DR. SAMPLE:** ...fields adjacent to
9 controls were sprayed with carbofuran, did these
10 studies inventory the pesticide usages in the time
11 frame of the studies...
12 **DR. PANGER:** They...
13 **DR. SAMPLE:** ...at all the adjacent
14 fields within a certain distance?
15 **DR. PANGER:** Yeah, they attempted to do
16 that, and they were...they, in some cases, were
17 successful and some weren't. They...they weren't able
18 to get information on all of the surrounding fields,
19 but they did get information on some, and that's how we
20 know some of the adjoining fields were treated with
21 carbofuran for the controls. Again, I mean, we do...we
22 can get these, copies of these studies, to the panel if
23 people want to look more carefully at those.
24 **DR. HEERINGA:** Dr. Grue, and then back
25 to Dr. Montgomery and Dr. Sparling and then over to Dr.

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1 Brimijoin.

2 **DR. GRUE:** Chris Grue. I just want to

3 ask two...two quick questions. You mentioned the

4 issues with the minor reporting.

5 **DR. PANGER:** Mm-hmm.

6 **DR. GRUE:** But then subsequently used

7 data on minor reporting later in your...in your

8 presentation. What...what are the issues with minor

9 reports? Because you indicated you get them, but

10 they're aggregated. Didn't really tell us what

11 information actually comes with that.

12 **DR. PANGER:** We...the information we get

13 with most of the minor incidents is there was an

14 incident, and that's all we have, and we...the only

15 information we have on the magnitude is that it was

16 lower than for birds 200 of a flock.

17 If we have...we get no other additional

18 information, and so, those are not put...my point was

19 those are not put in the EIIS system unless we do get

20 additional information on those. And so, those aren't

21 going to show up in our database, but I'm aware of the

22 ones that we got. You can go look and get...get the

23 information from some of our reporting folks on how

24 many were reported as minor incidents. We just simply

25 don't have detailed information associated with those.

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1 **DR. GRUE:** Okay. Well, my second
2 question relates to that 2006 sunflower case.
3 **DR. PANGER:** Mm-hmm.
4 **DR. GRUE:** Which I think you ascribed to
5 actually a labeled use but what you...what I believe
6 you described is a very unusual ecological situation
7 for that application. Could you clarify that? Because
8 you mentioned some wheat...wheat seeds...
9 **DR. PANGER:** Yes.
10 **DR. GRUE:** ...and also that the field
11 had been treated with two herbicides plus carbofuran
12 related to a burn down, what I assume is going to be
13 weeds associated with the field.
14 **DR. PANGER:** Weeds and sunflowers,
15 right. Yeah, no, that's...that's just it. There
16 was...I mean, previous in...the incident occurred in
17 the spring of 2006. In July, 2005, that same field was
18 damaged. It was a wheat field at the time, was damaged
19 by hail. So, for the previous year, there was...for a
20 year, apparently, there was seed available in the
21 field.
22 Now, during that time, some weeds had grown
23 up. The farmer no-till planted the sunflower seeds in
24 that field in the following...the following year, and
25 that's when he did this burn down. And so, that's why

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1 it's...you know, used it at the rate. There was a lot
2 of...for flowable carbofuran, but because it...it could
3 have been considered at plant, it should have been in
4 furrow and it wasn't. So, that's the...that's the
5 complexity with that one.
6 **DR. GRUE:** Thank you.
7 **DR. PANGER:** Uh-huh.
8 **DR. HEERINGA:** Dr. Montgomery?
9 **DR. MONTGOMERY:** I know we're focusing
10 on birds, but I was curious, since you did bring
11 the...you did introduce topic, you did mention that
12 your database looks at non-targets.
13 **DR. PANGER:** Mm-hmm.
14 **DR. MONTGOMERY:** And I was interested to
15 hear what, you know, just a synopsis of what non-target
16 information might have been provided, what types of
17 things might have been impacted, the numbers. We've
18 heard a lot about birds, but you did mention that there
19 was other information available.
20 **DR. PANGER:** Yeah, there's...for the
21 incidents we know for carbofuran, quite a few do. Even
22 if there's a reported bird kill with the carbofuran, we
23 also see some mammals associated with some of those
24 bird kills. A lot of times, there are rodents
25 associated. We get everything from rodents...I'm just

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1 trying to, because I didn't do this analysis for the
2 mammals but just kind of thinking back of some of
3 the...the mammals that we did see associated with some
4 of the incidents. For mammals, feral pigs, dogs, cats,
5 and just a range of...a range of mammals. Most of them
6 tend to be rodents.
7 **DR. MONTGOMERY:** Again, they're sort
8 of...at the risk of sounding...this doesn't sound very
9 technical, but they're big things?
10 **DR. PANGER:** Some.
11 **DR. MONTGOMERY:** They're things that are
12 easy to see?
13 **DR. PANGER:** Some are, some aren't.
14 Yeah, some of the smaller rodents, but if I recall,
15 most of those are also associated with bird kills. So,
16 please were out looking at the...the incident.
17 **DR. HEERINGA:** Dr. Sparling?
18 **DR. SPARLING:** Don Sparling from
19 Southern Illinois University.
20 In the incidents of kill...avian die-offs or
21 kills, especially in the larger situations, I would
22 imagine that only a sub-sample of the birds are
23 sampled. If carbofuran was found on a bird, was the
24 entire...would the entire population be attributed to
25 carbofuran?

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1 **DR. PANGER:** Yeah, in most cases, we
2 have more than one bird, but yes, we don't test every
3 single bird, and if we do find evidence of...of
4 carbofuran and the results are consistent...the
5 mortality is consistent with that, then yes, we just
6 assume, yes.
7 **DR. SAMPLE:** Okay. And then, in the
8 reporting of the incidents, if there are multiple
9 pesticides found among the birds that were sampled, are
10 multiple...I mean, still carbofuran would be
11 associated, linked? All we're looking at is a linkage?
12 **DR. PANGER:** They can be, that's
13 correct, but in my analysis for the numbers, I removed
14 all my...you know, any incident that had more than one
15 chemical involved.
16 **DR. SAMPLE:** Okay.
17 **DR. HEERINGA:** Dr. Brimijoin?
18 **DR. BRIMIJOIN:** I shouldn't be asking a
19 question at this point, but I...I would just like to
20 see if I understand the logic of your interpretation of
21 this 1989 study where on the face val...on the face of
22 it, it seems to suggest or the statistics suggest
23 there's no statistical argument for an excess of deaths
24 attributable to carbofuran in comparison with the
25 controls, and EPA, it seems to me, is discounting that

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1 or say that we can't leap to that conclusion, because
2 there are adjacent fields treated with other
3 pesticides. And so, some of the...in other words,
4 there may be excess deaths occurring there as well.
5 So...so, I just...I just want to clarify the
6 logic of this, not the technical aspect. And so, it
7 seems to me there are two logical cases. Either the
8 adjacent fields were treated with something that, in
9 fact, doesn't cause any excess deaths or weren't
10 treated, and in that case, a failure to find
11 statistically more deaths in the carbofuran field
12 would...would tend to mitigate our sense of the level
13 of risk.
14 Or, (b), that your control fields are
15 experiencing excess deaths, and in that case, would we
16 not at least be left with the sense that we don't have
17 any evidence that carbofuran is more dangerous than the
18 other approved pesticides which are not under
19 discussion for de-registration?
20 **DR. PANGER:** Well, I think one of
21 the...the main points here is that...that these
22 deaths...and these probably don't represent natural
23 mortality, and because we have these searches that
24 occurred pretreatment that we could assume that, you
25 know, most of these deaths or carcasses that we found

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1 weren't there before the treatment...you know, they
2 occurred afterwards...that we can say something about
3 some of these numbers.
4 We can't really...none of our uses...we can't
5 really quantify, use...use this quantitatively because
6 of these confounding factors, but what it does show, in
7 some cases or the cases here, all of the carbofuran
8 treated plots experienced more mortality than these
9 pretreatment plots which we don't know how long...over
10 what period of time these were accumulating in these
11 fields also. So, they did a pretreatment search, but
12 we don't know how long, you know, these...these
13 carcasses might have be collected...been collected in
14 that field.
15 **DR. ODENKIRCHEN:** But our take home is
16 that, basically, if you look at that pretreatment as
17 sort of the background mortality that's occurring from
18 whatever causes other than something you've introduced
19 onto your control field, if you look at that in all
20 cases, the mortalities are higher in the treated plots,
21 the carbofuran treated plots, than that background
22 mortality would suggest.
23 And then, if you go back and you look and you
24 say okay, let's consider the ones where there's control
25 plots that aren't...that don't involve something like

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1 carbo...chlorpyriphos. In that case, we are still
2 greater than the control plot.
3 The only situation where you run this...run
4 into a situation where the control plot becomes very
5 close to the treated plot is a situation where we had a
6 confounding factor with another organophosphate, with
7 an organophosphate, in this case, chlorpyriphos.
8 So, we...when we look at that, we sit there
9 and say well, it looks to us like the treated plot is
10 above background levels of mortality, and, indeed, if
11 you...if your control doesn't involve something fairly
12 toxic, it's higher than your control levels.
13 **DR. HEERINGA:** Dr. Delorme?
14 **DR. DELORME:** I was just curious...Peter
15 Delorme, Health Canada. I was just curious if in any
16 of your incident reporting there's any evidence of
17 secondary poisoning.
18 **DR. PANGER:** Yes, there is. I didn't go
19 into that, but we do have several reported incidents of
20 secondary po...poisoning. Actually, in one of these
21 studies, they did find...I can't forget...I
22 remember...I can't remember if it was the corn or
23 alfalfa study...they did find, I think it was, a
24 harrier feeding on a...a rabbit that had 0.1 ppm
25 carbofuran, and that...the harrier was incapacitated.

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1 It didn't die, but it was incapacitated. In a lot of
2 the incidents, we do have inc...reports of
3 secondary...potential secondary exposure from their
4 eating of...of contaminated prey items and birds.
5 **DR. HEERINGA:** Dr. Bailey?
6 **DR. BAILEY:** Ted Bailey. I haven't
7 looked at these studies, but are they like replicated
8 studies? They have several plots and the different
9 treatments?
10 **DR. PANGER:** Yeah, to go back to the...
11 **DR. BAILEY:** And then, and how many
12 total plots would there have been to get one that...in
13 one of those...
14 **DR. PANGER:** Yeah, so here there was
15 a...in the Nebraska portion of the corn study, there
16 were 15 plots. Again, each of those were roughly 10
17 acres in size.
18 **DR. BAILEY:** Right.
19 **DR. PANGER:** And then, in the Texas-New
20 Mexico border, there were 16 plots.
21 **DR. BAILEY:** So you had some controls
22 and some treated.
23 **DR. PANGER:** Right, and so this is...
24 **DR. BAILEY:** Okay.
25 **DR. PANGER:** Yeah.

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1 **DR. BAILEY:** And now, were...were
2 they...the treatments randomly allocated to the plots?
3 **DR. PANGER:** I think it was
4 depend...they...they had some discussion with the
5 farmers and in terms of who was going to apply what is
6 my understanding. So, that is not exactly how they
7 determined those...
8 **DR. BAILEY:** But if they are, okay, then
9 a lot of these questions we're talking about I think
10 are not as relevant, because you've randomized over
11 that very building of what...where the other chemicals
12 are being applied, I think. So, I think...and to say
13 you can't quantify it, well, sure you can. You've
14 already done it by writing down these numbers.
15 **DR. PANGER:** Well, okay, point taken.
16 **DR. BAILEY:** And so, you can calculate,
17 you know, some means if you wanted to averaged over the
18 number of, you know, the number of reps per treatment.
19 **DR. PANGER:** Yeah. Actually, I think
20 Dr. Salice does a little bit of that in his talk, so
21 you'll actually see some of that, that analysis.
22 **DR. BAILEY:** I believe you're just in a
23 stronger position if they are randomized trials
24 than...than you're saying.
25 **DR. PANGER:** Well, I'm not sure they're

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1 randomized. I'll have to look at exactly how they
2 picked the fields and which fields, the distribution of
3 those fields.
4 **DR. HEERINGA:** Dr. Chambers?
5 **DR. CHAMBERS:** Jan Chambers. You may
6 have said, but in that pretreatment, the ones you had
7 up there a little...little while ago, was that
8 collected over the same period of time as the treated
9 were?
10 **DR. PANGER:** In terms of...well, they
11 did one...one pretreatment search that was done within
12 10 days of the application. Actually, they...they did
13 the pretreatment searches over several days within 10
14 days of application, and so, there was the...but we
15 don't know, again, how many...how much time those
16 carcasses had been accumulating in the field. They
17 did...we just know that they searched the fields within
18 10 days of the treatment.
19 **DR. CHAMBERS:** So, it isn't really the
20 same collection time then? Is that what you're saying?
21 **DR. PANGER:** I'll have to loo...I'll
22 have to double check on that. There were two
23 applications, so two...two searches with the...with the
24 applications, post-applications.
25 **DR. HEERINGA:** Dr. Grue?

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1 **DR. GRUE:** Chris Grue, University of
2 Washington. Just a comment about that. We know
3 carcasses don't last very long, so I think you can make
4 the argument both ways here.
5 **DR. PANGER:** Mm-hmm.
6 **DR. GRUE:** A...a search 10 days prior to
7 application where you remove all the carcasses and you
8 come in post-treatment and you find carcasses, just as
9 Dr. Chambers had mentioned, that time element is
10 important. If that's relatively equal across this,
11 then it ends up confusing the interpretation, because
12 you...it's difficult to argue one...one way in one case
13 and not extend that argument across the board. So...
14 **DR. PANGER:** Yeah, they did...
15 **DR. GRUE:** ...one has to be very careful
16 how you...how you interpret that in terms of
17 differental...differential time steps unless you make
18 the assumption that the carcasses that are present have
19 to be relatively fresh, because anything, let's say,
20 older than 48 hours...and there are studies that have
21 documented that...those carcasses are going to be gone.
22 **DR. PANGER:** Yeah, they actually did a
23 scavenging test in here using the dead chicks, and what
24 they found in...in their scavenging test that 6...I
25 believe it was 16 carcasses that they put out, they'd

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1 get like after 7 days, there were a remaining 18
2 percent or something. So, the rest of them had been
3 removed. So, they did do some scavenging tests on
4 that.
5 **DR. HEERINGA:** Dr. McCarty, then Dr.
6 Sparling.
7 **DR. MCCARTY:** John McCarty. Just,
8 again, one quick follow-up to that. They're also
9 including, though, feathered spots, not just carcasses,
10 and if those data were broken out separately, I mean,
11 a...a pile of feathers could last for months.
12 **DR. PANGER:** Mm-hmm.
13 **DR. MCCARTY:** Before something blows it
14 away.
15 **DR. HEERINGA:** Dr. Sparling?
16 **DR. SPARLING:** What was just said was
17 exactly the comment I was going to raise.
18 **DR. HEERINGA:** Very good. Now, what I'd
19 like to do at this point, unless there are urgent
20 questions from the panel, is to break for lunch, and
21 we'll have an opportunity to revisit if Dr. Panger's
22 willing right after lunch to anything that occurs to
23 you while you're eating, and if we've got no more
24 questions for Dr. Panger, we'll move on to the third of
25 the presentations on the ecological and environmental

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1 effects.
2 Oh, thanks. Let's take...let's take an hour
3 and ten minutes and be back here at 1:40.
4 **(WHEREUPON, a luncheon recess was taken.)**
5 **DR. HEERINGA:** Welcome back, everyone,
6 to the afternoon of our first day of our multi-day
7 session of the FIFRA Science Advisory Panel on the
8 topic of scientific issues associated with the Agency's
9 proposed action under FIFRA 6(b), Notice of Intent to
10 Cancel Carbofuran.
11 At this point, we have had a presentation
12 from several of the scientists with the Environmental
13 Fate and Effects Division of EPA. Melissa Panger went
14 last, and we had questions for her prior to the break.
15 I said that I would give a chance for any follow-up
16 questions that may occur to people over lunch.
17 Otherwise, we'll move on to the third of the
18 presentations.
19 Panel members, any additional questions for
20 Dr. Panger? Again, we can revisit it later on if...if
21 you would like, but anything that's pressing at this
22 point?
23 **DR. PANGER:** Could I announce that,
24 actually, we're getting copies of the studies put on CD
25 now, and we're going to make them available to the

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1 panel since there were so many questions about them.
2 So, you'll be getting those as soon as
3 they're...they're on the CD.
4 **DR. HEERINGA:** Thank you very much, Dr.
5 Panger. Dr. Odenkirchen?
6 **DR. ODENKIRCHEN:** Yes, one other thing.
7 We had a...we had owe question earlier from Dr. McCarty
8 about the use of a...a...the frequency on field
9 information and how exactly that was used in the model.
10 **DR. HEERINGA:** Yes.
11 **DR. ODENKIRCHEN:** And I...I'm afraid
12 that the answer at the time wasn't exactly clear, so
13 I'd like to clarify that, if I might.
14 **DR. HEERINGA:** Please do, if you'd like
15 to. If it's a clarification, go right ahead.
16 **DR. ODENKIRCHEN:** Sure. Basically, what
17 the...what the model does is let's say, for the sake of
18 argument, we have...we have census data that shows 100
19 birds on the field and 200 birds off the field at a
20 given sampling period which basically indicates to us
21 that there's a 1 in 3 chance that any given random bird
22 will be on the field at any given time that you were to
23 look.
24 So, that gives us a frequency on the field, a
25 propensity to be on the field of 0.33. What we do is

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1 we establish a minimally biased distribution for that,
2 and the...and the details with regards to establishing
3 that distribution are described in our document. We
4 establish a distribution for that.
5 We randomly sample. When we pick a bird, we
6 randomly sample from that distribution and assign a
7 propensity to be on the field for that bird. So, let's
8 say the bird has a propensity on the field of 0.1. And
9 what happens then is that each time step in the course
10 of the model, we ask the bird a question, are you on
11 the field or off the field? And the answer comes from
12 a binomial that is...that is based on a...a...a
13 propensity to be on the field of 0.1.
14 So, that's how the model works and uses
15 that...that census data to decide whether a bird is on
16 the field or off the field.
17 **DR. PANGER:** I want to do one follow-up,
18 too, to Dr. Montgomery's question regarding the...the
19 distribution of the fields in these studies. Looks
20 like they were a quarter mile apart, at least,
21 the...the control fields and the treated fields in
22 these studies.
23 **DR. HEERINGA:** And the actual papers and
24 reports will be put right on the CD?
25 **DR. PANGER:** Yes.

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1 **DR. HEERINGA:** Dr. Grue?

2 **DR. GRUE:** Chris Grue, University of

3 Washington. This is a follow-up.

4 The reason not to then just randomly select

5 each time for the bird, would that...would that alter

6 the distribution at all?

7 **DR. ODENKIRCHEN:** What it would do is it

8 would...it would say...what we...it would be the same

9 thing as instead of running 10,000 birds, we'd be

10 running 100,000 birds or, in this case, 140,000 birds

11 is what that would do or 140,000 time steps.

12 So, I think we cover pretty much the

13 distribution by doing 10,000 samples of that dis...of

14 that distri...what happens in TIM 2.1, though, is when

15 you have that...that assigned value, then we ask the

16 bird a question, what did you do the time before, and

17 how wedded are you, bird, to that...that decision of

18 what was done the first time?

19 So, in other words, if you could incorporate

20 things like avoidance by doing that, by biasing the

21 birds away from their natural propensity because of the

22 presence of a chemical, for instance, or you could do

23 something else like gorge feeding or whatever if there

24 was an environmental factor.

25 So, that same data is still used, but it's

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1 used in a slightly different way.

2 **DR. HEERINGA:** Thank you very much for

3 those clarifications on this morning's questions. At

4 this point in time, I think we'd like to be able

5 to...to move on to the third of the presentations, and

6 maybe, Dr. Odenkirchen, you could introduce your

7 colleague.

8 **DR. ODENKIRCHEN:** Yes, this is Dr. Chris

9 Salice. He's a biologist with the...our Fate and

10 Effects Division.

11 **DR. HEERINGA:** Welcome, Dr. Salice.

12 **DR. SALICE:** Thank you. Good afternoon,

13 and I'd like to extend thanks for everyone and for

14 participating, and I look forward to hear your

15 comments.

16 Just a brief overview of what I'm going to be

17 talking about. I'm going to touch briefly on TIM 1 and

18 TIM 2.1, provide a little more information on those two

19 models. I'm also going to talk about some new analyses

20 that were conducted in support of the PRA, PRA being

21 probabilistic risk assessment. I'll use that acronym a

22 lot.

23 And then we're going to look at the impact of

24 the new avian data that was submitted by the

25 registrants, the impact of that on the PRA outcomes,

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1 and then also consider an alternative probabilistic
2 risk assessment model that was also submitted by the
3 registrant, and then finish up with some conclusions.
4 So, before delving into the sort of nuances
5 of the probabilistic model, I think it's important to
6 set a little bit of context. In 2007, the National
7 Resource Council published a report on the use of
8 models in environmental regulatory decision making, and
9 in that, they have some really interesting insights
10 into how models are used.
11 And a couple things to highlight:
12 models will always be constrained by computational
13 limitations, assumptions, and knowledge gaps, and,
14 indeed, we push up against this in this very discussion
15 in terms of what we do and don't know. It's important
16 to keep in mind that we can really never build the
17 perfect model that describes reality perfectly, and
18 that's something to keep in mind.
19 And that transparency of model results and
20 construct and the evolution of those models is...should
21 be sought after more so than completeness, completeness
22 being, you know, a complete description of reality.
23 It's also important to continually evaluate individual
24 models and also to consider family of models and how
25 their results comport to either provide insight to

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1 similarities in response or even highlight some
2 differences that may need further research.
3 And, in general, it's...it's best to keep
4 the...the viewpoint that models are used to help inform
5 decisions. As such, TIM 1 and TIM 2.1 are one line of
6 evidence in a weight of evidence approach in
7 concluding...in making conclusions about the risks of
8 carbofuran, in this case specifically, to avian
9 species.
10 So, I'm going to go over a little bit of what
11 Dr. Odenkirchen went over just to sort of review.
12 TIM 1 formed the basis of risk conclusions in
13 the original risk assessment for carbofuran. At the
14 time, it was the only fully functional probabilistic
15 model that we had available. Importantly, as he
16 mentioned, it uses two time steps per day which can be,
17 as it turns out, useful when you're trying to look at
18 some elements of the model or the incorporation of some
19 data.
20 TIM 2.1 is an updated version. It
21 incorporates many of the same elements but does have
22 notable differences. It was used in support of a
23 Notice of Intent to Cancel in addition to TIM 1.0.
24 Similar...as I said, it's similar in construct to TIM 1
25 but more refined in its uses, an hourly time step.

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1 More actually capture bird behavior, it's able to parse
2 out a bimodal feeding behavior. It incorporates more
3 realistic puddle and rainfall algorithms, again, at the
4 request of the SAP, and it can also be used to estimate
5 risk for multiple applications and multiple exposure
6 routes.
7 Now, we're going to be seeing a lot of graphs
8 of this. This is a comparison of outputs from TIM 1
9 and TIM 2.1. On the X axis is average mortality or
10 probability of mortality. So, that's the primary
11 output. Dr. Odenkirchen showed those tables. That's
12 basically what those numbers would represent.
13 And along the X axis is the percentile
14 sensitive species. As he mentioned, we don't have
15 toxicity del...data available for all species. So, we
16 use the available data we have, the entire distribution
17 of toxicity data, and pull from that toxicity values
18 that represent the response of a sensitive species, a
19 medium sensitive species, and a less sensitive species.
20 And so, that would go...the more sensitive
21 species, what we pull is a 5th percentile, so that
22 would be on the right side of the X axis, the less
23 sensitive species...or, I'm sorry...yeah, on the left
24 side of the axis, less sensitive species on the right
25 side of the axis.

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1 And here, these curves represent basically
2 either if you're in a TIM 1 construct with a particular
3 species or if you're in TIM 2, it's a type of species.
4 In this case, it's an edge granivore, and I'll get into
5 that a little bit more a little bit later on, but right
6 now, it's just important to see those two curves as
7 representing two different species, and these curves,
8 in particular, represent the boundaries on our risk
9 projections from the RED.
10 And so, looking at this...oops, wrong one.
11 There we go. So, throughout these, the indigo curves
12 are going to represent an insectivorous species and
13 considered basically a vulnerable species, and that's
14 due to its habits, basically, its time on the field and
15 also its diet. The green curves represent granivorous
16 species which are on the low end, less vulnerable.
17 And from this graph, you can see the...the
18 solid line represents, in all cases, baseline risk
19 projections that would be either similar...they
20 incorporate the same inputs that were used from the
21 outputs represented in the chapter, so, the basis of
22 original conclusions regarding carbofuran toxicity or
23 risk to birds.
24 And so, what we're looking at, then, are the
25 differences between the solid line, again, representing

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1 the baseline, and the dashed line which is representing
2 whatever factor we happen to be looking in terms of its
3 impact on average mortality.
4 So, in this case, TIM 1, again,
5 representative of what was in the carbofuran chapter,
6 is the solid line, and the dashed line is the output
7 from TIM 2.1 with all similar input values. And you
8 can see that, generally, TIM 2.1 and TIM 1, in this
9 case for this scenario, are fairly close. Yeah, there
10 are some differences, but in general, pretty close.
11 An important consider, as came up already,
12 for probabilistic risk assessment is the risk within
13 field variability and pesticide residues. The
14 distribution used to describe within field residue
15 variability is important, because, in general, just by
16 doing some model runs and, if you think about it,
17 greater variability will tend to increase risk. Lower
18 variability would tend to decrease it; you'll have less
19 chance of a high exposure.
20 Also, another implication of having variable
21 pesticide residues is it's possible that birds could be
22 exposed to higher concentrations through time, and that
23 would occur if, at time step 1, a bird randomly eats
24 from an area where there's low pesticide residue
25 variability and, in the second time step, perhaps eats

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1 from an area in the field where there's higher residue
2 variability. This takes into account...is still taking
3 into account the fact that the pesticide is degrading
4 through time.
5 And also, if you think about how birds would
6 feed and how they would use a field, it would seem
7 unlikely to think that there's no variability. That
8 would be akin to saying in a given field, a bird, over
9 a time step, samples randomly over the entire field,
10 thereby getting, quote/unquote, average concentration.
11 Or another way to look at it is they take the field,
12 homogenize it, and then consume food from that blended
13 mix.
14 So, to...to lend some sort of credence to our
15 approach which, as Dr. Odenkirchen mentioned, was based
16 on the UTAB database and the variability associated
17 with pesticide residues, we looked at four studies on
18 carbofuran, very limited data set, just to sort of
19 flesh out whether or not, you know, pesticide residues
20 do vary within fields. You'd be surprised. There was
21 a lot of data...no data on between field estimates of
22 residues compared to within field.
23 And so, we found that the coefficients of
24 variation ranged from about 0.2 to about 0.9 with best
25 estimates, best in quotes, because that's a function of

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1 both sort of number of values and also study quality,
2 around 0.6. In contrast, the coefficients of variation
3 used in TIM ranged from about 0.7 to 1.8. So, there's
4 some overlap, but maybe the coefficients used in TIM
5 are on the high end.
6 And another just sort of feedback to the
7 birds can be exposed at higher con...to higher
8 concentrations in subsequent time steps, a lot of the
9 data sources show that in samples, the pesticide
10 residues actually increase in time, and there may be
11 several factors contributing to that, but there are a
12 number of data sources that do show that.
13 So, this is just the four studies and the
14 range of coefficients of variation. Nothing really
15 special there.
16 But if we look at the risk projections,
17 incorporate some lower variability of pesticide
18 residues, and this...these runs actually used TIM
19 2.1...again, the solid curve represents our baseline
20 conditions. The dashed line represents now the
21 simulations with lower variability. And, basically,
22 less variability of pesticide resi...residues does
23 reduce projected risk slightly, more so in the
24 insectivorous species, the green curves, because the
25 relative change in variability was greater than in the

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1 granivorous species.
2 Another important factor that has also come
3 up in discussion, interestingly enough, is how birds
4 use different fields. So, as mentioned, we...our
5 assessment is focused on the field level, and EPA uses
6 census data that's been briefly discussed to estimate
7 the frequency that birds are on fields.
8 But there are alternative constructs that
9 vary bird behavior across fields. So, it says,
10 basically, that between...that fields are different,
11 and, therefore, birds use them differently, even though
12 we don't have or know of data or relationships that
13 would enable you to use that in a sort robust way. It
14 would seem that you would need more information. You
15 would extend the...yeah, you would need more
16 information to use that appropriately in a
17 probabilistic sense.
18 So, some data from radio-tracked birds in the
19 UK may provide some insight into how birds use
20 different fields. And this is, like I said, a radio-
21 tracking study, and, basically, one of the conclusions
22 is this approach, that is, assuming no variants in
23 among-field use by birds, can only be justified if it
24 could be shown that within a species, individuals
25 behave very similarly, irrespective of the crop they

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1 inhabit.

2 Our radio-tracking data on skylarks lends

3 some support. For example, there was no significant

4 difference in the proportion of time spent in five

5 major capture habitats, serials, broadleaf, roadsides,

6 grasslands, and stubble.

7 This, although limited in terms of data and

8 statement, we acknowledge that, but this is really the

9 best available that we have, and it suggests that bird

10 behavior across fields is similar, supporting the

11 current construct of TIM.

12 So, some...just to...to sort of summarize

13 this first section of the talk, some conclusions.

14 Although TIM 1 and TIM 2.1 differ in several notable

15 regards, they share some common elements, and similar

16 results may be expected under certain combinations of

17 scenario and pesticide.

18 TIM 2.1, however, ultimately has a lot more

19 flexibility. Dr. Odenkirchen mentioned the fidelity

20 factor which, by the way, for all these simulations,

21 was set to a value that didn't show a preference either

22 way. That value could be set to...so the birds in

23 subsequent time steps would have an increased

24 preference to stay on the field or a decreased

25 preference to stay on the field, and in these

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1 simulations, it was kept in the middle so that there
2 was no...so that to more similarly mimic what would be
3 going on in TIM 1.
4 Data do show that pesticide residues vary
5 within fields and that incorporating the slightly lower
6 estimates of variability produces lower estimates of
7 average mortality. Importantly, before we would
8 probably go on to making some large-scale changes in
9 how we use variability, we'd like to do a more
10 extensive data review.
11 And, again, best available data suggests that
12 birds use fields similarly within a species and across
13 field types.
14 Continuing, the TIM probabilistic framework
15 is designed to address risks at the field level, and
16 the best available data and peer review supports the
17 model construct to date. As mentioned earlier, the SAP
18 has commented on several elements of the TIM modeling
19 framework, both incorporating dynamics of carbofuran at
20 the site of action and also considering whether
21 avoidance or even preference might play a role in
22 estimating risks to avian species.
23 In 2007, in part to address some of the
24 issues previously identified by the SAP, the registrant
25 submitted four avian studies, and they included the

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1 mallard duck avoidance of feed containing furidan 4F
2 which is carbofuran, differential toxicity of
3 carbofuran to bobwhite quail when dosed as an aqueous
4 bolus which is your standard gavage method versus the
5 same dose mixed in feed, another study like that on
6 mallard ducks, and, finally, a brain...bobwhite quail
7 brain cholinesterase activity and recovery study.
8 And generally, if the studies were considered
9 suitable, they could be used to alter or add inputs to
10 the avian probabilistic model. And here I have note
11 the law of diminishing returns.
12 I mentioned that NRD...or that National
13 Resource Council publication on the use of
14 environmental models in...or models in environmental
15 regulation. An important concept is if we continually
16 strive to build really complex models that describe
17 reality perfectly, we could start brushing up against
18 the law of diminishing returns where as we add more
19 complexity, we don't really gain any more information,
20 any more useful information. That's not to say it's
21 not worth trying. It's just something to keep in mind
22 as we continue to develop models.
23 So, our approach for review of the studies
24 was basically to first, obtain them, review them, are
25 they scientifically robust or not. If so, more or less

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1 figure out how the studies could be used in the PRA,
2 and then use TIM 1 and/or TIM 2.1 to look...to evaluate
3 the impacts of the study results on risk projections,
4 and then, again, provide some overall conclusions,
5 taking into consideration the study quality on which
6 the data...the inputs or the assumptions were based.
7 So, now I'm going to talk a little bit more
8 about the scenarios chosen. In this case, the intent
9 was not to do an exhaustive risk assessment for
10 carbofuran incorporating the new data. It was merely
11 to see how the new data and assumptions might impact
12 our risk conclusions.
13 And so, we chose basically two representative
14 species, a killdeer in...it would be a killdeer in the
15 TIM 1 construct or an edge insectivore, and they're
16 basically the same. In TIM 2, it would be edge
17 insectivore and the mourning dove, and they represent,
18 respectively...well, the killdeer represents the sort
19 of more vulnerable scenarios and the mourning dove a
20 less vulnerable one.
21 And, for the most part, a lot of these
22 results are based on food consumption. That's, in
23 part, because three of the four studies submitted
24 direct...dealt directly with exposure via the dietary
25 route, and it was thought that that could be used to

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1 sort of highlight the impact on risk projections.
2 And, again, the toxicity estimates were based
3 on a distribution of toxicity values for...for tested
4 bird species, representing our sort of, you know, field
5 birds, killdeer and mourning dove. And we used the
6 5th, 50th, and 95th percentile sensitivities.
7 The scenario was a 1 lb/acre carbofuran
8 applied to corn which is on the label. This was
9 chosen, as Dr. Odenkirchen said earlier, in part
10 because there was a lot of data available for the use
11 of corn fields by birds. Corn covers a wide geographic
12 range, and, therefore, is...it's likely that when we
13 consider what species are there, we're encompassing a
14 number of different scenarios and crops from an
15 ecological standpoint or potentially.
16 And the Agency believes that...that this
17 scenario likely represents row crops at similar
18 application rates and probably other crops as well,
19 and, largely, the difference is going to be in how
20 birds would use those fields.
21 So, the first study was an avoidance of
22 carbofuran treated feed in mallard ducks. And,
23 basically, there's some more details here, but
24 essentially, the birds were individually housed,
25 individually caged, and offered two feed pans. One

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1 contained untreated feed; one contained carbofuran
2 treated feed. And then, food consumption was measured
3 on a daily basis, and body weights were taken
4 periodically.
5 There were six levels of carbofuran ranging
6 from about 0.7 to 145 mg/kg. That's...that's measured.
7 The implications of this type of data for the
8 probabilistic risk assessment would either to be
9 affecting the fidelity factor, as Dr. Odenkirchen
10 mentioned and I briefly described, or perhaps an
11 adjustment of food consumption.
12 Before we delve into some of the details,
13 there is considerable doubt regarding the utility of
14 this study for the probabilistic risk assessment, and
15 with that...that's within the Agency.
16 So, the results indicated that birds appeared
17 to show a strong preference for feed pan side even if
18 carbofuran treated feed was not present. This, we
19 thought, considering this is a behavioral study, is
20 likely a confounding factor.
21 There was observed reduced feed consumption
22 in birds at higher exposures, and we generally
23 considered the design suitable as a screen for possible
24 avoidance behavior but not necessarily definitive or
25 robust enough to use as...as an input for the

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1 probabilistic risk assessment. And, in fact, we
2 considered a robust study design to incorporate non-
3 concentration food sources, maybe the use of pens
4 instead of cages, and some measure of hunger stress,
5 mimicking what might be occurring with birds in the
6 wild.
7 If we look at total daily food consumption
8 normalized to body weight through time...this is for
9 all birds, all concentrations...day -1 is as a
10 acclimation period. So, birds...all birds, in this
11 case, were given two pans but no carbofuran.
12 Day 1, some birds, the carbofuran
13 levels...are...are now given one pan with carbofuran
14 and one pan untreated. And then, each day, actually, I
15 didn't mention earlier, but the pans are alternated.
16 So, one day, the treated, carbofuran treated pan is on
17 the right; the next day, it's on the left.
18 And what we see here is that there is a
19 decline in food consumption and then a steady incline
20 through time, and this is the case for all birds, all
21 concentrations. Note, though, there is a stronger
22 effect on the birds at the higher exposure levels.
23 So, if we look at an individual bird...and
24 this is really to provide just some perspective on some
25 of the behavioral nuances associated with this type of

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1 study...here we have a bird that is not receiving any
2 carbofuran. It's a control bird. Negative...day -3
3 through -1 represents, again, that acclimation period,
4 and then day 1 is the experimental phase began. This
5 bird didn't get any carbofuran, but birds that would be
6 getting carbofuran started to get it on this day.
7 So, again, we see a pattern that mimics what
8 occurs sort of when we looked at the...the graph for
9 all bird species, a sharp decline and then an incline
10 through time, and in this case, there was almost no
11 consumption of food on the right-hand side.
12 So, when we look at first at this pattern, we
13 say well, what's going on here? Is it potentially
14 growth in some way? No, we don't think so, because the
15 birds were close to maturity if not mature. Is there
16 some sort of compensation for an energy deficit that
17 somehow is created in here? We don't know.
18 Is there a behavioral response or maybe a
19 group response? The study design incorporated sheet
20 metal on the sides of the...of the bird cages,
21 individual bird cages, to prevent some interactions,
22 but, you know, they're still in basically a large cage
23 with X number of birds in it, and perhaps there's some
24 sort of group behavioral response associated with some
25 birds becoming sick. We don't know.

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1 Or is there some sort of experimental error
2 or design error that is introduced?
3 Regardless, it appears that birds favor one
4 side for field...for feeding.
5 When we look at a bird that's from the
6 highest carbofuran exposure level, we see something
7 similar. Note here that there's no...again, no
8 consumption from the left-hand feed pi...feed pan side,
9 and then, there's again a decrease and then an increase
10 through time. The yellow bars represent consumption
11 from carbofuran feeded treat...treated feed.
12 You know, I picked a couple of scenarios that
13 represent my point, but there are a number of birds
14 that show this sort of preferential feeding from one
15 pan side to the other.
16 So, some conclusions regarding the avoidance
17 study. It seems that there are significant
18 methodological limitations to the avoidance study. You
19 know, this behavioral factor could really confound
20 results, not to mention the fact that when measuring
21 something as complex as behavior, to get an estimate
22 for how you might apply some sort of factor for birds
23 in the wild and using a bird in a small cage to
24 represent that, one could see how that might introduce
25 some measure of error.

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1 There's also a non-uniform feeding rate
2 across all groups with an unknown cause. That was that
3 sharp decline...or that decline and then an increase
4 through time.
5 And it appears to offer limited utility for
6 avoidance and, again, as suitable as a screen. If you
7 look at the statistics for avoidance, there are
8 factors...there are numbers associated with whether
9 there's potential avoidance at this level or that
10 level, suggesting, again, we think it might be suitable
11 as a screen but not...not for much else.
12 But what else might the data tell us? If we
13 look at feed reduction as a function of carbofuran
14 dose, there appears to be a relationship. And so, at
15 higher doses, what we have is a decrease in feed
16 consumption. And this is for day 5, and, basically,
17 what we did was explore the use of this relationship in
18 TIM 1 to adjust feed consumption.
19 So, what happens is if a bird feeds and
20 obtains...let's see... 1 mg/kg body weight dose, we go
21 over here and say I think it's about a 0.25 reduction
22 in feed consumption. So, for about a 1 mg/kg dose on
23 the first time step, and in the second time step, its
24 feed consumption would re...would be reduced by 0.25.
25 And part of the reason we chose to use TIM 1

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1 was that the time step, which is two per day, is more
2 consistent with the study observation period which is
3 daily. If we incorporated an hourly, the hourly time
4 step used by TIM 2.1, we would have to make some sort
5 of adjustment or assumptions about what may be
6 occurring on those shorter time spans.
7 The other thing to notice is that those
8 points look like they're driving the relationship, but,
9 in fact, if you take them out, the relationship is more
10 or less the same. R2 improves a little. More or less,
11 they kind of change a very...very slightly, so we sort
12 of...we kept those data points in for...for analyses.
13 Just didn't want you to think we weren't being careful.
14 Sorry. So, looking at the impacts of
15 feed...of carbofuran induced feed reduction on average
16 mortality, we see that, indeed, the potential for feed
17 reduction in...in subsequent time steps associated with
18 an exposure occurring previously does, in fact, reduce
19 risks.
20 And this shouldn't be all that surprising.
21 Basically, birds are eating less. And so, this is the
22 case for both the edge insectivore and the edge
23 granivore.
24 However, it occurred to us that there are
25 probably other ecological implications of carbofuran

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1 induced feed reduction, namely, obviously, there's a
2 reduced energy intake which can result in deleterious
3 consequences for birds in the wild, particularly if you
4 think that many birds may be operating on a fine line
5 of obtaining enough energy to sustain, you know, their
6 daily activities and especially if you start
7 considering other periods within the year when energy
8 demands could be higher and reduced energy intake could
9 be significant.
10 Also, there could be alteration of other
11 behaviors such as foraging or mating associated with
12 perhaps being hungry or in a reduced energy state.
13 So, TIM 1 was adjusted to track energy
14 deficiencies in birds just to sort of get a sense of
15 what...what kind of energy reductions are we talking
16 about, and for killdeer, we saw, again over a 14-day
17 period, about a 40 percent reduction in energy intake,
18 and for mourning dove, about a 15 percent reduction.
19 Again, most of that reduction occurred early on when
20 exposure were higher, and then birds were allowed to
21 recover and sort of recoup. Well, they didn't recoup.
22 It was just summed at the end of that 14-day period.
23 And, importantly, reduced energy intake,
24 obviously, cannot be sustained. So, we looked at well,
25 what would happen if we said well, birds can compensate

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1 for decreased energy intake in a previous time step by
2 eating more when, basically, carbofuran effects may
3 subside?
4 So, when we do that, the...again, the solid
5 curve represents a baseline. In this case, the dotted
6 curves represent the average mortality associated with
7 feed reduction alone, and then this dashed line that
8 sort of follows the baseline represents that average
9 mortality when birds were allowed to compensate for
10 decreased energy intake in a previous time step.
11 And so, what you see is...and this isn't
12 altogether that surprising, either...when birds can
13 eat, are allowed to re...recoup some of their energy
14 deficiency, then risk would...would go back up.
15 Now, how this was functionally modeled is to
16 say that well, if two consecutive time steps, there was
17 a decrease in energy intake, then energy intake was
18 increased by a certain amount. I can get into the
19 details of that, but it wasn't doubled or tripled. It
20 was increased by, basically, the food requirement for a
21 daily time step or for...for one time step.
22 Okay, so...so, we can have all the
23 discussions about, you know, the nuances of this data
24 and how it applies to the PRA, but it also would be
25 beneficial to kind of look at what kind of evidence is

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1 available from incident field studies. And,
2 basically...and also to look at the study itself.
3 The avoidance study was conducted on mallard
4 ducks which are among the most sensitive species to
5 carbofuran, and that can impact, you know, the
6 potential results or the implications for PRA. The
7 registrants own risk assessment shows risk to waterfowl
8 in alfalfa, and the largest legal use incident is 2500
9 waterfowl birds killed, and there are a number of other
10 incidents associated with waterfowl kills, suggesting
11 that it's possible avoidance of carbofuran in food
12 items or reduced feed consumption as a result of
13 exposures may not be operating in wild birds.
14 Okay, so number...study number 2 and number 3
15 were the acute toxicity of carbofuran in feed matrix.
16 So, two studies, one on mallard, one on bobwhite.
17 Birds received a dose of carbofuran either mixed in
18 feed and administered via intubation or as an aqueous
19 bolus. That's, again, your standard gavage. There
20 were four dose groups for the feed matrix and three for
21 the aqueous bolus. No controls for aqueous-dosed
22 birds.
23 I have this in red, because, typically, if we
24 receive studies that don't have a control, we would
25 consider that a serious error. In this case, you might

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1 say well, really, they're looking at the effects of the
2 food matrix, but really, it's the effects of the food
3 matrix compared to effects in the aqueous bolus. The
4 application...and I say that, because the application
5 for the probabilistic risk assessment is to adjust
6 toxicity with the food matrix adjustment factor. And
7 so, I'll explain that. It will become more apparent.
8 If we look at the results in the bobwhite
9 study, birds dosed with the food matrix, carbofuran
10 mixed in a food matrix, had an LD50 was about...that
11 was about 3.9 times higher than the aqueous LD50. In
12 this case, the confidence intervals did not overlap.
13 For the mallard study, although some mallards
14 regurgitated the food matrix dose, calling into
15 question...potentially calling into question the study
16 results, when you compare the LD50s, birds dosed with
17 the food matrix, that LD50 was about 2 times higher
18 than the aqueous LD50, and in this case, the confidence
19 intervals did overlap.
20 So, what these tell us...represent are
21 possibles, possibilities. There's a possible food
22 matrix effect associated with this study design, and in
23 this case, you know, we're saying we kind of have the
24 bases covered. Maybe it ra...maybe it's nothing
25 confidence intervals did overlap in mallards. Maybe

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1 it's 2, maybe it's 3.9.
2 So, some of the interpretation of these data.
3 Really, it's uncertain as to how these results would
4 apply to other species. Bobwhite are among the least
5 sensitive species. Mallards regurgitated. LD50s
6 didn't differ. So, it's not exactly...I don't think
7 that we can conclusively come away from this and say
8 okay, we know...we understand how this operates in all
9 birds in the wild.
10 And so, with that, we're uncertain how the
11 results apply to exposures in the field. Here we have
12 carbofuran mixed in feed, and the field exposures could
13 occur from eating food items for which carbofuran is on
14 the surface. Uncertain how different food items affect
15 the food matrix effect. Are eating insects the same as
16 eating, you know, vegetation in terms of the food
17 matrix?
18 And is the slope of the response for food
19 matrix toxicity constant? So, as...as exposure
20 changes, does the slope change which would...which
21 would alter the application of the food matrix
22 adjustment factor?
23 So, given these uncertainties, we can still
24 use the data to explore and do a what if. What if, you
25 know, this described some aspect of reality for birds?

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1 How would this impact avian risk projections?
2 And ask you might guess, it would decrease
3 the average mortality. The...again, using our familiar
4 curves, baseline risk projections or average mortality,
5 percentile sensitive species. So, we see that with a 2
6 times food matrix adjustment factor, it reduces average
7 mortality. With a 3.9 time factor, it reduces it.
8 This is apparent for both species. In this case,
9 you're essentially multiplying the L...LD50 by either
10 of those factors and thereby, you know, lowering
11 the...the functional toxicity. So, that was study
12 number 3.
13 Study number 4 gets at some comments from
14 previous SAPs which is incorporating the dynamics of
15 carbofuran at the site of action. Hello? So,
16 carbofuran inhibits acetylcholinesterase activity,
17 dominant mode of toxicity. So, it...just briefly, it
18 reversibly binds to acetylcholinesterase, inhibiting
19 the enzyme responsible for breaking down the
20 neurotransmitter, acetocholine.
21 The neurotransmitter builds up in the nerve
22 junction, causing continuous signaling, and if activity
23 is not restored, mortality or other effects may occur.
24 And, again, the previous SAP has commented on using the
25 site of action to do the PRA potentially.

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1 So, this study...my apologies...was...was
2 pretty robust. It incorporated 10 groups containing 10
3 birds each that were dosed with three levels of
4 carbofuran. Treatments were...basically, birds were
5 sampled at different time periods, more sort of at a
6 higher frequency early on and less so after 5 hours,
7 and birds were dosed at 5 intermittal...5-minute
8 intervals to account for the time...or to allow
9 sampling of birds at the appropriate time step.
10 And the applications of this for the
11 probabilistic model would be that it impacts the
12 carryover exposure between time steps.
13 So, if we look at the results, there was 37
14 percent mortality in the high dose group, 1 percent
15 mortality in the medium dose group, and 100 percent
16 survival in the control and the low dose group. All
17 mortalities occurred in the exposure period.
18 The estimated recovery half-lives for
19 acetylcholinesterase were 1.1, 2.9, and 4.4 hours for
20 the three dose groups, so there is an apparent dose
21 response with a longer recovery half-life associated
22 with a higher carbofuran dose. And it is apparent that
23 a bird dosed with 3 mg carbofuran did not show recovery
24 to control levels within the study or complete recovery
25 for all birds.

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1 So, if we look at the projected
2 acetylcholinesterase recovery with the red line,
3 horizontal line, representing the baseline sort of
4 activity level that would be considered completely
5 recovered...this is when the study was
6 terminated...these are what the half-lives would show
7 would be the acetylcholinesterase recovery. And so,
8 again, at the high dose, birds, it looked like, might
9 not recovery until about 11 hours completely.
10 Granted, we have no data beyond here, so it's
11 kind of difficult to say.
12 And in general, though, the study was fairly
13 robust and produced results that were consistent with
14 what we know about carbofuran's mode of toxicity.
15 So, if we look now as to how those data would
16 be applied in the PRA, again, it affects the carryover.
17 So, if a bird is exposed at the first time period,
18 there is a carryover of that exposure. It's not
19 complete until the next time step, and so, when it eats
20 in the next time step, it gets added to what was
21 carried over.
22 For TIM 1.0 with two time steps per day, that
23 carryover rate constant was 0.41. For TIM 2.1, it was
24 0.93, and as you recall, Dr. Odenkirchen mentioned that
25 those numbers, at least the 0.41 that he mentioned

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1 earlier, is based on the elimination from a hen study.
2 If we look at the carryover effects based on
3 acetylcholinesterase recovery using the half-life of
4 4.4 hours, we see those rate constants drop to about
5 0.15 and 0.85. So, if we plug these into our model,
6 this is TIM 1. Again, we see that there is little
7 apparent impact of using acetylcholinesterase recovery
8 on risk projections, and that's mostly limited to
9 species at the...at the sort lower end of the
10 sensitivity distribution.
11 Now...and this also incorporates, by the way,
12 I looked of sort of at the last minute a 1.1 hour half-
13 life just to see how that would flesh out.
14 Now, an important point here, though...and
15 this represents why it's sometimes good to have two
16 models or anyway...one point is that it's clear that
17 because acetylcholinesterase happens...recovery happens
18 in a fairly rapid time step, it would probably be more
19 appropriate to use it in TIM 2.1. So, looking at that,
20 you see that yeah, in fact, using a model with an
21 hourly time step does then impart a greater effect to
22 using acetylcholinesterase recovery half-life.
23 And so, you know, if we look at these, again,
24 this dashed line is using a recovery of 4.4 hours.
25 This is 1.1 hours. And so, this represents probably a

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1 range of where we would expect, you know, the recovery
2 to impact predictions of average mortality, and notice
3 it's tighter, again, for the granivorous species.
4 So, so far, I've shown you predictions of
5 average mortality based on the dietary route of
6 exposure only, and, again, that was to highlight some
7 of the differences and to address some of the studies
8 that were primarily dietary based. Well, if we look at
9 the aggregate effects, that is, the incorporation of
10 acetylcholinesterase recovery and also the food matrix
11 adjustment factors...we didn't include the avoidance,
12 any data from the avoidance study, because we didn't
13 feel like it was robust enough...we see that, indeed,
14 there is an effect. This is for TIM 1.0.
15 For TIM 2.1, again, they produce similar
16 curves, similar estimates of average mortality, similar
17 effects associated with the...the incorporation of new
18 data, and so, let's see, again, food consumption only.
19 This still includes food consumption only, no drinking
20 water.
21 So, one of the advantages of TIM 1, as
22 mentioned, is it incorporates some sophisticated
23 algorithms to describe both puddle formation and
24 rainfall can also be incorporated. And so, when we do
25 that, looking at...this is now only TIM 2.1...with

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1 rainfall occurring after application, about 24 hours I
2 think I specified, if you can recall...it might be
3 difficult but...that risks actually increase,
4 particularly for granivorous species.
5 And that is not just impacts...or that's
6 mostly due to the fact that now these birds are able to
7 obtain drinking water from the field. Previously, they
8 weren't drinking water, or at least in our simulations,
9 and what happens is because they obtain less of their
10 water from food items, because they're eating seeds,
11 their relative sort of predictions of average mortality
12 increase.
13 Now, if we say okay, rainfall can occur
14 before application...and this, again, this scenario,
15 rainfall before application was in direct response to
16 an SAP comment that mentioned well, we may not be
17 capturing all possible sort of risk scenarios without
18 including this type of situation. So, in this case,
19 rain falls, puddles form, and then the pesticide is
20 applied, and pesticide concentrations are, therefore,
21 higher in the puddle, and we see actually risks go up
22 quite substantially, particularly in the middle range
23 of the species sensitivity, and in here, we have
24 actually flip where now the granivorous species show
25 higher average mortality. Again, now they're consuming

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1 water more, relatively more water from the field, and,
2 also, pesticide concentrations are higher.
3 Okay, and it's important to note that this
4 may seem sort of...well, it's important to note that
5 the great incidents that Dr. Panger had mentioned
6 earlier support drinking water as a complete and
7 potentially important pathway.
8 So, okay, to summarize our conclusions
9 regarding the avian data, we think that the avoidance
10 in foot matrix studies suffer from some methodological
11 deficiencies and offer some considerable uncertainties
12 regarding both what's going on in the study exactly and
13 also how these would app...how the results apply to
14 birds in the field and in wild...wild habitats.
15 Clearly, potential food matrix effects have the
16 greatest impact on risk predictions, although there
17 were considerable uncertainties, again, with regard to
18 field conditions.
19 The acetylcholinesterase recovery study, we
20 felt, was sound and consistent with the carbofuran mode
21 of toxicity, and we'll probably think more about
22 incorporating it or potentially incorporating it into
23 our sort of baseline model runs for carbofuran, but it
24 actually only applies to carbofuran. So let me scratch
25 that.

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1 Okay, so the Agency concludes that the risk
2 projections incorporating the new avian data do show
3 risks to birds associated with carbofuran use.
4 However, the new data broadens the range of potential
5 risk outcomes.
6 And you say well, wait a minute, we added
7 data. How...how are we actually broadening the range
8 of risk outcomes? And we...we're doing that, because
9 we're adding a different type of data. This
10 specifically speaks to the food matrix effects.
11 We don't have a large body of data or any
12 data, really, to relate that type of laboratory study
13 to what would be going on in the real world. The best
14 we can say is maybe it happens, maybe it's important,
15 and it's...and use it as sort of a boundary exercise to
16 say well, if these types of effects are occurring, then
17 it's likely a range of risk or average mortality
18 predictions are between these boundaries.
19 Another important point to make is that many
20 of the simulation...in fact, all the simulation results
21 do not include exposure from dermal or inhalation
22 routes and likely represent an underestimation of
23 exposure and, hence, risk.
24 Okay, so, in addition to us receiving the
25 four avian studies, we also received a probabilistic

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1 risk assessment from the registrant and which included
2 another probabilistic model called a Liquid PARAM which
3 we received in October of 2007. Generally, Liquid
4 PARAM predicts that there are no risks for modeled uses
5 of carbofuran except for waterfowl on alfalfa
6 undergoing a gorging behavior.
7 There are some useful elements of Liquid
8 PARAM that's...including a good survey of avian species
9 data in the literature review and updated field
10 metabolic rate equations for birds that are nice
11 but...but don't really...wouldn't really change risk
12 projections at all in the TIM construct.
13 However, there is no within field pesticide
14 variability within Liquid PARAM, so there's no
15 possibility for exposures to exceed first day exposure
16 for birds on a field. And, generally, that means that
17 individuals consume average concentrations. So, that
18 is they're homogenized in the field and then sampling
19 from that.
20 Exposure is multiplied by frequency on field
21 for every bird, every time step. So, every bird is
22 actually given...or so this is inconsistent with the
23 PRA approach and has been addressed previously in
24 various other SAPs. So, instead of saying well, here's
25 the frequency on field at this time step using the

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1 binomial, the bird is either on the field or off the
2 field, it basically multiplies the exposure route by
3 whatever that frequency in field value would be.
4 The food matrix adjustment factor appears to
5 be applied to drinking water exposures as well which
6 seems to be an error, considering the food matrix
7 adjustment factor is basically derived via a comparison
8 to exposures via the aqueous route.
9 Exposure was multiplied by 8 hours to
10 estimate food consumption reduction. So, as you recall
11 in that discussion of carbofuran induced feed
12 reduction, we used TIM 1, because we felt the construct
13 more similarly mimicked the...or represented the
14 field...or the laboratory observation period.
15 In this case, Liquid PARAM uses an hourly
16 time step and multiplies exposure by 8 and then
17 calculates a feed reduction estimation.
18 Also, insect residue estimates appear to be
19 biased low in Liquid PARAM or the version that we have.
20 The mean value was 1.7. The value that we use,
21 apparently from the same data set, was 5.7. It
22 occurred to me that okay, well, that may be...the 1.7
23 may represent a subset of data. So, the 5.7 value
24 represents a range of studies looking at insect residue
25 estimates. Some of those are, you know, the specified

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1 orchard air blast as an application method, aerial. I
2 pulled out the air via air thinking that that would be,
3 you know, somewhat representative and, in fact, the
4 insect residue value increased, and in...in doing a
5 survey of available literature for other pesticides,
6 our values seemed to be representative, if not low in
7 some cases.
8 Okay, so, also, the registrant submitted a
9 comparison of Liquid PARAM to the...to the two field
10 studies that Dr. Panger mentioned earlier, and,
11 actually...so we have average mortality on the side,
12 and here is Liquid PARAM and three...three data bars.
13 You can barely see them. Those values are...those
14 represent sort of percentages, average mortalities for
15 the Jorgensen '89 study on corn. I limited it to corn
16 because that's basically what the scenario has been,
17 and these different values involve various correction
18 factors.
19 And this, if you notice, I mean, this is a
20 near exact match between what Liquid PARAM produces and
21 the estimates from the field studies. And it would
22 indicate wow, this is a perfect model, able to describe
23 a very complex system with a lot of variability
24 perfectly but with no estimates of variation.
25 Our review of this, we couldn't quite

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1 recreate these numbers. Oh, wrong one. Couldn't quite
2 recreate these numbers, and in general, we wondered
3 what the implications are for...for the applicability
4 of Liquid PARAM, given all the study's shortcomings
5 that we mentioned previously. And now that you...the
6 SAP has or will have those studies, it would be helpful
7 to...to have your input.
8 Well, there's an alternative view that can be
9 taken, as one would think with studies of a complex
10 nature such as field studies, so we went back to the
11 data. This is the Jorgensen. And when we look at the
12 data, a table on page about 400 or so, there's an
13 analysis that includes parameters such as average bird
14 abundance, search efficiency, number of dead birds on
15 field, and what the ultimate output is is a perversion
16 of furidan 4F population killed.
17 Looking at these data, it..it would...just
18 looking at it, it would appear...and, again, we haven't
19 done an exhaustive tracking down to figure out where
20 all the...all the inputs into that table come from, but
21 it would appear that those might be estimates of, you
22 know, probability of mortality.
23 And these are based on a DREAP analysis
24 which, for the life of me, I can't remember what that
25 acronym stands for, but it essentially is a paired

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1 comparison. So, there's a...there's a treated field,
2 and it's paired with an untreated field, and this, in
3 general, the approach is meant to increase the
4 statistical power of the study which, incidently, for
5 the...for this study, was way below abilities to detect
6 differences that would be considered reasonable, such
7 as a 20 percent effect level.
8 However, when you look at that and the...the
9 last column is that proportion killed, and you sort of
10 group those together so you end up with this. This is
11 from 8 paired studies. You end up with a range from 0
12 to about 0.62. I think this is the me...yeah, these
13 are the means, and these are the medians. These are
14 TIM 1 outputs for a range of bird species from the RED.
15 They tend to overlap...or they don't tend to overlap,
16 they do overlap.
17 But an important point here, really what I
18 was...the point I was trying to make is that these
19 field studies can be interpreted in a variety of ways.
20 We didn't post-process these data, and there may be
21 nuances associated with it that we haven't quite
22 grasped. However, you know, our inspection of it seems
23 to indicate that it represents what you would expect to
24 the probability of mortality for birds in a given
25 field, and it ranges from 0 as to...to quite high, and,

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1 again, if we look at TIM results for medium sensitivity
2 species for a range of species, there is some overlap.
3 But the mo...but recall the study's
4 shortcomings and also the likely underestimated
5 mortalities, and I think that we'll probably be
6 discussing this further.
7 But the main point that we really want to
8 drive home is that in the field studies, everything
9 considered, there...there is more dead birds associated
10 with carbofuran treated plots than other plots. And
11 so, we've mentioned that these studies can't be used
12 quantitatively to...to...to really relate, you know,
13 projections of a model to what may be occurring on the
14 field, and I think once you start reviewing the studies
15 and looking into it, you'll maybe have a different
16 perspective, or you may see that maybe yeah, that's
17 true.
18 But, really, the point we want to make is
19 that the studies show that exposures...there's a
20 complete exposure route for carbofuran for birds and
21 that effects occur.
22 And so, again, to rehash, the models in
23 environmental regulation are best used to help inform
24 management decisions. The perfect model is impossible,
25 and to expect exact predictions under field conditions

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1 is unfounded.
2 The PRA or avian PRA, compared to available
3 field data, ultimately, we said the field studies are
4 not suitable for rote pest quantitative analysis. The
5 important point is that they show some mortality.
6 The other thing related to models in
7 environmental regulazation...regulation is the
8 consistency of results within the TIM family of models,
9 suggesting that at least these two models and the...and
10 the...the vagaries of their constructs produce similar
11 results.
12 And, really, we can discuss the details
13 regarding is this a beta pert or a truncated
14 exponential, is the value 0.6 or 0.65, and all those
15 sort of subtleties associated with the model which are
16 all very important, but at some point, we have to step
17 back and look at the big picture.
18 And the big picture is, in part, that the
19 probabilistic risk assessment provides one line and a
20 weight of evidence approach for evaluating ecological
21 risks of carbofuran. The model scenarios, including
22 new avian data, show risks to birds from the use of
23 carbofuran. The implications of the newly submitted
24 data and review of those data was conducted and
25 was...the implications for the PRA was explored, but

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1 keep in mind the deficiencies and the uncertainties
2 associated with those studies.
3 Another important point, that all exposure
4 routes, all likely exposure routes were not
5 incorporated into the estimates of mortality associated
6 with the TIM models, namely, dermal and inhalation
7 which, in some studies, have been shown to be strong
8 contributors to total exposure, and reproductive
9 effects or any type of non-acute toxicity effects were
10 not considered.
11 And so, in general, when you look at the
12 weight of evidence, there is support for the TIM
13 modeling framework which includes, you know, the
14 deterministic with RQs in the thousands, suggesting
15 that, okay, well, you would have to reduce exposure
16 factors by several thousand to get an exposure level
17 still equivalent to an LD50 that represents mortality
18 for 50 percent of tested species.
19 In addition, if you look at the field data,
20 it again supports the notion or the...the conclusion
21 that there's a complete exposure and that effects
22 occur. Also, the TIM modeling framework, TIM 1 and TIM
23 2, have been through extensive peer review and
24 widespread presentation, international presentation.
25 So, overall conclusions regarding the

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1 ecological risks of carbofuran, there's the
2 deterministic assessment, the probabilistic risk
3 assessment, incident reports and field data, our three
4 lines of evidence that...that show one or more exposure
5 pathways are complete, and exposure levels meet or
6 exceed levels to show...shown to cause adverse effects
7 in the laboratory for the deterministic.
8 The probabilistic exposure is variable, but
9 one or more pathways are complete. Exposure levels are
10 sufficient to cause mortality, and mortality is
11 frequent and, under some situations, severe.
12 The incident reports and field data, one or
13 more exposure pathways, again, are complete, and
14 exposure levels are sufficient to result in field
15 observable effects that include mortality,
16 incapacitation, and reproductive impairment.
17 Thank you.
18 **DR. HEERINGA:** Thank you very much, Dr.
19 Salice. At this point in time, I'll open it up to I'm
20 sure will be questions from the panel, and I see Dale,
21 Dr. Hattis, first.
22 **DR. HATTIS:** In order to produce the
23 probabilistic results that you briefly presented, you
24 have to have two distributions. One is a distribution
25 of sensitivity among species, as I understand it, and

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1 the other is a distribution...and that's where I think
2 you come...can't come up with your sensitivity analysis
3 with the form of 5 percent less sensitive, the middle,
4 and the most sensitive, and the other is a distribution
5 within species of different sensitivity that's
6 essentially in the form of a proven slope or...or...or
7 some such.
8 In order to, you know, review these, we...we
9 need to know something about what those
10 distribution...a little about the spread of those
11 distributions are. What are the...the log standard
12 deviation of your distributional sensitivities that you
13 use among species, and what are the proven slopes that
14 you're using?
15 **DR. ODENKIRCHEN:** We can provide you
16 with the distributions for the sensitivity among
17 species. I don't have them right off the top of my
18 head. We can pull those out for you and provide them
19 out of the report.
20 The distribution within for...within a given
21 species I believe relied on a slope of, I think, 4
22 point something, 3.2. I...I'll have to get that for
23 you, too.
24 **DR. HATTIS:** 4.2 in log base 10 space?
25 **DR. ODENKIRCHEN:** Yeah, yeah.

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1 **DR. HATTIS:** Okay, that's fine. Well,
2 anyhow, that's...that's a number that can be reviewed
3 anyhow.
4 The other question relates...now I
5 just...come back to me later. I don't remember my
6 second one.
7 **DR. CHAMBERS:** Additional questions?
8 Dr. Clark?
9 **DR. CLARK:** Yeah, on slide 19, you're
10 talking about the...the difficulties there were with
11 the interpretation relative to growth, compensation for
12 any energy deficit, et cetera. When you were looking
13 at this analysis, in the size bias issue from right to
14 left, was another analysis run, basically, with a dummy
15 covariant that would account for that?
16 **DR. SALICE:** Sorry. No, it was not.
17 Actually, this...yeah, this was a fairly coarse sort of
18 assessment. It was just pulling out a bunch of
19 different species and...to sort of...it appeared,
20 looking at the data, that yes, birds were, in fact,
21 preferentially feeding, and so they...it was just
22 involved going through and looking at what sort of
23 patterns of a bunch of individuals.
24 **DR. CLARK:** Okay. A second question, if
25 I may. The...there are a lot of data that are

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1 available for an analogous pesticide, medra, the
2 carbamate pesticide, with respect to animal
3 experimentation in terms of avoidance. Was that taken
4 into context in...in looking at these data effects?
5 **DR. SALICE:** No, it wasn't.
6 **DR. CHAMBERS:** Dr. Montgomery?
7 **DR. MONTGOMERY:** I have a question on
8 the...part on the same slide that he asked you, and I
9 missed this when you presented it. When you went
10 through and you did this sort of left side/right side
11 preference, a couple of things crossed my mind. One
12 was, did you do this on...this kind of analysis on more
13 than these two birds? Did you...dosing and run through
14 this with birds at different doses, and did they...did
15 you see a similar pattern of, if you want to call it,
16 right brain, right side/left side type of preference
17 for feeding pan?
18 **DR. SALICE:** Yes.
19 **DR. MONTGOMERY:** That's part of it.
20 **DR. SALICE:** Okay. Yeah,
21 actually...okay, this behavior is fairly complex thing,
22 and so, it sort of jumped out immediately, looking at
23 some of the data, that there seems to be a side
24 preference. So, yes, birds from several dose groups
25 appear to show a behavior. It's not all. In

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1 some...and some birds, actually, you know, flip-flop
2 more so, but there seems to be a number of birds, in
3 fact, that...that do have a preference for side.
4 **DR. MURPHY:** Okay. I'll come...I have
5 to write something. I'll come back with the second
6 part of my question. Thank you.
7 **DR. GRUE:** I'm sorry. Chris Grue,
8 University of Washington. Sorry to go back to this
9 12th hour, but is that a 12 of daylight/nocturnal
10 cycle, or is that a 12...just a standard 12/12?
11 **DR. SALICE:** Are you talking about the
12 TIM?
13 **DR. GRUE:** Yeah, your 12-hour step.
14 **DR. ODENKIRCHEN:** Yeah, it's two 12s.
15 **DR. GRUE:** Two 12 related to bird
16 behavior?
17 **DR. ODENKIRCHEN:** Before noon and after
18 noon. It's 12-hour time steps. So, it's a...you're
19 talking about with regards to the TIM model, TIM 1.0?
20 **DR. GRUE:** Right.
21 **DR. ODENKIRCHEN:** Yeah, it's two 12-hour
22 time steps. What we do is we take a total daily feed
23 and divide it separately into two 12-hour time steps.
24 **DR. GRUE:** So, the model doesn't
25 incorporate a time when animals would not be feeding,

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1 then?

2 **DR. ODENKIRCHEN:** No. TIM 2.1 does; TIM

3 1.0 does not. TIM 2.1 divides the day...the day into

4 24 hours and gives hourly time steps and birds...and it

5 follows a bimodal feeding pattern. Starts at sunrise

6 and ends at sunset, so there's an overnight period that

7 doesn't have any activity whatsoever.

8 **DR. HEERINGA:** Dr. Schlenk and then Dr.

9 Clark.

10 **DR. SCHLENK:** Yeah, Dan Schlenk. I'm

11 curious on species sensitivity issues, you had

12 predicted that the insectivores or edge insectivores

13 would be more sensitive in the field. I'm just

14 curious, do data in field studies support that?

15 **DR. SALICE:** No, that's in part a

16 function of their behavior, and then that's their

17 frequency, I'm sure. Part of the...part of the driver

18 behind the higher sensitivity of the...or the increased

19 average mortality...let's say that...projections for

20 the insectivore are a result of its frequency on field

21 value being higher than for the granivore.

22 So, for the same body weight, to answer your

23 question, species, if they were the same body weight,

24 they would have the same sensitivity from a toxicity

25 standpoint, but the actual risk appearing, you know, in

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1 the model would also incorporate their behavioral which
2 is their food item ingestion, seeds versus insects, and
3 also how much time they're on the field.
4 **DR. SCHLENK:** Just to follow up, I'm
5 just curious why killdeer...I mean, do you see a lot of
6 killdeers, particularly, in...in fields? I guess
7 that...that would be the question.
8 **DR. ODENKIRCHEN:** Yeah, actually, the
9 analysis for those was in TIM...it was in the SAP for
10 TIM 1. We looked at the data with regards to which
11 species appear to most frequent within fields.
12 There was some controversy with regards to
13 killdeer and what their behaviors would be. They are a
14 ground nester. They do spend a considerable amount of
15 time on the ground nest in those situations.
16 Dr. Best provided us comments, I believe, and
17 they're...I think some of that is actually captured in
18 the...in the points considered document or the...I
19 can't remember the name of one of the documents that we
20 provided you with that summarizes the SAP comments, and
21 one of those comments was with regards to the killdeer
22 itself and how much time it spends in the field versus
23 how much time it spends nesting in the field, and there
24 are some differences there.
25 One of the...but we did also bias our

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1 selection process in birds on the basis of birds that
2 were found dead in the fields as well. So, I believe
3 red-winged blackbirds, there's a fair number of them
4 have been found dead in the fields and a few other
5 species that were identified. If you go to the...the
6 RED document where we describe all of that, you'll see
7 the write-up for how we came up with those...those
8 frequencies.
9 The other thing I want to do is address
10 the...the earlier question with regards to slope. The
11 slope we used was 5.7. It's the mean slope for all
12 data. We could vary that. We did not in the TIM 1.0
13 version.
14 And if you go to pages 61 through 63, you'll
15 get the Eilenberg slope procedure that was used to
16 derive the 5th, 50th, and 95th for each of the species,
17 and there's a table, table 3....put my cheaters
18 on...3.11 which will give you the 5th, 50th, and 95th
19 for each species as it's been taken out of the
20 distribution and then readjusted for body weight.
21 **DR. HEERINGA:** Dr. Clark?
22 **DR. CLARK:** Larry Clark, USDA. Just a
23 clarification for me. When you're running the
24 calculations or the simulations that were looking at
25 avoidance, potential or possible avoidance behavior,

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1 were the conditions in the time step, was that part of
2 the mark off process, or are they set some other way?
3 In other words, the probability of avoidance was
4 contingent upon the various time steps?
5 **DR. ODENKIRCHEN:** Actually, what you
6 describe with the mark off chain, the construct behind
7 the fidelity factor in TIM 2.1, but that was not used
8 in these simulations. What was used was the sort of
9 reduction in feed consumption associated with, you
10 know, receiving a dose of carbofuran in the previous
11 time step. So, it wan't...it wasn't...there wasn't any
12 probability factor incorporated. It was just a simple
13 plug into the regression, you get a feed reduction in a
14 subsequent time step.
15 **DR. SALICE:** Yeah, it's really important
16 to understand the differences between avoidance and
17 feed reduction. Feed reduction is the bird is too sick
18 to eat. Okay? It's responding to an intoxication, and
19 it reduces its food ingestion rate.
20 Avoidance means it's still keeping up its
21 ingestion rate. It's just trying to eat from some
22 other place. If that's not available, then there will
23 be...if there is no other alternative food, then there
24 would be a food reduction.
25 The concept of having a pan choice of clean

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1 food versus contaminated food is supposed to get at the
2 idea of whether or not that's just food reduction or
3 avoidance. The problem with the study that we have
4 presented before us is...is that there are a number of
5 confounding factors, namely, this unexplained reduction
6 ingestion regardless of whether there was exposure or
7 not, and then, also, this right sided versus left sided
8 pan behavior. And those taken together, we don't feel
9 we can conclusively say that we have food avoidance.
10 So, therefore, we didn't adjust our mark off chain to
11 incorporate an avoidance factor.
12 But we did believe that if we pushed the data
13 as far as we feel comfortable doing, we could say that
14 there's a potential for some food reduction, food
15 ingestion reduction, as a result of...as a result of a
16 sub-lethal response to intoxication.
17 **DR. HEERINGA:** Woody Hill?
18 **DR. HILL:** I have a couple questions on
19 this. The first, when I read over a lot of this
20 material previously, I became confused, and you have
21 reinforced my confusion. But anyway, taking a look at
22 some of this food reduction data on...I guess it would
23 be number 21, if I understand that, that is pooled
24 data. Correct? And then show a reduction. No?
25 **DR. SALICE:** No, that's...so, if there

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1 were...I forget how many birds were in the study. If
2 there were 50 birds, all right, this is their
3 calculated dose, and their calculated feed consumption
4 between based on, I think, the day 1 sort of regular
5 food consumption previous to exposure, that
6 consumption. So, it represents a reduction as a
7 function of the calculated dose.
8 **DR. HILL:** Over what time period?
9 **DR. SALICE:** Over one day, just from one
10 day, yeah.
11 **DR. HILL:** Which day?
12 **DR. SALICE:** Day 5, the last day.
13 **DR. HILL:** Well, the interesting point
14 about all of that, though, has to do with inspection of
15 your other table which you don't...the figure that's on
16 page 17, and you notice the...that, for some of the
17 exposure levels, of course, the food consumption is
18 actually increasing, and I have seen in studies where
19 carbofuran as a matter of fact and other carbamate
20 chemicals where you will have birds not only recover
21 quite quickly but then actually eat more than what the
22 control eats, and you've got some indication of that
23 here. Certainly, some individuals are probably doing
24 it.
25 So, that all is interesting, but it seems to

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1 me that you've got a lot of birds on the recovery slope
2 as opposed to the slope that would probably kill them
3 eventually, and you project when they will finally die,
4 starve to death, and so forth, and they're not actually
5 doing that, and I was wondering how that is accounted
6 for, because my question isn't clear that...you think
7 it's clear, but it doesn't seem clear to me that you're
8 looking at two different responses in a real world
9 situation, how the animals actually forage, how the
10 food is presented to them as opposed to how you choose
11 to look at it from the standpoint of a reduction. Is
12 that helpful?
13 **DR. ODENKIRCHEN:** Well, I think one of
14 the issues that we had all along, as Dr. Salice had
15 shown, is that even if you look at the control on that
16 slide, you'll see the control on that slide from day 1
17 all the way up to the end of the study increases their
18 food consumption, and we don't know why. We don't know
19 whether that's a function of increased body weight. I
20 don't think it is, but I do know that they're feeding
21 at a greater rate.
22 And we see that same pattern on almost every
23 single one of those dose...dose levels. So, I don't
24 know whether we're dealing with a recovery or some
25 other artifact in the study, and we...we do have a

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1 great deal of...of discomfort in pushing this data to
2 the point where we say it's definitively showing that
3 there's a food reduction.
4 So, what we have done is try and explore what
5 we thought was a reasonable estimate of that food
6 reduction as a function of dose and...and just see how
7 that would impact our...our estimate of our model. It
8 does to some extent, but, again, like we say, we feel
9 that the study is pretty limited for even that kind of
10 information. I'm not quite sure what we're seeing
11 there.
12 **DR. HILL:** Well, that was the thing that
13 did concern me, because I've done a lot of my
14 experiments with carbamates, not just carbofuran but
15 with others. I have seen this, and I've hardly ever
16 seen it with any other kind of chemical. You almost
17 always get that...that temporal reduction, as long as
18 they're exposed to the chemical that will continue to
19 reduce their food intake until the end of the
20 experiment, if it's designed properly. Some of them
21 will die, some won't, or whatever happens to them when
22 the behavior changes.
23 Yeah, in fact, it got to me even from the
24 standpoint of the semantics, because as I recall, this
25 is a food avoidance study, and yet, you come up with

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1 your 50 criteria here, and it seems to me that where an
2 equal amount of treated feed and an equal amount of
3 untreated feed and if it comes out equal, instead of it
4 being avoidance, why wouldn't that be acceptance?
5 **DR. ODENKIRCHEN:** Yes, yes, although...
6 **DR. HILL:** It doesn't...it doesn't quite
7 click.
8 **DR. ODENKIRCHEN:** Right.
9 **DR. HILL:** I was also curious as to a
10 question that's certainly going to come up with...with
11 FMC Corporation when they make their presentation, but
12 did you folks collaborate with them in the design of
13 some of these experiments or was it just...
14 **DR. ODENKIRCHEN:** No.
15 **DR. HILL:** Okay.
16 **DR. HEERINGA:** Dr. Delorme and Dr.
17 Montgomery.
18 **DR. DELORME:** Peter Delorme from Health
19 Canada.
20 One of my questions was just asked. The
21 second question is more a clarification followed by a
22 question. If I understand this correctly, when you
23 redid your probabilistic scenarios that included in
24 these factors from the studies that FMC submitted, you
25 only did those for one application rate, and that was

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1 the 1 lb/acre?
2 **DR. ODENKIRCHEN:** Correct.
3 **DR. DELORME:** Have you done any...have
4 you looked at all at varying the application rate and
5 seeing whether or not that affects greatly the response
6 of the models?
7 **DR. SALICE:** Varying the application
8 rate?
9 **DR. DELORME:** Yeah, above and below.
10 **DR. SALICE:** So, the effect of the
11 application on risk or average mortality?
12 **DR. DELORME:** Well, on...on your result,
13 because you're...we're looking at general results.
14 Okay?
15 **DR. SALICE:** Right.
16 **DR. DELORME:** And comparing with a
17 baseline?
18 **DR. SALICE:** Right.
19 **DR. DELORME:** With including in these
20 other factors. So, if you were to do it at another
21 rate, does that impact what those relationships are
22 between the baseline and...
23 **DR. SALICE:** Oh, so it's a
24 nonlinear...are you getting at sort of a nonlinear kind
25 of...

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1 **DR. DELORME:** No, just..just a direct
2 comparison between rates in terms of the response of
3 the model to these other factors and whether or not
4 that affects the risk profile.
5 **DR. SALICE:** Yeah, well, a lower rate
6 won't lower the risk profile.
7 **DR. DELORME:** Okay.
8 **DR. SALICE:** But we have not run...I did
9 not run any...I mean, I did some spot checks here and
10 there just to sort of see how they would play out, but
11 I didn't do a comprehensive analysis.
12 **DR. DELORME:** So, the 1 lb/acre...got to
13 use American units here, not 1 kilo/hectare...the 1
14 lb/acre, then, how does that situate with respect to
15 the range of rates that carbofuran is currently
16 registered for?
17 **DR. SALICE:** I believe it's...it's a
18 maximum. No?
19 **DR. ODENKIRCHEN:** It falls below the 2-
20 pound maximum for some uses, falls right on the 1-pound
21 maximum for others.
22 **DR. DELORME:** Okay.
23 **DR. ODENKIRCHEN:** And it's probably just
24 slightly above, about...about 30 percent higher than
25 the typical rates for, say, corn which is about 0.75

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1 pounds.

2 **DR. DELORME:** Okay, thank you.

3 **DR. SALICE:** The other thing I just want

4 to highlight is that in part, the utility analysis is a

5 comparison to our baseline which represents, you know,

6 two species that are...for which the original

7 conclusions regarding carbofuran and the risks

8 associated to birds represent. So, it's...it's just

9 kind of important to...there's...there's the total

10 risks or total average mortality estimates, but then

11 there's also, you know, how does that compare to what

12 the basis of the original conclusions were.

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

14 **DR. MONTGOMERY:** Cheryl Montgomery. I

15 have two questions for you on the daily feeding

16 consumption. I remember what it was I wanted to ask

17 you now.

18 The dose that was used in the study, has it

19 been compared to what you would anticipate actual food

20 consumption would be in the field by animals? I assume

21 what we're supposed to be thinking about with this is

22 that if they would avoid it in the lab, then if they

23 encountered it running across a field that they would

24 also avoid it in the field, and I'm just wondering if

25 these dose levels in the feed were actually equivalent

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1 to something...if it was, in fact, avoidance of...of
2 carbofuran, if they encountered a beetle or, you know,
3 grains that had these other residues, would it be at
4 this level, or would it be greater or less?
5 **DR. SALICE:** Yeah, I guess if you look
6 at those, you know, they fall within the range of what
7 we are estimating some residue levels to be in the
8 probabilistic model such as, you know, 5.7.
9 **DR. MONTGOMERY:** A daily...a daily
10 intake...sorry, 12-hour?
11 **DR. SALICE:** Yeah, but...but you raise,
12 you know, an interesting point, and one of the
13 uncertainties we have in this kind of thing, how does
14 this really relate to wild food items both from an
15 exposure standpoint and a consumption standpoint.
16 **DR. MONTGOMERY:** Okay. And then, the
17 second thing, I...I know...I...I did look through the
18 study. I didn't see any mention of this, and I don't
19 think it's typically written up even in a guideline
20 study. I thought mallards were considered to be messy
21 feeding birds, that they, you know, that they take
22 their food, they spread it around, the mess feces in
23 it, they do all kinds of like bird things, and...and I
24 know that it's difficult to track consumption even with
25 radio-labeled chemicals sometimes with mallards. And I

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1 was wondering if any...if you had any thoughts or any
2 comments on that particular aspect of the study. It
3 wasn't, that I saw, addressed in the actual writeup of
4 the study itself, yet it's often brought forward as one
5 of the uncertainties in dealing with, in particular,
6 this type of bird.
7 **DR. ODENKIRCHEN:** Yeah, we always run
8 into that same situation that it's difficult to track
9 consumption in...in mallards because of the spillage
10 issues. They really are messy feeders.
11 I would...if we're going to talk about the
12 conduct of the study and something that's not written
13 up, I think probably when the...the registrant comes up
14 and gives their presentations that that might be a good
15 question for them, since it's their study and we were
16 not involved in the protocol of that.
17 **DR. HEERINGA:** Dr. Sample?
18 **DR. SAMPLE:** Yeah, excuse me, I wanted
19 to ask a question of how you...staying on this food
20 avoidance study, how did you integrate it into the
21 model? Did you just use it as a simple adjustment on
22 the...their ingestion rates? So, you...it's just a
23 var...a deterministic adjustment?
24 **DR. SALICE:** Exactly. It is basically
25 an if/then statement. If exposure in the preceding

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1 time step was whatever, then the...the exposure in this
2 next time step is going to be adjusted by this factor.
3 So, yes, it was just deterministic.
4 **DR. SAMPLE:** Okay, and that was just in
5 terms...and this is referring to what was in your
6 writeup, not so much on the presentation. So, that was
7 a factor was reduced by whatever that calcu...the
8 calculation from that equation?
9 **DR. SALICE:** Right.
10 **DR. SAMPLE:** Okay, that...
11 **DR. SALICE:** Yeah, it can become
12 difficult, because you're calculating things based on
13 one time step but applying them in another, and so,
14 it's kind of...just really wrap your head around it.
15 **DR. SAMPLE:** And did you consider taking
16 the error term into account, seeing as it has a
17 significantly large uncertainty regarding regression?
18 **DR. SALICE:** I...not explicitly in
19 this...in this, in what was presented, but in reviewing
20 the data and thinking about it some more, I actually
21 had started to think about, you know, what would be the
22 implications of that.
23 **DR. HEERINGA:** Dr. Hattis and then
24 Dr....
25 **DR. HATTIS:** I remembered my question.

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1 You said you had a fairly strong finding that the
2 regeneration...what you measure is the regeneration
3 half-life for the cholinesterase inhibition, is so
4 longer at higher doses than it is at lower doses. Have
5 you reflected on the mechanism underlying that for
6 either a...well, it would have to be a saturable
7 something. Would be a saturable metabolism or a parent
8 chemical or a saturable metabolism of the...what it is
9 that generates the...that regenerates the enzyme.
10 **DR. ODENKIRCHEN:** Well, we've had
11 some...I mean, there is a uncoupling which is a rate
12 limited step, and I...I think you're probably going to
13 get a lot more discussion on that when...when you're
14 talking to folks from HED on...on that uncoupling step,
15 et cetera.
16 I mean, there's also other factors. You
17 know, we can only, you know, provide some sort of
18 speculation with regards to that, but it's also
19 entirely possible that it isn't...that the whole
20 concept of this recovery is a function of two things,
21 it's clearance of the chemical and recovery of the
22 enzyme itself, and there's probably some, you know,
23 multiple compartment analysis that would need to be
24 done in order to really clarify that and a lot more
25 experimental work.

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1 But at this point in time, it's just...we're
2 just taking the values at face value. We've looked at
3 the upper values and lower values and see how much they
4 make a difference, and they appear to be pretty much
5 interchangeable with our previous assumptions of...of
6 elimination of the compound, they track pretty close.
7 Whether that elimination is...is a saturable
8 process may be one of your limiting steps on why it
9 takes longer for the compound to...for the
10 acetylcholinesterase to recover later. It just may be
11 that there's just more of a reservoir of carbo left in
12 the body. I'm not quite sure.
13 **DR. HEERINGA:** Dr. Edler?
14 **DR. EDLER:** More for curiosity,
15 actually, have there been some deaths actually between
16 the day 1 and day 5? Because I find in the...the
17 listing of the...of the data some...some birds actually
18 with a minus food consumption.
19 **DR. SALICE:** Yeah, I...I don't believe
20 there were any mortalities, but it's been a while,
21 actually, since I...I looked at this, so I'd have to
22 get back with you, but I believe that there weren't
23 any.
24 **DR. HEERINGA:** Dr. Sample?
25 **DR. SAMPLE:** Changing topics a bit on

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1 the Liquid PARAM model in the subsequent or the follow-
2 up material that was sent to us prior to us coming, you
3 made some statements that you couldn't reproduce the
4 calculations and suggested that there might have been
5 an error, but in your presentation, you did not...did
6 you identify what the problems were or is it...
7 **DR. SALICE:** Yeah, we fixed it. Well,
8 we're not...we're still not confident or necessarily
9 having run through all the simulations to determine if
10 the...if the results mimic what was presented in the
11 risk assessment, but there appear to be some...just
12 some small programming errors or something that were
13 subsequently fixed, and we're able to run it.
14 **DR. SAMPLE:** Okay. So, there was an
15 error, but that has been resolved in the...
16 **DR. SALICE:** Believe so but not...I
17 can't...I can't say with confidence that it's been
18 thoroughly tested so that results match what we would
19 anticipate.
20 **DR. SAMPLE:** Okay.
21 **DR. HEERINGA:** Dr. Montgomery and then
22 Dr. Delorme.
23 **DR. MONTGOMERY:** This is...this is
24 really quick, and I...I think it's been asked in part
25 on other studies. Are all these additional studies

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1 that were non-guideline studies submitted by FMC, were
2 they developed in conjunction with EPA's input, or were
3 they...are they being presented by FMC as supplemental
4 data that is the approach of themselves and people that
5 they have engaged to do these activities?
6 **DR. SALICE:** It's..it's the latter. We
7 were not...we were not involved in the...any design,
8 study design issues here.
9 **DR. MONTGOMERY:** Okay, so
10 there's...certainly a far cry from...mostly a consensus
11 but not a two-party or three-party or peer developed
12 process?
13 **DR. SALICE:** Correct.
14 **DR. MONTGOMERY:** Okay. And that's for
15 all of the data that it would be non-guideline?
16 **DR. SALICE:** Dr. Odenkirchen has
17 mentioned to me that they do have their own peer review
18 process, but that...your statement is cor...correct in
19 that...so, there was...there was no peer review by an
20 outside group.
21 **DR. MONTGOMERY:** Right, there was
22 external review but not in the way that SAP did for the
23 development of the TIM...
24 **DR. SALICE:** Correct..
25 **DR. MONTGOMERY:** ...and...and the...

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1 **DR. SALICE:** Correct.

2 **DR. MONTGOMERY:** Thank you.

3 **DR. SALICE:** And there's one, actually,

4 Dr. Sample...am I permitted to...

5 **DR. HEERINGA:** Certainly.

6 **DR. SALICE:** Part of the review related

7 to Liquid PARAM was really an analysis more so in the

8 review of the construct elements and not necessarily of

9 the complete functioning of the model. So, kind of a

10 step even in the NRD...NRC report, you know, is an

11 evaluation of model construct and assumptions. And so,

12 some of that...a lot of what was presented was

13 reflected...more a reflection of that. Some of it was

14 sort of digging into the model somewhat, but just to

15 clarify, it wasn't all based on having...running the

16 model numerous times.

17 **DR. HEERINGA:** So, just to be absolutely

18 clear, Dr. Salice, I think you've answered this, but

19 you feel that your evaluation of the Liquid PARAM

20 model, the model, all you can say at this point that

21 there are some programmatic errors or anything that

22 would produce the discrepancy.

23 **DR. SALICE:** Right. I'd say that it

24 appears to be functioning as intended, and so, the only

25 thing that would really need to be required is to make

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1 sure that the outputs match what...you know, it would
2 be like running the scenarios that were presented in
3 the risk assessment to see that the...the outputs
4 matched. If...but I'll say that it does appear to be
5 functioning as intended.
6 **DR. ODENKIRCHEN:** We concerned our...our
7 review primarily, as...as Chris has said, to the
8 more...more on the lines of the underlying
9 assumptions.
10 **DR. HEERINGA:** Yes. I guess you've
11 listed those on your slide here, too, so thank you.
12 Sure, Dr. Montgomery, please.
13 **DR. MONTGOMERY:** I think I only have one
14 more. In the...the volumes of documents that I read,
15 there was references to the EPA model as not being
16 validated and that they were not...they should not be
17 used for regulatory decision making. I was wondering
18 if you could clarify that for me. It seems like an odd
19 statement to have read in a...in a response, and yet,
20 we have a...a Liquid PARAM model that doesn't appear to
21 have been...I'm not sure what validated means, but it
22 doesn't appear to have been through a larger review
23 process as well.
24 I was wondering if you could help me
25 reconcile those...that apparent dichotomy.

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1 **DR. SALICE:** I think...I think Dr.
2 Odenkirchen...
3 **DR. ODENKIRCHEN:** The Agency has been
4 struggling with the term validation now for about 20-
5 some odd years. I would prefer to consider the...the
6 model in terms of verifying some of the outputs. We've
7 gone through and gone through the calculations by hand.
8 We've gone through and...and looked at how the outputs
9 relate to those hand calculations, have been satisfied,
10 and are now contesting that the model is predictable.
11 We've gone through and varied the model
12 inputs and looked at the outputs of the model and
13 determined that the model responds in a way that we
14 would have expected the model to run. In other words,
15 there's no real surprises.
16 We've gone through and looked at the data and
17 compared to existing data sets, for instance, with
18 carbofuran with regards to exposure, and we've verified
19 that the distributions we have do, in fact, encompass
20 the distributions from measured carbofurans in the
21 field for various food items.
22 So, we feel that...that the model is
23 predictable in terms of its construct. We feel that
24 some of the...many of the underlying assumptions are
25 upheld by existing data and do, in fact...the outputs

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1 do, in fact, represent results on the exposure side
2 from those which can be measured from the field for a
3 selected series of field studies.
4 Now, when you're talking about running a
5 model with 10,000 combinations of species with...or
6 1000 combinations of 20 birds in a field, I don't think
7 you can validate that model. I don't think you could
8 run enough field studies to sit there and say that the
9 model predicts X percent and, therefore, the field
10 studies should comport with that X percent mortality.
11 This is the challenge of all complex models,
12 how do you validate something. If we....if we could
13 validate, if we had an adequate data source, we
14 probably would just produce some sort of
15 experimentally-based model as opposed to...or
16 empirically-based model as opposed to one that's
17 theoretical. So, I think what we've done is we...to
18 the extent that we've been able, have identified where
19 it's sensitive. We've been able to sit here and
20 compare that to existing input values from alternative
21 data sources. We've looked at the outputs as...as
22 compared to some of the other outputs from...from field
23 studies, and we've looked at the field study
24 predictions of mortality and said look, I think we're
25 bracketing what's going on.

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1 That's about the extent that, from a
2 practical standpoint, we can achieve what is, in
3 quotes, validation. The Agency...and perhaps Dr.
4 Bradbury will want to expand on this more, but there
5 are some policy implications about how the Agency has
6 given instructions to the various programs on how to
7 approach the concept of validation or verification
8 which is probably a better...better term, and if he has
9 anything to add to that, I...I think that would be
10 valuable.
11 **DR. BRADBURY:** Thanks, Ed.
12 **DR. HEERINGA:** I don't think you had a
13 choice.
14 **DR. BRADBURY:** The man is subtle.
15 The NRC report which Dr. Salice referenced
16 does get into this topic, and I may not quote it
17 exactly right, but they...they talk about this term,
18 validation, anyway, start to point out that that word
19 is a very dan...to be a loaded phrase, and it's
20 validation for a purpose. And what is the context in
21 which you're using a model and how is it integrated
22 into your decision making processes is sort of the
23 essence of what...what the point is.
24 And so, within the context of how a model is
25 used in the Agency to make a decision, we think about

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1 is the model a physical model, an empirical model? Is
2 it a bird LD50 test? That's a model. It's just a
3 physical model, an empirical model to try to give us
4 insights as to what may happen in the real world, so to
5 speak, as if we knew how to measure what's happening in
6 the real world with 100 percent confidence.
7 So, we...we talk about what model we're
8 using, what are the attributes of the model, what are
9 the strengths and weaknesses of the model, what are
10 the...what are its key assumptions, and how...how
11 should a model be properly interpreted and integrated
12 with other information.
13 And that applies to an LD50 test. It applies
14 to a hydrolysis half-life experiment. That's a
15 physical model, an empirical model, and it applies to
16 mathematical models. They're all attempts to try to
17 make...give us some insights on reality.
18 So, in the context of the mathematical models
19 that the group's been talking about here, they've gone
20 through numerous science advisory panels, so there's
21 been a lot of peer review to give us input and feedback
22 in terms of the assumptions, what are the strengths,
23 what are the weaknesses, what are the things to be
24 thinking about when you interpret the results.
25 Transparency. Is it reason...can someone

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1 read about the model, understand how the model is built
2 from a conceptual standpoint to the mathematics to
3 ultimately the computer code to have some confidence
4 that what it intends to do the code actually does, and
5 is it publicly available so others can...can play with
6 that all come in to...to the concept of is the model
7 appropriate, has it been appropriately evaluated for
8 the context.
9 I think the other aspect of looking at any
10 model or sets of models is taking a look at, again, the
11 strengths and weaknesses of the empirical models and
12 mathematical models and try to understand to what
13 degree is there concordance in how those models are
14 behaving or lack of concordance. The NRC report talks
15 about families of models and seeing if families of
16 models sort of lead you to the same place, or do
17 families of models lead you...lead you to different
18 places, give you some insight to some uncertainty.
19 In this case, the family of models, if you
20 will, are some families of mathematical models, TIM 1,
21 TIM 2.1. There's a family of models that are the
22 bioassay methods, empirical data, that's associated
23 with the incidence information, the field study
24 information, and then there's the deterministic model
25 that's just sort of a surrogate for the basic LD50

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1 studies.
2 So, I think in...in reflecting on validation,
3 I think, it's more evaluation, and it's looking at
4 context, and it's looking at a concordance and the
5 extent to which similarities and differences in
6 different lines of evidence are...are making sense. Is
7 it transparent? Can you follow...can you understand
8 what some of the assumptions are and what the
9 implications of the assumptions are? They're just
10 qualitative description of the uncertainties around the
11 question at hand.
12 **DR. HEERINGA:** Dr. Delorme and Dr.
13 Sample.
14 **DR. DELORME:** Following along the line
15 of earlier questions with respect to the assumptions of
16 Liquid Param, I...I just wonder if you could clarify
17 some more for me the blank on slide 42, exposure
18 multiplied by frequency on field for every bird, every
19 time step. I'm not sure I quite grasp the...
20 **DR. SALICE:** Okay. Basically, I'll just
21 sort of relate it to the construct that's used in TIM.
22 So, as...as Dr. Odenkirchen mentioned, we use census
23 data to come up with a frequency on field for a given
24 bird...or species. And that, at every time step, it's
25 used to basically develop or come up with a is the bird

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1 on field or not, using a binomial.

2 **DR. DELORME:** Mm-hmm.

3 **DR. SALICE:** Okay. And then the bird,

4 if it's on the field during that time step, it consumes

5 food from the field during that entire time step. And

6 then, ultimately, over the long term, what happens is

7 that if that, you know, since that value is not 1, the

8 bird...all birds are not on the field all the time.

9 What happens...the construct element used in

10 Liquid PARAM seems to be taking that...that

11 value...let's say it's 0.75 from the census data...and

12 for...so, exposure occurs during a given time step, and

13 now that's multiplied by 0.75 to...to saying well,

14 okay, on that hour, say, the bird is only on the field

15 75 percent of the time or something, and then the

16 exposure is...so, there's no sort of binomial choice,

17 and the...and the time step is broken up, essentially,

18 into part of the time it's on the field or not and...

19 **DR. HEERINGA:** But does the bird ever

20 leave the field in Liquid PARAM?

21 **DR. SALICE:** That's a good question.

22 **DR. HEERINGA:** If it never leaves the

23 field, I think the expectations are the same.

24 **DR. SALICE:** It could be.

25 **DR. HEERINGA:** My statistician friends

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1 probably think about that. Be good to figure...I'll
2 guess we'll get that tomorrow morning.
3 Other questions? Dr. Sample?
4 **DR. SAMPLE:** Yeah, I would want to go
5 and ask a couple of questions about the application of
6 the cholinesterase recovery study. You...I'm trying to
7 figure out exactly which values you used and how you
8 applied those.
9 So, you used the...the half-life or the 50
10 percent recovery, the half-life recovery? Now, is that
11 for the highest dose or for which dose did you use that
12 for?
13 **DR. SALICE:** Well, in the...in the
14 curves in the section, basically, on
15 acetylcholinesterase incorporated the half-life
16 estimates from both the 1.1 hour and the 4.4 hour
17 recoveries. So, it used both of those.
18 Now, but when I looked up the aggregate, it
19 only incorporated the 4.4 hour half-life. So,
20 presumably, you would be slightly if you...
21 **DR. SAMPLE:** I guess is just trying to
22 come to terms with the...the nature of the...I know it
23 only...we recognize the data that we have, but there's
24 a very different slope between what's occurring with
25 the lower doses and the higher dose, and at that higher

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1 dose, it's a much, much longer recovery time which
2 means it's going to be, in essence, at risk for a
3 longer period of time. And was that...did you include
4 that in any of your evaluations?
5 **DR. SALICE:** Well, not necessarily.
6 What...what happens is using the 1.1 and the 4.4.
7 provides sort of a...a boundary.
8 It sounds to me what...sort of what you're
9 getting at is that there might be a function of
10 acetylcholinesterase recovery as a function of dose and
11 that that would...it's nonlinear and it changes, and
12 that's a good point but not...has not been done for
13 these simulations.
14 **DR. SAMPLE:** Okay. So...so, basically,
15 you didn't use these...it's just as a point estimate?
16 **DR. SALICE:** Correct, correct, exactly.
17 **SPEAKER:** Which compounds did you use?
18 **DR. SALICE:** Well, both were used to
19 sort of flesh out the res... No, please. Okay.
20 Both were used to sort of look at the effects of using
21 either half-life, but when we looked at the aggregate
22 effects...that's the food matrix effects and the
23 acetylcholinesterase...we only used the 4.4.
24 **DR. KEHRER:** So, I'm confused. The 4.4
25 is a time point.

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1 **DR. SALICE:** Yeah, the...I'm sorry, go
2 ahead.
3 **DR. KEHRER:** Wouldn't the...the half-
4 life is a different thing, 4.4 versus 1.1.
5 **DR. SALICE:** The half-life is actually
6 4.4 hours. That gets adjusted to re...to a time step
7 specific value representing the carryover effects, and
8 it's basically a...
9 **DR. KEHRER:** So, essentially, you used
10 the longer half-life?
11 **DR. ODENKIRCHEN:** No, no, we used both.
12 We used the 1.1 hour and a 4.4. If you look on the...
13 **DR. KEHRER:** Oh, okay, so these are
14 half-life.
15 **DR. SALICE:** That's correct.
16 **DR. KEHRER:** Not time points.
17 **DR. ODENKIRCHEN:** That's correct. So,
18 what that does is you take those and translate the rate
19 constant for them for whatever time step you're working
20 with.
21 **DR. HEERINGA:** Dr. Sparling?
22 **DR. SPARLING:** Back on the slide number
23 42, you've got the Liquid PARAM. Could you explain to
24 me the...the exposure time is 8 hours to isolate the
25 food consumption. Are they actually looking at

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1 consumption over 8 hours? I thought it was a 1-hour
2 model.
3 **DR. ODENKIRCHEN:** No, what's done is
4 remember that there is a...a food consumption reduction
5 that's over a considerably longer exposure time step.
6 So, what was done in the model, as far as we can
7 ascertain, is that food exposures...carbofuran exposure
8 over a given shorter time step, in this case, 1 hour,
9 is multiplied by 8 to come up with a surrogate
10 equivalent for what the dose would be over 8 hours time
11 step. Then, the food reduction factor is then back
12 calculated into the...into the equation to reduce the
13 food rate on the basis of that...that function of...for
14 an 8-hour time step.
15 So, we have some concerns with regards to
16 that. We're not quite sure whether or not food
17 reduction responses over 1-hour increments are...or
18 food hour...food reductions over 8-hour increments are
19 as reliable when you get down to 1-hour time steps
20 which is why, when we analyzed the data, we used TIM
21 1.0, because it has two 12-hour time steps, so we
22 figured that was a little bit closer to the 8 hours
23 than a 1-hour time step, and that's why we did not
24 incorporate that data into our TIM 2.1 analysis.
25 So, there is some...some question there, and

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1 I would imagine that if you have further question over
2 that, over the validity of that extrapolation, you
3 could probably bring that up with folks who present the
4 results.
5 **DR. HEERINGA:** Yes, Dr. McCarty, please.
6 **DR. MCCARTY:** I just want to...I'm not
7 sure I understand the response to that. Is what you
8 were saying...let me see if I've got it right. Is what
9 you're saying that in the Liquid PARA...Liquid
10 PARAM...we've got to figure out a consistent way to
11 pronounce this. In Liq...in this model, are you saying
12 that in terms of recovery for the carryover to the next
13 time period, a very short half-life is being used, but
14 in terms of the length of time that the food reduction
15 occurs, it's going on for 8 hours?
16 **DR. ODENKIRCHEN:** What...what it is is
17 that the food consumption data is based on a protracted
18 exposure period. So, in other words, it isn't...they
19 don't track food per 1 hour.
20 They track food consumption over a
21 considerably longer period of time, and Chris could
22 probably tell you exactly the..the time duration for
23 each measurement, but what was done, as near as we can
24 figure, is what was done for food consumption
25 reduction...remember, food consumption reduction is a

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1 function of exposure to carbofuran. That's the
2 operative assumption here. So, what's being done is
3 for every hour's time step, you have an assumption of
4 what carbofuran exposure is, but it doesn't match the
5 8-hour time step that is in the empirical study.
6 So, in order to make them match, the 1-hour
7 value is multiplied by 8 to bring it up to that same
8 time duration, and then that reduction value...let's
9 say it's 10 percent, 15 percent, whatever is
10 interpolated off that curve...is applied back down to
11 the 1-hour food consumption rate, and the next hour has
12 a reduced food...food consumption on the basis of that.
13 Does that make sense? Well, I mean, does
14 that...does that adequately describe so you can
15 understand what the model does?
16 **DR. MCCARTY:** I'll let you...
17 **DR. HEERINGA:** I think we'll...we'll
18 also have a chance tomorrow morning, I'm sure, to have
19 a presentation, I think, in the public comment period.
20 **DR. ODENKIRCHEN:** Right. I think it's a
21 little unfair for us to comment on...on those things.
22 If we don't understand some nuance associated with that
23 model, I think that the...the study author would be in
24 a better position to answer that.
25 **DR. HEERINGA:** We're testing you at this

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1 point.

2 **DR. ODENKIRCHEN:** Yeah.

3 **DR. HEERINGA:** Okay. Other questions?

4 Just for everyone's information, we're

5 approaching 3:30, and I...I wanted to call a break. In

6 terms of the progress of this session, it's...it's my

7 expectation that I'd like to have a full treatment of

8 the human health presentation by the Environmental...or

9 by the EPA scientists this afternoon, including our

10 discussion, but that we probably will not turn to the

11 public comments until first thing tomorrow morning. I

12 apologize for anybody who came in for this afternoon,

13 but I think we're set up so that the initial

14 presentations were scheduled with people who probably

15 expect to be here all week and then the shorter

16 presentations, public comments, would have been

17 probably scheduled for tomorrow morning anyway.

18 So, I think that, in fairness to everybody,

19 to make sure that all the presentations get a full

20 hearing and that we have ample time to answer

21 questions, I'd prefer to work it that way.

22 So, any additional questions, though, on

23 the...the environmental and avian risk assessment model

24 piece? And I think we'll have a chance in the

25 summaries before we answer the charge questions to

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1 revisit any questions of clarification you might have.
2 Dr. Montgomery, did you have one left
3 or...okay.
4 At this point, then, not seeing any
5 additional questions, I'd like to call a 15-minute
6 break. If you would come back here at 20 minutes of
7 4:00, we'll turn to the presentation on the human
8 health risk assessment.
9 **(WHEREUPON, a brief recess was taken.)**
10 **DR. HEERINGA:** One administrative
11 detail. It's important maybe to only one person in the
12 audience, but there's a pair of...a set of Chrysler car
13 keys here that someone found in the men's room, and
14 they were retained here. So, we maybe eliminated 50
15 percent of the audience. So, if...if you're missing
16 your car key's they're right here at the front desk.
17 Okay, at this point, we have heard the
18 presentations from the EPA scientific staff related to
19 the ecological risk assessment, and we are going to
20 turn next to presentations on the human health risk
21 assessment component, and we'll begin, I think, this
22 afternoon with Jack Housenger who is the Associate
23 Director of the Health Effects Division of the Office
24 of Pesticide Programs.
25 **DR. HOUSENGER:** Okay, thank you. I'm

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1 going to try to make up a little time, because I know
2 how many slides we have to go through. My comments are
3 just going to give you a...a broad overview of some of
4 the methodologies that we use and then wrap up with
5 some of the risks that we're...we're seeing from our
6 human health risk assessment.
7 The first slide just shows all the people in
8 OPP Health Effects Division that have worked on this
9 assessment as well as the people in ORD that have
10 helped out. I just want to point out that ORD not only
11 helped us analyze and interpret the study results, but
12 they actually conducted some of the studies, and we're
13 greatly appreciative of that.
14 Ginger and Woody are both here in the
15 audience also with us today, so...
16 Well, the Health Effects Division, we assess
17 the risks to...to humans from pesticide exposure.
18 Start out with hazard identi...hazard identification.
19 We look at food exposure, water exposure, worker
20 exposure. Carbofuran does not have residential
21 exposure, but if it did, we would look at that as well.
22 And also looked at any epi and incident reports to help
23 us interpret the...our worker exposure assessment or
24 worker risk assessment.
25 As you can see, risk is a function of hazard

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1 and exposure. And by now, you know that carbofuran is
2 an n-methyl carbamate and that its mode of action is
3 the inhibition of acetylcholinesterase which, when the
4 exposures are high enough, can lead to clinical signs
5 of neurotoxicity. Carbo acts rapidly, but recovery is
6 also rapid, and because of the rapid recovery, we're
7 interested most in acute toxicity.
8 When we conduct...when we look at a chemical,
9 we'll conduct a aggregate risk assessment for a single
10 chemical, multi-pathway, and in the case of carbo, we
11 looked at both food and water. Carbofuran also shares
12 a common mechanism with the n-methyl carbamates that
13 was brought before the SAP in 2001. However, since
14 carbofuran was deemed ineligible for re-registration,
15 the domestic uses were not part of the cumulative
16 assessment that we analyzed in 2007.
17 Between 2005 and 2007, approximately eight
18 new toxicity studies became available, six of these in
19 2007 alone. These data significantly upgraded the
20 overall quality of the animal toxicity database, and
21 you'll be hearing more about this later.
22 This just presents what I'm going to be
23 talking about as we go through the presentation.
24 A pyrifuran food exposure assessment is
25 considered highly refined. It's a probabilistical

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1 assessment that is conducted using DEAN. The residue
2 data relied heavily on USDA's pesticide data program.
3 This collects residue information on commodities at the
4 point of distribution right before it goes to the
5 grocery store, so it's...it's close to the dinner
6 plate.
7 We also have available carbamate market
8 basket survey that was conducted by a task force of
9 carbamate registrants, and when we didn't have
10 monitoring data, we used field trial residue values.
11 For consumption, we use USDA's continuing
12 survey of food intake from 1994 to 1996. They also
13 have available a children's survey in 1998. We take
14 this data and use recipes to turn it into all
15 agricultural commodities which then we apply the
16 residue values to.
17 The DEAN software has been reviewed by this
18 panel in 2000, and it's been used extensively in many
19 of our risk assessments, and some of those risk
20 assessments have also come back before the panel. We
21 use it for both registration and re-registration.
22 In terms of the drinking water exposure, the
23 assessment presented in the EFED science chapter for
24 the IRED presents an extensive summary of all the
25 available monitoring data for carbofuran. Most of the

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1 monitoring data is 10 years old with the exception of
2 data from the USGS NACRA program which was summarized
3 through 2003. Each study is summarized and described
4 in detail in that chapter.
5 Finally, other studies, we have 5 targeted
6 and more than 25 non-targeted studies, including a
7 national scale USGS NACRA data that's considered one
8 study.
9 Surface water, 3 targeted, 12 non-targeted
10 studies, and we also had drinking water information
11 from community water systems where monitoring was done.
12 The original assessment that EFED did
13 was...go back to that. No, that's right. I'm sorry.
14 The original assessment simulated seven crops for
15 surface water scenarios, representing the majority of
16 carbofuran use. Use rates for these crops range from
17 the minimum efficacious rate to maximum labeled rates.
18 The refined assessment represented all crops,
19 making them to crop groups for modeling purposes. The
20 result...this resulted in the addition of several
21 additional modeling scenarios for cucurbits and bananas
22 in the 2007 updates.
23 This slide just shows how many times the
24 panel has reviewed various aspects of the modeling.
25 You can see from...all the way from the 190s up through

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1 2005.
2 Between August and December of 2007, FMC
3 submitted additional assessments of drinking water
4 exposure to EPA. Two of these addressed surface water
5 exposure, and two addressed groundwater exposure.
6 EPA summarized these assessments in the
7 documents cited on this slide. The vast majority of
8 the data described in the recent submissions was
9 included in EPA's original assessment.
10 FMC's conclusions were not substantially
11 different from the Agency's conclusions. We haven't
12 asked for the panel to...specific questions on the
13 drinking water exposure, and that's mainly because of
14 the concordance of our results with FMC's, and a lot of
15 the tools and methods have already gone through this
16 panel's review.
17 When we look at worker exposure, we look at
18 two groups of workers. One is the handlers, the
19 mixers, loaders, applicators, and then those workers
20 who enter the fields after they've been treated, in the
21 case of carbofuran, like scouts or irrigate...or people
22 moving irrigation equipment.
23 For handler exposures, we looked at mixing,
24 loading liquids and granulars, aerial and ground
25 applications, flagging operations, and applications by

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1 hand or hand-held equipment. Looked at both dermal and
2 inhalation exposures, and we used the pesticide
3 handlers' exposure database along with use and label
4 information and different levels of protection, single
5 layer of clothing or engineering controls to determine
6 the exposure values.
7 For post-application exposures, we looked at
8 scouting, weeding, irrigation. We took dislodgeable
9 foliar residue data along with use information from the
10 label and job-specific measures of exposure or transfer
11 coefficients to calculate the exposures. The AgriEntry
12 Task Force data we used to generate the transfer
13 coefficients.
14 Just for people's information, transfer
15 coefficients is how much contact with a plant people
16 come in...come in contact with, and the dislodgeable
17 foliar residue data is how much rubs off on your skin
18 when you touch the plant.
19 This slide shows the number of times that the
20 SAP has reviewed our worker exposure assessments,
21 handlers in 1986 and the review of the guidelines,
22 draft guidelines for post-application in 1998. We've
23 held public workshops in '94, '97, and 2002, and then
24 last year, we took before the SAP certain methodologies
25 for monitoring exposure that would be relevant for both

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1 the AgriEntry's Task Force as well as the Peahead.
2 You're going to hear a lot more about the
3 hazard assessment and identification after I get done.
4 I just want to point out that we...we did have several
5 human studies available for carbofuran. We took them
6 to the Human Studies Review Board in 2006.
7 You can see the Earl studies were...were
8 scientifically deficient, based on a number of...of
9 issues, including problems measuring RBC and small
10 studies group. Dermal studies were deemed ethically
11 deficient as well as scientifically deficient. Based
12 on what the HSRB told us, we're not using the studies,
13 the human studies, in this risk assessment.
14 So, this gives you some...a very broad look
15 at some of the risks that were identified in our risk
16 assessment. At the 99.9th percentile of exposure,
17 levels of concern are exceeded for food alone, ranging
18 from 230 to 310 percent for the most exposed
19 population, infants and children. Water alone from
20 both ground and surface water here results in greater
21 than 10,000 percent of acute PAD.
22 Workers, the handlers, mixers, loaders,
23 applicators, many scenarios had levels of concern, even
24 considering engineering controls such as clothes,
25 mixing, loading, or in closed cabs. For post-ap, we

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1 look at the current re-entry interval on the label.
2 Most of those are inadequate. They need to be
3 lengthened in order to achieve a risk that...that isn't
4 of concern to us.
5 Given all the times that the various
6 methodologies have undergone review by the SAP, we
7 wanted to focus on the hazard assessment. You can see
8 the various categories up here. You're going to see
9 this later, so I'm not going to dwell on it, but we're
10 not focusing on the exposure side of the equation.
11 We're focusing more on the hazard assessment, given all
12 the prior SAP review.
13 Dr. Anna Lowit is going to go into a lot more
14 detail on the risk assessment, and I'll turn it over to
15 her next.
16 **DR. HEERINGA:** Dr. Lowit, maybe before
17 you begin, if there are any questions...yes, Dr.
18 Chambers.
19 **DR. CHAMBERS:** Jan Chambers. Clarify
20 something for me. When you talked about the cumulative
21 risk for the n-methy carbamates, did you include
22 carbofuran or not?
23 **DR. HOUSENGER:** We...not in our...well,
24 yes and no. We included the import tolerances for, I
25 think, four commodities. We did not include the

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1 domestic uses of carbofuran, because those were deemed
2 ineligible. We did conduct a sensitivity analysis that
3 looked at the uses of carbofuran, but it was not in our
4 baseline assessment.
5 So...so, you can see what the results of
6 carbofuran in the cumulative is through the sensitivity
7 analysis.
8 **DR. HEERINGA:** Dr. Lowit?
9 **DR. LOWIT:** One quick thing before I
10 start my presentation, and like Jack, I'm going to try
11 to go quick to pick up a little bit of time, because I
12 know how many...how many slides Dr. Reaves has, but I
13 may have put half of those in, so I can't really say
14 that...may have asked her to, I guess, is a better way
15 to.
16 One addition, though, to supplement some
17 information that EFED had given Dr. Hattis earlier in
18 the question and answer around the lengthening of the
19 half-life recovery from cholinesterase for increased
20 dose is this is not the first time that we've seen
21 something like this. As we show...showed in the
22 cumulative in rats, this is not the first. It is not
23 an unusual phenomenon. There are other carbamates that
24 are showing that pattern, that the higher the dose, the
25 longer the recovery. So, I just wanted to add that to

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1 the record.
2 Okay. I'm going to relatively quickly go
3 through an enormous amount of material, some of which
4 could have had days and days of SAP comment all on
5 their own, but what I'm going to do is mostly provide
6 you with some context in three key areas before we move
7 on to the information behind our questions.
8 The first one is the results of the human
9 health risk assessment regarding food and drinking
10 water, and the second one being OPP's policy around
11 using cholinesterase data in human health risk
12 assessment, and then the third one, just to give you an
13 idea of why ORD was doing studies on carbofuran in the
14 first place, to give you some context and background
15 around that.
16 To reiterate what Jack said, our dietary
17 exposure assessments are probabilistic in nature. We
18 use the DEAN model. DEAN stands for Dietary Exposure
19 and something model. I wrote it down earlier, and now
20 I forgot what it stands for, but that's not that
21 important. And it has been reviewed multiple times by
22 SAPs going all the way back to '98 and 2000, most
23 recently in 2005.
24 Both the...just one kind of comment to the
25 panel. The dietary assessment, both the food and the

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1 drinking water, are done in combination of three
2 divisions within our office. The bulk of the
3 probabilistic work and the modeling with DEAN is done
4 in the Health Effects Division where I work with some
5 very talented people who've done these analyses that
6 are in the room, so if you have any questions, we'll
7 defer to them.
8 The drinking water assessment is done by our
9 colleagues also in EFED who do the...the fate in
10 drinking water component, and they're also in the room
11 if you have any questions about that.
12 And percent treated which I'll touch on very
13 briefly is...is provided by our colleagues in
14 Biological and Economic Assessment Analysis Division,
15 which the acronym is BEAAD. So, it's a coordinated
16 effort among three...among three divisions.
17 On the consumption side, as Jack just said,
18 in our food assessments, we use what we call the CSFRI
19 which is a database made of up somewhere in the order
20 of 20,000 people, 5000 of which are children,
21 supplementary of the '98 survey. Information reported
22 in CSFRI is on an as-eaten basis, apple pies, Cheerios,
23 pizza, and that sort of thing, and what we do is we use
24 the...what's called FCID which is a Food Commodity
25 Intake Database to convert apple pie and pizza to

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1 things like wheat flour, milk, and tomatoes, and all of
2 that is publicly available information.
3 In the case of carbofuran, field trial data
4 was used. USDA PDP monitoring data was used and, in
5 addition to the market basket survey done by the
6 carbamate registrants, provides some of the residue
7 data.
8 The panel that's made of...this particular
9 panel is a mix of...of panels that we've had in other
10 meetings before, so I don't want to dumb this down too
11 much, because these are pretty simple calculations. I
12 just want to make sure everyone's on the same page
13 of...of how we're calculating these...these numbers.
14 We use a metric we call the percent APAD or
15 acute population adjusted dose, and what that is is the
16 acute reference dose adjusted for the FQPA factor using
17 information out of the hazard identification which
18 you'll hear from Dr. Reaves around the uncertainty
19 factors in the point of departure to calculate what we
20 call the APAD or the acute reference dose adjusted for
21 FQPA. So, in the case here, the point of departure for
22 risk in infants and kids is 0.03 divided by 500 gives
23 us 0.0006.
24 And we calculate using food and water
25 exposure numbers, the percent of the APAD. Not very

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1 complicated calculations, considering what we talked
2 about this morning. Just a simple context purpose
3 here. So, you simply divide the exposure, divide by
4 the...the APAD times 100, gives you that percent
5 number, and values over 100 represent exposure greater
6 than the APAD and what we would consider our current
7 level of concern.
8 And so, you'll see in the next few slides
9 that our focus is on values that are greater than 100
10 percent.
11 Okay, so this slide provides the results of
12 the food exposure assessment in a variety of age
13 groups. The...the high level rows in yellow represents
14 the children up to youths of age 12 where we see the
15 percent APAD estimates over 100. The...the blue values
16 of...of 1 to 2 and 3 to 5 are the runs for the toddlers
17 which I'll focus on in a...a few subsequent slides.
18 We put a lot of emphasis in our dietary
19 exposure assessments on USDA's PDP database. It's a
20 very strong database. The design of the...of the
21 database is statistically driven to do assessments like
22 this one we're doing for purposes of risk assessment.
23 It is also...the residues are taken at the point of
24 distribution, so they're very close to the point of
25 consumption.

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1 PDP reports things that are less than the
2 limit of detection as zeros by convention. However,
3 sometimes a value of less than the limit of detection
4 may not, in fact, be a, quote, true zero, but there may
5 actually be a residue there, and it is important in our
6 assessments to get a sense of...of when we...the LOD,
7 something below the LOD is a residue or not.
8 What we do is we use the national percent
9 crop treated estimates to...to estimate what those
10 portion of...of true zeros are, and I have an example
11 just to show you how those calculations are done.
12 So, we have a...a little pie chart here. The
13 green area, we'll assume for this example that there's
14 30 percent of a crop treated around the country. That
15 leaves 70 percent that's not treated that would be a,
16 quote, true zero. For...in this example, roughly 10
17 percent is treated and has residues above the level of
18 detection, but the remaining 20 percent are below the
19 limit of detection.
20 And in our baseline risk assessments, we
21 assume that those that are treated but below the limit
22 of detection, we assume a half LOD residue in our risk
23 assessment.
24 But for purposes of risk assessment, what we
25 want to do is to evaluate the degree that those

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1 assumptions, in fact, are...are bottom lines. So, what
2 we have here are two plots or two tables. The blue
3 table is...are the same results I had in...two or three
4 slides ago focusing on the toddlers age 1 to 2 and 3 to
5 5.
6 It's not an unusual finding in this sort of
7 assessment to see the...the toddler range kids to be
8 the most exposed for two reasons, in part, because kids
9 this age tend to eat...eat more for their body weight,
10 and the other piece is that some compounds like
11 carbofuran, the kids seem to tend to be more sensitive.
12 So, those two factors in combination, it's not atypical
13 to see this pattern of...of the toddlers being the
14 highest exposed.
15 So, in the sensitivity analysis, we have two
16 things. We have a baseline assessment in the blue
17 which includes the assumption of the half LOD for the,
18 quote, treated non-detects, the yellow table being we
19 take all those half LODs, convert them to zeros, and
20 you can see even at the 99.9 at the toddler age, when
21 we convert everything to zeros, we still have risks
22 above what we consider our level of concern.
23 Another sensitivity we've done is to look at
24 eaters. The...the values I've shown on the previous
25 few slides are on a per capita basis, but in a

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1 situation like this where we have a variable point of
2 departure, it's not...what we want to do is just to get
3 a sense of...of what eaters may have for their
4 individual risk.
5 So, what we have here is an example using
6 cucumbers. So, this is actual raw PPD data out of the
7 PPD database. There are roughly approximately 1400
8 samples, 11 detects of carbofuran on cucumbers. So,
9 that...there are not 11 rows here, but, for example,
10 there are two residues at 0.029. So, don't add the
11 rows and ask me where the rest of the 11 came from.
12 There are two calculations here, and they're
13 relatively simple calculations, the first one at
14 approximately the 50th percent consumption which is 6
15 grams of cucumbers. That's about 0.2 oz, and I don't
16 know how much a slice weighs, but it's not many slices
17 at 0.2 oz for a 20 kg child which is approximately a
18 kid 3 to 5. You can see the highest do...the highest
19 two measured residues of carbofuran give us percent
20 APAD over 100.
21 If you think about a child eating a larger
22 amount of cucumber, something closer to a half a cup,
23 the majority of those residues would give that child
24 eating those, the cucumbers, something over the APAD.
25 All right, another slide with colored tables.

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1 The top yellow table is the same one I've shown in the
2 last couple of slides. It's the...the toddler age
3 children exposed for food only, and what I've added
4 here is the estimates for groundwater and surface
5 water.
6 In OFTPA, we have to do what's called
7 aggregate risk, and so, typically what we will show is
8 food...risk to food, risk to water, and then the
9 aggregated or combination of the two, but in this case,
10 as the values in both food and water exceeded the level
11 of concern, you can just, if you think about putting
12 them together, it only gets bigger. So, we won't go
13 through that exercise.
14 The groundwater and drinking water that's
15 shown here is for melons applied in the Delmarva
16 Peninsula using typical application practice of
17 approximately 1.2 lb/acre, and the methods and the
18 scenario used here on the slide are similar to that
19 used in n-methyl carbamate cumulative assessment, and
20 it's meant to represent private little wells with
21 shallow acidic groundwater under sandy soils with low
22 organic matter content. On wells which are deep and
23 with neutral or alkaline aquifers or under fine
24 textured soils would be less vulnerable and have less
25 risk.

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1 So, in the case of a surface water, we have
2 an example of the water by EFED, and this one is
3 Illinois corn, and as you can see, all the...all of the
4 estimates are well above 100 for groundwater and
5 surface water.
6 As you've heard several times today, and I'm
7 sure Dr. Reaves will say it again, toxicity of
8 carbofuran is typically an acute event. The onset and
9 the recovery of the toxicity of carbofuran is rapid,
10 onset within a few minutes, recovery within hours, and
11 in the case of evaluating human health risk to
12 carbo...to thinks like carbofuran and carbamates, we
13 have to think about the 10-day exposure to that.
14 DEAN sums exposures that will fit along over
15 24-hour periods, but in the case of something like
16 carbofuran and other carbamate, it's not an
17 unreasonable thing to consider if you've been exposed
18 at breakfast how much you would be affected by dinner
19 or vice versa, if you've been exposed at dinner, the
20 following morning if you would still be...have
21 cholinesterase inhibition, for example.
22 And we're cognizant of that, that we don't
23 need to do a...a good job of matching exposure and
24 hazard, so what we've done is a couple sensitivity
25 analyses to look at the extent to which adding up

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1 exposure over a 24-hour period does or does not
2 overestimate risk and what it does to our overall
3 conclusions.
4 We use two approaches, both of which that
5 have been used in either the cumulative risk assessment
6 for the carbamates or other similar chemicals or both.
7 In the first one, we've used information at the upper
8 0.2 percentile to evaluate the number of distinct even
9 events that con...contributed to carbofuran. That's
10 using a combination of the CSFII and FCID databases.
11 And in the second one, we've done that and
12 included on top of that information about the half-life
13 to recovery for cholinesterase inhibition from pups,
14 rat pups, and the information about, govern the eating
15 and drinking.
16 So, we think about the first one. Some of
17 you might be familiar with these pie charts. We
18 presented this sort of approach to the SAP in 2005 for
19 a cumulative risk assessment. What our team does is
20 extract out of the outputs the individuals who were
21 exposed to carbofuran and how often, and I'll...if you
22 want the details, you can...I will pull someone else up
23 to the table, but the pattern here is the same as we've
24 seen for the carbamates in general in that the purple
25 or the light blue as it looks here, over 70 percent of

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1 the individuals, the person-days at the upper 0.2
2 percentile, those individuals were only exposed to
3 carbofuran one time each day in their food, suggesting
4 that summing that exposure over 24 hours is not an
5 overestimate and that there's not a dinner and a
6 breakfast or a breakfast and dinner for the vast
7 majority of people.
8 Okay, if we add on top of our analysis like a
9 drinking water and also consider the impact of...of
10 half-life in our risk estimates, the second column over
11 is a 24 estimate output by DEAN. They're the same
12 numbers that were...would have been on the previous
13 slides.
14 The right two columns represent a half-life
15 to recovery of 150 minutes, with the last one being 300
16 minutes, and these are...these values were selected out
17 of...out of data from rats, rat pups, so they represent
18 young rats which would be the population that we're
19 interested in here. And you can see in the food, the
20 food rows, that incorporating a half-life really didn't
21 change the qualitative answer here that exposure to
22 carbofuran to the young children exceeds the...the
23 APAD.
24 Drinking water, as you can see, a reduction
25 on the percent APAD from the 24 hour to...to half-life

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1 estimates. However, it still doesn't change our
2 qualitative answer. They're still well above 100.
3 So, in conclusion, we believe daily food
4 exposure to carbofuran most often comes from a single
5 eating event and that summing the food over 24 hours
6 does not really overestimate risk. Accounting for
7 that, for water exposure, we think it would reduce
8 exposure by somewhere on the order of approximately two
9 to three fold, but that does not change our qualitative
10 bottom line that the APADs are still well above 100 for
11 drinking water.
12 Okay, so we'll change gears and move away
13 from the risk assessment and into our cholinesterase
14 policy, how we, cholinesterase statement.
15 Acetylcholinesterase inhibition is a key event in the
16 mode of action for carbamates such as carbofuran which,
17 of course, you're going to hear a lot about in a few
18 minutes. With, we assess more than just cholinesterase
19 inhibition when we do these analyses, we also look at
20 physiological and functional effects.
21 However, it's very difficult to relate
22 function effects inhibition with cholinesterase
23 inhibition, although with the help of Ginger Moser and
24 Stephanie Padilla who have done some parallel
25 experiments for us for the cumulative, we're getting

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1 better. It's still very challenging though.
2 Cholinesterase inhibition in both the central
3 and the peripheral nervous system provides a direct
4 evidence of adverse effects in the nervous system. In
5 laboratory animals, it's common for us to see data and
6 from brain, whether that be a whole brain homogenate
7 or...or different compartments of the brain. That's
8 very typical data that we see.
9 Data from the peripheral nervous system is
10 very rare, in fact, extremely rare. In the absence of
11 peripheral data from the peripheral nervous system, we
12 often use data collected from blood as a...as a
13 surrogate, and we use data from the blood as a
14 surrogate for the peripheral in laboratory animals when
15 we don't have it, central data from the central nervous
16 system when we don't have it, and in humans for both.
17 In general, we prefer red blood cell
18 cholinesterase data over plasma. Plasma can contain a
19 combination of both uterocholinesterases and
20 acetylcholinesterases, depending on the species, and
21 acetylcholinesterase is the...is the target here and
22 not uterocholinesterase.
23 RBCs contain only the acetylcholinesterase,
24 and we believe that using RBC would be a better
25 reflection on potential changes in the nervous system

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1 than would the plasma. And as you'll see, I don't
2 believe we're going to talk about plasma at all today.
3 One more thing to...to add to the
4 cholinesterase policy. In recent, in the last few
5 years, is we've increased our use of benchmark dose
6 techniques. We have...we have been typically using a
7 10 percent response. However, it's important to note
8 that we do not have a fixed percent we have
9 predetermined to be that separates adversity from non-
10 adversity. We've been using the 10 percent change as a
11 result of some pretty robust analysis we did several
12 years ago as part of the OP cumulative assessment where
13 we did analysis of over 1000 measurements of
14 cholinesterase inhibition which showed that at or
15 around 10 percent, most studies submitted by the
16 registrants can detect them, and we have also not seen
17 any studies where inhibition less than 10 percent
18 produces functional behavioral effects, so we hope
19 we've struck a nice balance between statistical
20 capabilities and also biological considerations.
21 We've not done that thorough analysis for the
22 carbamates, although our experience with the cumulative
23 suggests that the same pattern holds, and we have thus
24 been using the 10 percent.
25 One more...one more final clarification for

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1 the panel, and then I'll pass it over to Dr. Reaves.
2 Around 2004 and 2005 when the Agency began on the
3 problem formulation phase of the cumulative assessment
4 in earnest, the Health Effects Division identified a
5 couple of areas of research regarding some open-ended
6 questions around carbamate hazard assessment that we
7 felt that ORD can help with. We have, in the last two
8 years, had a wonderful collaboration with our
9 colleagues at ORD, and we're very proud of...of that
10 collaboration, and what you're seeing today is...is
11 still a continuation of that.
12 For those of you who haven't...some of you
13 have been on panels with...with the cumulatives and you
14 know this as well as I do, but for those of you who
15 haven't, just quickly, the cumulative assessment uses a
16 relative potency factor method which means that we
17 select one of the compounds as the index chemical and
18 scale all the rest of them to the benchmark dose of the
19 index.
20 What that means in practice is that we're
21 assuming the carbamates work in dose additive way
22 where, essentially, they're dilutions of one another.
23 So, dose additivity makes the foundation assumption for
24 the entire cumulative assessment, and we felt something
25 that important deserves some experimentation around it,

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1 and one of the...the things that ORD has...has done to
2 contribute to that assessment is some mixture data.
3 They've actually been working with seven
4 carbamates, carbaryl, carbofuran, formetanate,
5 methiocarb, methomyl, oxamyl, and propoxur, so it's not
6 just carbofuran, it's seven chemicals, and we're
7 looking at both adults and juvenile rats. And the plot
8 you see, they're actually the plot of the mixture data
9 from the adults, and we see there is a nice prediction
10 of dose additivity from that...from that study.
11 Prior to conducting the mixture experiments,
12 ORD first had to conduct individual chemical
13 experiments to determine the dose levels and also the
14 time course for the mixture. So, that's where the
15 single chemical assessments from ORD data, our in...our
16 in-house ORD data came from.
17 After those experiments were conducted and
18 after the Health Effects Division had done a more
19 thorough analysis of what data was available from the
20 registrants, we made a decision to also use the ORD
21 data for the single chemicals in the cumulative
22 assessment. We believe that using all of the quality
23 data provides the...the most robust BMD estimates and,
24 thus, potency estimates that we could find.
25 And just like on the data for the propoxur

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1 and the methiocarb, the ORD data were the only data
2 that met the criteria of a sediment assessment. For
3 the remaining chemicals, the ORD data was in
4 combination with those from the registrants, and in
5 August, 2005, we presented some plots of the comparison
6 of data developed from ORD with a lot of the
7 registrants, and we found very nice concordance among
8 them.
9 In the case of carbofuran around the...the
10 plot data...and Ginger can speak to this if you have
11 any more questions...the idea is to do a mixture
12 experiments in pups and PND17 animals, so she and her
13 lab are continuing to work systematically evaluate pups
14 and the PND17 pups, and she, as I understand, she likes
15 to do the age...the age of 17, because you can evaluate
16 motor activity in those animals that you cannot do in
17 the PND11s.
18 After the conduct of the first FMC
19 comparative cholinesterase study, we asked Ginger to do
20 an experiment on the PND11s to add additional data to
21 that data set for the simple reason that we believe
22 that more data is...provides the most robust analysis,
23 and with that, I will answer any quick questions or
24 turn it over to Dr. Reaves.
25 **DR. HEERINGA:** Questions from the panel?

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1 Dr. Sparling?
2 **DR. SPARLING:** Don Sparling from
3 Southern Illinois University. A couple of questions.
4 What is the range of half-lives for
5 carbofuran in water?
6 **DR. LOWIT:** In water? I'd have to
7 ask...Danny? Come to the table so you can use the
8 microphone.
9 **DR. HEERINGA:** Please step up to the
10 mike, yes. Thanks. And introduce yourself, too.
11 **DR. JONES:** I'm Dan Jones. I'm senior
12 agronomist in the Environmental Fate and Effects
13 Division.
14 I'm afraid I don't have the precise value in
15 my hand. The important part for carbofuran is it's
16 very sensitive to pH. At pHs, acid pHs, it can be very
17 persistent, on the order of hundreds of day. At high
18 pHs above 7, it can be more...more on the order of
19 tens, tens of days. I'm afraid I don't have the
20 numbers memorized, but I can get them to you tomorrow.
21 **DR. SPARLING:** I was just
22 looking...looking for range of it.
23 Secondly, when we're talking about drinking
24 water, are we concerned only about effluency of well
25 water that's found in wells on surface waters, or can

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1 carbofuran also make it through water purification
2 plants?
3 **DR. JONES:** Carbofuran can make it
4 through plants. It can be removed to some extent by
5 groundwater activated carbon when it's present. Also
6 softening which raises the pH will also reduce the
7 amount of carbofuran, but many plants neither use GAC
8 nor use softening, but in those cases, there's an
9 expectation that it's going to make it through, and, in
10 fact, we've got some evidence, a little bit of data,
11 showing it gets through drinking water, so it is...
12 **DR. HEERINGA:** Other questions? Yes,
13 Dr. Hattis?
14 **DR. HATTIS:** I notice you used the pup
15 rat half-life residue, stress that, importantly. Do
16 you have any reason to believe that the half-life
17 wouldn't be longer in people, because, of course, we're
18 big and slow with lots of other things?
19 **DR. LOWIT:** For other carbamates, we're
20 thinking whether or not we have some human data from
21 other carbamates in that format. It certainly would be
22 an easy thing we could look at and maybe provide in the
23 morning if...if you'd like.
24 My memory is that I think we have some, and
25 it's not that much longer. We...we can provide it in

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1 the morning. That's a very easy thing to look up.
2 **DR. HATTIS:** And I also noticed that in
3 your presentation, a lot of...a fair portion of the
4 dosage was attributed to milk in the VIN dietary
5 assessments, the overall dosage that went to the higher
6 percentiles. I believe it was over 60 percent.
7 The registrant has...has suggested that
8 that's due to usage in alfalfa. Do you have an opinion
9 on that one way or the other?
10 **DR. LOWIT:** Here comes Thurston. I
11 think he has a comment on that. It takes an army to do
12 these assessments, so bear with us.
13 **DR. HEERINGA:** We understand. Please
14 introduce yourself.
15 **DR. MORTON:** Thurston Morton, ATD.
16 Yeah, we looked at that, and there was also the corn
17 use, and if you look through the...kind of construct
18 the dietary burden, you actually come up with a higher
19 dietary burden using the corn 48 than you would with
20 the alfalfa. So, there's no way you could say that
21 dropping alfalfa would cut down on the detects in PDP,
22 because for all we know, those cows are eating alfalfa
23 or the corn forage.
24 **DR. HATTIS:** So, the cows eat a fair
25 amount of corn...

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1 **DR. MORTON:** Yes.

2 **DR. HATTIS:** ...one way or corn...

3 **DR. MORTON:** And/or alfalfa, sir, yes.

4 I think we'll see the detects either way.

5 **DR. HEERINGA:** Dr. Handwerger?

6 **DR. HANDWERGER:** Is carbofuran present

7 in human breast milk?

8 **DR. LOWIT:** I'm not aware of any data.

9 **DR. HANDWERGER:** I think that would be

10 really important data to know, because certainly, that,

11 you know, a woman may absorb that readily through the

12 gastric mucosa and could have some consequences on

13 fetal metabolism. Would be very, awfully easy to

14 measure, I would think.

15 **DR. HEERINGA:** Other questions at this

16 point before we move on to the next presentation?

17 **(No response.)**

18 **DR. HEERINGA:** Not seeing any, I guess

19 Dr. Melissa Reaves.

20 **DR. REAVES:** Okay, like Dr. Lowit said,

21 I have a fair number of slides, but I've kind of broken

22 it through different sections, so, hopefully, it will

23 make sense as we go through these. I'm going to go

24 through the bulk of the data that we have received

25 since 2005 for both the oral and the dermal routes.

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1 Prior to 2005...

2 **SPEAKER:** Can you hold your microphone

3 closer?

4 **DR. REAVES:** Sure. Can everybody hear

5 me now?

6 Prior to 2005, the Agency was relying on a

7 one-year dog study as the basis for the point of

8 departure for all routes of exposure, and this was

9 based on a LOEL from plasma cholinesterase, and as Dr.

10 Lowit mentioned, we prefer to sue red blood cell

11 instead of plasma. And so, we have a great deal of

12 data since the 2005 assessment.

13 In 2006, we received the first FMC

14 comparative cholinesterase study which I'll go through

15 a little bit later, but just for context, we relied on

16 this study from the brain data to then derive the point

17 of departure, the BMDL, in fact, of 0.03. Then, we

18 apply the uncertainty factors, the 10x intraspecies,

19 the 10x interspecies, and then we also have to account

20 for FQPA, and due to the lack of reliable red blood

21 cell data in the pups and the fact that we thought red

22 blood cell was more sensitive than brain, a 5x was

23 applied in this risk assessment.

24 The Agency noted in the 2006 risk assessment

25 that the converted cholinesterase study should be

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1 repeated and that a follow-up study will be considered
2 for reevaluation of the FQPA factor, and like I said,
3 I'm going to go through next some of the information
4 that we've received.
5 I'm not going to spend a lot of time on this
6 slide. Again, the carbamates have a rapid onset of
7 cholinesterase inhibition followed by recovery,
8 typically within hours, sometimes dose dependent, but
9 the focus here is acute toxicity with
10 acetylcholinesterase inhibition the most sensitive
11 endpoint for risk assessment.
12 We did look at other toxicities specifically
13 for carbofuran, and acetylcholinesterase inhibition is
14 the most sensitive for the reproductive and
15 developmental toxicity or the cancer data as well.
16 So, first, then, I'm going to go through the
17 oral data base for carbofuran. We have two studies,
18 Padilla, et.al. and McDaniel, et.al., which are
19 actually Stephanie Padilla from the ORD laboratories
20 here in EPA and McDaniel also from ORD. The next two
21 studies are the first FMC study, comparative
22 cholinesterase study. A second study, also a
23 comparative, a repeat of the first study. And then, we
24 have a PND17 pup study from ORD as well as a
25 comparative cholinesterase study in the PND11 pups,

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1 comparing pups to adults.
2 So, if we look first at the Padilla study,
3 there's a time course component in which adult male
4 rats were used. Seven measurements were taken from 30
5 minutes to 24 hours post dosing, and the rats received
6 a single oral dose of 0.5 carbofuran or a control.
7 And from this graph, you can see the...the
8 brain inhibition is on the top curve, and the red blood
9 cells are on the bottom, and you can see at the
10 lowest...or at the first time point, you have peak
11 inhibitions. We were talking about the acute
12 inhibition phase followed by recovery, and at the first
13 time point of 30 minutes, you have significant
14 inhibition. You have 30 percent in the brain and 55
15 percent in the red blood cells. And here, recovery in
16 brain was typically by 6 hours and in the red blood
17 cell between 6 and 24 hours, because this was
18 relatively higher dose of carbofuran.
19 The second study is the McDaniel study. This
20 was the dose response component. Adult male rats were
21 used in this study. Five doses of carbofuran ranging
22 from 0.1 up to 1.5. Clinical signs were recorded at 10
23 to 12 minutes for tox score, and this was typically
24 things like tremors, rapid inhalation, other toxic
25 effects.

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1 The motor activity assessment began 15
2 minutes after dosing. A recession length of 20
3 minutes. Immediately following the assessment, the
4 tissue samples were taken for cholinesterase
5 measurement, and approximately 35 to 40 minutes after
6 dosing. So, again, very acute within an hour plus
7 dosing.
8 This is a graph from the dose response, and
9 we have both cholinesterase activity and motor activity
10 in the adult rats. We have motor activity on the
11 bottom, both the horizontal and vertical activity, and
12 we also have brain cholinesterase activity in the
13 triangles and red blood cell in the diamonds.
14 You can see that motor activity was
15 significantly decreased beginning at the...the 0.3
16 dose, and then with the dose response decline, that
17 says there was a greater increase in the number rats
18 showing toxic signs. The cholinesterase activity, the
19 red blood cell and brain cholinesterase inhibition
20 ranged from 15 percent to greater than 50 percent, and
21 you also notice at the low dose, where cholinesterase
22 and motor activity measurements are similar, kind of
23 grouped up here, that there is a statistically
24 significant decrease in brain cholinesterase inhibition
25 compared to controls.

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1 So, again, like Dr. Lowit said, we do...we
2 are being protective of other behavioral and clinical
3 effects by using cholinesterase inhibition.
4 So, the first FMC study was submitted
5 November of 2005, and the study was...included PND11,
6 postnatal day 11 pups, and then in postnatal day 60 or
7 adult rats, and let me mention that this data was used
8 in the 2006 risk assessment. There was a time course
9 component, and this included seven measurements over a
10 period of 15 minutes to 360 minutes, and, again, it was
11 to the single oral dose of 0.6 mg/kg carbofuran.
12 The time course study showed peak brain
13 cholinesterase inhibition around 15 minutes, and brain
14 cholinesterase inhibition was greater in pups than
15 adults in both sexes and at all time points.
16 Brain was reduced 40 to 50 percent at the
17 first measurement of 15 minutes. In adults, the first
18 measurement also showed significant inhibition of 60 to
19 70 percent. And from this information, 15 minutes was
20 selected as peak inhibition for the dose response
21 component.
22 For red blood cell activity, there was no
23 inhibition, however, at any time point in any group for
24 pups or adults. So, this didn't make much sense based
25 on the tox profile for carbofuran. You would expect

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1 red blood cell inhibition where you were seeing
2 significant brain inhibition. This does also cause
3 significant decreases in motor activity.
4 I should say this was a similar dose, and we
5 saw more activity decreases in the McDaniel where we
6 also saw red blood cell and brain inhibition at 0.3.
7 And based on this information, the red blood
8 cell data was considered unreliable, and that's why the
9 brain data from this study was used in the 2006 risk
10 assessment.
11 The dose response component used PND11 pups,
12 again adult rats. This time, a single oral dose
13 ranging from 0.3 up to 1.0 mg/kg. Measure...clinical
14 signs were taken between 15 minutes and 720 minutes
15 post dosing. Cholinesterase activity for both red
16 blood cell and brain was assessed either at 15 or 12
17 hours post dosing, and motor activity was not evaluated
18 in this study.
19 So, in this first comparative cholinesterase
20 study, there were tremors in PND pups at all doses.
21 The onset of the tremors was earlier in pups, and the
22 duration of the tremors were longer in pups compared to
23 adults. Tremors in pups began at 2 minutes post dosing
24 and persisted for up to 120 minutes.
25 The tremors in adults were at a lower

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1 incident rate than pups but occurred in a dose-related
2 trend. The tremors in adults were observed starting at
3 7 minutes post dosing and persisted for up to 60
4 minutes.
5 For brain cholinesterase activity, there was
6 a dose-related decrease in brain at all doses in both
7 age groups. The lowest dose of carbofuran resulted in
8 almost 50 percent inhibition in pups and 25 percent in
9 adults at the 15 minute time frame.
10 Although the lowest dose inhibited brain
11 activity almost 50 percent in pups, there was no red
12 blood cell inhibition at any dose, either pups or
13 adult, at any time point, so similar to the time course
14 component.
15 Overall, the four CCA studies show that PND11
16 pups were more sensitive than adults, based on brain
17 cholinesterase inhibition and clinical signs. However,
18 we still had uncertainties surrounding the dose
19 response relationship of brain at low doses in pups,
20 and we were still missing that red blood cell
21 inhibition data.
22 So, the second FMC comparative cholinesterase
23 study kind of starts where we started receiving a lot
24 of new data. This study was received the end of May,
25 2000 study, and like the first study, they used PND11

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1 pups. For the range finding component, they used pups
2 only. Due to tremors in all pups in all pups at a dose
3 of 0.3 and higher in the first FMC study, the dose
4 range was lowered. So now, the highest dose is 0.3
5 with 0.03, 0.1 added to the study.
6 A single oral dose of carbofuran was given to
7 pups, again measured at 15 minutes post dosing.
8 Tremors were observed within 15 minutes in 2 of 5 male
9 and 2 of 5 female pups at the high dose of 0.3. So,
10 this agreed with what we had seen in the first FMC
11 study.
12 For cholinesterase activity, for brain, there
13 was a dose-related decrease in both male and female
14 pups. Males were decreased almost 10 to 60 percent, 11
15 to 50 percent in female pups. However, statistical
16 significance was not achieved until the mid and high
17 dose levels in both sexes.
18 For red blood cell cholinesterase,
19 statistical significance was not achieved, again, for
20 any dose in either male or female pups, but although it
21 wasn't statistically significant, there was a dose-
22 related decrease in red blood cell activity in male
23 pups with 13 percent at the lowest dose and almost 30
24 percent at the high dose. In female pups, red blood
25 cell cholinesterase was not inhibiting until the mid

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1 and high dose, overall resulted in just over 20 percent
2 red blood cell inhibition.
3 In this graph, we have both the male and
4 female pups from the range finding component. We have
5 brain in the males in the blue and brain female in the
6 blue, and the green is the red blood cell, and you can
7 see here that the brain has a nice dose response,
8 whereas the red blood cell, you don't...you don't get
9 that nice decrease in inhibition.
10 Next is a time course component of the FMC
11 study. Again, they evaluated clinical signs between 15
12 minutes and 6 hours. This time, the dose used was 0.1,
13 whereas the previous time course used a higher dose of
14 0.6, and there were 6...I said that, 6 measurements
15 between 15 and 6 hours.
16 For clinical signs, there was no adverse
17 observations in either adult or pup. For
18 cholinesterase activity in pups, red blood cell did not
19 fit the typical peak inhibition curve or the recovery
20 profile that we would expect for a carbamate.
21 Examination of control values over time yield
22 inconsistent values, and I'll show you this in the next
23 slide.
24 In treated female pups, for example, red
25 blood cell kind of would decrease, would recovery to

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1 within 12 percent, and then it would decrease again, so
2 that's what I mean by inconsistent. For brain
3 cholinesterase however, pups followed a more typical
4 pattern for a carbamate. Brain levels continued to
5 decline through 1 hour post dosing, then followed by
6 recovery, and in female pups, brain cholinesterase
7 declined through 2 hours with recovery around 4 hours.
8 So, this is the red blood cell graphs done in
9 this time course, and you can see that in the treated
10 pups, instead of the typical downward or peak
11 inhibition with recovery, you have actually an increase
12 in activity followed by a decrease, and this is kind of
13 also seen within the controls. Typically, your
14 controls should be fairly consistent. However, we...we
15 do have fluctuations in control values, and the same is
16 seen with the male pups. It goes up, comes back down,
17 and then comes back up again.
18 Whereas in this graph, you have brain
19 cholinesterase inhibition. You have the downward peak
20 inhibition portion around 1 hour, followed by recovery
21 up to background or control levels, and, again, in the
22 male pups, you have a decrease at 60 minutes followed
23 by recovery.
24 So, for cholinesterase inhibition in adults,
25 then, the maximum inhibition occurred around 30 minutes

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1 in male brains. It fit the expected patterns like we
2 did for the brain in the pups. Recovery occurring
3 around 6 hours in males.
4 In females, brain activity was decreased
5 almost 20 percent by 30 minutes post dosing but
6 basically recovered by 1 hour and then slightly
7 decreasing, so there was a little bit of fluctuation in
8 that, but for red blood cell activity over the course
9 of the time points, again, it didn't fit the typical
10 profile. A similar pattern was observed in the adult
11 red blood cell data as was in the pup.
12 As you can see here, this is the brain. You
13 have the peak inhibition followed by recovery. Same in
14 the adult males. And for red blood cell in adults, you
15 have the increase followed by a decrease and in kind of
16 a consistent profile.
17 So, again, the red blood cell data didn't fit
18 the profile of what we would expect for a carbamate,
19 and we felt that the red blood cell data from this
20 study was not a reliable measure.
21 So, the third component to the comparative
22 cholinesterase study is the dose response component.
23 Based on the range run in the time course, red blood
24 cell in brain was determined in the PND11 and adults at
25 30 minutes and at 4 hours. Three doses of carbofuran

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1 were evaluated, as in the range finding, from 0.03 up
2 to 0.3 mg/kg. Clinical observations were measured in
3 pups 15, 30, 60, and 120 minutes post dosing. A
4 similar for adults. However, post dosing, it was at
5 240 minutes.
6 Motor activity was evaluated at 30 minutes
7 post dosing and adult rats only assigned to the 4-hour
8 time frames.
9 So, results of the dose response component,
10 unlike the first comparative study and then the second
11 study here from the range finding, if you remember,
12 there were tremors observed in pups and adults at 0.3
13 and higher. However, in this study, there was no
14 tremors, no changes in motor activity.
15 We saw in the McDaniel study that motor
16 activity was starting to decline at 0.1 with
17 significant decreases in motor activity at 0.3. So, at
18 the doses that they used in this study, you would
19 expect some decreases in motor activity.
20 For cholinesterase activity in brain in pups,
21 activity was decreased in a dose-related trend at 30
22 minutes. Males decreased 13 to 50 percent, females 20
23 percent at the...at the low dose to almost 60 percent
24 at the high dose, and at 4 hours, male and female pups
25 at the mid dose were still inhibited 20 percent

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1 compared to controls, so hadn't recovered yet. In
2 the...in the low dose, males, there was still about 10
3 percent and in females, 5 percent. So, in the low
4 dose, almost returning to the control levels.
5 In adult rats, in males, there was a dose-
6 related decrease in brain activity, 13 percent at the
7 low dose to 35 percent and 50 percent at the high dose.
8 In the female rats, there was no inhibition at the low
9 dose at 0.03 mg/kg. The mid dose, however, there was
10 20 percent brain inhibition followed by 40 percent at
11 the high dose.
12 And recovery of brain activity in the low
13 dose males, almost 20 percent still and at the mid
14 dose, and over 50 percent in the high dose males. In
15 females, brain activity was...was only 5 percent in the
16 low and 9 percent in the mid dose.
17 So, this is just a graph of the...the PND11
18 pups and the adults for brain inhibition, and you can
19 see in the red curves on the bottom that the pups are
20 more sensitive than the adults in the blue, and...but
21 there is a dose response to the brain inhibition data.
22 For red blood cell, in pups, there is no
23 statistically significant decreases at any dose for
24 either male or female pups, and although not
25 statistically significant, the red blood cell activity

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1 was decreased 14 percent, 25 percent in the mid and
2 high dose. For female pups, there...again, there is a
3 dose-related decrease from 16 percent at the low to
4 almost 40 percent at the high dose.
5 At 4 hours post dosing, the recovery pattern
6 did follow typical recovery trend. In fact, the low
7 dose males, at 4 hours post dosing, the recovery
8 pattern did not follow typical dose-related recovery.
9 The low dose males had 10 percent inhibition, while the
10 mid and high dose male pups had recovered to control
11 levels. In female pups, red blood cell activity had
12 returned to control levels at the low and mid dose but
13 was decreased 15 percent at the high dose.
14 And for adult rats, the red blood cell
15 activity was statistically significant in all but the
16 low dose males, and there was a dose-related trend in
17 both male and female rats. Specifically, the red blood
18 cell activity was decreased 7 percent at low dose to
19 almost 40 percent at the high dose, and in females, red
20 blood cell activity was significantly inhibited almost
21 20 percent to 40 percent, and the red blood cell
22 activity had recovered to control levels in all dose
23 groups for both male and female rats.
24 So, again, in this graph, the adults in blue,
25 the PND11 pups in red. From this graph, it's not as

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1 apparent that the pups are more sensitive because of
2 the lack of dose response, basically, in the red blood
3 cell data, and so, the Agency actually considered
4 this...this data similar to the first CCA study, but it
5 didn't fit the typical profile or response you would
6 expect from a carbamate.
7 So, then, for the last two studies, the ORD
8 studies, the first one is of PND17 males. Four doses
9 of carbofuran were evaluated, ranging from 0.1 up to
10 1.0 mg/kg. Previous studies showed statistical
11 decreases in brain activity at the low dose in adult
12 males, but motor activity was assessed at 15 minutes
13 with a 20-minute session. The acetylcholinesterase
14 activity was measured at 30 minutes.
15 And I should also note that the radiometric
16 assay was used in this study, and you'll see it was
17 used in the second ORD study as well.
18 So, in this graph, we have motor activity in
19 the green. We have brain activity in the black and red
20 blood cell activity in the red, and you can see here in
21 the PND17 males, red blood cells clearly more sensitive
22 than brain, and that with motor activity, you really
23 start having a decline at the 0.3 mg/kg, and this kind
24 of coincides or agrees with data that we had seen in
25 the McDaniel study, but even at the lowest dose of...of

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1 0.1, you have significant inhibition in the PND17 pups
2 for both red blood cells and brain.
3 So, the last study, then, is the PND11
4 comparative study where ORD looked at PND11 male pups
5 and adult male rats, and this was in 2007. Four doses
6 of carbofuran, ranging, again, from 0.1 mg/kg up to 1.
7 Motor activity, however, was not evaluated in this
8 study. Like Dr. Lowit mentioned, it's pretty hard to
9 do a motor activity assessment on these guys, because
10 they're so young.
11 Brain and red blood cell activity was
12 measured at 40 minutes post dosing, and as, like I
13 said, the radiometric assay was used in this study.
14 The results for both the adults and pups are
15 shown here on...on one graph, the adults in the black
16 and the pups in the blue. Excuse me. If you look at
17 the pup data in the blue, again, you can see that the
18 red blood cell falls below the curve for the brain.
19 There's a nice dose response inhibition, and at the
20 lowest dose, again, you have significant inhibition at
21 the low dose for brain and red blood cell. Red blood
22 cell was decreased 50 percent to 70 percent, while
23 brain has decreased 15 to 40 percent.
24 And from...when you look at both the PND17
25 and the PND11 studies here, it's clear that pups are

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1 more sensitive than adults, and from these two studies,
2 it's also apparent that red blood cell is more
3 sensitive than the brain comparatively.
4 So, the next step that we took was to compare
5 all of...of the data that we had for carbofuran. So,
6 this includes the first studies that had dose response
7 data in juvenile rats, the first FMC study, the second
8 study, the PND17 male data, and then the PND11 data.
9 Typically, HED likes to include all the reliable data
10 for the development of a more robust data set to make
11 the basis of a BMD analysis or benchmark dose. So, the
12 comparison of the juvenile data includes, like I said,
13 these four studies.
14 And if we look first at the brain data from
15 these studies...we've got them on here on one
16 graph...you can see that there's nice agreement in the
17 brain data, and these are all at similar peak
18 inhibition time points between 15 minutes, 30 minutes,
19 and the 40 minutes. And so, the dose response that we
20 saw from these different studies all agree and
21 basically fit the criteria that should be included in a
22 robust data set for analysis.
23 If you look at the red blood cell data,
24 however, you get a different picture. The first FMC
25 study is up here, basically, where there's no dose

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1 response in the red blood cell activity. The second
2 FMC study is up here in the green and the blue. You
3 can see some dose response, but then it kind of tailors
4 out. The ORD studies are down here. Although at some
5 higher doses up here at this end, you can see that the
6 data from the ORD studies are lower than the FMC
7 studies.
8 I should also note that there's just a small
9 typo on here. This blue right here should actually be
10 the PND11, and this red here should be the PND17.
11 So, the disparity between the different
12 studies, kind of went back and looked at protocols for
13 measuring cholinesterase, and we also went back and
14 looked at the raw data to see maybe why we were getting
15 such differences in the red blood cell data.
16 So, the second comparative cholinesterase
17 study from FMC relied on the modified Elman's assay,
18 whereas I mentioned the radiometric assay was used in
19 the PND17 and 11 studies from ORD.
20 And we know from the development of the
21 cumulative risk assessment that there are some critical
22 factors when relying on a modified Elman's assay,
23 especially for measuring carbamates which have a rapid
24 reactivation, and if certain factors are not, I guess,
25 pretty strict, then you can have reactivation of the

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1 enzyme. In fact, the Agency compared cholinesterase
2 methodologies, like I said, during the cumulative risk
3 assessment, and then the FIFRA SAP meeting in 2005, the
4 Agency compared these factors for the modified Elman's
5 and a radiometric assay.
6 It was apparent that there...these critical
7 factors needed to be considered to prevent the
8 reactivation of the enzyme, and these factors include
9 the reduction of dilution factors, the dilution factor
10 having a big impact on activity measured with greater
11 dilution producing less activity for the carbamates.
12 The second factor was a lower temperature,
13 the keeping samples on ice and incubating at lower
14 temperature prevents, again, reactivation of the
15 enzyme.
16 And finally, the amount of time taken until
17 the final assay. The longer it takes to analyze the
18 sample, the chances for reactivation are greater. And
19 so, the FIFRA SAP in 2005 compared the protocols, and
20 we showed that if these critical factors are taken into
21 account that you can get comparable results.
22 So, we went back into the protocol for the
23 modified Elman's for the FMC study to see if some of
24 these critical factors were taken into account. So,
25 here in this slide, I have the protocol or the steps

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1 from the FMC study. I should also mention that we did
2 call the performing laboratory at Charles River to get
3 further details on the protocol for the cholinesterase
4 measurements.
5 The protocol required samples be kept on ice.
6 The blood sample was then spun to separate plasma from
7 the red blood cells, and the red blood cells were then
8 washed with a final dilution of 1:14. Between the
9 steps, however, the protocol had no guidance or
10 suggestion for mixing or vortexing of the sample.
11 However, the blood samples were to be processed within
12 10 minutes of collection, and the red blood cell assay
13 analyzed within 1 hour of the initial spin, with each
14 assay taking approximately 12 minutes.
15 We also discussed with Charles River about
16 the acceptance criteria for the red blood cell data.
17 The protocol required that samples be run in duplicate
18 and that these duplicates must replicate within 80
19 percent. Those samples that do not meet the 80 percent
20 are then coded as DNR or does not replicate. If the
21 sample fails the replication criteria, the sample may
22 be reanalyzed up to three times, and if the sample
23 fails the replication criterion after three runs, then
24 no value is reported for that sample.
25 So, we returned to the raw red blood cell

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1 data to investigate differences between the FMC studies
2 and the EPA studies, and examination of the raw red
3 blood cell data revealed several samples that failed to
4 meet this acceptance criteria, and so, we tabulated the
5 number of times that this occurred. We tabulated,
6 specifically, the number of times that the
7 replicate...or the duplicate did not replicate within
8 the 80 percent criteria. We also pulled out the number
9 of times that a sample was run, up to three times,
10 three additional times, and no value was reported in
11 the end. And then, there were also instances where a
12 sample was re...rerun or reanalyzed over the maximum
13 three times, and a value was still reported.
14 So, according to the laboratory, this was
15 out, I guess, of their criterion for the three times
16 maximum, so we pulled that out and tabulated it as
17 well.
18 You can see that for the red blood cell data
19 in the PND11 pups that there is a significant amount of
20 samples or number of samples that had to be reanalyzed
21 up to three times and sometimes more than three times,
22 and a significant number of them also did not have a
23 value reported. So, ultimately, that sample size, say
24 of 10, would be reduced, so you wouldn't have a value.
25 You'd have 9 out of 10 or 8 out of 10.

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1 Another important note is that this was in
2 all groups, not just treated groups. It also occurred
3 in the controls, and, in fact, in the controls, up to
4 60 percent of the samples.
5 If we look at the adult data for red blood
6 cell, it's a little bit better, but, again, even in
7 controls, you get up to 35 percent of the samples this
8 time, specifically, for the DNR, does not replicate,
9 specifically, so in the controls, then, you had 7
10 samples that had to be reanalyzed multiple times. And
11 the almost...it almost seems like they had better
12 reporting or better duplication with increasing dose,
13 35 percent in the control compared to 10 percent at the
14 high dose group. So, I don't know where that came
15 from, but, again, there's something going on here in
16 their protocol to measure red blood cell activity.
17 So, then we looked at the brain data to see
18 if this was occurring in the brain data as well. It
19 did occasionally but not nearly to the extent it did
20 for the red blood cell data, 5 to 10 percent in the
21 brain for pups, and then in the brain in adults, some
22 groups didn't have any at all. However, in the
23 controls, you had 10 to 15 percent where you had
24 samples that did not replicate.
25 So, the next step that we took was to review

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1 the details of the protocol for the radiometric assay
2 as well to compare with the modified Elman's. So, the
3 protocol for the radiometric assay calls for a 1 to 2
4 dilution of...of tissue to buffer with all samples
5 being vortexed immediately and placed on dry ice. The
6 samples were then stored at a -80 until the day of the
7 assay.
8 Samples were then placed on ice for fine and
9 for gran, specifically, was diluted 1:2 and homogenized
10 for 10 to 15 seconds. The red blood cell samples were
11 incubated for 4 minutes, while brain samples were
12 incubated for 30 seconds. I should also say that
13 samples were run in duplicate, as they were in the FMC
14 study, and the criterion that all duplicates must be
15 within 80 percent was not exceeded. So, there was not
16 a DNR in any of the samples from this study.
17 So, now we're going to kind of switch gears.
18 We're going to go through the BMD analysis that was
19 performed with the data and how...how we did that. I
20 should note that the red blood cell activity, there was
21 clear differences, and so, the next step was to see in
22 the BMD analysis the difference between the brain and
23 the red blood cell estimate.
24 First, for peer review of the benchmark dose
25 modeling and the methodology, there's been an extensive

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1 peer review. The Agency relied in a single chemical
2 assessment on the same model that was used in the
3 cumulative assessment. The application of this method
4 or this model for use with the cholinesterase data with
5 carbamate pesticides has been reviewed and supported by
6 FIFRA SAP on two occasions. The methodology for the
7 BMD analysis was reviewed for the pilot. Cumulative
8 analysis in February, 2005 and the evaluation of data
9 quality of the cholinesterase for the NMCs was reviewed
10 and supported in a preliminary cumulative risk
11 assessment in August of 2005.
12 The Agency...I should also mention the Agency
13 has used this BMD model in other single chemical risk
14 assessments for other NMCs, including aldicarb,
15 carbaryl, and methomyl.
16 So, first, if we take a look at the meta
17 analysis and the data that we've used for the benchmark
18 dose estimate, starting with the brain, for the brain,
19 we used all the data, including the FMC studies. There
20 was good concordance, if you remember from that graph,
21 and so, all the data was included.
22 FMC also submitted to us their meta analysis
23 for brain, and you can see on the top there, the EPA
24 and the FMC estimates for both the BMD and the BMDL are
25 very close which is encouraging and in the adult data

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1 as well, their meta analysis was very similar with the
2 EPA.
3 However, when you go to the red blood cell
4 estimates, EPA, for the pups, PND11 estimates, we
5 relied on the EPA studies. The red blood cell data
6 from the FMC studies we considered unreliable, so we
7 did not include that in our analysis, and I...that's
8 the main difference between the FMC meta analysis.
9 They've included the red blood cell data from their
10 studies.
11 And if you'll also notice that in the pups
12 that their BMDL estimate is almost as high as adults,
13 and we know that pups are more sensitive, so this BMDL
14 estimate, we feel, is not a reliable or good measure
15 for a risk assessment. However, I should also say that
16 because we missed the low ends of the dose response
17 curve that we had significant inhibition at the low
18 end. There's also a lot of uncertainty around this red
19 blood cell PND BMDL estimate, that we just don't have
20 the data at the low end of the dose response curve and
21 that we're trying to extrapolate from almost a 50
22 percent inhibition down to a 10 percent.
23 And looking at the adult red blood cell
24 estimates from both EPA and FMC, they're a little bit
25 closer, but you can still see that there's differences

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1 based on the data that they've used in their analysis
2 compared to ours.
3 So, what did...what did we use, then, for our
4 point of departure and uncertainty factors in our risk
5 assessment? The single chemical assessment begins, as
6 Dr. Lowit and Jack said earlier, at the point of
7 departure, and we typically rely on BMD modeling which
8 is a better approach than the traditional NOEL/LOEL
9 approach which relies on the dose and the dose spread.
10 EPA policy is to use the BMDL or the lower limit as the
11 point of departure, and in this case, we're using the
12 most sensitive endpoint which is acetylcholinesterase.
13 And also, we also apply uncertainty factors,
14 the 10x intra species for human variability, the 10x
15 interspecies to extrapolate from animal to human, and
16 then again, the FQPA factor for the protection of
17 infants and children.
18 And this is just a table of the options that
19 we had for using in risk assessment. Choice 1, we
20 would rely on the red blood cell data in the pups
21 which, as I said, because we missed the low end of the
22 dose response curve, have a lot of uncertainty. In
23 fact, it's 50 times lower than what we saw in the study
24 itself. The red blood cell in the PND17 pups would be
25 the second choice, but, again, we missed the low end of

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1 the dose response curve.
2 However, the third choice, the BMDL would be
3 based on the brain in the PND11 pups where we did a
4 better job at the low end of the dose response curve.
5 However, we've not taken into consideration, then, the
6 sensitivity of the red blood cell compartment in these
7 pups, and so, the Agency would have to account for that
8 in their FQPA factor.
9 So, the Agency used the BMDL of 0.03 from the
10 PND11 brain data, and this is data from both FMC and
11 EPA studies. Applied a 10x for the interspecies
12 factor, the 10x interspecies for animal to human, and
13 as Jack noted earlier, we have human studies, but we've
14 not relied on any of those because of the scientific
15 deficiencies from the HSRV back in 2006, so we did not
16 have the data to refine the interspecies factor. And
17 then, for the FQPA factor, again, we had to consider
18 the red blood cell activity in this compartment in
19 pups.
20 I'm not going to read this quote, but this
21 comes from the FQPA safety factor. In a nutshell, it
22 says that an additional 10-fold margin of safety is an
23 assumption. However, this may be changed if there are
24 reliable data as long as protecting infants and
25 children.

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1 And so, the Agency determined that at least a
2 portion of the 10x FQPA factor should be retained for
3 infants and...and children. The question then was how
4 do you compare dose response curves for refining the
5 FQPA factor.
6 And so, Dr. Setzer actually did some more
7 analysis for us. We know there's a lot of uncertainty
8 down at the 10 percent, the BMD 10 range, so we went
9 back and looked at the BMD 50 range. The relative
10 uncertainty of the BMD 10 is greater than the BMD 50s,
11 and in this graph, you can see that by the 10 percent
12 level, the dashed line on the bottom here and the 50
13 percent in the dashed line above, and this shows that
14 the uncertainty or the width of the dose response
15 curves is greater at the low end of the dose response
16 curve where the uncertainty around the 50 percent level
17 is tighter or narrow, so a comparison of 50 percent up
18 here compared to 10 percent down here.
19 And so, we went ahead and calculated the BMD
20 50s for both the PND17 and the PND11 pups, and the
21 table here, the juvenile rats, the red blood cell is
22 approximately 3 to 5 times lower than that for the
23 brain cholinesterase inhibition, and, in fact, in the
24 2000 risk assessment, we had applied a 5x to account
25 for the red blood cell sensitivity in our juvenile

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1 rats. And, therefore, we elected at that time to
2 continue to use the 5x. You'll notice that the PND11
3 for the BMD 10 range were out to almost a factor of 24.
4 And so, again, the ratios surrounding the
5 brain data are tighter at the BMD 50.
6 However, recently, FMC provided an
7 alternative approach, and this was examined by, again,
8 Dr. Setzer. However, during this exercise, he noticed
9 an error, a calculation in the BMD 50s, and the
10 corrected BMD 50 estimates which are depicted here do
11 not change the overall risk picture. They went from
12 4.6 down to 4.1.
13 So, now the...the ratio is between 3 and 4
14 for the 17 and PND11 pups, and although formal analysis
15 has not been done, if...if we guess the confidence
16 limits around this, it would be around, I think, 4 to
17 6. 3 to 6 is what Dr. Setzer had given us, and he can
18 answer questions surrounding this. And if you
19 remember, too, the percent exceedance of the APAD was
20 such that one out of five or a 20 percent reduction did
21 not change the overall risk picture for the dietary,
22 food alone, for carbofuran.
23 So, what about this alternative approach?
24 Dr. Setzer had a couple of...of comments on it.
25 Basically, the authors concluded that appropriate

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1 comparison should not be made for brain and red blood
2 cell inhibition but, rather, to evaluate brain and red
3 blood cell in each individual rat such that the ratio
4 of effects should be used. The first...the first
5 comment or thing that must be considered is the shape
6 of the dose response curve.
7 If the dose response curves were linear, then
8 the ratios of the inhibition would be equal to the
9 ratios of the BMDs. However, these dose response
10 curves are not at all linear, and brain and blood dose
11 responses have somewhat different shapes.
12 And the figure here gives the expected red
13 blood cell to brain inhibition ratio from the dose
14 response models to fit the PND11 animal data, and the
15 vertical lines show the doses in the EPA PND11 study,
16 and the horizontal gray lines bracket ratios between 1
17 and 2.
18 And note that except for the lowest dose
19 where the expected ratio is a little greater than 2,
20 all ratios are 1.5 or less, and that given that this
21 does not include the uncertainty associated with the
22 model fits which are made more complicated by the
23 correlation between the red blood cell and brain
24 measures in the same animal, this figure argues that
25 the ratios calculated by the landowner authors are

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1 consistent with our modeling.
2 The second comment surrounds the estimate
3 BMDs using two different models, linear extrapolation
4 between the observed points on the dose response curve
5 and fitting an exponential model. The authors claim
6 that the first method requires no assumption about the
7 underlying dose response models but, in fact,
8 interpolation using such a model does assume that the
9 linear model is close to the truth in the interdose
10 intervals.
11 This is most likely untrue in the interval
12 between a lowest dose and control.
13 The authors also fit an exponential model
14 similar to EPA's model, but unlike EPA's model, not
15 raising power to a dose...or raising dose to a power.
16 EPA has shown that dose must be raised to a fractional
17 power in order to fit the PND11 red blood cell data,
18 and, in fact, the data significantly reject a power of
19 1. So, results in this section are based on models
20 that do not adequately describe the data.
21 And, again, for more questions on that, we'll
22 have Dr. Setzie...Setzer, yeah, respond to those.
23 So, to conclude the oral data base for
24 carbofuran, EPA has relied on the brain cholinesterase
25 data from the FMC studies as well as the EPA studies to

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1 provide a robust BMD analysis and estimate for deriving
2 a point of departure for the carbofuran risk
3 assessment.
4 The Agency also used the data derived method
5 for refining the FQPA factor. It comes out to be about
6 the same as we used in the 2006 risk assessment.
7 However, the database is considerably more supportable
8 now.
9 The final portion of my talk is for the
10 dermal database for carbofuran, and, in fact, we have
11 two studies now for carbofuran that was received in
12 2007. That's a 7-day and a 21-day dermal study.
13 The 7-day was a range finding study with four
14 doses between 50 and 1000 mg/kg/day. The animals were
15 exposed for 6 hours per day for 7 days. Blood and
16 brain tissues were taken 1 hour post exposure.
17 Again, this was the same protocol, the
18 modified Elman's assay for cholinesterase activity.
19 At 1000 mg/kg/day, there was 1 female death
20 on day 2. Clinical signs included ataxia,
21 vocalization, repetitive movement, circling, ungroomed
22 coat, typical signs of toxicity, and this dose was
23 reduced to 750 on day 4 and 5. In the 500 dose group,
24 there was 1 female with whole body tremors, salivation,
25 splayed hind limbs, cold to the touch, salivation when

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1 roused. And in other females in this dose group, there
2 was myosis and lacrimation.
3 For cholinesterase activity, as we saw in the
4 other study, there was no significant decrease at any
5 dose. However, there was a dose-related decreasing
6 trend in males, 12 to 33 percent.
7 For brain activity, again, there was a dose-
8 related trend, 15 to 40 percent in males, 10 to 35
9 percent in females, with statistical significance
10 achieved at the three highest doses. There was no
11 dermal irritation.
12 And the other point to note here is that
13 there was no time course or peak inhibition data to go
14 along with this information, so we literally had just a
15 snapshot post exposure for this inhibition data.
16 Based on the 7-day, then, the 21-day dermal
17 study was performed, again with four doses, this time,
18 however, from 15 up to 250 mg/kg. Exposure was 6 hours
19 per day, 5 days per week for 21 days. Functional
20 observation on battery and motor activity was assessed
21 on day 20. The FRB was in hand and open arena, and the
22 motor activity was at 5-minute intervals for 1 hour.
23 After that, blood and brain tissues were
24 taken, and the cholinesterase activity was measured
25 with the same modified Elman's assay.

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1 Tremors were noted, 3 out of 10 females at
2 the 250 dose. 1 out of 10 females showed toxic signs
3 at the 25 dose. However, motor activity in the FRB,
4 there was...there was no changes at any dose, and,
5 again, there was no dermal irritation as in the 7-day
6 study.
7 For brain cholinesterase, there was
8 significance in the female at the 250 dose. There was
9 a dose-related trend in the females, varying from 2 to
10 18 percent, and 3 percent to 10 percent in males. As
11 we've seen in other FMC studies, there was no red blood
12 cell dose response and no significance at any dose, and
13 as in the 7-day study, there was no time course data,
14 no peak inhibition or recovery data with this study.
15 And so, the Agency had no way of determining
16 how this information, this inhibition data, fit into
17 the dermal tox profile for carbofuran. Typically, the
18 Agency has other time course data to support this
19 inhibition data. We have other 21-day studies for some
20 of the carbomates that included this information.
21 And so, the Agency considered this...these
22 two studies, the 7-day and the 21-day, unreliable for
23 assessing...for using in our dermal risk assessment.
24 So, for the dermal risk assessment, then, for
25 workers and adult workers, we've relied on the red

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1 blood cell data from adult rats with the BMDL of 0.02.
2 The dermal, because we're using an oral...oral data, we
3 used a dermal absorption factor of 6 percent based on
4 the Shaw, et.al. study from 1986, and then, of course,
5 we had the 10x intraspecies and 10x interspecies
6 factors again.
7 Even though we had two carbofuran dermal
8 studies, we took those to the HSRB back in 2006. Those
9 were both scientifically and un...and ethically
10 deficient, and so, we've not used those here in the
11 dermal assessment in either the point of departure or
12 for refining the uncertainty factor.
13 So, overall, then, the conclusions and why
14 we're all here today at this late hour, the second FMC
15 study contains reliable brain cholinesterase data but
16 not red blood cell data for use in human health risk
17 assessment. The Agency's dose response analysis for
18 brain cholinesterase in PND11 pups included data from
19 three studies, specifically, two FMC and one EPA ORD
20 study, and, thus, provide a robust estimate for use in
21 the point of departure.
22 Based on the current scientific evidence,
23 there is remaining uncertainty regarding the red blood
24 cell inhibition at the low end of the dose response
25 curve for extrapolating risk to infants and children.

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1 For the protection of infants and children, the Agency
2 applied a 5x factor based on the BMD 50 ratios in brain
3 cholinesterase and red blood cell in juvenile animals.
4 And, finally, based on the limitations of the
5 available carbofuran dermal studies, the Agency has
6 relied on oral studies for assessing dermal risk to
7 carbo...of carbofuran to workers.
8 And that's it.
9 **DR. HEERINGA:** Thank you very much, Dr.
10 Reaves. At this point, I'd like to open the floor up
11 to panel members who have questions on the presentation
12 that Dr. Reaves has provided. We'll begin with Dr.
13 Hattis. Dale?
14 **DR. HATTIS:** I noticed one other finding
15 from Woody Setzer's analysis, statistical analysis of
16 the benchmark dose information, and that is perhaps you
17 ought to...perhaps you should present it better than I,
18 and that is there's an apparent difference in the
19 recovery rate as well as the peak depression. So,
20 maybe it's better that you folks present rather than me
21 giving my memory of it, but I, as I recall, it
22 was...the benchmark dose for the brain was...brain peak
23 inhibition was about...had a central estimate of about
24 1.8-fold with some reasonably...with some broad range
25 around that, but the difference between the pups and

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1 the adults, PND11 and adults, whereas the...there was
2 also something like a central estimate of about 4-fold
3 difference in the rate of recovery between the pups and
4 the...and the...so, do you all comment on...on the
5 robustness of that result between the pups and adults
6 and the rates of recovery?
7 **SPEAKER:** I am not sure.
8 **DR. LOWIT:** Can I ask for clarification
9 before we start? Let me just make sure we're...we're
10 answering what it is that you're asking.
11 I've got some notes here in front of me that
12 indicate that the half...the recovery half-life differs
13 among brain and red blood cell but also differs among
14 the various studies. Is this what...are you talking
15 about a particular...
16 **DR. HATTIS:** I'm talking about the
17 combination...
18 **DR. LOWIT:** ...study or the trend or...
19 **DR. HATTIS:** This is for all of
20 the...this had nothing to do with the red blood cells,
21 all for the brain, comparing PND brain half-life of
22 recovery versus benchmark dose or...for...for the brain
23 between the pups and the adults.
24 **DR. SETZER:** I can quote you numbers and
25 confidence intervals. I'm not sure how to address your

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1 question about your...
2 **DR. HATTIS:** That's...that will be
3 sufficient.
4 **DR. SETZER:** It turns out that the...and
5 I believe this is partly because different studies used
6 different dose levels in the PND11s, so...or possibly
7 it's due to that, so we have ratios of PND11...well,
8 let's see. Yeah, adult to PND11 half-lives of, say, 3
9 for one FMC study, about 7 for another FMC study. No,
10 no, no, sorry, I'm reading the wrong lines. Okay.
11 The...no, it's a single ratio of about
12 4...about 4.4 with confidence intervals of about 3
13 to...to 6.
14 **DR. HATTIS:** Mm-hmm.
15 **DR. SETZER:** The ratio of adult to PND11
16 half-life.
17 **DR. HATTIS:** Right. And so, if you,
18 instead of having an acute toxicity scenario where
19 you're killing it, the peak depression after a single
20 dose, if, instead, you had a chronic or repeated dosing
21 scenario, then you would want to take into account both
22 those...both the recovery...recovery half-life
23 difference and the peak dose in constructing your
24 metric of...of, essentially, the AUC between the...the
25 animals.

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1 **DR. LOWIT:** I'll add, and, hopefully,
2 some people can help. Maybe Steve Maco if he's here?
3 No, okay. We'll try the best we can.
4 If you go back to my...think about my slides,
5 on the third...I may differ with you a little bit on
6 that. I think that we've convinced ourselves on...in
7 the food situations, specific for toddlers, that what
8 we would call the carryover effect from one day to the
9 next...I think that's what you're...you're going to be
10 getting at...is not such a big issue as food exposure
11 tends to happen in a single event, and, hopefully, it's
12 not a dinner/breakfast event which would be very close.
13 The infants, on the other hand, is...is a
14 different story, the kids less than 1. Kids less than
15 1 drink bottles throughout the day, and that's where
16 the bulk of their...their exposure would come, would be
17 bottles of treated formula, and the...the pattern of
18 that consumption is different.
19 It's however may eat...let me step back. An
20 infant is going to eat every few hours in smaller
21 amounts. The toddler may eat throughout the day, but
22 they're going to be somewhat more distinct events. So,
23 it...to the extent that there may be carryover in the
24 infant from one day to the next, we have not accounted
25 for that in...in any of our estimates, but because of

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1 that, I think the 24-hour and the...the 24-hour
2 estimate of something in the thousands of the APAD and
3 the...the values that Steve Maco developed that are
4 roughly about 3-fold lower than that of chemical
5 consumption however bound with it...with that is, and
6 what you're getting at is somewhere between there. And
7 then we just don't have the tools to do a better job at
8 doing that.
9 **DR. HATTIS:** Well, but the AUC measure
10 of effect which is basically to be...would be closer to
11 the susceptibility difference for a...a more continuous
12 dosing regimen.
13 **DR. LOWIT:** Yeah, that's probably...that
14 may be true. I'd have to think about that, but for a
15 conceptually higher, I would envision you would think
16 about the period of exposure and inhibition would
17 come...you would see a rise and a subtle fall and a
18 rise and a subtle fall. So, I don't want to use the
19 word steady state, but to the extent that you would
20 have a constant exposure over the period of duration,
21 the peak itself may actually be lower than that if you
22 ate it all...had all of that at once.
23 That's why we believe that the 24-hour lump
24 sum is...is a higher end, and the other end is only a
25 3-fold lower brackets that.

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1 **DR. HEERINGA:** Other...other questions?
2 Just questions of clarification, of course, so Dr.
3 Kehrer, then Dr. Bailey, and Dr. Chambers.
4 **DR. KEHRER:** There are two things that
5 I'm...I'm unclear about, and maybe you can clarify them
6 for me. One is...and this is stated in some of the
7 written documents, too, that the database is not
8 considerably more robust that supports the 5x FQPA
9 factor, but if that's the case, logic, to me, says that
10 either the previous 5x was too low or the current 5x is
11 too high.
12 And the other point I'm unclear about is
13 there's been a lot of talk...and I'm sure FMC is going
14 to talk tomorrow about the red blood cell data, but
15 it's my understanding that the...the effect on
16 cholinesterase in blood, red blood cells, is a nice
17 marker of exposure, but it's not a marker of toxicity,
18 and I'm unclear on why this is being used to set toxic
19 exposure levels rather than just focusing on the brain
20 data.
21 **DR. LOWIT:** That's two whoppers at once.
22 I'll take the first one and, hopefully, I'll remember
23 the second by the time I'm done with the first one.
24 We believe the database is now substantively
25 better than it was two or three years ago. If you

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1 think back where we were two or three years ago, we
2 were relying the entire assessment on a dog study with
3 some blood measures and, I think it was...I believe it
4 was plasma. There was not a single study that...where
5 we evaluated peak inhibition in...in the young.
6 The...the data around the time course wasn't really
7 available. There was...there was one study by FMC but,
8 certainly, we know a lot more about the time course
9 now. We know...we have a little bit more adult data in
10 the rodent.
11 We believe it's substantively more...better
12 than it used to be.
13 Why the FQPA factor now the same as it was?
14 I think that's just the way the...the ball falls. Over
15 2006 assessment, we had...at the time, we had the first
16 FMC CCA study. I always want to make sure I'm saying
17 the right thing. We had some adult rat data provide by
18 Stephanie Padilla and folks in her lab, and we had a
19 time course study from FMC, and that was really the
20 extent of the database.
21 And with that more limited data set, we had a
22 concern at the time, and I believe I have a back pocket
23 slide that shows where our concern came from. That
24 stemmed from some results from the cumulative, from the
25 preliminary cumulative assessment. Also, there's a

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1 plot...that one.
2 This plot is directly out of the preliminary
3 cumulative assessment from 2005, so keep in mind
4 that...on this, we'll say, I think it is 6 or 7
5 chemicals on this plot since then have more and better
6 data, and some of those error bars have...have shrunk,
7 so if you can, just focus on the carbofuran where the
8 blue arrow is.
9 The black dots represent benchmark doses in
10 red blood cell, and the red triangles represent the
11 brain. Part of our analysis for the cumulative was to
12 evaluate the databases for both compartments and our
13 selection process to determine which compartment would
14 provide the basis for that risk assessment. And so,
15 this is a consistent pattern we've done with the OPs to
16 look at the relationship between the two.
17 And based on what we...we had known based on
18 the information available in 2005, you'll see that
19 carbofuran is the only one on the plot where the...the
20 black dot is substantively lower than the red triangle,
21 leading us to be concerned that for carbofuran, that
22 red blood cell is significantly more sensitive
23 than...than brain.
24 And you'll notice that for all of the other,
25 the other carbamates, the opposite is true. Either the

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1 compartments are essentially concordant, or that brain
2 is...is somewhat more sensitive.
3 So, this plot led us to be concerned that for
4 carbofuran, red blood cell inhibition was significantly
5 more sensitive than...that the brain was, and actually,
6 the ratios of the triangle to the dot is 5x. And
7 what's the...where the derivation of the 5x came from,
8 the first 5x in the 2006 assessment.
9 Keep in mind that the Food Quality Protection
10 Act, as Melissa showed me...showed you in the quot...in
11 the quote, mandates that we start with 10. We begin
12 with 10, and if you have reliable data, you can reduce
13 that 10, and it's only with reliable data that you can
14 do that. The 10 is there. It's not something we add.
15 Something we either reduce or remove or retain.
16 You can take that down.
17 Since then, of course, we've had a number of
18 other studies, as Melissa discussed, come to
19 the...become available, not only done by FMC but done
20 by our ORD labs, and further analysis of those data led
21 us to the conclusion that the FMC study, again, the RBC
22 data just weren't what we believe to be reliable.
23 Unfortunately, Ginger's study just didn't use low
24 doses, and we believe that her study has a very clear
25 pattern, really, in the pups.

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1 Can you pull that slide up? In pups, the LDC
2 plots are consistently lower at each dose that she
3 tested, further, you know...yeah, there we go. Here we
4 go. The triangles were consistently lower than the
5 dots on this one. But RBD, actually, in pups is more
6 sensitive, and that led us to the conclusion that we
7 would need to retain part of that FQPA factor, because
8 it would be the most sensitive endpoint for this
9 compound. We're still lacking data in the...in
10 the...the most relevant part of the dose response curve
11 which would be the low end where we would prefer to do
12 this.
13 **DR. KEHRER:** That gets to the heart of
14 my second question.
15 **DR. LOWIT:** This is the heart of your
16 second question. Did I answer the first one?
17 **DR. KEHRER:** Yes.
18 **DR. LOWIT:** Okay. The heart of the
19 second question was in a typical practice and our
20 policy the way we've handled many compounds. It is our
21 practice and our policy to use red blood cell data
22 as...as a surrogate for peripheral when we don't have
23 it, and it's believably rare for carbamates just
24 because of the technical nature of...of doing that and
25 the rapid nature of toxicity.

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1 We have used red blood cell inhibition to
2 regulate several other carbamates and many OPs in cases
3 where it's not unusual for an OP for there to be a
4 large gap between compartments, and we have...we have
5 used red blood cell for many chemicals, including
6 carbamates. I want to say aldicarb and methomyl and
7 oxamyl, carbaryl. Several. I don't want to misstate.
8 It's several.
9 And it would be, as a matter of good science
10 policy, to protect public health and to be consistent
11 with the way we've handled other chemicals, we believe
12 that this is the approach in all three of those fronts.
13 If you have a different opinion, I'm sure you'll tell
14 us.
15 **DR. HEERINGA:** During the response to
16 the charge questions.
17 **DR. KEHRER:** Yeah, maybe I'm
18 anticipating that would be the time, and so, we can
19 drop this at the moment, but aldicarb is...is more
20 potent, and yet, it comes up with a higher exposure.
21 Isn't that the case?
22 **DR. LOWIT:** I'm bringing the other plot
23 back. That's not really...actually not true.
24 **DR. KEHRER:** That's the consistency
25 issue.

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1 **DR. LOWIT:** Well, if we bring back the
2 plot from the 2005 preliminary assessment, the 2007
3 revised assessment looks subtly different in that I
4 believe aldicarb in this 2007 is two-fold more potent.
5 Maybe three-fold but very close.
6 Considering we're talking about orders of
7 magnitude across these compounds, to only be a couple
8 fold different or, you know, based on what we knew a
9 couple years ago, they weren't different in potency at
10 all. So, you have to be careful. There are some urban
11 legends that...that people perpetuate.
12 **DR. HEERINGA:** Dr. Bailey?
13 **DR. BAILEY:** I've got a...just a ton of
14 questions, but I'd like to get one thing straight
15 before we leave. Just take any...any of these studies
16 I think you talked about for, say, PDF...PND11 or
17 PND7...17. So, the experiment was done, and there
18 were, what, 10 animals per age dose group?
19 **DR. REAVES:** Correct. PND17 was in
20 males only, though.
21 **DR. BAILEY:** Yeah, yeah, and some of
22 them were comparative and some were not, yeah. And
23 now, when you are in the laboratory and you've done a
24 whale of a lot of work measuring things, comparing
25 modified methods and so on and so forth, and so the

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1 samples of the brain that you gave to do all of that
2 work that you reported on...and I compliment you on
3 what seems to be a very thorough effort. So, how did
4 that happen? You had these animals. They were
5 treated. You had the rats. They were treated. And
6 then you took...it was samples that were taken and
7 frozen, and then you just went back to those samples
8 for all of this...to do your...all the different
9 measurements that you took? That's a lot of...lot of
10 work.
11 **DR. REAVES:** Yeah, Ginger Moser did the
12 PND17 and the PND11 works. We'll let her respond.
13 **DR. MOSER:** Okay, I want to make sure I
14 understand what you're asking first.
15 **DR. BAILEY:** Well, okay. Well, let's
16 just say that you could determine the effect of this by
17 weighing the animals. Then you would have just one
18 number for each animal. You'd just weigh it, and that
19 would be the end.
20 But now you've done lots...you've done a
21 study, taken measurements, then you've followed up with
22 another one, taken more measurements, and you've
23 followed up and so forth. And so, what did you do,
24 take a...a sample from the rat? I mean, took the brain
25 and stored it, froze it. Is that right? And then you

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1 keep going back to those...those frozen brains or what?
2 **DR. MOSER:** Okay. I guess I'm supposed
3 to identify myself. Ginger Moser. I'm with the NHERL.
4 There are different studies that did
5 different methods, so all the studies that I do in my
6 lab, in our ORD labs in RTPD is the radiometric assay,
7 and when we do that, we dose the animals, sometimes
8 test them with motor activity or other things, but
9 always end up sacrificing them at the same time, take
10 the brain out immediately, take the blood out
11 immediately, spin the blood immediately, put everything
12 on dry ice, and then we store everything at -80 until
13 the days when we pull them out to do the assays.
14 The way I understand it with a lot of
15 discussions that we've had with the contract labs that
16 did the FMC studies, they did not store the tissues.
17 They ran the assays the same day that they...this was
18 the modified Elman that they used. They dosed the
19 animals, sacrificed the animals, took the tissues out,
20 and ran the assays in a very short period of time,
21 within an hour, if I remember correctly.
22 There was one study with...with Stephanie
23 that we did that was we took...referred to earlier
24 where it was actually compared. The modified Elman and
25 the radiometric assay were compared in the same

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1 animals, and in that case, we took the brains out and
2 just dissected them, or, actually, we just split them
3 in half sagittally, froze the two halves, and took one
4 half out later and assayed it with the radiometric and
5 took the other half out later and did the modified
6 Elman.
7 Because we have -80 freezers, we
8 don't...we...we are able and we have shown that the
9 tissues are still just fine at -80 for months.
10 I hope that answers your question.
11 **DR. BAILEY:** Well, yes, and I asked it
12 because I think this...this takes out of the
13 possibility that there was something about the conduct
14 of the experiment and the way the animals were
15 held...handled and so that we can not worry about
16 whether, in fact, these...it was something in the way
17 the animals were handled during it, because you just
18 had the samples that were handled right away and
19 measured, or else they were frozen, and so, everything
20 is happening beyond what happens is normal.
21 **DR. MOSER:** Yes.
22 **DR. LOWIT:** Regarding the FMC studies,
23 you might want to repeat that question to them tomorrow
24 to...to...because that's Ginger's recollection about
25 those, just to make sure we're sort of...that you get a

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1 similar answer from them. I think that's accurate,
2 but...
3 **DR. BAILEY:** Sure.
4 **DR. LOWIT:** ...that question should be
5 directed at them directly.
6 **DR. BAILEY:** I'm sure if it's been
7 misrepresented, it will be corrected.
8 Then, I didn't know...could I see the slide
9 that was on page 16, or are we...have we shut down?
10 **DR. HEERINGA:** Ted, I want to...I'm
11 going to draw this to a close in about five minutes,
12 because I think all of us are fading. I know I am. I
13 wonder if...if you would be willing to hold the
14 question until tomorrow morning. I want to give...we
15 had a couple of other questions, if they're relatively
16 quick. Would you be willing to do that? Because I
17 think you're kind of exploring the experimental design
18 and things like that which is fine.
19 Dr. Chambers was answered. Dr. Edler?
20 **DR. EDLER:** Lutz Edler, Germany, the
21 Cancer Research Center.
22 I think they are short questions, so I just
23 go through a couple of them, but pretty sure. Maybe to
24 Dr. Setzer two short questions. One thing was
25 the...this fact...this parameter G in the exponential

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1 model. That was...that was definitely different from
2 1?
3 **DR. SETZER:** In the brain data, it was
4 not. In the...in the red blood cell data, at least in
5 the PND11 data, it definitely is, yes. In fact, it's
6 less than 1. It's a very steep drop.
7 **DR. EDLER:** Okay, because I was
8 wondering which family of exponential models one can
9 actually look...look for.
10 The other question, I think you used...we saw
11 all over the whole evening already we saw the...the
12 data normalized with the controls. You never saw
13 actually the original values of the ten animals or the
14 five animals, but as I understand your plots, you used
15 always the original data and did the BMD analysis.
16 Right?
17 **DR. SETZER:** That's correct, but we
18 don't...I mean, it...it's hard to see the data on a
19 simple graph like that if you don't normalize to
20 control, the percent of control, but, in fact, when we
21 analyzed the data, we used the individual observations
22 and...and the model adjusts for the percent control.
23 **DR. EDLER:** That was just for
24 clarification. Another thing I was interested in, we
25 are talking about peripheral nerve system as one

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1 end...one possible endpoint, then we go to the red
2 blood cell. So, the question is, if somebody actually
3 look at the correlation between the model activity and
4 the red blood cells on an individual animal basis?
5 **DR. MOSER:** Yes, we did actually do that
6 on the individual animal data. We have done that in
7 the adults, and we actually have a scattergram in that
8 McDaniel, et.al. paper that show...maybe not. Anna's
9 giving me a funny look, and I...I've got it here, but I
10 do have those data, and I can get them for you, and we
11 do see better correlation with motor activity and brain
12 inhibition in the same animal than we do with red blood
13 cell, but there is a correlation with red blood cell,
14 because, of course, red blood cell and brain are
15 correlated within the same animal.
16 **DR. EDLER:** Okay. Another question to
17 the...for the ORD studies. We saw for the FMC studies
18 this NOEL use and violations and so on, and you showed
19 actually that it's higher for the control and low doses
20 than for the higher doses. Did you see...see similar
21 things in the ORD studies, or that was different?
22 **DR. MOSER:** No, we're not...in all of
23 the studies of carbofuran, the 17-day-old and the
24 comparative adult and PND11, all of our duplicates
25 replicated at less than 20 percent difference. So, we

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1 didn't have any DNRs or anything.

2 **DR. EDLER:** You didn't have these

3 problems and also not these...those strange...

4 **DR. MOSER:** No, no, I went back and

5 looked, and we typically get maybe 1 out of 100 of our

6 samples that will do that, and we consider that a

7 pipetting error and withdraw the data.

8 **DR. EDLER:** Thank you.

9 **DR. HEERINGA:** Dr....I'd like to...Dr.

10 Bailey, would you like to ask your question this

11 afternoon or this evening or...you'd like to...okay,

12 you put it away already. Good for you. Someone who

13 pushes us out the door. That's good.

14 At this point in time, we have had a very

15 full day. A lot of information was provided to us in

16 advance of the meeting, and a lot of information is

17 being communicated and will be tomorrow.

18 What we will do, we will continue the series

19 of questions on this final topic tomorrow morning first

20 thing. I'd like to devote about a half-hour to that

21 and then turn to the public comment.

22 As you...if you are following the printed

23 agenda, we said this was a floating agenda. We know

24 which way it's floating. It's floating upstream, not

25 downstream, and I think that...I expect that we will

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1 make up some time on Thursday, but I'm also looking at
2 the possibility that we will be working Friday morning
3 here as a group, public involved.
4 So, we'll keep tabs on this, but I don't want
5 to rush things. I want thorough discussion, but at the
6 same time, so if people are planning, I think that
7 we're going to have a full three days if not three and
8 a half days for this.
9 So, thank you very much, everybody, and have
10 a good evening. See you tomorrow morning, 8:30.
11 Panel members, if we could just convene
12 briefly in the...in the breakout room, just a few
13 notes.
14 **(WHEREUPON**, the proceedings were recessed at 5:50 p.m.)
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