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 7, 2008

8:37 A.M.

U.S. ENVIRONMENTAL PROTECTION AGENCY

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February 7, 2008

DR. MATTEN: Good morning. Welcome back to the scientific advisory panel meeting that is considering the scientific issues associated with the agency's proposed action under FIFRA 6 (b) Notice of Intent to Cancel Carbofuran. This is day three.

We ended yesterday at about 7:00 p.m. and we're going to continue with the remaining public comments this morning. Before I turn it over to Dr. Heeringa, I just wanted to note, a note of appreciation for the panel, members of audience, and members of EPA management and staff that were here for the entire duration and participated with the challenging issues in front of them.

We hope that today, if we need to stay until 7:00 we will, and I'm sure Dr. Heeringa will let everyone know in sufficient time to be prepared for that. We do have a scheduled four-day meeting, and so if we need to do the four days, we will use the four days.

I wanted to also mention that as a designated federal official it's my responsibility to maintain the

integrity of our scientific advisory panel process, and with that appreciation it is a huge responsibility and with that it encumbers a certain amount of stress.

And this meeting with its weight I'm sure is very intense for a number of people, and so we wanted to at least mention how much we take our jobs very seriously and that of the panel, and that of the members of the EPA, and also the members of the audience. And with that I will turn it over to Dr. Heeringa.

DR. HEERINGA: Thank you very much, Dr. Matten, and welcome back everyone. We want to move right ahead with our period of public comment. A number of you have been here both days so far, but I still think it would be appropriate for a quick introduction of the members of the science advisory board that have been assembled here for this meeting. As Dr. Matten indicated, I'm Steve Heeringa. I'm the current chair of the FIFRA Science Advisory Panel. I am at the University of Michigan, and I am a statistician who primarily focuses on population-based research.

DR. CHAMBERS: I'm Jan Chambers with the College of Veterinary Medicine at Mississippi State University. My area of expertise is pesticide

toxicology, I'm a member of the permanent panel.

DR. HANDWERGER: I'm Stuart Handwerger. I'm a professor of pediatrics and cell and cancer biology in the College of Medicine at the University of Cincinnati. I'm a developmental biologist, and I'm a member of the permanent panel.

DR. PORTIER: I'm Ken Portier, director of statistics at the American Cancer Society national home office in Atlanta. I'm a statistician and member of the permanent panel.

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

DR. CLARK: I'm Larry Clark. I'm the assistant director of the USDA's National Wildlife Research Center. My expertise is in wildlife ecology, sensory biology, and wildlife diseases.

DR. DELORME: Good morning. I'm Peter Delorme. I'm currently acting director of the Environmental Assessment Division at the Health Canada Pest Management Regulatory Agency.

DR. GRUE: Chris Grue. I'm the leader of the Washington Cooperative Fish and Wildlife

Research Unit, University of Washington. My expertise is fish and wildlife toxicology.

DR. HILL: Elwood Hill. I'm a wildlife toxicologist, expertise is primary in organophosphorus carbomate and mercury toxicology.

DR. MCCARTY: John McCarty. I'm a professor of biology at the University of Nebraska at Omaha. I'm an ecologist and specialize in the ecology of birds.

DR. MONTGOMERY: I'm Cheryl Montgomery. I'm the principal and owner of Montgomery and Associates. I'm a chemist and my area of expertise is risk assessment.

DR. SAMPLE: Brad Sample. I'm with CM2M Hill. My background is wildlife toxicology and ecological risk assessment.

DR. SPARLING: Don Sparling. I'm with Cooperative Wildlife Research Laboratory and Department of Zoology at Southern Illinois University, and my area of expertise is wildlife toxicology.

DR. STINCHCOMB: Audra Stinchcomb. Associate professor, College of Pharmacy University at Kentucky. My area is dermal absorption.

DR. REED: Nu-may Ruby Reed. California Environmental Protection Agency. I do pesticide health

risk assessment.

DR. MACDONALD: Peter MacDonald. Professor of mathematics and statistics at McMaster University in Canada. I have general expertise in applied statistics.

DR. LU: Alex Lu from Rollins School of Public Health at Emory. My research interest in using biomarker for human exposure to pesticides and the health effect. DR. KEHRER: Jim Kehrer. Dean of the College of Pharmacy at Washington State University, molecular toxicology.

DR. HATTIS: I'm Dale Hattis, Clark University. I do mechanistic modeling and risk assessment.

DR. EDLER: Lutz Edler, German Cancer Research Center. Head of the Biostatistics Department working in experimental and clinical oncology and special interest in risk assessment.

DR. BUNGE: Annette Bunge. Department of Chemical Engineering at the Colorado School of Minds with expertise in dermal absorption and risk assessment.

DR. BRIMIJOIN: Steve Brimijoin. I'm at the Mayo Clinic Department of Pharmacology. My interest in biology, and toxicology, and enzymology of

cholinesterases.

DR. BAILEY: Ted Bailey, Iowa State University. I'm interested in applied statistics and special interest in design and analysis of experiments.

DR. HEERINGA: Thank you very much, panel members. At this point in time before we return to our period of public comment, I'd like to offer an opportunity to Dr. Steve Bradbury to say a few words.

DR. BRADBURY: Thank you, Dr. Heeringa, just take a couple minutes to again thank the panel for the long session yesterday. I appreciate all hard work and in depth discussion that happened yesterday. I'm looking forward to today and into tomorrow as we go through these issues, and I also wanted to extend my appreciation to the public who has been adjusting their scheduling in light of the deliberations going on here. And we're looking very much forward to hearing comments from the public. Thank you.

DR. HEERINGA: Thank you very much, Dr. Bradbury. At this point in time we'll continue with our period of public comment, and, again, the first public commentor is Dr. Michael Fry, who is representing the American Bird Conservancy. Panel members, I believe there is a set of materials distributed yesterday afternoon from Dr. Fry.

DR. FRY: Great. Thank you very much for giving me the opportunity to comment. I have prepared written comments. In those written comments I did not talk about the probabilistic risk assessments. I thought that you guys would have pretty ugly sessions for a couple of days on that and more of it probably wouldn't be useful. I will say that I did serve on the 2004 science advisory panel on probabilistic risk assessment that was referred to by Dr. Moore yesterday, and I have a completely different recollection of the panel recommendation and responses than were expressed by Dr. Moore yesterday.

The panel praised both the model and the work of the Environmental Fate and Effects Division. I can still remember the comments of the late Raymond O'Connor who uncharacteristically effusively praised the modelers in the EFED for being so proactive in developing models that truly reflect the important parameters in a risk assessment. The panel had recommendations.

Of course, we were all academics. We had to have recommendations, and the modelers have incorporated almost all of those into Tim's two. Dr. Heeringa, you were on that panel. In fact, you chaired that panel, and I think you can confirm my recollection

of the panels response. I thank this panel for asking questions yesterday that largely confirm that given the same input parameters, liquid param and Tim's give essentially the same answers. Dr. Moore, however, wants much less conservative input parameters.

The agency is conservative in its approach. It should be. After all, the name of the agency is Environmental Protection Agency. Tim's also largely confirmed the deterministic approach, the RQ approach, although it's much less sensitive. Let's please remember in this whole effort here that the agency is not trying to cancel all pesticides. They have over 1100 pesticides registered, but they should be trying to get rid of obsolete chemistry, these meat axes kind of pesticides like dieldrin, monochromophos, or carbofuran.

The charge questions range sort of widely, so in my comments I will too. Let's see. I'll figure out how to work this. Could I have my slides? I gave them yesterday to somebody.

DR. MATTEN: We put your slides on that computer not on that computer.

DR. FRY: Okay. Can you bring them up off that computer?

DR. HEERINGA: Dr. Fry, are you going to

retrieve them from your own storage, or do you want them to -- okay. Meanwhile, I think they're working on having them transferred here. We have them and they will be brought over. Sorry for the delay.

DR. FRY: I want to talk about the two databases the American Bird Conservancy has developed. Our Avian Incident Monitoring System database and the Bird in Agricultural Areas database. I included this pamphlet for the panel. It describes both databases. We did this a couple of years ago in an effort to sort of advertise the Avian Incident Monitoring System to states so we could get more voluntary reports submitted.

The Avian Incident Monitoring System is a web-based avian database that represents poisoning incidents. It's freely available on the web at our website abcbirds.org. There are about 2575 incidents in the database documenting the mortalities or more than 400,000 birds.

The species, the numbers, the pesticides involved, the residue data, the agency that reported this, their agency, report numbers are all included in the database. The database includes kills of legal use of the pesticide, misuse, and deliberate abuse of the pesticide. I think all three of these have utility

because legal uses, of course, are very much like the EIIS database.

DR. HEERINGA: Let's do the favor of loading your slides up here.

DR. FRY: The misuse incidents generally are incidents where someone was using the pesticide on a field crop. They may have used an incorrect dose or used it at the wrong time of year, or perhaps in an unregistered use, but they are generally, misuse incidents are generally incidents for the use of the pesticide on fields.

Deliberate misuse or deliberate abuse incidents are those where people have used a very toxic pesticide deliberately to kill wildlife, and the utility of those incidents shows the toxicity of the compound, the ease with which it can be abused, and in some cases how close the level is between legal uses and dangerous uses.

The Birds and Agricultural database does not have any source data that overlaps with the AIMS database. It has records from the published literature of birds being associated with agricultural crops. So far we've gone through about 1300 papers and excerpted documented from about 700 of those that had sufficient data to be included.

We have more than 22,000 records, which give the species, the conservation status, the location, the crop, the month, and the use, use in this case being the bird use, whether they were foraging, roosting, nesting, raising kids, using the edges, loafing, or say using it as a migratory stopover. Overall we have about 350 species and 67 different crops. I will say in the AIMS database we have data on 113 different pesticides. Okay. This is fine.

In the AIMS database, these are the top 20 pesticides that have killed birds. Carbofuran is number one. We have 555 cases, incident cases in there; 498 of those cases have a certainty of probable to certain. We have generally pesticide residue data, although not on all the birds with the probable cases. Certainty of certain indicates that we, you know, often have cholinesterase depression data.

We have pesticide residues in the bird that are of concentration that would cause the lethality, and we have the use data for the crop. So this is a pretty complete database and pretty conservative in what we call certain or probable. You can see on this list chloropyrophos is listed, and I think Dr. Brimijoin, what a week ago, two days ago asked the question with regard to Jorgensen's paper where the

controls used chloropyrophos and killed a lot of birds.

Why wasn't anything done about chloropyrophos? That paper was in 1989. Since that time, many uses of chloropyrophos have been cancelled. All over the counter sales of chloropyrophos have been terminated. So it was incidents like that, that would cause regulatory action, and I think there has been. Even so, chloropyrophos, you can see on this list, has many fewer incidents than carbofuran.

In contrast to Dr. Pranger's EIIS data, the number of cases of carbofuran over the years has not diminished appreciably in the AIMS database. You can see everything since 1994 and 1995 is entirely flowable. There is only a very small use of granular since that time.

Previous to that, of course, you have both granular and flowable incidents included. I've included on this chart both the number of cases in the AIMS database and the number of birds effected, largely killed. More of this large number here with more than 20,000 represents the deliberate abuse case that we heard about in Illinois in 2000. But my point is here that the cases of carbofuran go up all the way to where we terminated, maybe interrupted, the data input in 2005 when the grant we had to establish this database

ended.

The land use associations that are present in AIMS are not always complete. You can see here, this is for the 498 different cases. We have a larger number of records because multiple species are included in AIMS.

There are multiple records. So as I go through my, my converted Access database or Excel database, it's easier for me to do it by record rather than by just case number. But I've got things translated on a few of these. So in total for the 498 cases, we have 1024 records as you can see at the bottom.

Not all these cases have land use reported. We just reported what we got from the agency. So there are 444 of these that do not have land use, but 151 records for corn, 95 for agricultural areas. This are 88 cases for vineyards represents 39 separate incidents going back into the 70s all the way to 1994. We don't have vineyard cases after 1994. I will say that I inadvertently left out alfalfa on this list. Alfalfa is about in the middle.

We have 11 records for alfalfa representing seven different cases from all the flowable carbofuran between 1976 and the year 2000. We're very glad. ABC

is very glad that after 30 years of mortality data of birds being killed in alfalfa that the registrar is finally agreeing to terminate the uses in alfalfa. I think it's important to praise the registrar for that move.

The Birds and Agricultural database can duck tail with this information. I've included here the number of acres treated. These are the 10 highest treatment crops currently registered for carbofuran. The acreage came from the notice of intent to cancel, which was just published last month.

The corn data, 540,000 acres all the way down to sugar beets with only 10,000 acres per year, but these are the number of species that have been documented as occurring in these crops; 202 species of birds occurring in corn. We gleaned that out of 168 citations, and it totals up 4437 different records out of the 22,000.

So you can see there's a substantial body of literature that we -- we have not found any papers to date that document bird usage in potatoes. That's why we have no data for those. I'm sure that exists. We have a good 700 papers that we have not yet excerpted; that I'm sure if I ask Lu Best we'd be able to come up with data on that.

The Birds and Agricultural database indicates a large number of species utilize crops which may be treated with carbofuran. The birds select those specific crops for a reason. We don't always know that reason, but the birds are tied to that field at least temporarily. And I'll talk a little bit about that later. The extreme toxicity of carbofuran frequently causes acute mortality in a single exposure event so that I don't think chronic exposure, necessarily a bird being in a field for a long period of time is necessary. I will comment, yesterday it was brought up that the conservation reserve program has a registered use for the pesticide. I can only imagine what was the agency thinking for granting this. The CRP lands are frequently the only lands in these monoculture deserts of agriculture where birds can take refuge, and to nuke them with carbofuran I think is inexcusable. I'm glad that the registrant has also agreed to withdraw that use.

Raptors are disproportionately represented in AIMS; 216 of the 498 records we have, which is 43% of the cases involve raptors. And I will say, I went back and looked at the AIMS database and the BIA database after questions were brought up on bird size, and I haven't done an exhaustive analysis, but certainly the

species represented in AIMS are larger species of birds in general than the total number of species that are represented in the published literature. So why are raptors disproportionately involved? I think they're large birds. Bald eagles, of course, when you kill a bald eagle -- yeah, it's an endangered species. It was an endangered species for a long time. It's always picked up and turned in, so we have a very high number of cases, 127 records of bald eagles. However, red tail hawks are not in the same conservation status as bald eagles, and they really represent these birds in fields. Now raptors may be drawn to the field because that's where the easy prey is. So I would like to go through one small example of this kind of thing, not with carbofuran but with organophosphates.

In 1991, the California Department of Fish and Game requested that Professor Barry Wilson, Jim Seiber and I look at red tail hawks that were being turned in with organophosphate poisoning symptoms to wildlife care centers. And so we made a quick association, and they were geographically and temporally associated with almond orchards, dormant sprays. And so we took foot war samples, blood samples, fitted the birds with radio transmitters, and did a field study.

Now the red lines on this are roads, and they're basically half mile or a mile square blocks. So this is about eight miles across by six miles long. This is the home ranges of I think 20 or 25 red tails. We also mapped the pesticide use, methidathion, parathion, diazonon, and chloropyrophos were the four that were being used.

We overlaid those with the radio telemetry data, and you can see this one red tail here is devoted to an almond orchard sprayed with diazonon. And when we looked at the residues on the feet of these birds every residue that was sprayed in there home range within the previous two weeks was represented on their feet. So these birds were going into sprayed orchards every day basically. Why? We found feather spots of killdeer associated with the radio telemetry of these birds.

So red tail can't catch a killdeer. They're quick. They fly erratically and in an almond orchard they could easily get away unless of course they were debilitated, and walking around on the ground in an orchard sprayed with organophosphates, it slows these birds down. It makes a good place for hawks to hunt. Now we didn't, we didn't document the loss of any hawks in this. We did have several automobile collisions

with birds. Whether that's sublethal effects, I don't know.

My take home message in this is that birds are opportunist foraging species. Herbivorous and granivorous species will select suitable crops in which to forage. Ripe grains, of course, geese get into those. Alfalfa, we've seen a lot of data on that. Ripe fruits in orchards of course and raptors will select for debilitated prey.

Now when a raptor kills something he gorge feeds. He'll eat as much of that prey item as he can hold and still fly, a typical gorge feeding. Now we mention that birds were tied to a site for a variable amount of time. In migration, birds have one day. They fly at night. They stay over during the day. They forage. They have to gorge feed in order to get the calories needed to fly to South America.

So almost all species that migrate gorge feed at least during migration. During pre-migration, which may be a week in one location, the birds gorge feed so that they can build up reserves. When birds are roosting, they come back to the same place maybe for a week, maybe for a month, but they're going to be in there. If it's foliage spray, they're going to be exposed that way. Nesting and brood rearing birds are

tied to a site for at least a month, and if you have multiple feeding bouts in a field, say 4 to 30 per hour, it means these things are feeding kids.

They're going into a field, treated field, picking up insects or other material to take home and feed the kids. Kids are offsite. They're not going to be seen in any kind of a monitoring program. They hide the nests, but kids, we know, the baby birds, are more susceptible to compounds like carbofuran and so these birds are really at risk.

Dr. Pranger also brought up the drop in incident reports in her EIIS database. The AIMS database shows exactly the same thing. Since the year 2000, there have only been 15 to 23 reports in the EIIS database for birds since 2000. Previous to that the greatest number we had was 2001, but it was increasing all over the 90s.

Dr. Pranger mentioned that this is the current reporting requirement; 200 or more individuals of a flocking specimens like waterfowl, or gulls, or shorebirds; 50 more individuals of the songbird species, or 5 or more individuals of the predatory species, and fewer than that are reported as a minor incident.

We have gone through the AIMS database and

did an analysis of the reporting requirements for the 2575 cases, and there would only be 130 cases total if the reporting requirements were as they are now. So we think the incident reporting system is broken. We're working with the agency to try and fix this, and I would very much like to see that fixed.

I have one comment that I want to make on the dosing study that was done we talked about yesterday and then one last comment. FMC study demonstrates a 2 to 3.9x reduction in toxicity when dosed with a food bolus as compared to an aqueous bolus.

The RQ values, you know, a table like this is very dramatic. It shows very high risk to birds with RQs in the thousands or hundreds. If you reduce that by two to four times, it's still going to be in the hundreds or the thousands. So we think the results may be true with the food bolus compared to that, but I don't think they reduce the risk of carbofuran appreciably.

I have one last comment. I was, I have a very negative view of the quibbling that went on yesterday afternoon with regard to safety factors. The purpose of reducing a safety factor is so that you can allow more residues on food or in drinking water. Shame on the registrant frankly. We don't need higher

residues of pesticides in our food and our drinking water. We need fewer residues in our food and drinking water. I think the conservative approach by the agency is a good one, and I don't think there's been any data presented by the registrant that would change my mind in any way that carbofuran really does need to be cancelled. I'd be happy to answer any questions.

DR. HEERINGA: Quick questions from the panel. Yes, Dr. Sparling.

DR. SPARLING: Dr. Sparling from Southern Illinois University. Am I right? You had said that you agreed that the number of incident reports had declined since 2001.

DR. FRY: Yep.

DR. SPARLING: But also that the number of reports in your database up until 2005 on carbofuran had not declined?

DR. FRY: The number that were reported in the EIIS database did decline. We have reports, you know, we've gone to a lot of other state agencies. We've gone to US Official Wildlife Law Enforcement, so some of these cases of carbofuran since 2000 have been enforcement cases. We have a greater number of bird cases than EIIS, but they do reflect misuse and abuse as well.

DR. SPARLING: Secondly, the loss or the ending of your grant in 2005, do you have any idea if that was consistent with a decrease in funding for monitoring projects across the country, any consistency there?

DR. FRY: This grant was from the EFED at EPA, and we have since reapplied for continuation of that grant. I don't think it was, had anything to do with overall monitoring at all. It was just. We had a five-year grant. It ended. We're working to continue it.

DR. HEERINGA: Dr. Clark.

DR. CLARK: Larry Clark, USCA. What sort of vetting process do you use when reports are submitted to your database in terms of quality control, quality assurance point of view?

DR. FRY: Two things. First off we try to make sure that the data we enter is the same as the data that's been presented to us. We go over the reports. Many of the reports are the same reports that have been submitted to the agency, EPA, and we look at the data that's been reported by the agency. If there's residue data, we do the classification of whether it's certain, uncertain, or unlikely.

But, you know, we have our own quality

control just to make sure the data that's entered is right, but we take it on face value largely from the agency that's reporting the data, what that data represents. We haven't gone back to the agency, for instance, and inquired to them.

DR. CLARK: Just as a followup.

DR. FRY: Yeah.

DR. CLARK: 'Cause I noticed -- I went to the website and I looked at many of the records, and it says information available upon request.

DR. FRY: Yeah.

DR. CLARK: So do you get to see that information?

DR. FRY: What we've got is all the information is on hard copy, and we can copy the hard copies, the original reports and give you that if you, if you request it. It's a pain, believe me.

DR. CLARK: No. I'm not interested in particularly seeing it myself.

DR. FRY: Yeah.

DR. CLARK: But when you're doing the bedding to make sure that this reaches some uniform standard for reporting it is that I couldn't discern, you know, how you could put weight on one report versus another based on some of the records.

DR. FRY: True. And I think in some ways that's reflected in the certainty value that we give them, but we do have the paper records on all of them. And we make the judgment as to how good we think the data is when we enter it.

DR. HEERINGA: Dr. Grue, and then I'd like to move on.

DR. GRUE: Dr. Fry, I just wanted you to comment on the actual field use database that you described.

DR. FRY: The Birds in Agricultural Area.

DR. GRUE: Right, yeah. This is outside of the incident reporting, and to what extent has that database been utilized by the registrants as well as EPA?

DR. FRY: I don't really know. We have hit data. We can tell you how many times that's been accessed, but we can't tell you by who. We haven't been invasive in our cookie manipulation or utilization, so we don't know really who uses the database.

DR. GRUE: My comments related to the fact that it's part of the initial discussions in terms of species selection, behaviors and so on.

DR. FRY: Sure.

DR. GRUE: The comments have been made that there's a limited amount of data or at least publicly available data.

DR. FRY: That's why we started this database.

DR. GRUE: Exactly and that's the basis for my question.

DR. FRY: Yeah. And, you know, like this brochure, if we can disseminate this more widely, I think it would be more widely used. Also if we could complete it, it would be nice.

DR. HEERINGA: Thank you very much, Dr. Fry.

DR. FRY: Thank you.

DR. HEERINGA: At this point I'd like to invite up our next public commentor, and it's Dr. Jennifer Sass, who is representing the National Resources Defense Council. Jennifer, are you here? I spoke to her yesterday afternoon. She had taken a redeye in. Okay. We'll defer on that.

At this point then, I'd like to invite up Mr. Chance McLean, who is registered as a farmer. Just a note to public commentors. If you have presentation material that haven't been loaded currently, make sure

that you get those here as soon as possible. Panel members, thee is a handout from Mr. McLean, a picture of a combine is the first picture.

MR. MCLEAN: It looks like we're ready. My name is Chance McLean. I'm from Benedict, Nebraska. I'm going to tell you a story about my experience with Furadan. Recently I've graduated from Northwest Missouri State with a bachelor's in Ag Business. After that I decided to start a career in farming. In 2007 I had a field that was infested with corn root worm. The genetics was 33h27 with a punch of 1250 seed treatment for the root worm. In this picture is year-lage harvest.

It's fed to cattle. It's harvested at a high moisture basis. There's a misprint on the cover for the Furadan root worm. It's actually 6-19 instead of 6-9. On June 19th, my agronomist, Brian Bresnahan, which is here today to speak as well, noted a corn root worm infestation throughout my whole field. He contacted me immediately to treat it with Furadan. Right away I contacted the aerial applicator. The next day it was applied to the whole field, except a strip between the middle of the field.

The strip was an experiment to determine the difference between the two. In this picture is the

aftermath of the non-rescued corn. As you can tell the roots are lodging. The roots are lodged because the root worm has fed on the roots and result in horrible root structure, which the roots are pictured in my next slide.

I would also like to point out that if I had harvested this as dry corn, a majority of the corn would be laying flat on the ground and would lead to more of the substantial yield loss as well as income. Corn lying on the ground makes harvest stressful and time consuming. In this picture is the roots that we dug up. As you can see, the left side is rescued, and the right side is non-rescued. It's obvious that the right side the roots are much, much smaller.

In this one is the yield data that we had on our test plants with the treated and the non-treated, 178.6 bushels per acre to 224.7 bushels per acre; 26% increase. And this one is a spreadsheet of the difference between the two dollars. As a first year farmer in a competitive situation, a $24,000 loss severely impacts, could impact my future in farming.

In conclusion of my field, Furadan has helped me financially by having some working capital as a first time farmer.

I just want to point out that without the

rescue, it would make my first year stressful without those extra dollars to proceed onto the next year. Farming is a very expensive business. As a first time farmer, I cannot afford to take a hit. Finally, I had no idea that Furadan would have this big of an impact on my field. Thank you, guys.

DR. HEERINGA: Thank you very much, Mr. McLean. Any questions from the panel for Mr. McLean? Dr. Brimijoin?

DR. BRIMIJOIN: How did you get the idea to leave this vacant strip?

MR. MCLEAN: There was an FMC representative out in that area that's been doing some research on Furadan. He suggested to do a plot on it to actually just see the difference on it, so we decided to do that; that's where we come up with this.

DR. HEERINGA: Thank you very much, Mr. McLean.

MR. MCLEAN: Thank you guys.

DR. HEERINGA: At this point in time Dr. Sass is here, and I'd like to invite her up from the sequence. Jennifer Sass? Again, Dr. Sass is representing the National Resources Defense Council, and there are prepared comments, I believe, that were distributed to the panel, again yesterday, which should

supersede anything you received prior to that.

DR. SASS: Good morning. I'm Jennifer Sass with the Natural Resources Defense Council. I'm a scientist in the health program. I'm here in Washington, D.C., although I was on work travel, and I'm sorry I missed the first day of the meeting of EPA's presentations; but I'm looking forward to your deliberations.

My comments were handed out in writing, and I'm going to go very quickly through them. There are not going to be a whole lot of surprises because I'm one of the groups that has been petitioning EPA for a ban on carbofuran, but for these comments, of course, I've styled them specifically for the charge questions that you've been asked to address.

So skipping to page two because I'm not doing background with you obviously, I'm going to be -- because I'm a human health toxicologist and scientist, I'm only going to be addressing the charge questions that are appropriate for me. I'm not going to be addressing the ecological charge questions.

So first of all on page two, my responses to selected charge questions. The point of departure, you've been asked to comment on whether the scientific evidence currently before the agency supports the

agency's conclusions of brain cholinesterase data provided more robust point of departure than red blood cell cholinesterase data, and I do support the use of whole brain pseudocholinesterase data as preferable to blood because it's more stable and the variability is reduced by comparison an also, obviously, because it is a direct measurement of the target organ of interest for toxicity.

Next, comment on the agency's conclusions that a benchmark dose analysis of the brain cholinesterase data from three studies provides a scientifically appropriate basis for assessing carbofuran risks to infants and children.

While I do support the agency's approach to conducting the benchmark analysis from these data, I do disagree that sole reliance on cholinesterase data are sufficient to be health protective in terms of evaluating the risks to infants and children, and this is because while the methodology is a sound approach, it is limited by failing to identify possible region effects in the brain and also noncholinergic effects, which have been demonstrated for another class of cholinergic pesticides, the organophosphates, as well as the effects of various time points of exposure during development on the outcomes.

And because these methodologies are not designed to capture those potential outcomes, I think it's not sufficiently protective.

Page four of my comments, not that you have to follow along, but if you are, I'm helping you to skip. Comment on whether you agree with the agency's conclusions that based on the available scientific evidence, there is remaining uncertainty regarding lack of dose response data at the low end of the dose response curve for the red blood cell cholinesterase inhibition with respect to extrapolating to the risks for infants and children.

Again, NRDC, me, does agree with EPA that there is considerable uncertainty in the low dose response curve for these data, and while we agree with the approach, that the magnitude of this uncertainty has not been analyzed and the contributors to this uncertainty have not been documented or identified in your information.

So, for example, again, sole reliance on the whole brain cholinesterase inhibition data is to calculate the benchmark dose fails to incorporate the regional, possible regional effects, noncholinergic, long-term or permanent neurobehavioral or neurocognitive effects for example.

And experts have warned that, "the fact that alterations in neurodevelopment occur with the organophosphate exposures below the threshold for cholinesterase inhibition reinforces the inadequacy of cholinesterase inhibition for assessing exposure outcome that may be related to development neurotoxicity," which is what you're being asked to look at in this question. So, again, we support the approach, but we don't think it's sufficient or adequate on its own to provide protection.

On page five you're asked to consider the safety factor, which is being based on the ratio of the benchmark dose 50%, the BMD 50 estimates in brain and red blood cell cholinesterase in juvenile animals. Is this a regional approach?

Again, I believe that using nothing more than the comparative ratio of the cholinesterase, while a reasonable approach, is inadequate for basing an FQPA factor. The food quality protection factor is an uncertainty or safety factor and neither the uncertainty nor the contributors to the uncertainty have been documented, and so the magnitude of the uncertainty cannot be estimated. And, again, by failing to incorporate tests that do account for potential neurocognitive or neurobehavioral impacts,

means that there is a great amount of uncertainty there in terms of long-term or permanent effects.

The SAP which some of you served on that evaluated the organophosphates did early in the process recommend incorporating these data, but it was never done, or incorporate tests that would capture those endpoints, I mean. And I quote the SAP in 2002 that did say, "reliance on a single biochemical assay to measure brain damage may become problematic."

Page six, point of departure determination for dermal risk assessment for workers. Do you agree with the agency's conclusion that dermal toxicity in rats are not acceptable for use in extrapolating dermal risks to workers.

NRDC disagrees that EPA has to make a choice between either inadequate data from poorly conducted studies on rodents or else inappropriate data from an unrelated root of exposure, that is oral being extrapolated to dermal. EPA could have and should have required the needed data during the early stages of the reregistration and tolerance reassessment process, and in the absence of reliable data from pre-validated test methods, NRDC is recommending that the EPA presume 100% dermal absorption. Since repeatability is one of the most fundamental tenants of the scientific method, the

reliance on single studies for root or dose assessment is inadequate and precludes confirmation of the results.

Further, orally ingested residues are subject to digestion and subsequent metabolism in the liver while dermally absorbed and inhaled residues do not pass through the digestive tract but instead have direct access to the blood and lymphatic circulation. And EPA's failure to require robust dermal testing from pre-validated study protocols during the reregistration procedure adds an unnecessary level of uncertainty to the final assessment and to it's risks management decisions.

And finally but not pertaining to your charge questions, I have included NRDC's comments that we have filed with EPA calling for also the cancellation of import tolerance as well. So at the moment EPA is proposing to cancel domestic uses of carbofuran. We're concerned that the carbofuran will continue to be sold overseas, and unless the import tolerances are also cancelled, then it will encourage those uses overseas because it allows those imports to come back into the US. Thank you for your time. I look forward to your deliberations, and I'd be happy to take a question if there is any.

DR. HEERINGA: Thank you very much, Dr. Sass. Questions for Dr. Sass for clarification?

Dr. Brimijoin?

DR. BRIMIJOIN: Dr. Sass, apart from the issue concerning dermal absorption studies, which is very germane, I wonder if you could highlight for us any of the other concerns that you have, general concerns that you've expressed which actually pertain particularly to carbofuran as opposed to any pesticide, or as opposed to any anticholinesterase pesticide, or as opposed to any other carbomate pesticides?

Because I have the feeling that you would say perhaps the same thing about any other agent in this broad category, and I think we have to focus specifically on carbamates. So if you'll help us focus, I would appreciate it.

DR. SASS: Well you're right that my concern is with the cholinesterase pesticides and the organophosphates. The reason why I refer to, specifically to organophosphate data is because most of the research that isn't, that is outside of the research that's provided by the registrants for registration is on just a very few of the organophosphates and almost none on the carbamates. So there's just simply a lack of specific data that you

and I would prefer to hang our hat on, but the EPA has the option during this entire process of requiring any data that it wants to require. And the regulations for registering pesticides give them that authority.

So one of the things that is frustrating for me is that EPA, I think, has failed to exercise its authorities appropriately and require the kind of robust data that would allow all of us to make decisions that were based less on uncertainty and more on hard data. So, unfortunately, a lot of the data that I cite is organophosphate data, and, in fact, it's only coming from a couple of the organophosphate pesticides where there is a plethora of data.

DR. HEERINGA: Dr. Kehrer?

DR. KEHRER: You are recommending that the EPA assume 100% dermal absorption. I wonder if you can justify that a little bit given that even drug products that are designed to be absorbed through the skin are not 100% absorbed.

DR. SASS: My concern is that they're using an extrapolation from an oral root, and not only do I not think that you can do a real reliable extrapolation from oral to dermal, I don't think the experts have had to review that data with the HSRB thought that you could either.

So my concern, I guess the reason why I feel that my request is justified is because there is potential for direct access to the bloodstream because there is avoidance of the digestive system metabolism, and that potentially is a serious limitation. And because I don't think you can do a robust extrapolation.

I think it's a numbers game, and because I think EPA failed to request the data when it could have with plenty of time to get that data; and that shouldn't favor the registration of the chemical that the registrant or that EPA failed to submit or request that data.

DR. HEERINGA: Thank you very much, Dr. Sass. I appreciate your comments. At this point in time I'd like to call up our next public commentor who is Dr. Diana Post, who is representing the Rachel Carson Council. Dr. Post. Dr. Post, not here.

Then I'd like to move on to the next scheduled public commentor, who is Mr. Donald Sklarczyk. He is a farmer, representing the National Potato Council. With a name like Heeringa, I apologize if I mispronounced your name.

MR. SKLARCZYK: Thank you, chairman and also this SAP panel, and I do recognize the adversities

in trying to pronounce my last name. I've gone through many sessions where people have had a difficult time, and quite frankly the biggest surprise I think in my college career was when a professor pronounced it the way that I expected it to be and I didn't respond; and he said, did I not announce the name correct? But if I could move into my presentation now.

My name is Don Sklarczyk, and I'm here today representing potato growers from throughout the United States. In 2007 I served as the president of the National Potato Council, an organization that is the sole voice of the potato industry representing legislative issues. During that time the National Potato Council created some many advantageous things to help our potato industry, and some of them were the three IPM advisory brochures, one for herbicides, one for fungicide, one for insecticide to show growers that changing product name does not mean changing classes of chemistry. And that was done because of the importance to resistance management that the National Potato Council and the potato industry realizes.

Now I've also previously served as vice president of the National Potato Council's Environmental Affairs Committee for a number of years. From an occupational point of view, in 1982, we

developed a new concept in seed potato production that's implementing the use of tissue culture to reduce the symptomless bacteria and latent viruses in the seed potato industry.

This concept currently is mandated in all seed potato production throughout the United States and Canada. Presently all of our production is produced hydroponically to reduce that potential infection even greater. I also have to add that we produce 80% of the base seed potatoes for the Frito Lay Company, both for the United States and Canada, and as was referenced yesterday, enjoy a very good relationship with the sunflower industry. The two industries work together to try to create a healthier product as far as a snack food for our future generations.

Now what I've recognized in my positions with the National Potato Council is the need for growers to have a variety of crop protection products made available for them to be able to make their crop marketable. Furadan has been a very important product in the pest control toolbox. Carbofuran, the active ingredient of Furadan, has a unique set of characteristics including a spectrum of control, the efficacies, the consistency, the moderate cost, the systemic activities and use patterns that allow at

planting, post-planting, through emergence and foliar application.

The primary uses of carbofuran is in the Pacific Northwest where the current lack of pesticide resistance and the emergence of new pest species have made carbofuran an important pest control tool. I'll talk a little bit later on the new species of pests that's invading the potato crops in the Pacific Northwest.

Now potato growers in the Pacific Northwest are faced with insect pests that no other farmers in the world have, and during a routine season many growers will have to contend with the following key foliar tests, the beet leafhoppers, green peach aphid, Colorado potato beetles, the two-spotted spider mite, and potato tuberworm. This potato tuberworm is an insect pest that is coming from Mexico, which previously was a warm weather insect migrating into the northern states.

Presently it's creating a real devastation for growers in Oregon, Washington, and Idaho because of the lack of control methods. If a potato tuberworm gets into the tubers themselves, it can go undetected. Once it goes to the processing plant, the loads are rejected because of insect infestation. Usually

growers have control of mixed assemblages of the pest, making spectrum of control very important in their decision as to what products to use. Carbofuran is one of the two insecticides that can control all pests, with the exception of mites, within an integrated pest management program, which is very important to our industry.

The National Potato Council has relied on information from the University of Idaho's potato economist, Dr. Joe Getner, on what would be the economic consequences with the loss of carbofuran, and based on his calculations, the value of carbofuran to growers to control beet leafhoppers, Colorado potato beetles, and green peach aphids is estimated to be 4.6 million dollars. Dr. Getner estimated the value of a second carbofuran use pattern including the control of the tuberworm that I mentioned occurring in mixed assemblages with beet leaf hopper, green peach aphid, and Colorado potato beetle to be at 10.5 million dollars.

There's another class of insecticide that has similar but smaller spectrum of control, which is a synthetic pyrethroid insecticide. These insects, insecticides are often mentioned as an alternative to carbofuran because they control some of the same pests.

However, the insect pest guidelines, the IPM guidelines from Washington State University, Oregon State University, and the University of Idaho all restrict the use of pyrethroids during most of the growing season due to their well known ability to flare up aphids and mites.

The potato industry learned early on the devastation that can take place when applications of synthetic pyrethroids were applied in the Red River Valley. Growers unknowingly were negatively impacting the beneficial insects and causing flare-ups of aphids where they were trying to control other insects. Carbofuran can be used throughout the growing season without creating aphid and mite outbreaks, making an important tool in the Northwest IPM program.

There is one product that has a similar spectrum of control, that is methamidophos, which belongs to the organophosphate classes of insecticides. Carbofuran is commonly used in a rotation with methamidophos in an IPM program. While there are other products that control one of the pests controlled by carbofuran or a subset of the pest, with the exception of methamidophos, most alternatives have narrow spectrums of controls and label use limitation that are not disruptive to IPM or resistance management

programs.

Now an example would be that at planting if growers use a neonicotinoid or a thiophoxide at planting, then because of resistance issues, they cannot go back later and do a foliar application of a similar class of products.

Three of the key insect pests that Pacific Northwest potato growers are Colorado potato beetles, green peach aphid, and the potato tuberworm. They have a history of developing resistance to insecticide. In particular, the green peach aphid and Colorado potato beetles are notorious for developing resistance. These two pests have developed resistance within a decade of registration of insecticide in some potato growing regions.

Growers in the Pacific Northwest have learned lessons from the severe resistant problems faced by potato growers in the midwest and the east. The specific Northwest growers take resistance management very seriously. I personally have seen growers having laminated these sheets of IPM resistance management brochures that the National Potato Council has put together, and they use them in their pickup when they're going out to decide what classes of chemistry they need to control the insect pest.

The Pacific Northwest growers were also the first to adapt the use of positive displacement application equipment. This like many other new concepts in the potato industry in agriculture has allowed better control of the application of crop protection material. This is a very important issue that we need to consider. The growers in the Pacific Northwest rotate crops. They rotate modes of actions when they are selecting their insecticide. Carbofuran is the only carbamate insecticide that growers apply to the foliage, making it a key resistance management tactic for the potato insect.

Dr. Getner's study estimates that economic consequences of developing resistance that could occur should carbofuran be removed from the market. The study states that potato industry would suffer 37.5 million dollars in losses. Most of it would be associated to the decline in quality and yield if resistance developed after the cancellation of carbofuran. My personal comments would have to lean more toward not if resistance will be developing, it will be when it will develop.

Carbofuran is also the only means to control wireworm in potatoes once they've been planted. While this pest scenario is very limited to the application

of 1600 acres, it's extremely important to the growers who become aware that they have a wireworm infestation after they planted their potatoes.

There is no other rescue treatment available for them to use other than carbofuran. The value of this use pattern to growers and to the processors is estimated to be 3.6 million dollars. The net result is wireworm infested tubers are rendered useless for growers. They have no other potential use for the industry.

Since the Pacific Northwest potato production is closely linked to other economic entities such as processes, input suppliers, and labor forces, any losses experienced at farm level would have a multiplier effect resulting in a much larger impact on the farm economy.

Researchers, including Dr. Getner at the University of Idaho plus collaboration with the University of Washington, have analyzed the economic impact to the potato industry on the greater Pacific Northwest economy, and according to this research, the economic multiplier for the losses in the Pacific Northwest is estimated to be 3.4.

Applying this multiplier to the grower losses identified above, the estimated impact and the loss to

carbofuran to the Pacific Northwest economy would be a loss of 190 million dollars per year according to these academic researchers.

If carbofuran is cancelled, growers will be forced to replace a single application of carbofuran with eight niches of multiple insecticide applied more frequently at shorter intervals.

Now on a personal note, I have to add that I've experienced what has to take place because I have had to put cocktail mixes of multitudes of products to do an adequate control of pests and do that repeatedly every five to seven days to try to impact resistance buildup in the pests. The one impact that we had was that we negatively impact the beneficial insects. So we were fighting a reverse vortex, but we were forced to do that because of the loss of our crop because of the insects that had built up resistance.

In conclusion, carbofuran is a unique product with special benefits that cannot be replaced by any alternative on the market or in the registration pipeline. The loss of this product would result in the disruption of an integrated pest management program, the indicated resistance management program, and an increase in the cost of pest controls. It would also lead to yield and quality and quality reduction and

increase the use of insects on potatoes.

Now I have to add that farmers today are constantly changing and updating their application methods, and if we were to use technology five years old, the farmer would not stay in business. So some of the reports and some of the information that you receive that is referencing what has taken place five years ago in agriculture, is not a true reflection of the application rates and the application methods that we have today.

It makes a tremendous impact in the result in residue studies that you have and also the potential toxicity to the avian population. I will also add that I've grown up in a potato farming operation, and in all the years of scouting, I've never seen negative impact or death to the avian population through our growing fields. So consequently I feel that some of the suggestions have to be reviewed with the idea that is it really use patterns that are in practice today.

There's also another interesting side that recently at a research meeting a researcher had presented, and that was dealing with the potential of resistance buildup. There is work that suggests and it's proven that in the case of aphids, an aphid will build up a potential protection on the side of the

brain that's being impacted by the application of the pesticide.

In the case of neonicotinoids and thiophosphates, they shift their defenses to build up resistance to that side that's being impacted. If there is an application of carbofuran, it impacts the other side of the brain.

What happens is when that takes place, that resistant insect is eliminated. So the net result is that some of the newer, softer classes of chemistry would be able to prevent the build up of resistance if we maintain the use of carbofuran as a rescue treatment. It's application is not going to be all the time, but for a rescue treatment, it becomes invaluable for us in our resistance management program.

Again, I thank the Scientific Advisory Panel for allowing me to testify, and I hope that if you have any questions you'll feel free to ask them at this time.

DR. HEERINGA: Thank you Mr. Sklarczyk.

Dr. Sample has a question.

DR. SAMPLE: Yeah. I had a couple of quick questions. One was what would be the general frequency which carbofuran would be applied to potatoes?

MR. SKLARCZYK: If it was in a foliar application, the frequency would be a single application. If it was a granular application, it would be a single application as well. And either one or other, not in combination.

DR. SAMPLE: On an annual basis or in a --

MR. SKLARCZYK: No. Not on an annual basis. It's being used as a, I hate to say rescue treatments. It's as an as needed basis by the industry.

DR. SAMPLE: And then related to that was, do you have any suggestions why, is it the infrequent application that is resulting in why you wouldn't be seeing resistance developing for carbofuran too?

MR. SKLARCZYK: I'm sorry. I didn't understand.

DR. SAMPLE: Why wouldn't we also be concerned about resistance to carbofuran?

MR. SKLARCZYK: If it's used in combination and used infrequently, what will happen is the insect -- at least this is my theory -- the insect will build it's potential for protection and shift over to a different area. So consequently if carbofuran was

used frequently, the resistance would build up. By it's infrequent use, the insect then puts all of it's energy all it's defenses protecting against a different mode of action.

DR. HEERINGA: Thank you very much, Mr. Sklarczyk. At this point in time I'd like to call our next public commentor who is Mr. Michael Horrall, who is a farmer and also president of Melon Acres, Incorporated. I believe there is also a handout before the panel members that was distributed yesterday as to Horrall's presentation.

DR. MATTEN: If you could, could you just move all of those presentations. I saw that you had six or five, just move them all to the desktop.

DR. HEERINGA: Good morning, Mr. Horrall.

MR. HORRALL: Good morning. I'd like to thank you for this opportunity to be able to address the Scientific Advisory Panel. My name is Michael Horrall. I'm from a small town in Indiana. We're a melon farm called Melon Acres. We've been a family-owned and operated produce farm since 1976. I'm past president of the Southwestern Indiana Melon Growers Association, a current board member of the National Watermelon Promotion Board, and also an officer on the

Indiana Vegetable Growers Association Executive Board.

Indiana melon growers fill a special niche in the melon industry. Our market is mainly July through September, and we ship mainly in the Midwestern area all the way from Nebraska to Maryland, Minnesota to Florida, and most places in between. Indiana in 2006 was fifth in cantaloupe and sixth in watermelon production in the nation. This brings us to Furadan.

Furadan helps us control our risks by controlling mobile pests and allowing us to take advantage of some profitable early markets. Furadan is effective in helping us control nematodes, which are the microscopic worms that live in the soil and feed on plant roots. Often nematodes are not discovered in the field until the plants are suffering from their feeding on the roots. In 2006 we had a field that was infested with nematode and would have cost us approximately $8000 if we had not had Furadan to use. Also Furadan helps us in controlling wireworms.

Wireworms also live in the soil. In the absence of Furadan, wireworms have killed up to 50% of transplants. Several years ago before we started using Furadan, we had a field that had 50% transplants killed by wireworms; that's something that you remember and let it only happen once to you.

Furadan also helps us control seed corn maggots, which the flies fly into the area and lay an egg by the plant, and then a larvae grows and feeds on your small plant. If seed corn maggots and wireworms kill the seedlings in the field, then you'd have to walk individually down each row and plant them by hand instead of mechanically, and that would cost you about 10 times the expense as doing it mechanically.

You also have to wait for some time to pass to see what plants have died before you can do this process. If we didn't have Furadan to help control these pests, our estimate on financial loss would be somewhere around $95,000 on our farm.

The main thing that Furadan helps us in is controlling cucumber beetles, both striped and spotted. The cucumber beetle is a vector for bacteria wilt, and bacteria wilt is a plant disease for which there is no remedy.

If cantaloupe plant becomes infected, it wilts until it dies. Then you don't get to pick any fruit off that plant. In that top picture you see a striped cucumber beetle feeding on a plant. So Furadan prevents the early infestation of cucumber beetles while the plants are small, and that's a picture of a cantaloupe plant that is suffering from bacteria wilt.

What happens is those cucumber beetles, they feed on the plant when it's small, and it may be three or four weeks or even longer before the plant shows signs of the bacteria will; so you cannot replace the plant. Time passes and it's too late.

So on our farm, roughly, if we do not have Furadan to use, we would have $44,000 in loss. Also to take advantage of early markets we use tunnels over the seedlings that helps protect from the cold weather and promote early growth so we can get early markets. Whenever you cover the plants with the plastic you cannot use other types of insecticides and spray the plant and protect it from cucumber beetles.

There's no way to get an insecticide there. So Furadan is applied underneath the plastic prior to transplanting, and you leave the hoops on until the plants have made it through the cold weather. If we didn't have the Furadan underneath the plastic to help protect from the cucumber beetle, we would not be able to do this, so we would lose the early market. The estimated financial loss from not being able to capture the early market on all of our crops on our farm would be roughly $500,000.

Also the presence of Furadan in the soil has another value to us. It saves the cost of other

insecticide sprays, at least one application of some other kind of insecticide like Asada or Pounce, and you save that cost also.

So at least one insecticide spray would save you $6600. In the 2006 growing season the Furadan did a good enough job protecting against the cucumber beetles that we did not have to use any foliar insecticide sprays.

So in conclusion, our financial loss would be substantial if we did not have Furadan. We use Furadan as a pre-plant soil incorporated pesticide. It's an environmentally safe and economical choice for our growers. Currently we know of no other alternative to replace it with. Melon Acres strongly favors maintaining the availability of Furadan to protect your triggers. Thank you.

DR. HEERINGA: Thank you very much, Mr. Horrall. Any questions? Yes, Dr. Montgomery.

DR. MONTGOMERY: I just have a quick question for you. On your very last slide you said you have no viable alternatives, are there no registered uses on any product labels anywhere that you can use to help you with this?

MR. HORRALL: No systemically like it performs underneath the plastic and that also Furadan

does several pests, nematodes, wireworms, and cucumber beetles. We don't know of anything that would take the place of that. You might get by with maybe two or three different ones, and you have foliar apply most of them; but nothing to put in the ground to do the same thing. We used to rely some on methylbromide as a soil fumigant.

DR. MONTGOMERY: Mm-hmm.

MR. HORRALL: But it's being phased out.

DR. MONTGOMERY: Right.

MR. HORRALL: So we've tried to find other alternatives. I don't know of any. I asked Dr. Rick Bosit from Purdue University before I came if there was any, and he didn't know of any other good alternative.

DR. MONTGOMERY: Okay. Thank you.

DR. HEERINGA: Thank you very much, Mr. Horrall.

MR. HORRALL: Thank you.

DR. HEERINGA: At this point I'd like to check again if Dr. Diana Post is in the audience, Dr. Post? I'd like to invite up then our next listed public speaker, which is Mr. Brian Bresnahan, who is a crop consultant with Servi-Tech, Incorporated.

MR. BRESNAHAN: I would like to thank

the members of the panel. I appreciate your time, and I'm sure your back is as sore as mine after sitting through so many of the questions and sessions here. I'm a crop consultant in Benedict, Nebraska, which is kind of in the middle of the state. I've been a crop consultant for six years.

I was a seed company agronomist as well for seven years, so I've been walking corn fields for pretty much the last 13 years, except for a trip to Iraq for a while but that's a whole other study. Anyway, I'm a certified crop advisor and a certified pesticide applicator as well and working on my master's degree there at the University of Nebraska in plant protection.

As part of the program that I provide for my customers, I do scout for corn root worm. It's one of our major pests there in the state of Nebraska, and we scout that on all of our corn acres. Some of those acres are continuous corn year, after year, after year. Some of them are just second year corn and even first year corn acres.

In doing so as part of our corn management program, we use all the integrated pest management principals that are available to us. Primarily we use seed-applied insecticides, at-planting insecticides,

which actually go in the furrow and even the biotech events that are available from Monsanto and from Dow Corporation, the YieldGard and the Herculex events to be able to control the root worm in our fields.

We start scouting for corn root worm roughly when the corn is knee high, B7 in corn language is when that would take place, and we have to scout for corn root worm even though we've used an at-plant insecticide or even one of the biotech events because what we see is those other measures sometimes fail. Corn root worm insecticides have a history of failing in many areas of Nebraska. We've actually even seen that now with some of the biotech events as well. So it's still incumbent upon us as part of the program to scout those fields, even though we've used some sort of control measure.

This year was pretty much like other years where our seed-applied insecticides, those things that actually are applied to the seed by the seed company and come in the bag on the seed and are supposed to be translocated through the plant and into the soil for control of the root worm, they tended to give us poor control again this year, actually failed in some cases, and we had to take some rescue actions at that point. Our at-plant insecticides, those things actually get

applied in the furrow by the corn planter itself.

They did all right this year, but we have seen those fail in the past. The Biotech events do well for us, but we have seen failings by those in the past; and we did see some feeding upon those events this year.

You got to listen to Chance McLean earlier, and this is actually pictures from his field, a close up of one of his pictures. And he had a seed-applied insecticide, so one of those that's actually applied to the seed in the bag that comes from the seed company, and in scouting that field, when we got to that knee-high stage, just a little bit above. And digging the roots is how you scout for corn root worm, so it's always fun carrying a shovel around the field with me.

Reminds me of my good old Marine Corps days. In his field we had at least eight root worm larvae per plant that we were finding; 12 were not uncommon in that field, and that's a lot considering the threshold for treatment is six root worm larvae per plant that you can actually find once you knock the soil off the roots, and sift though the soil and dig through the root mass. And you can see from those pictures what we're talking about for damage.

Those black bands you see in that picture,

those are actually where the roots are supposed to be, but that's where the root worm had gone and eaten the roots off of the corn plants. And so we've got different sorts of rots and diseases starting to infest those corn plants as well as the lack of roots all effect the plants ability to produce an ear.

So as chance talked about, we went ahead and had carbofuran applied to that field. We did leave a check strip. I like to do that anyway whether I'm using Furadan in a field or other pesticides where we can. It always gives us some sense of how those insecticides are performing, and if we're making the right calls, if the thresholds are meeting our needs out there.

And we did see that 45 bushel increase where we treated versus the untreated check, and that turned out to be about $25,000; and as a first year farmer, that's a pretty hard pill to swallow. It would have been difficult for any of my customers. Some of them are very large farmers, thousands and thousands if acres.

It's hard for them. It would have been especially hard for a young guy like that farming a relatively small number of acres. So there is a pretty big financial impact that Furadan brings to us out

there.

I wanted to address real quickly the Biotech events that are coming, the impact that, that might have a couple of reasons, both on it's possible substitution as Furadan or at least the way it gets talked about as well as resistance management, which is one of the reasons why we sometimes turn to Furadan because we see those root worm populations that do become resistant.

The Monsanto gene, the YieldGard root worm gene, we've seen that fail in cases, and I just came from the Independent Crop Consultants Meeting in Seattle here a couple weeks ago.

In visiting with others that are managing corn acres, what they're doing is using those Biotech events as well as insecticide at planting time because they've got root worm that are being able to come through both of those things and that's their best option is to basically double up their control measures to try to keep the root worm at bay. The other event that's out there, the Herculex root worm event.

It works well but what we see is substantial yield impact to the corn plants themselves. So there's some hesitancy by us to use those things. And where the seed companies are planning to stack those genes

together, we still have those negative impacts of both that we would have to deal with here in the future.

One of the things we have trouble with, especially in our western corn root worm species is that they have shown a tremendous ability to become cross-resistant to multiple insecticides, multiple modes of action, as well as shown behavioral changes to produce what we would call resistance within the species, whether that is by extended hatches so they avoid the insecticide or by the extended by diapause where they delayed the hatching of the eggs for a full year. It takes two years instead of one, so they hatch in a corn crop what would normally be a bean crop.

We've seen all those sorts of things happen in our, in our root worm populations, and as I see it's reasonable then to expect that we would see the same with the Biotech traits. Again, we've already seen where the YieldGard Monsanto gene has failed us in some cases, and we've had to come back and rescue those fields, especially in our western corn root worm species, which seems to be the trouble across much of the corn belt.

In that light if we have to look at not only needing to rescue our at plant insecticides, our other control measures, as well as these biotech events, our

only tool that we have to do that is Furadan, is carbofuran, and we use that again in that IPM role; that's the way we use it is just that rescue treatment because we really have no other options. It's the only one we have out there.

Lorsban, Dr. Montgomery, you'd asked if there were other options. Lorsban is actually labeled on irrigated fields, but from experience, it does not work and so we do not recommend it in those cases. It's kind of pointless to even have the label for it for that option because it just simply doesn't work for us. And so we only use Furadan in that scenario, and that's the only time we use it. Again, following those rules of integrated pest management, we're very judicious in our use of Furadan as we are with all our other insecticides.

We only use them if we have to for all the right reasons. For me, I've only had to use Furadan twice in the last three years. In that scenario I expect that I would probably have to do that more in the future as we see what is happening with ethanol production on more corn acres and thus more increased root worm pressure from year to year. And so we would have to have that.

I sat through Tuesday's session when we were

talking about dead birds, and there's been a lot of talk about it today. And I actually added this in Tuesday night and felt compelled to address that. In walking all those miles, 10 to 15 miles a day I walk through corn fields. In walking all those miles behind those Furadan fields every week, week in and week out, I've not seen any dead birds.

I've found muddy old golf balls, rusty horse shoes, and even a meth lab one time, but I've never come across any dead birds out there, so I thought it relevant to the panel that you should know that.

If we wouldn't have had Furadan in those cases where we have to come in and rescue, especially in Chance this year and those we've had in the past, the best we can really do is to try to water; if we've got an irrigated field, is to over water to try to stimulate some root growth and try to compensate for the lack of roots by having an over abundance of water, and we would have had to basically pray a lot, would have been our two options; and both of those have their limitations when it comes to the real world of corn production.

I'd be happy to answer any questions that you might have at this time.

DR. HEERINGA: Thank you very much, Mr.

Bresnahan.

MR. BRESNAHAN: Thank you.

DR. HEERINGA: Questions? Yes, Dr. McCarty.

DR. MCCARTY: So if I'm not mistaken Benedict is in the northern part of the Green Water Basin --

MR. BRESNAHAN: It is.

DR. MCCARTY: -- Region of Nebraska, which is one of the most important landscapes for birds in North America.

MR. BRESNAHAN: Yes.

DR. MCCARTY: Thousands of small wetlands embedded right in the middle of corn fields.

MR. BRESNAHAN: yes.

DR. MCCARTY: When applying Furadan what procedures -- how do you deal with the existence of these wetlands, especially like the sheet water wetlands that may have corn planted in them until you get a good inch and a half of rain and then suddenly it's standing walking?

MR. BRESNAHAN: Always an interesting aspect of things. I actually live just two miles from one of those basins and spend quite a bit of time there, so I have a great respect and love for those

basins myself. I'm a natural resources background actually.

DR. MCCARTY: Mm-hmm.

MR. BRESNAHAN: One of the things that we try to do when we make our recommendations is to the producer, the farmer, the guy who actually ends up calling the pilot, is to say remember you have this water feature to consider, and we need to stay away from that water feature. And then it becomes incumbent upon the areal applicators.

All of ours getting applied aerially to avoid those areas is how we do that. One of the things that we have trouble with is because of wetland, we don't often have pivots on those fields, and I only recommend Furadan where we have a pivot irrigated field because we have to be able to water the Furadan into the soil; 90% of the corn root mass lies in the top six inches of the soil, and so we have to move it into the soil.

The systemic activity is not enough to control the root worm in the root system, so we water it in. But I don't normally end up recommending on those fields where the basins are because those don't normally have pivots on them because of the irregular shape. You know, most of them are set up on a quarter

section of land, a big square with a pivot running around, and so I don't run into that; but if we have another water feature in the area, even a reuse pit that picks up tail water --

DR. MCCARTY: Mm-hmm.

MR. BRESNAHAN: -- one of the things we do is make that recommendation to stay clear of that and then have that passed along to the aerial applicator who puts it on.

DR. MCCARTY: And can I continue just brief? What's the time span in the summer when you're doing this? You mentioned knee-high; that's mid June. What's the latest?

MR. BRESNAHAN: We would not go probably past thigh-high corn, which would be about that V9, V10 range, one, because we see a lack of effectiveness at that point and, two, the root worm have already done so much damage it becomes pointless. It would be a revenge treatment, and we don't do that, again, for all the right reasons because it would be pointless at that time. It would be wasting the guy's money, and you'd be putting insecticide out there inappropriately.

DR. MCCARTY: And then the guys that are starting to do it at planting now, are they using carbofuran? In other words, they've given up on the

GM?

MR. BRESNAHAN: No.

DR. MCCARTY: Are they using carbofuran in planting?

MR. BRESNAHAN: No. We only use carbofuran in that rescue scenario that I described where we apply it aerially after we get that knee-high to thigh-high corn. At planting time we're using things like bifenthrin and petralophyra in the furrow, Force, which is a granular product in the furrow, and we're using those sorts of things primarily as our control. We don't use carbofuran at planting time.

DR. HEERINGA: Several quick questions from Dr. Lu and Dr. MacDonald.

DR. LU: It might not be a fair question for you, but I just want to get your comments. You are the third of fourth farmer that come to the panel and try to convince that carbofuran is the last weapon.

MR. BRESNAHAN: Mm-hmm.

DR. LU: Last line of defense. But yesterday the FMC stated that the usage of carbofuran actually decreased dramatically from 1995 until today, so I'm getting some sort of conflict pictures in terms of, yeah, this is very important but actually we don't use a lot. So can you comment on this?

MR. BRESNAHAN: I can't comment on the whole Furadan market. I have no concept of that. I can comment on what I know about corn production in Nebraska and corn production across the Great Plains that I got to see quite a bit of when I was working for a seed company. I was an agronomist and traveled from the Dakotas down to the panhandle of Texas. My wife didn't like that very much.

As far as it pertains to why we don't use it that much, one of the things that happened in Nebraska is we were very much a continuous corn state up until I'd say the late 90s where it was just corn, after corn, after corn, and we had tremendous root worm problems; and that's where we developed all these different resistance to all these other insecticides; and that's where carbofuran became our rescue treatment when those failed. We ended up after the fact realizing we had a resistant population.

What happened then is the soybean market kind of made soybeans more attractive, and so more and more soybean acres were being planted, which gave us the rotation so we could put corn behind soybean acres instead of continuous corn where you don't have extended diapause of root worm.

Then your soybean acres become your root worm

control measures. So corn planted on soybean acres in our part of the world, you don't have root worm as a concern, and so all the insecticide uses would have dropped dramatically for us as well as what I saw in other parts of the Great Plains because we just have pure corn acres. We had purse scenarios where we had corn root worm.

DR. HEERINGA: Dr. MacDonald quickly.

DR. MACDONALD: Well this question comes from a city person, but in your opinion is this style of farming based on irrigation and pesticides going to be sustainable over many decades?

MR. BRESNAHAN: Unfortunately it has to be because we have to figure out how to feed the world, and there are some really neat biotech events coming from all these companies that are going to dramatically increase yield and better utilize nitrogen and utilize less water within a corn plant to produce the same amount or more yield.

So there's some really neat things coming that biotechnology is going to help us with, but what we see is a pest, whether it's an insect pest or a fungus, a disease, that continue to find ways to get around whatever we throw at them, whether it's a biotechnology event or a pesticide. And so in that

regard, yes, this is going to be the way we grow it whether it's in Nebraska or back east in Illinois and Iowa.

DR. HEERINGA: Bring this to a close. We have a number of additional public commentors, and in case we haven't noticed we have about nine charge questions to address much later.

MR. BRESNAHAN: Okay. Thank you.

DR. HEERINGA: I want to thank you very much, Mr. Bresnahan

MR. BRESNAHAN: You're welcome. Thank you.

DR. HEERINGA: -- for your presentation. I think panelist if you have specific questions, you could probably speak to Mr. Bresnahan over the break or the lunch and report back if it's obviously relevant to the proceedings. So at this point in time I'd like to call a short break. We have a few additional public comments, but I think just so that everybody stays sharp and clear, let's call a 10-minute break; and let's come back here at 25 minutes of 11:00.

(WHEREUPON, a break was taken.)

DR. HEERINGA: Okay. Let's get back underway, please. I'd like to ask before we continue if Dr. Diana Post is in the audience or present, Dr.

Diana Post? Welcome back everybody to the second half of our third morning meeting of the FIFRA Science Advisory Panel. We are in the period of public comment, and at this point in time I'd like to invite to the speaker's chair Mr. Scott Schertz, who is an aerial applicator, retailer, and farmer of Schertz Aerial Services, Incorporated.

MR. SCHERTZ: Okay. Thank you. As he said, I am an aerial applicator, and retailer in central Illinois near Bloomington, Illinois. And just as a bit of introduction, I have been an aerial applicator and pilot for over 20 years.

I have shared in various leadership positions in our industry. Currently I'm the president of NARUF, which our main duty is administrating and operating our stewardship program which is called Pass. And I know a detail of that is beyond the scope of this, but the main emphasis of it is safety, and stewardship, and security; and it is a nationwide program that has been in effect for 10 years, and we have seen a benefit as far as reduced accidents and drift claims from that time.

Okay. And one of the other things that I will say. It is probably unique in this room or relatively unique, I have actually handled a fair

amount of product over the last 20 plus years and applied it, and I think the expertise, I'll try to keep it primarily to the handling and the application constraints. First of all, Furidan is actually packaged in a very good manner to reduce handling exposure.

The dry break fittings are actually ones that work, that are good. As you'll see in the next slide, they can be set up to rinse the products from lines and fittings. It does make for a very clean and efficient to dispense, handle this product, and also it does allow for a completely closed system. We typically use another dry break on the bottom of the airplane to load it through. It's a different model, different manufacturer, but it's basically along the line of the Micromatic that you saw yesterday. But it does allow for clean closed systems all the way through the airplane.

Typically we do not open the hopper during the loading process, so it is a good well thought out system. And this picture shows the Micromatic fitting that FMC did demonstrate yesterday actually on one of the U-turns where the arrow is of the fitting. And then this is actually one that I have set up to use where the black fitting on the top is where we actually

draw out of, and then the fitting on the right allows us to rinse through and then also prime. And this is a comment that may seem elementary, but it is very useful on exposure reduction to have it prime, and get the air out of the lines, and clean them out. I mean, this may seem a little too practical, but as far as the effective exposure, mitigation measure, it is very helpful.

Also something called smokers are very common in ag aircraft, once again 72% in the industry survey. It's probably higher now, but this is very important. It does tell the pilot much more about how the spray is moving, where you need to leave off to protect drift concerns, and even from an occupational exposure standpoint from the pilot is very useful in that you can avoid flying back through it.

Anyway, both of these are tools that are effectively and actively used to ensure proper placement. And then this is something you probably won't see very often, but this is actually what it looks like out of one side of the cockpit when I do release smoke. Basically what it does is it pumps oil into the exhaust. And then if you notice at the top left there is some gray, and that is next to my landing strip in McLean County.

And then this next one is coming back around the turn from the opposite direction, and those arrows show how the smoke is moved. And this allows a pilot to not only tell what direction it is moving but also the vertical disbursement of it, and it does tell a pilot much more about what is going on out there then just speed and direction. Okay.

And then also this is a pilot's view of the GPS. If you notice the red arrow, down there in the center of the cockpit there is basically a TV screen on this particular model that shows where I've been. One of the concerns I've picked up over the last couple days of discussion is whether or not we can apply it evening, and this is a very effective tool to position the airplane properly.

The current system that I have actually updates the position 20 times a second down to about a meter accuracy. So it is a very, very useful tool. We can also use this for positioning, findings fields, etc, although the main use is guidance as far as pass spacing. Okay.

Now I understand that the farmers and consultants have really talked about this in depth, but it is a unique product. I am in the middle of the corn belt. There are several million acres of corn in my

trade area, and this is not a big product; but it is something that is occasionally needed.

And also one of the things that has concerned me in the conversations over the last two days is that there's been a lot of discussion over the avian risk of carbofuran, and then there's been a discussion of the past history of avian risk on corn. Now we do need to take that as we look forward to the potential remaining uses to consider that subset of the prior corn applications, and with the limitation to a rootworm larvae control rescue type label, you really do need to consider that there are considerably fewer birds present at that time. I mean, a couple weeks later when you get into the reproductive stage of the corn, it is a different plan.

You have a lot of insect pest out of it, out there. The birds are coming to eat on that, and particularly when you get late in the season into the grain fill time for corn, there are certain birds that will come back to feed on the corn. And when this risk assessment is done for avian risk, I do think it is a fair point to bring up that the remaining proposed use is actually a small subset of the prior use on corn. And also there really is a continuing need. We are seeing where the sheet and metal type solutions to

rootworm control is not always adequate.

But anyway, I do believe that carbofuran and Furidan is what I'm used to referring to it as, it is an important product. It can be put on safely. It is packaged in a manner that that is very responsible for reducing exposure, and as a professional applicator to put it on in a safe manner. And I do appreciate your interest in this chance to be in front of you.

DR. HEERINGA: Thank you very much, Mr. Schertz.

MR. SCHERTZ: Are there any questions?

DR. HEERINGA: Questions from the panel? Dr. Montgomery. Okay. Dr. Portier.

DR. PORTIER: I wanted to ask this question on the last one, but he wouldn't allow me; so I'm going to ask you this questions. There's a lot of pressure right now for additional corn acreage in the states for ethanol production, and I suspect that's going to product more corn on corn in the midwest. Do you see, have you seen in the last few years more of this request on acreage, same acreage flying multiple years, rescuing it every year? I'm just trying to wonder if, because of this production, you're going to be without the soybean interplanting, whether rescue becomes the norm rather than rescue?

MR. SCHERTZ: Well, I mean, it is hard to predict what will happen. I can tell you what has happened the last several years with the increased percentage of corn on corn. This has been a very small market. I mean, actually I have sprayed more Furidan on alfalfa and soybeans than I have on corn as far as the foliar application in the recent years.

So, I mean, I think this will remain a niche market because one of the things that hasn't really been brought out to my knowledge here is that it really does take a active scouting program to find the need for this because once you can see it from a pickup truck it's too late. Okay. I mean, the revenge is not a good practice. So it does take a very proactive scouting system to even find out about this need, and many farmers are still up to the point that they think that the GMOs are a solution instead of a tool.

DR. HEERINGA: Thank you very much, Mr. Schertz. At this point I'd like to invite up Mr. Gary Edwards who is also identified as a farmer but also representing the Iowa Corn Growers Association, president elected of the association.

MR. EDWARDS: Good morning Mr. Chairman and panel members, I appreciate you giving me five minutes to speak to you here, and you should have a

handout of my verbal comments with the Iowa Corn Grower logo on it.

DR. HEERINGA: We do.

MR. EDWARDS: Okay. As I said, my name is Gary Edwards. I farm 20 miles northeast of Cedar Rapids, Iowa. Today I'm speaking as a representative of all the corn farmers around the nation and particularly of Iowa. As stated, I'm the president-elect for the Iowa Corn Growers Association, and I've been on the conservation and environmental committees of both the Iowa Corn and the National Corn Growers Association for the past number of years.

I would like to take my time here to expand a little bit on FMC's opening statement that Furidan is only going to be labeled as a rescue treatment for corn rootworm.

The corn growers would like to thank FMC for that label. We feel that's a very important label. Some ask why I would come to Washington, D.C. for four days for a five-minute presentation when it's only a rescue treatment, but I want to make sure this panel understands that your decision, what you tell EPA and what EPA does, is essential to the future of corn production in the United States.

I have been involved in the biotech arena

since 1999 when Staley and ADM first sent a chill across the corn belt when they said they were not going to accept any GMO corn for processing. Since that time we've made some great strides in getting biotech accepted with our trading of partners across the world and also in establishing some environmental safeguards here at home.

The Insect Resistant Management, IRM, is a key tool in preserving the genetic modified corn traits. To prevent insect resistance the IRM program requires refuge area of 20% to 50% depending upon what crops are being grown, and the refuge area basically, an area where a treatment is needed by a GMO is not allowed to be planted there.

The results of an annual Insect Resistant Management growers survey from 2006 shows that a vast majority of the growers surveyed are following the refuge requirements. They are aware of the IRM requirements. The seed foreign companies and dealers are their main source for this information, and more than 94% believe that IRM is important. BT corn growers receive an average of three to four pieces of IRM during the year, and more than 92% of all growers say they have sufficient information.

This shows that the IRM program is working.

This Insect Resistant Management program requires the non-GMO refuge has become the cornerstone program used by farmers to prevent insect resistance to BT corn. You've already heard from two public speakers that say that they are findings some problems with resistance already, and so the IRM program becomes more valuable every year.

The new corn rootworm refuge requirements are complex, and they require, they raise a number of questions to the farmer that he doesn't have answers to, one being it requires refuge to be used on like acres. Now what are like acres?

Is it first year corn has to have first year refuge, second year corn, etc, etc, or some combination? And this is important because the rootworm population varies from year to year depending on how long that crops been in corn, so the refuge requirements would change. Many farmers no longer have the equipment necessary to apply a granular insecticide with their planter, and others just plain do not wish to apply a granular with their planter. And they have switched to seed treatments, which have already been discussed and shown that they don't always work either.

So under these circumstances, you know, should a farmer apply a planting time insecticide on

top of the seed, or should they go to an integrated pest management approach, a wait and see, to see if there are actually any insects out there before they apply a herbicide, or insecticide, excuse me? You know, no control method is perfect.

The corn rootworm failures occur each season. The seed treatments with planting time insecticides and even GMO as been stated. With all these uncertainties, it is not uncommon for the farmer to discover that he has some corn acres being damaged by corn rootworm.

Furidan is the only insecticide that can be used as an in-season rescue treatment. Seed treatments, as stated, often are less than effective, as Dr. Marlin Rice from Iowa State University sent a letter to EPA which shows that only an 8% to 21% consistency rate over three years; 8% to 21% leaves a high risk for corn rootworm.

Other farmers have utilized, as I said before, integrated pest management by choosing only to apply the insecticide when the insects reach an economic threshold. In either case, Furidan is the only insecticide available for late post rescue application as stated by Dr. Kevin Stefy from the University of Illinois Extension Service in his letter to the EPA.

The ability to rescue corn that has become infested with corn rootworm through either a lack of insecticide performance or integrated pest manage approach is essential to the refuge program. Without a corn rootworm treatment available, farmers will feel that the risk of a damaging infestation is too great and will consider eliminating the non-GMO refuge entirely, replacing it with BT corn contrary to the IRM requirements, and this practice will only hasten the resistance of corn rootworm and make the GMOs ineffective. So the risk of reducing refuge, refuge takers and increased resistance insect numbers becomes more acute each year as the corn demand and the price goes up.

I mention that I'm from Cedar Rapids, Iowa, because within a year or two Cedar Rapids will be processing nearly one million bushels of corn a day; that is four and a half to five million dollars a day in commodity corn. This is no longer a ma and pa trying to scrape out a living on $300 an acre gross income. This is big business with the gross returns approaching nearly $1000 an acre.

As the demand for corn continues to climb, industries and the farmer will look for ways to ensure that the farmer can maximize yield and profits.

Without a rescue treatment for corn rootworm, infested refuge, refuge acres are in danger of extinction. This is your challenge.

You must weigh any use risks against the environmental consequences of losing a product important to growers and Insect Resistant Management programs. Whatever you recommend for Furidan through your registration, you are also recommending for IRM. Rest assured the end users and the biotech industries are anxiously awaiting your findings. Thank you.

DR. HEERINGA: Thank you, Mr. Edwards. Comments or questions of clarification from the panel? Thank you very much. At this point in time I'd like to invite up Mr. Douglas Hanks. Douglas Hanks is also a farmer. Mr. Hanks has written comments and summary materials too that have been distributed to the panel to be available in the docket.

MR. HANKS: I'm Douglas Hanks. Is that better? I'm Douglas Hanks from Saint Anthony, Idaho; that's just north of Idaho Falls at the beginning of the Snake River Plain and the Snake River as it goes down through the potato-producing areas of Idaho, Oregon, and up into Washington.

The potato production follows that main river system. I'm wanting to show that Furidan is used as

either a soil, applied at planting, early post-plant treatment or as foliar treatment. FMC's amended label process retention is in Idaho, Oregon, and Washington. The first attachment is long, so on the fourth page if you go to the first column of acres produced in the nation.

I had them highlighted, but they were printed instead of copied so the highlight isn't there. I'll just tell you briefly that Idaho, Oregon, and Washington's acres in that first column of 2007 production are 48% of the potatoes produced in the United States. In the last column, the 2007 numbers of Idaho, Oregon, and Washington's production are 56% of the national acres produced. So it is an important producing region.

When I first started farming in 1977, we did use TMA Caneldico for the suppression of nematodes, still used mainly in the control of Colorado potato beetle and green peach aphids. Then the pre-harvest interval (PHI) of aldicarb was increased to 150 days, making a hardship on some of central Idaho and all of southeast Idaho where the major Idaho potatoes are grown in that production area because of the short season.

So if a grower wishes to use aldicarb, his

ability to take advantage of early pressure process markets of July and August are lost due to that long PHI. That missed market could be a value from $1.00 a hundredweight to $2.50 a hundredweight, on which I grow 200 acres at 500 hundredweight ranges from $100,000 to $250,000 loss of market.

In the mid 80's we started using vacon and tellum as soil fumigants for nematodes. That conjunction had to apply to pyrethroids and neonicotinoids class insecticides for a foliar sprays, and those, as has been mentioned, are showing resistance more; and so we have to alternate the uses of them. The last four to six years Furidan had real marking in planting in conjunction with Live-A has provided an excellent suppression of nematodes and control of Colorado potato beetles and aphids. When Furidan is used in rotation with fumigants, if the numbers of the soil tests are low enough and not excessive, I can use this combination of Furidan and Live-A for a savings of about $208 an acre. Again, on my 200 acres that is $41,600 savings on inputs, giving me an input cost reduction.

Potatoes are very intensive input use. They're also labor input intensive, and so while Furidan can be used as a foliar and soil-applied

treatment, my experience has been with the pre-plant roll mark out application and is handled in shuttles and pumped into tanks on the tractors of the handouts that you'll see in a minute. It is very little worker exposure, as has been demonstrated yesterday in the container displays and today also.

It is then injected at 6 to 8 inch soil depth and immediately covered up, thereby reducing ecological risk, and that's in attachment three on the pages of attachments. You can see the line of the depth and the sprayer at the point of that attachment. The sprayer has grip-free nozzles reducing potential again for ecological exposure as either the plant or mark out are lifted up and turned around at the end rows.

In summary, one might want to ask the question, is there a replacement for Furidan's pest coverage including insect control of nematode suppression? And my response is, first, only if taming for aldicarb has a 150-day PHI restriction reduced to 120 days.

Second, it is an excellent systemic product for a programmed approach to nematode control, namely rotating alternate ear treatments with the fumigant, and, third, it is a necessary tool for Insect Resistant Management in a foliar insect status treatment program.

So at the end I just want to say too, I had it here with me, a card that I carry in my wallet that I have to be a registered restricted use pesticide applicator, and that comes through going to school to learn how to handle with workers and the products to label uses and applications. So I just wanted to add that briefly at the end. Thank you.

DR. HEERINGA: Thank you very much, Mr. Hanks, for that presentation. Any questions of clarification from Mr. Hanks? Yes, Dr. Montgomery.

DR. MONTGOMERY: I had a quick question for you about, was it temic?

MR. HANKS: Temic, cholic, right.

DR. MONTGOMERY: I assume the level right now is 150 days harvest interval?

MR. HANKS: Yes.

DR. MONTGOMERY: And you're saying that this is the only product that if it had its interval reduced to 120 days would be able to assist you --

MR. HANKS: In that part of Idaho.

DR. MONTGOMERY: -- with the pest pressure?

MR. HANKS: Because of the short growing season.

DR. MONTGOMERY: Okay. Thank you.

DR. HEERINGA: Thank you very much, Mr. Hanks. It's much appreciated. At this point in time I'll put out one last call is Dr. Diana Post in the audience. We have no one else presented to Dr. Matten to register as a public commentor, and, therefore, I would like to bring the period of public to a close and thank everybody for their contributions.

Obviously we have heard and received a tremendous amount of information over the past few days, and the period of public comment has been valuable in that regard as well. So thank you everybody, and, again, my apologies to people who couldn't get back to Cedar Rapids and other places like that. I suspect you would have gone back to a storm anyway, so enjoy the warm weather. It's like springtime.

Okay. At this point in time we're going to shift gears, and I want to be a little clear about how I would propose to manage this too. Those of you who have participated in other science advisory panel processes I have tended to, as we go into the period of discussing the charge questions, to actually promote a considerable amount of communication and additional scientific exchange.

At this point in time we're going to enter a

period when I'll turn back to the EPA who has presented the charge questions to us. I'll run the charge questions including access to the microphone through them. We'll stay systematically on the initial charge questions, and then I'll turn to the panel for any other scientific issues that they will want to address on the specific topics; and we'll divide that in terms of the ecological risk assessment and the health risk assessment.

So at this point in time, I guess, I'd like to call forward the group that will be in effect doing the overview, Dr. Bradbury and Dr. Brady, who will be doing an initial summary on the environmental and avian risk effects, and then we will turn to the first of the charge questions. Dr. Bradbury.

DR. BRADBURY: Thank you, Dr. Heeringa. Just before we get started, and we'll be efficient with time because I know time is tight, just to recap very briefly, as we moved forward with the NOIC there are two processes going on.

One process is to receive a scientific peer review that you all are providing to us in terms of the basis of the ecological risk assessment and the basis of the human health risk assessment that underlines the decision that we made. I, of course, provided charge

questions to you, and as I indicated in my opening comments and Dr. Heeringa described of course, other scientific issues related to our analyses that you may have or the public may have brought up, of course, is our topics. We'll be interested in hearing your deliberations.

At the same time that the scientific peer review is ongoing with the SAP, the USDA is undertaking the benefits analysis and the potential impact of this decision on the agricultural economy. And, again, the process bifurcates the two review processes, while you're focused on the scientific issues, that's where the scope of your charge, the USDA has the charge to provide us feedback on benefits and just to clarify some of those distinctions.

Then again the last comment which creates sort of a difference to the SAPs were all used to is that we're dealing with a decision that we have to make based on our statutes, and timeframes, and our statutes.

So other topics we're usually talking about an evolving issue where there is time to think about additional data, additional studies, additional model development to help with an evolving issue. In this case we need to get your advice on what is available

today in terms of information, what's available today in terms of accepted scientific methods and your thoughts on the certainties, and the strengths, and limitations of that data and methods may have, of course, is very important to our decision-making.

So with that as very brief opening comments, I'd like to turn it over to Dr. Odenkirchen to give a brief synopsis of the issues underlying the ecological charge questions and then, or course, turn it back to the panel.

DR. ODENKIRCHEN: Well good morning. I was told I have 30 minutes. I ate my chocolate donut, got my sugar rush, and if it's possible I can actually go faster than I did the other day. Well I learned a lot over the course of the last couple days, and I'm sure all of you have had a lot of information thrown at you.

There were a number of issues over the course of that where you had questions and some of those are, in fact all of those questions are very material to the charge questions, and so I thought it was appropriate to sort of tie up some loose ends with regard to some those questions. I don't think we've had a lot of time to answer some, and indeed some of them we promised to get back to you on them.

Remember our charge topics, they center around a number of different issues. The effects of model version on what the predictions of the models are. The impact of new data as it's incorporated into those models and how that changes the conclusions, how incidents in field studies inform where our models are and both deterministic and probabilistic and whether or not that information can inform us on how to re-parameterize models, and then the overall conclusions on the weight of the evidence of three different lines that we have, which are the deterministic assessment, the probabilistic assessments, and the field studies, monitoring studies, and incident information.

Let's talk a little bit about model versions. There was a statement made yesterday, I believe, with regards to TIM 2.1 availability. It was stated that it isn't available to the public right now, and that is a very fair statement. The reason why it's not available right now is we're presenting working on a report, summarizing the sensitivity analysis of the model, and we're finishing up a user's manual.

We don't want to throw it out to everybody without everybody knowing how it runs, and what it's sensitive to, and how to break it. TIM 2.0, however, has been available to the public for over three years.

If you recall back in 2004 it was released to the public. It is currently and has been for these many years resident on two separate places within EPA's website. You can go there today.

I pulled it down this morning and loaded it up on a machine that's not limited by my computer police here at EPA and was able to run it instantaneously. The important take-home message, though, with regard to that is there are no functional differences between TIM 2.0 and TIM 2.1 that are relative to comparison without the TIM 1.0.

Well to be sure, why would we have a version 2.1 if there weren't some changes. So what really did change between version 2.0 and 2.1? There were some slight changes to the polo algorithm. We had an introduction of a routine that allowed for variable volumes into the puddle as recommended by the SAP in '04. There was the addition of the ability to assess multiple applications.

You will recall from yesterday's presentations with regard to liquid param is the ability to assess multiple applications. Well under 2.1 we can do that. We haven't done that for the purposes of our comparisons here because our previous models could not do that. We felt that would be sort

of piling on in terms of the risk comparisons.

Neither of these differences really effect the dietary risk predictions for a single application, especially for a single application as it was run under the assumptions and under the data sets associated with how we ran 1.0 for the carbofuran risk assessment. So I just wanted to make sure that everybody kind of understood where 2.1 lies in the evolution of the model.

One of the things that came up repeatedly over the last couple days is the concept as we move from two time steps to a bimodal feeding pattern with regard to version 2.0, 2.1 of TIM. Back in 2001 when we brought 1.0 to the SAP, they recommended that we consider a bimodal feeding pattern, two peaks in the food consumption, one after sunrise and a second before sunset; and there would be a lull in the feeding in the early afternoon due to part because of high midday temperatures. Mad dogs and dixocells don't go out in the midday sun, I guess.

The other question was with regard to this bimodal feeding pattern, how it relates to gorging. Now gorging, if you go back to the Ecofriend document, it's not quoted her, but the Ecofriend document, which proceeds all of our efforts and probabilistic risk

assessment gives us some indications that gorging is usually the punctuated consumption of food often exceeding the food requirements for a given day.

So you're actually really feeding up. You're loading up for birds with the crop. You're loading up on a lot of food in your crop for passive reforms that may not be the case because we don't have a large crop, but they do feed rather intently for a very, very short period of time.

And I think you had comments earlier this morning with regards to some past reforms as they crossed the gulf or the Caribbean and come to the United States, and as they migrate through, that really they are under energy stress as a result of migration and do, in fact, have punctuated ingestion rates when they land on areas of suitable resource. But to be sure, Ecofriend did highlight the fact that in the wild food intact can be highly variable within and among individuals, across age classes, and species. And many of you have pointed out similar observations and conjectures over the course of the last two days.

The SAP in 2004 highlighted the importance of a bimodal feeding pattern and then need to consider other feeding modes as well. And TIM 2.0 and 2.1 can represent a variety of patterns. What you're going to

see here is a representation of what happens in the 2.0, 2.1 model with regards to that bimodal pattern and how it relates to the concept of gorge feeding and the changing in the patterns and how those patterns relate to what the SAP has said in the past would be appropriate things to consider.

First off what you'll see is there are four drafts here. I'll get my little laser pointer here. On the left side is the feeding pattern, and while you have seen depictions of this feeding pattern as examples. I think you should realize that past depictions of this over the course of presentations yesterday did not necessarily come with the caveat that those were hypothetical examples of the output of the model. They were used in the presentations of 2004 and report to 2004 to illustrate how that model in an extreme form could really represent differences in the pattern. And you'll see here, again, you'll see the same kind of pattern, but that's not really the whole story.

The whole story is, number one, how that relates to feeding fractions on a given field, and I think it's very important when you look at these to pay attention to the scale. Remember gorge feeding. You got to eat an awful lot of food in a very, very short

amount of time. Well notice on this pattern that none of the hourly time steps exceeds about 20% of the food ingestion rate on a given day. Now, admittedly, there are two peaks. It goes shortly before sunrise.

In the afternoon there's a peak and it dies back. And in this case, in this model there's actually very little happening in the middle of the day, which in some situations that's fairly representative of what the SAP had recommended. But they said there may be other patterns as well.

The other thing I think is important to look at is the total algorithm also considers whether the bird is on or off the field in a given step and how that manifests out to whether or not that feeding pattern with this on and off the field actually represents are you getting food on the field. So you'll see when you put these all together, that you do get food on the field, but it's not nearly representing the entire pattern, only the situations where the bird is actually present on the field.

There's another pattern as we run. Again you'll see there's two peaks. They look rather heinous here, but as you'll see they don't get very high with actual hourly feeding fractures. On and off the field you'll see, again, that the birds in this case are

really not on the field quite often at all. We'll run another example, and here you'll see that, yes, there is a drop, and there was a criticism with regards to a drop in the feeding pattern.

These are all randomly selected outputs of the model by the way. That there is no feeding in the middle of the day. Well in this case, while it is very low, there is feeding in the middle of the day, and as you can see, this bird did not spend much time in the field at all, except maybe early in the morning and a few times in the afternoon. And, again, that's manifested out to what it's dietary contributions are over the course of the day.

Here's another case where we have some overlap with regards to the pattern. Again, there is very little going down in the middle of the day, but you'll notice that the fractions are very low, in this case just barely above 10% in each case. Doesn't appear to be gorging behavior to me, although I'm sure there are probably other interpretations of that.

And last but not least, here's a situation where we see peaks very close to the beginning of the day and the end of the day, which is largely coming very close to the kinds of patterns that are being represented under liquid param. That's very

interesting. The model is capable of producing those patterns and does when it's sampled through the Monte Carlo sampling technique.

So, bottom line from our interpretation of that is that TIM 2.0, 2.1 is flexible. It's scalable, and it does not confine birds into a locked pattern of behavior across all time steps. Recall back that the Ecofriend recommended that time steps may vary in time, may vary in space, may vary across fields, may vary by individual and species. TIM 2.0, 2.1 can accomplish that.

Also remember that the 2004 SAP recommended that the model be able to, can offer different patterns, not just a simple bimodal pattern and not simply a static pattern but a variety of patterns, and the model does do that.

So when we set foraging behavior parameters, one of the things that the SAP said in 2004 was that adult altricial birds, and I'm not too sure who did this. I'd like to go back to the actual transcripts of the 2004 SAP, but I do know that one of the statements was made was that adult altricial birds that are provisioning nestlings would most likely have a more uniform feeding distribution throughout the day.

Well that's very good, and I don't disagree

with it. I can imagine that birds really divide their time rather eloquently between going out and gather food and rushing back to the nest to give that food to their offspring, making sure the offspring are protected and sheltered, and making sure that predators are identified etcetera. So I'm sure there's a lot of time spend and a lot of foraging time for nesting birds, and, by the way, liquid param, as presented, relies on a nesting bird foraging behavior and is representative of a narrowing defined adult behavior in this case.

The TIM model may be more flexible and, therefore, applicable to other periods of the life cycle or may be carry other reproductive capacities or birds or stages in the reproduction cycle in any given part of the calendar year.

So what haven't we taken into account with regard to each of these models and how we presented those versions? Well we didn't take into account dermal and inhalation exposure and many of you brought that up. We brought that up in our comparisons. We didn't account for drift. We all assumed that exposures only occur within the treated field.

We know that we wouldn't have drift labeling on our pesticide applications levels if drift was not a

concern at some point. And exposure during nesting and sample food items being taken back to the nest, or biological vectoring, or secondary exposures, which was illustrated earlier today by, I think, Michael Fry and some of his presentations.

Those haven't been considered in the models either, so those are things that are worthy of consideration when we begin to talk about evolution of models in the future. I think one of the things we have to realize is you sort got to run for what you brung in this kind of contest.

So talk about running with what we brung and the incorporation of new data as we've made every effort to give new information a fair hearing and incorporate it into our model. What new FMC data did EPA consider in its modeling? Well, it considered the effect of dietary matrix on the bioavailability and subsequent toxicity of carbofuran.

You got to remember though that, that's in two species of birds. I'm not convinced that those two species of birds represent all species. There may be differences in dietary matrix. Dietary matrix may alter that bioavailability and indeed a species may have different matrixes in the course of their feeding. It also may be different in terms of the length of the

allometric canal, residents in that allometric canal.

All those things might have important influences on how portable that data is to others, but in fairness we did use the information just like other models did.

The recovery of the acetylcholinesterase activity with time was done in one species of bird. Is that necessarily the same recovery rate that you would see in every species? I don't know. I would suspect that there's probably some differences. In mammals there may be some type relationships between some species and maybe different in others. I would suspect that may also occur in birds, but the other part of that also is remember that when we looked at acetylcholinesterase activity when we ran the model, we considered both extremes of the outputs of half-life in terms of that analysis, both a short half-life and a long half-life.

Also the potential for reduction in food consumption in one species of bird as a result of toxic anorexia. It's very interesting that term came up in two places yesterday, upstairs while we talked about this data and downstairs here in the SAP, same terminology.

What new FMC data did we not consider? Well

we did not consider the potential for avoidance of carbofuran by one species of bird, and really avoidance is a lot different than just not feeding as much. Avoidance is we're going to try to select not to eat it at all if at all possible. The bird makes a choice. It doesn't like that.

It's not going to eat it versus I'm too sick to eat. Well why did we not consider that? Well the available study methodology could not differentiate the effects of behavioral biases not pesticide related from the effects potentially attributable to carbofuran. That was our position. I believe there was a number of questions with regards to that. FMC has asserted that there is no bias. Well that was one of the big issues.

Is there a bias from side to side with the birds? They asserted there is no bias to feed cup side selection in the birds, and the agency believes this is an erroneous conclusion.

Now I won't go through too far on this, but we looked at every single bird for six time steps in that data. Somebody asked us to look at that, I believe, on the first day. We talked about that. I believe, Dr. Montgomery, you did. So we looked at every single one, and we looked at whether or not there was a feeder selection bias as related to the intensity

of feeding, the amount of food ingested from one cup, left side or right side, regardless of whether the chemical was presented. And what did we find?

The number of birds that six out of six times selected one side in preference to the other, 15 birds on the left, 15 birds on the right for a total of 43% of the birds that are very obvious and super strong preference for one side or the other. A very strong, in terms of five out of six, again another 27% of the birds and a somewhat strong four out of six, which I'm going to leave out of the rest of the analysis, another 14% of the birds.

So we finally came to the conclusion was that 70% of the birds demonstrated a strong preference in the side of the cage where they fed, and it was not related to chemical presence or to dosage level. Something going on there, and it's not entirely related to the presence or absence of carbofuran in the diet.

Well what did the study authors say about developing side to side bias? Well indeed they said the test birds developed habits during the acclamation period that led to favoritism toward one feeder or another, but they did go on to say that at the two highest doses there might be enough repellency to influence these habits. I don't know whether they

meant that it would negate those habits, but they did say it would influence those habits. But I have some questions with regard to those two highest dose levels because we had some concerns with regard to the dose calculations in general.

What did all the evaluations use from this avoidance study? Well we all developed a regression that related food ingestion rate to carbofuran exposure, and we all came to the agreement, and I'm sure a lot of you did too, that it had lots of scatter. Had very poor goodness of fit pretty much no matter what shape of that regression you put to that, and the agency considered this data to explore the possibilities of what that food ingestion reduction might mean.

But I think it's important to realize that, you know, if you took a linear regression and took it to illogical extremes, one would consider that the really, really super high doses of carbofuran would somehow be protective. And we know from the standpoint of actually baiting birds that, that doesn't happen. Birds do eat it, even at very high doses. So the regressions at the extremes begin to be called into question I think.

So should we be confident in food ingestion

reduction rates from the avoidance study? Well the first question I would have is, is there a problem with feeding during the study that's not related to the chemical? FMC has said that reductions in feeding after the acclamation period are attributable to human factors, in this case the presence of observational period changes, more people, more activity.

The birds are more stressed. They're not eating as much. So we went back and looked at that data. I'm just looking at the controls here so we can eliminate any of the effects of the chemical, and indeed it looks like reduced feeding without the chemical influencing the effect is real. Okay. But as you can see in both males and females, there is a marked reduction, but I think what's very interesting is, is that it also occurs twice in this study; and I'm not quite sure why that is, and I haven't had an explanation with regards to that.

And what that leads me to wonder is, are there other influences? There may have been some conjecture this morning with regards to that. I'm not quite sure why that's happening, but it does make me ask, does this affect, leave me to have high confidence in the numbers?

So the other thing that we notice also in

these is we have a question of, does food ingestion reduction seem to abate over the course of the study? And indeed it seems, the food ingestion does go up as you can see here, but what is very interesting that we thought was also that there appears to be an overcompensation of feeding above the preexposure level. And there is a number of explanations for why that might happen.

There might be acclamation of the birds to carbofuran intoxication. They get used to being sic, or the reduced body burden in the compound as a result of anorexia is somehow protective; or finally that the energy requirements overwhelm anorexic responses. I'm not quite sure which one that is. I do know that it is actually in the data set 'cause I can see it. There is an effect happening, and as FMC is indicated, perhaps it is better to use data than ignore it.

So was feeding rating compensation considered? If you look at liquid param feeding rate only was evaluated within the confines of regression, and remember there's lots of scatter, poor fit, and questionable accuracy there.

We're not quite sure whether that's portable across all species, and the agency when it incorporated into its model that feeding rate regression as well as

the potential for entry requirements to overwhelm a toxic anorexic response. The idea being here is birds get so hungry that they just got to eat.

So when we looked at that, what we found was that allowing birds to come, and you saw this in Dr. Salice's presentation, that allowing birds to compensate for reduced feed intake effectively reduces any anorexic effects. So what would happen to liquid param if we removed the impact of what they termed avoidance but really is toxic anorexia? Well what you'll notice here is that for this use of killdeer and to be fair using some insect residue distributions that are more in line with what's in the data that was used in our model.

What you'll definitely see though as a take-home is that removal of the avoidance does cause a marked increased in risk.

So our avoidance study conclusions: Insufficient methodology, ability to separate non-chemical behavior bias from chemical influences. Avoidance may be suggested but is by no means proven here. Toxic anorexia was explores, but there are serious concerns about the accuracy of the actual ingestion reduction numbers, limits the confidence in the values and the risk impacts. And accounting for

observed compensation and dietary ingestion largely cancels out much of the anorexia effect.

So let's go on to those incidents reports and field studies. There are a number of questions there. We spent an awful lot of time on incidents and field studies, lot of field biologists here I would imagine. Incidents involving registered uses of flowable carbofuran using currently registered application rates are not limited to mortality in waterfowl from alfalfa use alone. Indeed, there are a variety of birds effected in a variety of use sites. We can talk about that at length if you have questions of that, but I don't have a lot of time to get into that right now?

One of the other issues that came up was this graph. There were some questions with regards to this graph. We looked at California and New York. We actually went and talked to the people in New York. We wanted to find out whether or not there were any non-chemical influences with regard to reductions in reporting of incidents.

Was that an artifact of programs? And indeed New York had stated some things with regard to the lack of resources was preventing their ability to report, and I believe a member of the panel here asked us, "Well what about California?" And remember, first off,

the interpretation of this graph is not that these are carbofuran incidents. These are incidents across all chemicals to be fair. And the next, the next issue though is let's look at California.

Well we went back and looked at California and according to the gatekeeper of our database. California has disbanded their pesticide incident reporting team. It has been subsumed by the Rapid Response Team in the state of California, and since that folding of these tasks into that Rapid Response Team, we have not received a single report from that team with regard to incidents. I don't know what that means, but I do know it's not a chemical or stewardship issue.

Ecological incident reports conclusions. When carbofuran is using as currently registered, while life mortality can and does occur, you've seen this before, instant reports can demonstrate that for registered uses under field conditions one or more exposure pathways are complete and exposure levels are sufficient to result in a field observe rule effects.

Field studies. 1989, FMC field studies, we spent a lot of time on those. We sliced and diced them. We moved them around. We considered densities. We considered efficiencies, etcetera. Take-home

message is we found bird mortality post-treatment in 14 of 16 corn plots and 12 of 16 alfalfa plots that were treated with carbofuran. Other field studies have found adverse effects at rates as low as 0.12 pounds active ingredient per acre in wildlife, and that 0.12 pounds of active ingredient represents minimally effective rates of application for carbofuran.

So what do field studies say about the mass mortalities that occur, that are being attributed to the TIM model? Well let's look at that 1989 field study data. If you actually go back to that data and you start looking at individual species, and let's just pick two here, casing sparrow and house sparrow. Their two treated plots had zero mortality, but some of the others had one dead bird.

And if you start looking at the density of those birds and adjusting for the rates or for the densities of the birds across the fields and the size of the field, you realize that you rapidly achieve 87% to 100% and 71% to 100% mortality for house sparrows and casings. And at plot A on the edge for meadow larks 57% to 75% and morning doves 71% to 100%. Now look, those numbers we all agree are really, really high numbers. But remember, this is one bird.

So the take-home message with regards to this

is, is that birds' density of a given species matters. Low density species, a mass mortality may only be one or a few species. So the question is whether you see those all the time? If I'm seeing one dead species in a large field study and I'm really looking for them, how lucky am I going to see that as I'm going by on my ATV or walking through the field on a simple transit?

So interpretation of field data. Average mortality comparisons of liquid param to field data. We saw this yesterday, and indeed there appears to be some concordance there when we take those densities and mortalities and distribute them across the field across all species.

We also saw as we go through and look at the Jorgenson data on specific species and look at the drepe analysis and compare it to TIM 1.0. We have some concordance there. And indeed as we got out and look at individual species and compare a range of mortality rates, it also appears to come fairly high. When we start to consider that a few dead species of a low density species results in a high mortality rate for that species.

Field studies conclusion. Carbofuran use and current application rates can adversely impact wildlife. Model predictions and field position. This

is very important. The liquid param does show some concordance with field data. I'm going to put that in quotes, not to say that it's wrong, but just to say you have to be careful on how you interpret that. What does the field data present?

Well here's a picture of the field studies methods and the search area with regard to that, and if you look very carefully at that shaded area, it doesn't take long to realize that the search area represents the parameter of the habitant. So what I might say is that liquid param shows great concordance with perimeter habitat mortality. Well what about the rest of the treated field?

Remember density and the number of birds across all those fields matters, so the mortality can and does occur throughout fields. Stensen in 1994 said, "Seventy-four percent of the mortality in that particular study occurred in the field interior." Liquid param may understand morality for the total field, but it does a pretty good job on the parameter.

So how do the models compared under similar assumptions of inputs? That's really important because we talked about families of models and how models compare and how they comport. Here is a comparison. This is, this is liquid param killdeer with avoidance

percentile similarity as well compare that with taking out the avoidance. We saw that the model goes up, so actually if you remove avoidance, the model response in a way that you might predict and that's upward.

Again, if we look at liquid param, again, with and without the avoidance in killdeers, and we add in a consideration for drinking water. Exposure should go up and, therefore, the risks will probably go up. Again, if we run the model with removal of food matrix factor for water exposures as was discussed yesterday in terms of whether or not that food matrix supplies to a liquid portion of the diet, if that would tent to increase exposure, and again the model may go up.

I don't know how much. Again, if we do more variable exposures for non-nesting birds, it's entirely possible, at least by analogy how the TIM 2 models deals with the bimodal feeding pattern, the predicted risk may go up. And then finally if you look at drift, nestling feeding, dermal exposure, inhalation exposure, etcetera, the question would be does the risk go up and by how much?

So what we've take home form this is as we converge on inputs between the models, the question will be is, "Will we converge on the conclusions?" So, again, back to that interpretation of field data. If

you look at the data as it was interpreted with liquid param presentations, appears to be good concordance. As you look at 89 and TIM 1.0, as we look at the drift analysis, appears to be good concordance. And, again, as we look at individual species, mortalities appear to be higher than we predicted by liquid param and in concordance with the TIM 1.0 and 2.0 model predictions.

So finally, our overall conclusions, and these are material to your consideration of the individual charge questions. Our deterministic model, one or more exposure pathways are complete. Exposure levels meet or exceed levels shown to cause adverse effects, mortality, and reproduction in the laboratory.

The probabilistic model exposures are variable, but one or more pathways are complete. Exposure levels are sufficient to cause mortality based on laboratory fixed data, and mortality is frequent and under some situations severe. Incident monitoring and field data suggests that one or more exposure pathways are complete and exposure levels are sufficient to result in field absorbable effects of mortality, incapacitation, and reproduction impairment. Thank you.

DR. HEERINGA: Thank you, Dr. Odenkirchen. I want to give the panel an opportunity

for questions of clarification, and I want to make sure I emphasize the questions are clarification on this presentation. I wouldn't like to revisit all of our discussion of Monday afternoon on this, and we'll have a change in the charge questions as well. Anything on this new material that you would want to clarify? Dr. Kehrer.

DR. KEHRER: Jim Kehrer. FMC yesterday indicated that liquid param changes the maximum body burden, but TIM 2.0 did not change it from TIM 1.0. You didn't cover that in this.

DR. ODENKIRCHEN: The maximum body burden?

DR. KEHRER: That was on one of our their drawings.

DR. ODENKIRCHEN: In terms of -- I think that's a very good question. We debated back and forth on whether we were going to do that because it's really kind of an unfair comparison. One of the things you got to understand is when you run this model, there are a whole host of variables that are going on. Those birds are moving around. They're getting exposed.

I would agree that if you sat there and held the exposure consistent over every single time step such that the birds were exposed to a high level one

time, a low level the next time, etcetera, etcetera, and you only looked at half-life, the half-life of clearance rate as it relates to a food item, as it relates to an exposure window, that, yes, the exposure window will matter. But you have to remember the more frequent exposure window in TIM 2.0, the more opportunities there are for the birds to encounter other parts of the field.

We don't integrate exposure across the entire field and pretend that a bird can cover all areas of the field in a one hour feeding time. We just don't feel that, that's reasonable. We let that bird move around the field. We characterize variability.

Now if you characterize that variability, what you quickly realize is, is regardless of what the half-life is in the bird and regardless of what the half-life is with regard to, to the food item itself, the residues on the food item, what you quickly realize is that you could indeed encounter with each subsequent time step a higher exposure than the first time step.

If you have a uniform feeding rate across the whole thing, then it's dominated by half-life, and, therefore, exposures have no choice but to go down unless you feed really more intently in the given average across the field and really wear yourself out,

I guess, as a bird feeding.

So it's very much more complex then just comparing one or two variables. You have to analyze all those variables as they fit in, and I think that's one of the strengths of these type of complex models, is you can really play around and do a lot of what ifs.

But it's also largely a weakness in really complex models in general because unless you wrap your mind around the whole totality of the model, you can reach some really erroneous conclusions. So what I would say is body burden is a response to how frequently it feeds, where it feeds, how variable that feeding is across the field, as well as the elimination rate, half-life there as it relates to half-life on the food items and the variability of the residues across all the feeds, and I think you have to compare all that together.

DR. HEERINGA: Dr. Bailey and then Dr. Hattis.

DR. BAILEY: I need just some information. You are referring to field data. Was that an experiment that was discussed, or are you just giving me the information about --

DR. ODENKIRCHEN: Yes.

DR. BAILEY: What was that?

DR. ODENKIRCHEN: Yes. That '89 data is the field data that was discussed at length over the last two days.

DR. BAILEY: And what was the nature of the study?

DR. ODENKIRCHEN: Those are the corn and alfalfa studies that we discussed where they had control plots. Some of them were treated with chloropyrofos or other pesticides where there is mortality differences basically in pre and post-treatment, etcetera. We could call back up those slides if you wanted to see them, but --

DR. HEERINGA: Let me step in. I think those studies were reviewed both by yourself and by FMC fairly extensively.

DR. MATTEN: The references are Booth et al, 1989 and Jorgenson et al, 1989. They were provided to you on a disk a couple days ago.

DR. HEERINGA: Dr. Hattis.

DR. HATTIS: I just wanted to get a little bit clearer in our minds, you know, what's being varied and what the status of the different models is with respect to variability and uncertainty of different parameters. My understanding of the liquid parameter, liquid model and perhaps your model is that

half lives are not given variability among individuals or among species, is that right?

DR. ODENKIRCHEN: I can't comment for liquid param, but I can say categorically that under our model, yes, they were not varied. And the reason why they were not varied at this point in time was, and this is probable a copout, but they hadn't been varied at this point in time because all of us were getting tired of spending 16 hours watching the thing chug.

So we made some simplifying assumptions and, yes, I would think that as we go through iterations of additional model development over the course of many years, we'll build in more functionality. We'll be able to deal with that.

What would probably be something maybe in the next year or two would be a useful analysis for all of these models is to go back and vary those half lives low, medium, and high. We did that when we ran the models early on in TIM 1.0.

We presented some of that information, I believe, if memory serves in the first SAP and how the model responded to those different half-life assumptions and indeed how the time steps effects the rate constant assumptions for those. But, no, in both models was a run for carbofuran, and I don't know about

liquid param. In those models we did not vary those half lives.

DR. HATTIS: And the effect of not varying the half-life or not varying in the case of the liquid param model, either the avoidance or the matrix effect is essentially to make the response of a model much sharper relative to, so that essentially you would get some mortality among lower --

DR. ODENKIRCHEN: Right. I think what it does is it really starts to compress the tails. We widen that out, the tails of the model get wider. It gets thicker and thicker in the middle. It's probably lower in the center, so it effects that mean value to some extent; but I think the greatest extent is it will probably -- and this is just purely conjecture on my part since I haven't run it with the variable values in there -- but I think the tails will get fat. So there would probably be more incidents of extreme values, and more incidents of zero values, and less incidents of mean values.

DR. HEERINGA: Okay. Dr. Clark.

DR. CLARK: Larry Clark. When you were running your species specific adjusted mortalities based on the densities and you're estimating that it might kill a higher portion of the population, so when

you were reviewing those '89 studies, did you also look then at the census data to see --

DR. PANGER: That's exactly how we did it because what was presented by FMC was a total bird based on their census, their 0.88. We still hadn't been able to replicate that number, and we're not clear. We've gone back to their write up and the study. We're still not clear how they got that 0.88, but we do know it seems to be a total bird count and a total number of birds killed.

DR. CLARK: Right.

DR. PANGER: But when we went to specific species and plots, and we found there was mortality in a Cassin's sparrow. Go back to that survey data, we can tell for the four weeks that they did the survey what the density per acre is for that species on the field. So we used that survey data to tell us the density of birds, and then we used the mortality, bird per acre.

DR. CLARK: I understand that.

DR. PANGER: Okay.

DR. CLARK: I guess my question was if you look at the census data as well, do you seen an impact on the census data? So you're looking at mortality events to adjust your mortality. I mean, do

you have census data to adjust your mortality events; but there's also, the census data would look at also is there a reduction, or a stasis, or an increase in the species of concern?

DR. PANGER: Well the census data, we're taking it from the time that we did the, they did the searches also. So I don't completely understand your question.

DR. CLARK: You can adjust for the mortality estimates based on what the population was, but was there an effect on the population?

DR. PANGER: Oh, there was some confounding factors because of the timing of this study. There were some of the censuses were done during a time when they weren't flocking, and then through time there was flocking or it might have been a reverse. It wasn't, they didn't make comparisons in that way because of the confounding factors in terms of the changes in terms of the population densities overall.

DR. HEERINGA: Additional questions of clarification on the new material that's been presented, arises as a result of this presentation? What I'd like to do at this point then is I'd like to break for early lunch. We are at eight minutes of

12:00. If everyone could be back here at 1:00 p.m., we will begin with the first of the charge questions. Thank you everybody.

DR. HEERINGA: Welcome back everybody. If we could find our seats, we'll begin the afternoon session. Panel members, members of the EPA scientific staff, and any other speakers, we have now gone to a dual microphone system. Dr. Handwerger had to leave to give a talk in California, lame excuse, but he's gone. And joining us is Dr. Gary Isom, and Gary, if you have heard me, would you introduce yourself, please.

DR. ISOM: Yes. Can you hear me?

DR. HEERINGA: Very well.

DR. ISOM: I'm Gary Isom from Purdue University. My area of research expertise is neurotoxicology. I'm sorry I couldn't make it earlier, make the meeting. I had travel difficulties here in the midwest. We really had some terrible weather the last few days. So I'm glad to join you by speaker phone.

DR. HEERINGA: Thank you very much, Gary. And a technicality, if you use the microphones to speak, not only do you have to remember to state your name, but you have to remember to activate both buttons. If you don't activate the button on the light

gray adapter, Isom will not hear what you're saying. Dr. Isom is joining us as a special favor to make sure that we retain appropriate quorum of permanent scientific advisory panel members. We are currently at quorum with four. Gary makes five, and as Dr. Matten mentioned yesterday, depending on a specific discussion, we may have to refuse one member, so we would remain with four.

At this point in time I would like to move ahead to the charge questions on the ecological risk issues. Before I do, I want to make one comment, and that is in this process it's a process of a presentation of a tremendous amount of information. We want the panel to avail themselves with any information that is relevant to the discussion to the questions.

Any public commentors from yesterday or this morning who would have any additional comments following the EPA summary statements, I'm asking you that you present them in writing as a written comment to the panel and submit them to us to Dr. Matten, and they will be shared with the panel. And I will be, as chair, sure that we revisit those comments, that the panel members have read them, and have opportunity for any additional comments or clarifications on their response to the charge questions that might reflect

those comments.

But that's the process that I'd like to use, and at this point then I'd like to move ahead with the formal charge questions that have been posed to the Science Advisory Panel. I think Dr. Salice or Dr. Odenkirchen, are you going to read the charge question into the record?

DR. BRADY: This is Don Brady. I'd just like to say that Dr. Salice will read charge questions one and two, Dr. Panger three and four, and Dr. Odenkirchen number five.

DR. HEERINGA: And Dr. Salice and Dr. Panger, I've talked to the panel members. If the question has multiple parts, can we read them one part at a time?

DR. SALICE: Indeed, yes.

DR. HEERINGA: Let's, let's do that. And panel members you still agree with that? Obviously as lead discussant, if there are ever any panel member as we move on through all the charge questions, if you're the lead discussant and you would rather take a charge question as a package, part a, b, etcetera, let us know. Otherwise we'll break them down into the subparts. Dr. Salice.

DR. SALICE: All right. Good afternoon.

First question, terrestrial model version effects on risk conclusions. In 2001, the Scientific Advisory Panel supported the modeling approach presented by EPA and provided recommendations for additions to the agency's probabilistic risk assessment model, TIM version 1, terrestrial investigation model.

This model was developed to estimate risks of acute mortality to birds at the scale of an agricultural field treated with a pesticide. The recommendations included addressing dermal inhalation exposure routes, more frequent feeding time steps, and aiding diurnal behavioral patterns. These recommendations were addressed in TIM version 2.0, which was reviewed by the SAP in 2004, and who again supported the agency's approach.

In the period of time between these two versions of TIM, the probabilistic risk assessment for carbofuran was initiated. At that time TIM version 1 was the only fully functional avian PRA model available. Subsequent to the SAP review of TIM version 2 and the release of the carbofuran IRED in August of 2006, the agency has conducted modeling for subset carbofuran scenarios using TIM version 2.1, the version that incorporated the 2004 SAP recommendations to ascertain the extent to which the updated model version

would offer carbofuran risk conclusions.

So question one, based on the document provided for review containing model results using TIM version 1 and the newer version TIM 2.1, which addressed the 2004 SAP recommendations, EPA has determined that the results of the new modeling do not support altering the previous conclusion that carbofuran poses a risk of mortality to avian species in and around the carbofuran treated use site. Do you concur with EPA's determination? Please provide a basis for your conclusions.

DR. HEERINGA: Our lead discussant on this question and subpart is Dr. Brad Sample.

DR. SAMPLE: I want to start by sort of acknowledging that we as a group had discussed this question outside of the panel here and have come to a general agreement. There will be some additional expansion on some of these by some of the panel members as we present and talk about this.

I also wanted to clarify that we interpreted the charge question as focusing primarily on the comparison between the application of TIM 1.0 and TIM 2.1 models and their suitability for estimating risk to birds based on the exposure to pesticides.

We would like to note that the models, TIM 1,

2.1, and liquid param represent a large step forward in environmental risk assessments from the sole reliance on deterministic approaches.

EPA has recognized the need to modernize their approach to environmental risk assessment in order to keep pace with our evolving knowledge of this and increasing availability of technology and methods that can take advantage of these advances. We recognize that the models used for risk assessment must be scientifically sound, but also recognize the need for consistency, both of cross assessments for different chemicals and also consistent in approach over time. For these reasons, advances in risk assessment occur in a stepwise fashion. As had been seen by going from TIM 1 to TIM 2, TIM 2.1, and some of the additional modifications that are evident in liquid param.

The panel acknowledges that both TIM models have been through extensive scientific peer review and include input from the stake holders. The results and advice resulting from the previous SAPs have been considered and are being incorporated.

The results and comparisons using the same or very similar scenarios and presented show consistency in joint probability distributions and result in

similar conclusions with respect to the risks posed by carbofuran to avian fowl. And it should also be noted that liquid param builds on TIM 1.0 and includes many of the recommendations made by the 2001 and 2004 SAPs. So there's a lot of similarity in all of these models.

It should also be noted that our review of the most recent version of TIM and liquid param are limited by the fact that we do not have the code for any of these models available for our evaluation. Consequently, we are only basing our conclusions on the materials provided by the EPA and the registrant, their analyses and modeling results, their descriptions of their model structure, and our own evaluation of the more recent data, which will be addressed in more detail in charge question number two.

Given this information, our conclusions are that we concur with EPA. The results of the new modeling do not support altering the previous conclusions that carbofuran poses a risk of mortality in avian species in and around carbofuran treated use sites.

We have some additional recommendations. Some of those reflect what we would like to see, both in presentation of the models and as this modeling framework is moved forward to other pesticide

registration procedures or processes. Number one, we'd like to see or recommend the capture of the numerical or percent changes in output between TIM 1 and TIM 2.1 runs for the same scenario.

The percentage change and results should be the result of, related back to the degree of change, which would result in a change to the risk conclusions. The capture of numerical or percent changes in model runs based on modified inputs based on the most recent registrant data. Number three is evaluating the comparison of TIM 1 and TIM 2 would be greatly enhanced if the parameters in both of the models were listed side by side and identified as to which are fixed, which vary, and what distribution types are used, what changed between models.

The conceptual flow diagram that was presented for TIM 1.0, slide 34 of the initial presentation for TIM 2.1, these are the sorts of data that would be particularly useful. And we notice that in the model description for liquid param, they do provide this sort of information, and that is a good example to use for comparison. And we suggest inclusion of the air and uncertainty metrics associated with the risk estimated presented by the TIM 1 and 2.1 model runs.

I have an addition note, and this one is my own comment; and the other panel member can concur or disagree as appropriate. I suggest that in future assessments multiple models be considered to address different aspects of exposure and risk and be tried as part of a robust modeling framework.

This would include spatial explicit models and population models. Spatial explicit models integrate the variability and spatial distribution of residues, habit availability, and exploitation by potential exposed receptors. An example of this would be the seam model that has been developed by the US Army, chicken wire.

Population models such as Leslie Matrix models or more recent variations of this type would also allow investigation of the implications of differential mortality and reproductive strategies by species. This would allow us to help address the percent effects that a given species would be able to support. Using multiple models with complimentary strengths and weaknesses would be benefit and be used as a component of an overall weight of evidence evaluation. And with that I will open up to other panel members with additional comments to add.

DR. HEERINGA: Our next associate

discussant is Dr. Delorme.

DR. DELORME: I think Brad has captured any of my thoughts. We did work on this together, and I have no further comments to add at this point.

DR. HEERINGA: Dr. Grue.

DR. DELORME: Maybe I would like to just add, add a couple comments and maybe reinforce what Brad indicated. There was no question that both versions of the model as parameterized, and I would argue also FMC's liquid param indicate that carbofuran poses a risk of mortality of birds in and around the fields.

The magnitude of the risk is what I believe is still in question, given uncertainties associated with the best ways to incorporate the recommendations of the 2004 SAP, in other words, the most represented actual field conditions. When new data and approach is presented by the registrant, liquid param, and the changes in the uses of labor-proposed for retention by the registrant.

Making the best decision and recommendations are always important and ideally this goal should not be sacrificed for expediency. And while the agency has suggested that the law of diminishing returns applies here, and there's still plenty of remaining questions

related to model parameterization, and I think these have already been highlighted.

Also conclusions are made difficult because of the lack of time to adequately compare the performance of the two most recent models in 2.1 liquid param and having to make simultaneous decisions on model parameterization, performance, and resulting conclusions based on outputs. The underlying concerns is that both the agency and the registrant have sought to incorporate additions or improvements to the models suggested by the 2004 SAP, some of which, depending on how their parameterized have significant and disparate facts on the resulting outputs and conclusions for the particular species.

The majority of these improvements relate to the duration and magnitude of exposure and the fact that the LD-50, essentially measured inherent sensitivity reflect the dose response curve or acute exposure is a measure of hazard with the risk defined as a probability at given encountered dosage instead of foraging activities that will result in mortality. And issues associated with the incorporation of these improvements are the subject of our subsequent discussions.

DR. HEERINGA: Thank you, Dr. Grue.

Dr. Montgomery.

DR. MONTGOMERY: I have one very minor addition to make to this, and it concerns the issue of registrants submitting models that are put in parallel with a model that has been developed through a public peer review process, and I understand that the registrant did employ an external peer review process and everyone agrees that there are many similarities between the two models.

But I still have reservations in terms of how this might be extended to consistency when we look at other chemicals, other risk assessments. I'm not talking about regulatory policy or strategies, but I'm talking about how we would assess the fairness and consistency of risk assessments for chemicals. And that's basically it in a nutshell.

DR. HEERINGA: Other comments or recommendations from the panel? Dr. McCarty.

DR. MCCARTY: Yes. An issue of assumptions and parameterization, especially how they differ between the TIM models and the liquid param model as emerged this week, that I'd like to comment on. In particular, it has to do with the feeding behavior of birds as a key uncertainty in both the TIM and liquid param models.

It was pointed out today that the 2004 SAP noted that, "Adult altricial birds that are provisioning nestlings most likely would have a more uniformed feeding distribution throughout the day." That's a reasonable and testable prediction, and the review of the studies of the rate at which adult passerines deliver food to their dependant young, which was reviewed by the registrant, is a reasonable basis for supporting an initial hypothesis that adults themselves feed at an even rate through the day, which is then assumed in the liquid param model.

However, the fact that this assumption about patterns of feeding behavior emerges as a key variable in the liquid param model that makes it different from the results of the TIM models, makes it imperative to carefully examine the assumptions about feeding behavior.

Use of feeding rates derive from adult passerines using central place foraging to feed dependent non-mobile nestlings. To then conclude that the feeding of the adults is consistent over the course of the day requires an assumptions that adult feeding follows the same pattern as their foraging to feed rapidly growing dependent young. Given how critical this assumption appears to be for the liquid param

model, this assumption needs to be reexamined using a broader range of published studies.

First it's clear that the lack of crop in birds does not mean that birds need to eat consistently. While the smallest birds, such as hummingbirds, do need to eat frequently, most of the birds we're discussing are at least in order of magnitude larger than hummingbirds and can easily go several hours between feeding bouts.

This is demonstrated by the ability of birds to spend hours migrating without eating or fasting very long winter nights when energy demands of thermal regulation can approach the demands on parents feeding dependent young.

Work on captive passerines shows that many birds do exhibit a diurnal pattern in feeding with peaks in the morning and evening, and I can cite Polo and Baptista 2006 for that. I'm hoping to have chance for the final report to refine the citations that I'm going to mention. It just seemed to have emerged.

In addition, at least some of the time, budget studies of wild passerines show birds do show a temporal pattern of feeding over the course of the day with peaks in feeding in the morning and evening. And, again, things that I was able to find last night,

Morton 1967, Huddo 1981 are examples, and this likely applies to some non-passerines such as doves and shorebirds, Lacito et al, 1990.

Based on these and other studies. It is plausible that the temporal pattern of feedings for wild birds during relevant times of the year when they might be exposed to pesticides. Even if there is a pattern of feeding, hold on, even if the even pattern of feeding used to justify the assumption in the liquid param model turns out to be valid for the nestling phase, it's important to consider other phases of birds life histories when they may be exposed to pesticides including migration, pre-migratory fattening, and other peak periods when they're not feeding dependent young.

For many small passerines, dixocells have been mentioned, the nestling phase lasts around 10 days. This leaves ample time for other behavior patterns. The EPA modelers are to be commended for paying attention to previous recommendations, but the feeding pattern model needs to be flexible.

In addition, the assumption of movement patterns of feeding birds is also derived from central place foraging. It appears in the liquid param model, even if the assumption that adults feeding young eat constantly is accepted, this period can be short.

During the rest of the spring and summer seasons, adult birds can move in a much different pattern, either remaining in one place for a long period of time or being freed from a central place ranging widely in search of food.

Alternatively, the data on feeding patterns used in liquid param could be used to model risks to nestlings, the ones who are actually being fed. This would, of course, introduce new unknowns regarding the sensitivity of developing altricial birds to pesticides. Data from precocial species, such as mallards and quail, would not be acceptable for this purpose. For adults it is a reasonable assumption that consumption patterns of adult birds are variable and may mimic those described in TIM more closely than the liquid param models.

DR. HEERINGA: Thank you very much, Dr. McCarty. Other contributions or recommendations from panel members on this question? Dr. Hattis.

DR. HATTIS: The contrasting results for different avoidance assumptions and different feeding behaviors indicates that the model predictions for mortality are very sensitive to these variabilities. So just as a non-ecological modeler, it seems to me that if you're taking results from a single experiment

or single species, you got to worry about whether your results are, in fact, sensitive.

And as a general matter, if you're making assumptions about uniformity, you're probably understating the fluctuations that occur in real life situations. So I would say that it's likely that the direction of change as the models become more sophisticated will be to say that, well maybe our maximal possible mortality conclusions are not right, but our conclusions about very low risks are probably about right.

And if that matters, then it seems to be that's relevant to communicate to the folks who are making choices in terms of risk management.

DR. HEERINGA: Thank you, Dr. Hattis.

Dr. Edler.

DR. EDLER: Very shortly. I think when we come up with different models, what we actually heard over the days here, it might be very interesting to see or to define them, the most important factors, which may explain differences between these models. We heard a couple of them, the time stamps, the rate of metabolism, avoidance behavior if that's really an important feature.

I think defining them and then actually

trying to calibrate or non-calibrate or whatever you can do with the models might be an interesting thing to do.

DR. HEERINGA: Thank you, Dr. Edler. What I would like to do, Dr. Salice, is to move on to part roman numeral little I, I guess.

DR. SALICE: Okay. Also in 2001, the SAP suggested that the agency explore a separation of pesticide residue variation into two components. Variance within a given treated field and variance across different fields.

The agency's probabilistic model approach for birds is assumed that variability estimates in the UTAB database represent within field residue variability and has described why this may result in some conservative model estimates.

An alternative assumption is that all variance associated with avian exposures is a function of avian body size and behavior; that there is no residue variance within the field. The agency has conducted a brief review of a number of pesticide residue data sets and carbofuran-specific field data and has determined that residues on food items do vary within a field. Based on support document that was provided for review, EPA has determined that assuming

within field pesticide residence variance to be zero is not supported. If you concur with EPA's determination, please provide a basis for your completion.

DR. HEERINGA: Dr. Sample.

DR. SAMPLE: Yes. We concur with EPA's determination pending more thorough analysis of the U-tab database to examine within and between field variance. The normal assumption is that variance exists unless data are shown otherwise. The analysis presented in the document 348020 based on field data indicates that there is variance in residue and food items within fields and includes data provided by the registrant.

There are a number of factors which contribute to this variance including application equipment, meteorology, microtomography in the field and so on. For example, some of the application methods by their nature produce variable concentrations within a field such as branded applications.

While the coefficient of variation reported within the field is less than the values used in the original model results, the subsequent assessment in TIM version 2.1 using both original and lower variability did not alter the risk conclusions.

DR. HEERINGA: Dr. Delorme anything to

add to that?

DR. DELORME: I have nothing to add at this time.

DR. HEERINGA: Dr. Grue.

DR. GRUE: The only thing I'd like to add is that, and I think I mentioned this earlier, is that we need to be clear in describing what variance this actually reflects; that is variance initial concentration of food items, say time zero, all of which realize some degradation through time and not that residues are actually increasing through time; and I think that distinction is important, and it's really just verbal clarification. As such, a bird, for example, could encounter a higher concentration on the same type of food at time two versus time zero.

DR. HEERINGA: Dr. Montgomery.

DR. MONTGOMERY: I have nothing to add at this time.

DR. HEERINGA: Other contributions on this particular sub item? Yes, Dr. Bailey.

DR. BAILEY: Ted Bailey. Ted Bailey again. I would like to ask how the statistic of coefficient variability is computed, and then I want to think about how it could be used in the program. Thank you.

DR. HEERINGA: Dr. Salice.

DR. SALICE: It's just the standard method of the mean compared to the standard deviation, and then that was used to then adjust or basically come up with standard deviation for the model residue value.

DR. HEERINGA: It would be the standard deviation of the residues divided by the mean of the residues and including any zero residues?

DR. SALICE: Yes.

DR. BAILEY: Ted Bailey. So then the value of the CV depends on the mean as well as the variance.

DR. SALICE: Correct.

DR. BAILEY: And that captures the information you need in the program. A high CV doesn't mean high variance necessarily. Thank you.

DR. HEERINGA: Additional comments.

Dr. Grue?

DR. GRUE: Just one additional comment and that would be though the model runs indicated that there was little effect of the 2 to 4 x factor, it would be good for the agency to provide the rationale for that, for what appears to be a safety factor in those calculations.

DR. HEERINGA: Dr. Grue, the 2 to 4 x

factor, just so that we're all clear, in which parameter, or is that the safety factor you were talking about?

DR. GRUE: That appears to be applied to the coefficient various that was seen in the actual field data.

DR. MCCARTY: Thank you. I may ask a naive question, but if I didn't catch it, maybe 85% of the rest of the population did.

DR. HEERINGA: At this point, Dr. Portier.

DR. PORTIER: This is Ken Portier. I just wanted to point out in one of the documents EPA stated an important implication of the within field variability of pesticide residue is that it is possible for a given bird to be exposed to higher concentration on the days following pesticide application than it was exposed on the day of the application, and I was thinking about this.

With degradation of product and all the other things that are going on, I doubt it's what you're going notice, you would notice a day-to-day, hour-to-hour within that first day that they start feeding post-application. I would expect that to vary quite a bit, but when you start having decay, given the kind of

half lives we're talking about, I doubt at the second day. That would be a very probability event, and I think it -- I mean, you might observe it but not very often.

So I think you might want to look at your -- I think you meant hour to hour and not day to day, but it just kind of caught my eye.

DR. ODENKIRCHEN: Actually in TIM 1 we did see it in the time step to time step analysis. So, you know, one time, morning to the afternoon. In actuality, it is a much rarer event as we get farther and farther along, and as you might imagine with the variances being what they are, that half-life in terms of carbofuran as compared to maybe some other compound, the longer the half-life the greater the opportunity for that to happen.

DR. PORTIER: And I guess I was thinking more in TIM 2. When you're modeling it on an hour to hour basis you can see a lot of that jumping around early on, but again by the next day -- I mean, you've had 14 hours of eating and another 10 hours of no eating. I just don't see that.

DR. ODENKIRCHEN: Right. I think the biggest distinction is that we're trying to draw here, regardless of whether it's time step or hour is the

function that if you assume that there is no variance within the field, half-life dominants and you're never going to result in an exposure harder than the first day, unless your bird really alters it's behavior on the field to a drastic extent, you know, in other words, 10% on the first day versus 90% of the time spend the second day and however liquid param deals with that variable, but in TIM 2 what we see is we do see quite a bit of oscillation, and because of all the other issues with clearance and the exposures expresses as a body burden, that's compared to the dose response curve. It becomes pretty important to be able to capture that.

DR. HEERINGA: Dr. Bailey.

DR. BAILEY: Ted Bailey gain. You have measured the variability on a within bird basis. In the model then is there also variability among birds that comes in play? We expect that to be much larger than within bird cases.

DR. ODENKIRCHEN: Yes. It's larger among birds than it is within birds primarily because the feeding pattern, for instance in TIM 2.0, 2.1, the feeding pattern does vary for each individual bird. So you will see quite a bit of variance there, but the important thing to realize is that at this juncture, in

both the newer models and the older models, we can actually track that day to day and perform that analysis if somebody really wants us to do it. So it is possible to track all those.

I don't think we spent at this point in time a lot of time characterizing that within and among variability. So what I'm giving to you is out of my best recollection of watching the model working it's way through.

DR. HEERINGA: Dr. Sparling and then Dr. Sample.

DR. SPARLING: Dr. Sparling from Southern Illinois University. There's an element of infield variation that I think should be accounted for, and, as far as I'm aware, it's not accounted for in any of the models. And that is with regard to the presence of puddles in the form of carbofuran, which is ingested by the emergent plants. All of the studies carbofuran, as a food bolus has a much higher LD-50 than that as in water, and I think that, that's the element whether the animal is consuming carbofuran in water or with the food should be modeled into that. That may occur elsewhere in the model, but it seems to me that, that's an element of infield variation.

DR. HEERINGA: Dr. Sample, did you have

a comment? Dr. Bailey.

DR. BAILEY: Ted Bailey again. I'm thinking that in the model you'll want to have some kind of value for each bird at some point, and I think that would be thought about as the value of that animal as measured in different environments within the field. And so there is sort of a genetic component to each bird, but that genetic entity, that bird also exists in different environments, and its behavior is the function of both the environment and the genetics.

And it also allows their type environment interaction, and that's sort of my concern about. We're talking about the variability within bird basis, and how we're getting the value for that bird. I can imagine at some point we'd like to know the variability of within bird basis. But somewhere in the program you need a value of that bird in the context of the environment that it's in.

DR. HEERINGA: Thank you, Dr. Bailey. What I'd like to do is to move on to question two because based on experience, I know that some of these issues will come back. And what we tend to do is to move issues forward.

It hasn't happened so far, and I want to compliment everybody on the incisiveness of their

statements. So if you're in agreement, Dr. Salice, let's move on to question number two, and this has multiple parts, so we'll take them one at a time.

DR. SALICE: One at a time. Okay. Question number two, analysis of new data impacts. Between April and June of 2007 the agency received four studies from FMC. These studies were intended to provide data to address uncertainties in the avian risk assessment which were identified by the 2001 SAP. The agency has reviewed these studies and evaluated the extent to which these data would alter the agency's carbofuran risk conclusions. The following questions relate to the results of EPA's review and analysis of each study and their overall impact on risk conclusions.

2A - Avoidance of pesticide treated feed. Due to a lack of relevant test data, the terrestrial probabilistic risk assessment presented in the 2006 Reregistration Eligibility Science Chapter for Carbofuran, Environment Fate and Effects Science Chapter does not quantitatively address the potential that birds may avoid carbofuran-treated food items. In May 2007, FMC provided EPA with a study on one bird species purporting to demonstrate avian avoidance of carbofuran-treated feed.

EPA reviewed the study and concluded that it was suitable as a screen for potential avoidance behavior, indicating that avoidance of carbofuran by birds may occur. EPA believes however, that robust avoidance studies should include pens instead of cages, non-concentrated food sources, and some degree of hunger. The studies submitted by FMC included none of these considerations.

However, to evaluate the potential impact of avoidance on risk conclusions, EPA conducted probabilistic model runs using the relationship between carbofuran concentration in feed and reduced avian feed consumption.

In conducting the evaluation of reduced food consumption as a function of dietary exposure, EPA used the TIM 1 model. EPA elected to use this model as opposed to the TIM 2.1 model because of important limitations to the data in the food avoidance study, namely that the date were based on daily observations of food consumption.

To use this data in TIM 2.1, which has an hourly time set, would require adjusting the direct relationships between carbofuran dose and reduced food consumption to an hourly basis, which is inconsistent with the registrant-provided data. For example, one

approach would be to multiply hourly estimates of exposure by eight hours or other duration representing study observation times.

EPA did not use this approach because of a likely bias towards low consumption rates and hence, lower exposures.

2A.I - In light of the limitations of the FMC study methodology, please comment on EPA's decision to use this study only as a screen for potential avoidance behavior. Please provide a basis for your conclusions.

DR. HEERINGA: Dr. Delorme, do you want to take these in pieces, or you want them all three together?

DR. DELORME: All three.

DR. HEERINGA: All three. Please, Dr. Salice.

DR. SALICE: 2A.II - Given the limitations in the food avoidance test study, did EPA employ a technically sound approach to use the data from the study as inference to the TIM version 1 model to evaluate the potential for food avoidance to alter mortality risk estimates? Please provide a basis for your conclusions.

Question 2A.III - Given that the data on food consumption is based on daily measurements, did EPA

incorporate these data appropriately into TIM version 1, which has a time step that is more consistent with the observation times and the data provided? Please provide a basis for your conclusion.

DR. HEERINGA: Dr. Delorme is our lead discussant on this.

DR. DELORME: As for question one, my response at this time reflects discussions that most of lead discussant and the associates had on this over the last couple of days. This is a long and complicated question. It's mainly related to the use of models to characterize risk in the incorporation of the additional data, and we're going to deal with this in parts. I just want to start with a few general comments of my own before I get into the response from the group.

There was a lot of information to consider in a relatively short period of time. I think we have to recognize that we've been up to midnight I think the past couple of nights discussing, analyzing, doing various things.

Given the information provided on TIM in liquid param, it appears that each have strengths and weaknesses. One of the things I want to note is that some people call this environmental risk assessment.

Other people call it ecological risk assessment. One of the comments I'd like to make is the ecological reality of the models is slowly evolving, okay, and I think that was one of the whole points of moving to probabilistic risk assessment is to get some of that ecological reality.

In fact, many of the issues discussed and debated relate to how we can adequately represent ecological aspects of animals, animal behavior such as habitat use, eating behavior, sometimes with limited data or information with mathematical constraints.

I'd like to go back to something that I know Ed Odenkirchen has often used, all models are wrong, some are useful. And we have to keep that in mind when we're discussing these models. They represent reality to a certain extent. In addition, we are trying to bridge and interpret effects from lab studies to field situations.

This is not an easy task, okay. So I think we have to keep these things in mind when we're talking about modeling and modeling results. They're useful in informing us what could happen, not necessarily what does happen. Okay. I also want to acknowledge, I come at this from the perspective of being a risk assessor for pesticides, and I recognize the need to make

decisions and that you can't wait for the science to catch up or you can't always use the best science. At some point you have to make a decision. So you have to use what you have and go forward, and I think that's what we're really charged with doing here.

The panel has been presented with two different approaches in risk characterization. Both started from a common point, the TIM 1 model and the SAP comments. The results differ in part because of differences in model structure and in part because of differential interpretation of the currently available science. We have been charged to comment on one of these approached, but being scientists, our nature is to be inquisitive; it's to be curious.

Now to consider alternative information from a scientific perspective, and I think this is reflected in our response. Okay. That's why you're going to hear us talk about LP. I'm not going to call it liquid param. I can't get that out.

So then moving onto the actual charge question, we had considerable discussion about the avoidance, repellency, toxic anorexia, call it what you may, but the bottom line here is that the panel believes that while the study designed was less than optimal to achieve it's goal, the concept of examining

avoidance repellency, toxica anorexia, is a reasonable issue to be addressed, given the results of the previous studies, and I have a number of citations here, Bennet and Price, Bennet and Drew et al.

As it could potentially have an impact on exposure to birds, and I think we certainly seen that demonstrated in the model results we've seen. However, because of confounding factors, definitive conclusions with respect to avoidance repellency cannot be draw from the submitted study. As such, it's use as a screen is justified.

With respect to avoidance, there are several factors which need to be considered with respect to its use in environmental or ecological risk assessment. The study was not designed really to assess repellency in our estimation. Rather results focused on impact on food intake. So there needs to be some clarification of the terminology used and what's actually being done.

From a scientific perspective, information on the avoidance repellency or effects on food intake for a wider range of species is desirable to better interpret the potential impact on exposure for focal species. You need to have that differential response by different species in order to take it and use it consistently within a risk assessment context, and

certainly only having it for one species is not going to move us forward. I think we need to recognize that.

It was apparent to the panel that the results indicate, and you'll find some of these results scattered because I haven't had time to integrate three days of information yet. But it was apparent to the panel that the results indicate an effect of the setup of the holding facility used to conduct the experiment, and this may have further confined the results.

And I think that Larry is going to comment on that a little bit later on. Basically we thought that the current study compounds three things, neophobia, the fear of new things; physiological response to a toxicant, i.e. toxic anorexia; and condition avoidance response. The panel did conclude that there is a dose-dependent feeding suppression with toxic anorexia.

I have a little bit here that was provided to me by one of the panel members on anorexia versus chemical avoidance. The study compounds two possible effects, anorexia and the selective avoidance of contaminated food in favor of clean food. Anorexia might be expected to be dose-dependent, while the ability to detect and avoid contaminated food might be expected to be concentration-dependent. The study designed "buries" these, making it impossible to

determine which is driving any change in consumption. Okay.

Some of the other considerations that the panel members brought up included nutritional status of the birds, and this is a comment that was made by Dr. McCarty. Just in brief, echoing some of his earlier comments I think he made on comment one, at certain times of the year birds eat more or less, migration periods of reproduction, establishing territories, laying and incubating eggs, raising young, molting. Okay.

So sometimes these conditions will emphasize the stress on birth to find food and limit their ability to be picky. On available food choice, there is concern about a final study to result the field situation as soon as there is clean food available for birds to chew. This might be the case in some situations, highly mobile groups of birds, but for many birds of concern during the relevant time periods, individual be confined to territories and may need to remain near the nest and not have the luxury of moving to an unsprayed field. Okay.

With respect to results and interpretation, the results state that no signs of intoxication were observed, yet the failure to feed is listed as one of

the symptoms of cholinesterase inhibition and the reference is provided, Berber et al 2002. It was thought that the presentation of the data analysis was incomplete.

The pest are described but the full results are apparently not presented, and this goes to I think how things were reported, and John may have a comment on that later on. Finding my way here. Regardless, the failure to present a clear report of the results of analysis justifies EPA in not accepting these results without serious question. The derived variable should be subject to an analysis that includes air propagation. Food consumption of the control group appears to have declined as well, as the experimental. I mean, that was a question of, you know, why is that happening. We break it into questions.

One of the things we did is we have a number of excellent people on this panel who, I don't know, they just have a desire to work really hard I guess; but they did some additional analysis, and it reveals high variance in response to treatment over days, indicating little difference between days during pre-exposed time period and days during the exposure period.

I put a couple figures on the computer there,

and if you could just bring them up and show them 'cause we're going to include them in the report. In addition, the dose response relationship is discontinuous. Significant responses were only observed in the 3 PPM diet for males and in the controls in the 135 PPM dose for the females.

At this point I just ask Brad, who did this analysis, to just give a brief run through, and then I'll continue.

DR. HEERINGA: Dr. Sample.

DR. SAMPLE: Pulling up the raw data from the back of the study, this is laying out the repellency factor, which is the percent consumption of portion consumption of treated food relative to total food and looking at the measures for all individuals in all treatments over all of the days, both pre and post in looking at the total distributions, and did they rank analysis of variance within treatments over days.

And listing out only, in this particular figure here we're looking at, the males, you can see that we have a significant difference between days only in the three part per million exposure range, not in any of the other ones. If you look, you see a general decreasing trend in the highest dose, but again because of the high variance the high between day, there's not

an overall difference in response. And we look at the next three with the females, same type of data. We have a significant variation in response over days in the control and then not in any of the treatments until we get into the highest dose, and because we are seeing responses in the control and in the highest dose, raises concern whether this is an artifact.

DR. DELORME: Thanks, Dr. Sample. Just to continue on, to apply an even well designed study to the field would also require field data showing that it's typical for birds to be exposed to a sublethal dose, recover, and then be exposed again at which point they avoid the contaminated feed. Given the lack of data suggesting this scenario, it's likely, and I would not advocate including this in the risk assessment model; and that was a comment from one of the other panel members.

To the extent that this scenario might occur in the field, it would be most likely to be important for larger species such as mallards rather than the songbirds. For any species the dose response for carbofuran makes it unlikely that a bird will receive a sublethal dose and survive the secondary effects of intoxication, e.g. predation.

And just a point that I would like to make,

nothing that was discussed among us, is that I'd like to note that based on the information provided in the FMC presentation, the species chosen for the test, the mallard, was purported to be the most discriminatory. Well normally using the most sensitive test species is viewed as conservative.

In this case, because of the potential impact on exposure, use of a sensitive species is not representative of species that don't avoid. You have to think about it to get your head around it, but because it's going to effect exposure, maybe you don't want the most sensitive species, the most discriminatory species. And that's why, I think, that one of the themes we see emerging here is the needs to have these kinds of data, whether it's avoidance, whether it's cholinesterase inhibition, whether it's matrix effects, across a range of species. Okay. I think that's very important 'cause that brings in that eco into the risk assessment.

So moving on to A2, given the limitations and food avoidance, did EPA employ a technically sound approach to use the data from the study as input to TIM version 1? Please provide a basis for your conclusion. The response that we come up with is given the design flaws, the failure of the registrant to adequately

present results in the study reports provided, and the apparent lack of repellency, avoidance from our analysis, the panel has concluded that EPA would have been justified in it's leading the study from consideration.

It's not unreasonable to include avoidance or avian anorexia as effects in their analysis nor compensatory eating. Given the limited data available to parameterize the model, the EPA's approach appears to be appropriate. However, development of protocol to evaluate avoidance repellency should be carried out to ensure quality data is available.

Further investigation of the impact on outputs would be warranted if this attribute is to be included in the model on a regular basis. It was interesting to note that the results from the LP model presented, that when they removed avoidance from consideration, the risk is similar to the result observed from TIM. And that's something that was pointed out this morning in EPA's presentation, but we had come to that conclusion last night.

It is clear to me -- it's interesting we came to the same conclusion. It's clear to me that the whole issue of avoidance, repellency, or avian anorexia and how it's characterized, and how it affects

exposure, and how it's incorporated into the model is very, very important, you know, and I think that's seen by the sort of what if analysis, if you include it in, if you don't include it in. It's certainly something that warrants some attention in the future.

Moving on to the third part of this sub-question, given that the data on food consumptions based on daily measurements, did EPA incorporate these data appropriately into TIM 1, which has a time step that is more consistent with the observations times than the data provided? Please provide a basis for your conclusion. I went back to the SAP results from 2001 and 2004, and I just want to read something that was in the report. "A time step model as presented by the agency is reasonable as a tier-2 approximately." This is from the 2001, so this referenced to TIM 1. "And should produce credible out put provided pesticide intake does not affect the continued rate of intake, i.e. no avoidance, either conditioned diversion or post-ingestional feed incapacity, or avoidance occurs too late relative to an intake commensurate with lethality."

So really what this study was trying to address, I think, was this comment. Okay. That's the origin of it. I think it's important to acknowledge

that. So there's a bunch of other stuff here that will be in the record, but just to show where it's coming from.

What we concluded with respect to this question is the EPA approach has merit as would an approach using an hourly time step as done with LP. However, we must recognize that food avoidance is intimately linked to foraging behavior. Therefore, the driving factor in the choice of approach, i.e. 12 hour or 1 hour, should be the feeding biology of the focal species in question.

Therefore, food avoidance must be applied concurrent with food ingestion no matter the foraging behavior. So this is getting to the point of bringing the ecology into our model constructs to make sure it's appropriate. So if you have focal species that follow both, you have to have the information relevant to that as well as the modeling structure that allows you to assess both.

That's the end of what I have to say. I think that some of the other associate discussants definitely have input on this. I've tried to capture the high points, but I wasn't able to catch them all.

DR. HEERINGA: Thank you, Dr. Delorme.

Dr. McCarty is our next associate discussant.

DR. MCCARTY: I concur but I would just like to emphasize one thing. Peter mentioned the presentation of the results, and I won't go into the details here, but just in comparing the results as they were presented in this paper versus the acetylcholinesterase paper, the study was designed with multiple individuals in each treatment to give us an estimate of variance among individuals, yet as far as I could see, there was no standard error, no standard deviation, no error bars.

We shouldn't have had to go and manually extract the raw data from a PDF file in order to figure out what the competence intervals were. And this is my personal opinion, I think based solely on that, EPA would have been justified in not considering this paper further.

DR. HEERINGA: Dr. Hill.

DR. HILL: I generally concur with what's been said, and I think John just hit on an important point here just a moment ago. And so at this point I don't have anything further to say.

DR. HEERINGA: Thank you. Dr. Sample.

DR. SAMPLE: I concur. My comments have been captured.

DR. HEERINGA: Dr. Clark has comments.

DR. CLARK: I just want to follow a little bit up on the discussion of repellency, versus avoidance, versus food suppression or feeding suppression. In looking intrinsically the avoidance or repellency involves some sort of learning process. Suppression of food intake may not involve that process, whatever the mechanism might be. If you take a look at it from a learning point of view, the actual intake pre during the exposure and post, there are several interesting things.

If you actually look at each individual bird's learning pattern or consumption pattern I should say, is that it becomes clear that regardless of side bias effects and all the criticisms it doesn't really matter. What happens is you find a dose-dependent relationship of decreased intake of food. So what do we have from that?

Well if we're going to take about repellency, the study only showed us one thing; is that some dose-dependent relationship about minimizing food intake occurs, but we don't know anything about the learning process or any other process by which the mechanism is mediated. That is not to say that it's not important, and really that's the crux of trying to include that parameter into the model. Is there basis? Is there

some flavor characteristic?

So what the study did tell us is in a two choice test situation based on flavor characteristics which would include things like taste, odor, and irritation, and tactile views, the animals aren't able to make a discrimination on any of the concentrations. So normally what would happen if you're talking about avoidance in the field, it doesn't mean that that doesn't occur.

In these sorts of paradigms, and there's ample literature with methiocarb to show that birds attend to visual cues much more appropriately. So if they would have colored the pans, they probably could have shown a repellency of that. So that doesn't preclude the fact that avoidance would not be important in the field. You would have to, however, within a timeframe of the malaise that occurs, the 30 minutes, the animal has to associate that with another cue, and this has been documented in other literature for carbamate compounds.

In fact, USDA used to use methiocarb as the best repellent we ever had until it was withdrawn for other reasons, but the point behind this is if you survive the initial assault of the toxicant, it does seem reasonable, given the mechanism and mode of action

of this agent -- let say you put a dot on the field treatment, like human dioxide, or put pie plates in the field for crying out loud. And we've done those sorts of studies with these other compounds, but there might be sight avoidance 'cause what birds are very good at is associating their malaise to an object.

It's unlikely that they'll generalize to a grasshopper, but it's the weirdest newest thing in the field that occurs after their illness, so some sort of pigment or whatever would be a reasonable next step as a test to that. So it's not that it wouldn't occur and couldn't be used as a model parameter, but this particular test didn't explore all of those the possibilities.

DR. HEERINGA: Thank you, Dr. Clark.

Dr. Hill.

DR. HILL: One thing did just come to mind, seemed to me in the design of this that they would have included, since this was a sublethal test by far, it seems they would have included a no-choice diet also in the experiment; that is where it would be just the chemically treated feed by itself because that would certainly put to rest whether or not these animals will eat the stuff.

If they don't have the control option

available to them, and of course in the field sometimes when birds do get into the center of the field, which does happen despite some people find it upsetting to that idea, we do know that birds will get out there, and depending on their feeding behavior and so forth, they will gorge in one place and not really have a choice.

DR. HEERINGA: Dr. Grue.

DR. GRUE: I'd like to just follow up on a couple of comments that Dr. Clark made. The first one, and I mentioned this earlier in our discussions, is that these terms need to be clarified. The test results are more appropriately described as a pesticide-induced reduction in food consumption or anorexic and not repellency and not avoidance.

I don't believe the tests measured that. Secondly, the dose response in reduction in food consumption that was observed is similar to what I personally observed in chonylgrackels exposed to four different organophosphates. And I believe there's sufficient information in the literature suggests that not only may this reduction in food consumption be associated with malaise but also cholinergic effects on the central nervous system.

The work that I've done personally and the

results of this study are similar, both in terms of the dose response and in the development of a threshold. And I personally believe both do exist. The question is then, the data in this data, is adequate to come up with that.

If the test is considered by the registrant as a screening study, then I would argue that the results do suggest that this is something that needs to be considered and evaluated further, and I think the balance of the committee reinforce this.

My last point is that I'm not sure that the design features that have been suggested by EPA are necessarily design features that should be considered or included in the study to actually test these parameters, and I would argue that I know OBCD and so on is debating this right now in terms of what are appropriate protocols to look at this. And I would just make the point that I think we need to be very careful in making recommendations as to what is the best approach until there has been some type of SAP scientific task force review on this so we don't end up with a situation where the results may not as applicable as we hoped. Thank you.

DR. HEERINGA: Dr. Grue. At this point I'd like to move on to part D, and again, panel members

-- okay. Dr. Bailey.

DR. BAILEY: Ted Bailey. The last comment about having factors in the study that protect the model, but I do feel like you need to have the factors that ground the model in that experiment, but you should have another experiment also. You do want to check the model that it's a significant and important model.

DR. HEERINGA: Dr. Edler.

DR. EDLER: A statistical design problem about the avoidance study. Actually this reminds me to clinical trials where we look at the survival and the quality of life, and it's very, very difficulty to resolve actually both things out. The worst case of avoidance is just the death of the bird. So in some sense I think you have to combine through several data if you really go to the avoidance and get a real good picture. This design could be pretty complex.

DR. HEERINGA: Dr. Portier.

DR. PORTIER: I want to ask Dr. Delorme to clarify on question three. I was wondering if I was hearing, would you go as far as to say that it would have been possibly better if they had actually implemented this in TIM 2.1 or looked at this question in the hourly stack model.

I was trying in my own mind trying to decide whether this should have been looked at in TIM 1.0 or in 2.1 with some kind of eight hour to one hour adjustment, and I thought you got close to that but maybe I kind of want to see how close you get to that.

DR. HEERINGA: Dr. Delorme.

DR. DELORME: Peter Delorme. Yeah. We discussed it. I think that we what we were coming at it from the ecological perspective and recognizing that, you know, the ecology should really be considered. There may be cases where the hourly approach is warranted. I don't know that I would be comfortable in proposing criteria for that, but from an ecological perspective there may be times when that's warranted. And I think that's what, you know, one of the things that we were saying, but we recognize the merit of both approaches.

It would be interesting to see what TIM 2.1 would come up with. I think this is what I would like, where my sense is, if there's time to allow. But I think that at the end of the day with respect to our current charge here, there is sufficient uncertainty with respect to the study and how it would be put into the model structure. But you really question if that's going to make an impact, and I think it was pointed out

earlier, the whole question of exposure -- just to be clear, I had a discussion with Wayne Nork yesterday. One of the questions I didn't get to ask was what are the major differences between these models, between LD and TIM 2.1, and a lot of it has to do with how that exposure calculated, okay.

And that's key here 'cause if the exposure is lower, then you're not going to reach the threshold and you're not going to have the effect, and I think that's part of what this question goes to. And at times that is important enough. Does that answer your question?

DR. HEERINGA: Dr. Grue and then Dr. Montgomery.

DR. GRUE: Chris Grue. Just as a quick followup to that, I think the time step is important because the question is if in fact a threshold exists that will induce the birds to stop feeding, then it's important to be able to identify that time course up to which, what it's going to take for the bird to achieve that dosage.

If it occurs early in the day, then the animal, the bird may be put off food then for the balance of the daylight hours, then through the night, and then potentially be able feed then again the following morning. So the duration of the impact of

the I'm going to call it pesticide-induced anorexia is in part, depends on how quickly the bird itself received that threshold dose.

DR. HEERINGA: Dr. Delorme. I guess we'll return in a little bit to Dr. Montgomery.

DR. DELORME: Yeah. And I think, Ken, in responding to your question also, that's one of the reasons I put in the statement from the SAP because I think it's relevant, you know. They said that the tier-2 approximation is credible provided that the pesticide intake doesn't affect continued breed. If it does, then maybe an hourly time step is more appropriate. So in this case it's kind of equivocal. It might or might not. You can't tell from the data, so a what if analysis might have been good.

DR. HEERINGA: Dr. Montgomery.

DR. MONTGOMERY: I'll make this brief because most people have covered, touched on the points I thought of. The one thing that did occur to me in the course of this -- this does relate to the charge question though it does extend beyond it as well -- is that the likelihood of a registrant in this debate he registrant coming with a different time step then what is allowed in the model.

It's probably going to come up again, and it

seems to me that if we're looking for a more universally applicable model, you have to have some way of taking this model and adjusting it between 1 and 12. And having to pick one model because you're closer to 12 and you're closer to 1 is not the best thing when we're trying to design a more universally applicable model.

I'm not saying a solution to it is easy, but if we don't have a standardized way of adjusting the time step, we are always going to have these discussions about how we're going to be viewing the exposure, and the carryover, and all the other issues that follow from that.

DR. HEERINGA: Dr. Sample.

DR. SAMPLE: One followup note with the discussion here, it's sort of getting at the linkages between the modeling component and the ecological aspect of it is needing to emphasize that this has scale to the dose. You can't apply it as it's not, it's not ideal to apply it as a simple adjustment an ingestion rate. You have to have an estimate of the dose, and then once you know what that dose is, then make your adjustment because any given exposure level you may or may not have a dose adequate to require an adjustment to your ingestion.

DR. HEERINGA: Dr. Bailey.

DR. BAILEY: It just occurred to me, do you have the standard error of your estimated values? I think that would be really very important. Otherwise you'd have only one point, and the only thing you could do is keep repeating the experiment to try to get some notion of the variability that comes through with that estimate.

DR. HEERINGA: Dr. Odenkirchen.

DR. ODENKIRCHEN: Just a couple things to clarify. First off, the reason why we asked this question was to differentiate between making very little assumption in terms of what the dynamic is between uptake of the compound, maintaining a dose over a period of time as might be viewed in the "avoidance study," versus a time step where you're going to try and figure out how long, for how long and how high that dose will be; it's not just the magnitude of the dose; it's the duration.

And one of our concerns was to begin with was when we looked at using our hourly time step or liquid params hourly time step was the assumption that you had to make with regard to this adjustment by taking your exposure, multiplying it by something, interpret 57:26 and backing that number back in, was that a hours'

worth of exposure to any given dosage versus 12 hours or eight hours of exposure at any given dosage level has to be assumed to be equivalent at that point in time.

We weren't prepared to make that assumption, so we tried to pick the model which gave us the time step as close to the duration of that dose estimate as best we could tell from the study, and that was the nature of that question. But I think to take it one step further was not that we've heard the ecological aspect, and you've now heard with regards to why we asked this question to begin with, the real question I have is now, how should we interpret the results that we've gotten from or 1 or indeed 2021?

How should be interpret those given the single estimate of response that we have from one given species with the data limitations that we have? So that would be helpful to clarify for us.

DR. HEERINGA: In response though to Dr. Bailey's question, I think that in terms of variability, uncertainly on these risk distributions. Can you address that for him?

DR. ODENKIRCHEN: With regard to variabilities, what you see presented in the model in the central tendency values, there are variability

estimates given for every species, for every combination of sensitivity. In other words, in the output of the model we provide you with a 5th, 50th, and 95th percentile, three points along that distribution.

We can draw distributions from that. We can pick great numbers to look at the variability of output for each iteration of 20 birds on the field. We can provide you with that. When we compare the results, we focused on what we thought was the most robust portion of the curve, which is that central tendency portion, and we compared those across the sensitivity values as it was put out by the model. So you don't see in the comparison values what the fuzzy rat is around each of those, but just the simple tendencies.

But in the model itself you're given each off those variable. So I'm not quite sure what you're asking for.

DR. BAILEY: I guess I would like to ask question. Exactly what it is you're trying to estimate? We've talked a lot about, you know, the bird and within bird variability and things like this. But what is it. You're trying to estimate risk, risk of what?

DR. ODENKIRCHEN: Mortality, percentage

of mortality at the mean levels, what's presented. We're trying to look, calculate is how many birds out of any given set cohort are dying and what's the frequency and magnitude of those projections.

DR. BAILEY: And so things like the avoidance and things like that, or you're not concerned about estimating the effects of those. It would be more like a covariant or something.

DR. ODENKIRCHEN: Well avoidance is incorporated into the exposure side of the model. So what we're looking at is the relative differences in the predictions of what ever position on the curve you want to look at for those cohorts of birds.

DR. HEERINGA: Okay. I would like to move on to part 2D, and I'm not, I am rushing things 'cause we want to stay on track; but I also recognize that when we're finished with 2A to 2D there's a chance to rejoinder. And, again, I've often found that if we take things in sequence, item one gets hits pretty hard and draws into 3. So let's proceed with 2B, recognizing we can return to the other components. Dr. Salice.

DR. SALICE: 2B - The role of dietary matrix in acute toxicity. In 2001, the SAP indicated that the oral LD-50 was more appropriate then the LC-50

for use in avian probabilistic assessments for a chemical with an effective data sets similar to carbofuran. However, they did recognize the dietary matrix could play a roll in modifying acute toxicity of a compound.

In May and June of 2007, FMC provided the agency with two studies on two bird species, purporting to demonstrate that a dietary matrix can reduce acute toxicity of carbofuran. EPA's conclusion regarding the studies is that there does appear to be an effect of the dietary matrix on acute toxicity of carbofuran.

However, the study designs were limited by small sample sizes and insufficient experimental variability that ads uncertainty to the interpretation of results in at least one study. In addition, EPA does not believe that these two studies capture the range of likely responses for wild bird species associated with carbofuran use sites.

However, to evaluate the possible impact of the food matrix on avian risk conclusions, the food matrix effects identified in these studies were used by EPA as inputs to the TIM version 1 and TIM version 2.1 model to provide insight into the extent to which risk estimates could vary.

2BI - Do you concur with the agency's

conclusions regarding the limitations of the data available in food matrix studies? Please provide a basis for your conclusions. Would you like me to read through all these?

2BII - Given the limitations in the food matrix studies, did EPA employ a technically sound approach to use the data from these studies as inputs to the TIM version 1 and TIM version 2.1 model to evaluate the potential for food matrix effects to alter mortality risk estimates. Please provide a basis for your conclusions.

DR. HEERINGA: Dr. Delorme again is going to lead.

DR. DELORME: Peter Delorme. So the answer to the first one is actually fairly short. Yes. We concurred, or the group of us that discussed this concurred with your concerns. Certainly small sample size, variability adding to uncertainly in the interpretation is important.

Again, we're coming back to that species sensitivity question, which is key when you're considering a range of species out in a field. You know, personally I don't think that's going to be unique to this chemical. It's something that you're going to need to have to address chemicals in the

future as well.

As well, we had additional concerns that the food items in the field are qualitatively different in how the exposure is presented, i.e. they're on the surface as opposed to in the matrix. So it's not clear how that could affect the results of the study. You know, it's suggested that they might be more readily available with less matrix interference. In addition to that, the composition of the matrix itself could be important, and it should really be representative of the natural food items of the species of concern, whether it's insects, plants, or seeds. Okay. So that didn't seem to be taken into consideration.

From a big picture scientific perspective like outside our actual charge here, it would be interesting to explore the issue of cross pesticides to allow considerations of differences between different chemistries and examine relations with phys-chem properties. So maybe there's a way of getting at this without actually having to test it all the time. We could establish some sort of relationship between phys-chem properties and matrix.

Maybe it's an absorption/desorption study. I don't know, but I think that if you had the data, that you could do that; and, you know, the animal rights

people would certainly like that for using less birds.

With respect to 2B or B2 and the approach used, the approach the EPA used has merit given the available data. Ideally a full dose relationship should be used rather than multiplying by the central tendency. However, we recognize that matrix could have an effect. It may be linked to food preferences. Therefore, again, the driving force and the choice of approach, both for testing and for modeling, should be the feeding biology of the focal species in question. In addition, to compare with EPA again that species sensitivity is an important factor to be considered, to allow for consideration potential for effects across the ranges of species which can be exposed.

DR. CHAMBERS: Thank you, our second discussant, Dr. McCarty?

DR. MCCARTY: My comments have been captured. I have nothing to add right now.

DR. CHAMBERS: Thank you. Dr. Hill.

DR. HILL: I believe mine have been captured too.

DR. CHAMBERS: Okay, Dr. Sample.

DR. SAMPLE: My comments have been captured.

DR. CHAMBERS: Okay. Any followup from

any other -- okay. Dr. Grue.

DR. GRUE: I just like to indicate that the analysis that EPA conducted reinforces the potential importance of this as a factor of mitigating exposure, and I think that should be considered here relative to what you've presented.

DR. HEERINGA: Dr. Portier.

DR. PORTIER: Something Dr. Delorme said just got me thinking. You know, what we're really talking about from an ecological perspective is that you have in the population of birds you have a distribution. So to think that you can capture the distribution with two points is the biggest problem. So you can't even put a distribution for this factor into your simulation until you look at least 10 or 15 different birds to get a feeling for that perspective. So I like the idea of kind of doing this once, maybe for a whole class of chemicals, but I would argue that you need to do it for a whole group of species and not just two birds.

DR. HEERINGA: Dr. Hill.

DR. HILL: As I think about this more, one thing that always concerns me is the fact that so often we use various types of approximate studies, short, abbreviated type things in order to get the

information that we want, and I am a little troubled because of the fact that these two studies have come up with a couple of numbers, 2.0 and 3.9 as factors to be now in place forever.

And that troubles me because these studies were not really complete studies, even for the determination of the LD-50 because of the appropriate slopes and so forth and the other statistics associated were not determined. So I get around to a philosophical problem that I guess has probably plagued me perhaps since the inception of EPA. But I think when you're taking too much liberty with tests that were conducted without a lot of consultation, and description, and discussion, and you come up with data that is perhaps questionable, then I guess I just go out for the idea that philosophically I'm opposed to putting questionable studies into something that you're trying to refine and make better. It seems to me if you put a questionable study into a situation like this, you've destroyed the whole damn thing; that's kind of how I look at it, but that's from a perspective of not a risk assessor but a researcher.

DR. HEERINGA: Dr. Delorme.

DR. DELORME: And just a followup with that in speaking to Dr. Portier's point, you know, one

of the side effects from moving from a deterministic to a probabilistic approach is that the uncertainties become much more apparent. I think in the past that we've done these deterministic assessments without much consideration for the uncertainty, and as we've moved forward and seen the uncertainty, it points out to us, you know, some of the assumptions that we're making and what data we need in order to fill it.

And in some cases these become important points of the data. For example, data on field use and whatnot with respect to the interpretation of the results. So we just have to be aware of that.

Again, as I said at the beginning, this is a step forward. The availability of these models is a step forward, but we have to take a point in time and say, okay, we're going to use it in this form until we can develop more science. And I'd actually like to commend FMC for doing some of these studies because they do help move us forward, whether it's in study design or in data interpretation, or point out other things we need to know.

DR. HEERINGA: Dr. Hattis.

DR. HATTIS: Yes. I think that's well taken. I think on the other hand if you've found this 3.9 fold factor for one of your two tests and you

applied it to everything without recognizing that you at least have some uncertainty about that, then I think that's -- it helps that you have this recognition of some potential bias in the early estimates, but I think you better, if it's going to be central to your computation of your estimates of policy relevant risks, then you probably ought to take into account the fact that you might be wrong; you might have different answers for different food matrixes for different animals for different contexts. And to recognize all of those difficulties, at least qualitatively and preferably with some assumptions about how uncertain a variable --

DR. HEERINGA: You touched your mic off. Dr. Montgomery.

DR. MONTGOMERY: I can't resist this. This is almost a philosophical issue, you know. It's not just science. As scientists we just can't stand if we don't have every little "i" dotted and "t" crossed before we take the big step and move forward. And then you have to realize that functionality at some point you've got to draw a line and say this is the constructs. This is what we need to do to deal with it. We're going to look at how things develop, and then we're going to modify the construct. And no one,

I don't think anyone here really believes we're ever going to come up with the perfect model that regulated and regulatory communities are all going to be happy with. I mean, I think that's just a fact of life, and this is almost philosophical that manifests itself in these very, very detailed technical discussions that we've had today.

And I think that, that's something that as a scientific community we always struggle with, but we need to realize that, yes, at some point we just got to say, stop. We're going to work with it. We realize it has limitations. These are the limitations. Let's watch for where it manifests itself, and then see what we need to do to correct the course. And as SAP has shown in the evolutions that it's had, there's recognition in this process. It's an ongoing thing, but, honestly, at some point you just got to say is it, you know -- we're not asking anybody to hit a home run.

We're maybe doing a base hit right now and just trying to make a base hit. So, you know, I think that it really is a chicken and an egg thing, and it's almost, it's a philosophical point of science if you will.

DR. HEERINGA: Thank you. At this point I guess I'd like to move on to 2C again with the

recognition that we can return to a summary of question 2. So

Dr. Salice, if you would be willing to.

DR. SALICE: 2C - Estimates of carbofuran, acetylcholinesterase for recovery kinetics. The PRA presented in the 2006 Reregistration Eligibility Science Chapter for Carbofuran, Environmental Fate and Effects Chapter used whole bird elimination rates of carbofuran to estimate carry-over exposure, and its contribution to potential effects, between model time steps.

The 2001 SAP suggested that compounds with well characterized modes of action might also be assessed on the basis of a target site clearance or using some biomarker indicating toxic activity. In April 2007, FMC submitted data on acetylcholinesterase inhibition and recovery that purported to provide recovery estimates based on carbofuran's known mode of action. EPA has reviewed this study and found that results are consistent with carbofuran's known mode of action and recovery kinetics. However, at the highest dose, avian mortality was observed and, moreover, surviving birds did not reach full acetylcholinesterase recovery.

For these reasons, EPA believes there is

still uncertainty regarding recovery kinetics for birds receiving higher exposures to carbofuran. In order to account for the potential impact of these uncertainties on risk conclusions, the highest estimated acetylcholinesterase recovery half-life was used as an input in EPA's PRA model.

Do you concur with the Agency's conclusions regarding the acetylcholinesterase inhibition and recovery data provided? Please provide a basis for your conclusions.

2C-II - Given the limitations in the acetylcholinesterase inhibition and recovery studies, did EPA employ a technically sound approach to use the data from these studies as carbofuran carry-over exposure estimates in the TIM version 1 and version 2.1 models to evaluate the potential for alternative mortality risk estimates? Please provide a basis for your conclusions.

DR. HEERINGA: Dr. Delorme, lead again.

DR. DELORME: I'm not used to getting so much airtime. I think that the panel concurred with the conclusions regarding the acetylcholinesterase inhibition and recovery data. The study is technically sound and provides an excellent description of carbofuran-inhibited brain acetylcholinesterase

recovery for young fully grown northern bobwhite.

Our data study is excessive for the purpose of the study, as the sample result likely could have been achieved with as few as 40 or 80 birds, and there's some further description there. Many studies have indicated that brain cholinesterase is inseparable for adults non-breeding northern bobwhite. However, since the ample data sets have been generated for both sexes, it's used to determine if there is a difference between sexes in recovery of the carbofuran-inhibited brain cholinesterase.

The panel did have concerns that during the recovery phase, behavioral responses were not considered. It is well established that animals with inhibited cholinesterase show altered behavior, and you just have to point to the rat studies that were presented with the motor activity tests following exposure in the period during recovery. In the wild, the altered ability to react could increase secondary effects such as susceptibility to predation or weather conditions. In addition, dependent young of parents could be at risk.

The panel noted that the study design did not allow for full recovery of cholinesterase at all those levels. So in order to estimate the recovery kinetic

with appropriate precision, it is necessary to establish approaches to develop appropriate timeframes for study duration and sampling intervals. Perhaps existing data for birds and other animals would prove useful in this respect.

Moving on to the second part. Given the limitations in cholinesterase inhibition and recovery studies, did EPA employ a technically sound approach to the use of the data from these studies as a carbofuran carryover exposure estimates in the TIM model to evaluate potential for alternative morality risk estimates? The agency used a technically sound approach for inclusion of the cholinesterase inhibition and recovery in the TIM models.

One member noted that ED-50 for brain cholinesterase is not indicative for mortality, but if a dead animal has a brain cholinesterase inhibited by at least 50%, the level has noted to be a sound criteria for diagnosis of death in cholinesterase exposure. There was some discussion about the half-life, the time that was used in the EPA assessment, but I didn't capture all that. I can't remember which member had that as a concern in our discussion. I think we couldn't figure out if you had used the 4.4, or if you had bracketed and lined up choices made.

DR. HEERINGA: Dr. Salice, can you answer?

DR. SALICE: Yeah. To clarify, well, we used both the 1.1 and the 4.4 to provide sort of an overall sense of the impact of using acetylcholinesterase recovery on the model projections. When we looked at the aggregate data, that is the inclusion of the food matrix effects as well, we only used the 4.4 hour half-life.

DR. DELORME: Then I guess the question was why you guys had recalculated those half-lifes and indicated that they were longer?

DR. SALICE: Longer than?

DR. DELORME: Yeah.

DR. SALICE: I thought they were, our half-life --

DR. DELORME: They were your half-lifes, okay.

DR. HEERINGA: Dr. McCarty, associate discussant on this.

DR. MCCARTY: My comments have been captured.

DR. HEERINGA: Dr. Hill.

DR. HILL: Yeah. For the most part, mine have been too. I agree with what all was said. I

just wanted to elaborate a little bit on one point here. And it does have to do with the fact that here we are discussing the lethality and so forth, the mortality associated with carbofuran in natural systems, and then we choose to go ahead and for whatever purpose, seemingly don't go into the literature to find out just what else has been done; and we use this outlandish number of 300 birds to develop a rather simple result that could be done with, that experiment, with far fewer birds.

I do worry about that because from being sensitive to the animals that we are working with and the fact that we don't necessarily have a good reputation as toxicologists among the animal welfare people. I think it might be useful to try to do whatever we can to reduce the number of animals that we necessarily use, particularly when we've got something that's pretty well documented in the literature.

I don't believe this study necessarily needed to have been done even, but I think it could have been extrapolated from other literature. But given that, it's always nice to have your own data, and it's always nice to have it from groups of animals that you have a good history on. So I don't disagree with the idea of actually doing the study, but I do feel that had this

particular project been discussed a little more widely, gotten a little more input, that I think people would have recommended phasing it down because, really, using 300 animals to come up with this information is nonsensical in my estimation; that's my perspective and not necessarily represents the other people in the group.

DR. HEERINGA: Dr. Sample, go ahead.

DR. SAMPLE: My comments have been captured.

DR. HEERINGA: Comments from other members, Dr. Grue.

DR. GRUE: There was a comment made about the recovery slopes and whether or not we would expect to see a differential slope associated with differences in the magnitude of the initial inhibition, and I just recently completed studies looking at recovery in carbo with some monarchs. And there's other data already in the literature that looked at that as well, and the pattern we see here talking about fish is identical to the pattern we're seeing with carbofuran and quail. So I think that's a real pattern we're seeing.

The other point I just want to make is that irrespective of whether you take the ultimate or the

endpoint of the number of hours on your projection up to the actual control mean, which looking at your graph the worst case scenario is about 10 hours, it's important to note that during the evening hiatus of the feeding you would expect then at that time, that's 10 to 12 hours, you would expect a recovery back to control levels at that point. But it hasn't been clear to me through the process how we're dealing with the evening hiatus or the nighttime hiatus on some of these things, but I think that's an important point to the study.

DR. HEERINGA: Dr. Hattis.

DR. HATTIS: Again, I think that if we're going -- the FMC for using a uniform 3.9 factor to adjust the dose for matrix effects and things of that sort, we ought probably not -- you know, it's reasonable for sensitivity analysis to use your 4.4 hour half-life, you know, as one point in your sensitivity analysis, but if you're going to do your modeling to represent the likely reality, then it seems to me you have some sort of a relationship between dose and half-life, and you probably, at the minimum, have the dependency incorporated into the modeling.

At the same time, it's likely variability across individuals and across species in the rates of

recovery, and one could make estimates of what that, what that variability is likely to be from external data on how variable elimination rates happen to be in all kinds of other contexts.

DR. HEERINGA: Dr. McCarty. Dr. Schlenk first and then Dr. McCarty.

DR. SCHLENK: Actually I have a couple comments, and this is based upon some comments Dr. Lu had yesterday. I didn't even see this until he brought this up. But in looking at the registrant's data, particularly on slide #20, which actually shows the recovery curves, it actually dawned on me, I gave a lecture last week on ethanol pharmacokinetics, actually really the kinetic pattern there, if you do the kinetic analysis, it's actually a first zero-order process as opposed to a first-order process.

So because of that you really don't have a half-life. You can only estimate an elimination rate constant for that, which is what you do with ethanol, sort of elimination. So I think you're justified in not using the 4.4, but in fact actually calculating elimination rate constant for the cholinesterase, you're going to implement that. However, when I looked at your model, the TIM, this was this morning, I noticed that all of the curves that were calculated

actually were first-order processes.

So I think you might have to tweak something in that model. Obviously you got the real data from the 300 bird studies, so something has to be tweaked on that high dose to get that curve simulation appropriate. I know we're not suppose to recommend methodology or anything, but one thing that kind of puzzled me was why wasn't a PBK type of approach utilized as far as departmental analysis with plot transformation separate from a target organ kind of input.

I would guess that you would know most of those blood flow constants, definitely for the rat, which I guess we're going the human stuff tomorrow, but definitely for the rat human comparisons. I think that would, you could get an estimate of how much it would actually be in the CNS if you're going to be using brain and get a fairly good estimate of those tissue concentrations. I don't know what's available in terms of the birds as far as blood flow parameters and that type of stuff.

But anyway, again, we're not supposed to be recommending additional methodology, but it just seemed to me that would be kind of a first approach if you wanted to reduce that uncertainty as far as the kinetic

patterns.

DR. HEERINGA: And I think that's perfectly appropriate because it has relevance to the current data and the current model. Dr. Odenkirchen.

DR. ODENKIRCHEN: Yeah. Just to respond to that. Back in 2004 when we presented TIM 2, we actually had a presentation by ORD with regard to the exploration of PBK models. That remains an initiative with regards to the office of research and development.

When they get to the point where they're ready for us to start to incorporate them into these kinds of models, which I would suggest is probably still fairly far down the road, we'll start looking into that. You are correct, it is a departure from the current methodology, and it's a rather complex departure from the current methodology as well. It's been something that I believe Dr. Portier at the very first SAP with regards to looking at clearance rates, etcetera, where we relied on clearance rate much as we've done in 1 and 2 for carbofuran.

And, again, these models are a little far out for us in terms of developmental maturities. So we're trying to make use of the data we have within the construct of the model that we have now, and the model right now we're dealing with, unfortunately or

fortunately, is constrained right now by a first order assumption. So it would require some rewriting of the code, etcetera to do that, which would result in version 1.1 and 2.1a or something; I'm not quite sure what. But that is something that we can consider as we go farther down for other chemicals in departing from that first door.

DR. SCHLENK: Just to follow up too, I noticed -- I should have brought this up earlier, but it kept skipping my mind. The other component is the metabolite issue with the 3-hydroxy; that hasn't been raises as well, and I think obviously if you could do a V-max KM component, apparently it's equitoxic in terms of potency with cholinesterase inhibition. That also may explain perhaps some of the kinetic variance that you see as well, just a guess on that.

DR. HEERINGA: Dr. McCarty.

DR. MCCARTY: I just want to follow up on something Dr. Grue mentioned in hopes of inappropriate bird ecology not being perpetuated from SAP to SAP. He mentioned the evening hiatus, and I just want to remind people before this gets incorporated that, first of all, the tests were done in 8-hour light, 16-hours dark, which caught my attention but I'm told it's standard operating procedure.

The birds that are going to be exposed are more likely to be encountered in the 16-hour light period, so keep that in mind. And secondly, a lot of birds feed at night, including some waterfowl, shorebirds, things like that, so maybe there's always an evening hiatus. So I just wanted to put that on the record.

DR. HEERINGA: Thank you very much. Dr. Hattis.

DR. HATTIS: Just briefly, I think that Dr. Schlenk's suggestion of a zero order process is quite, quite likely in fact. Essentially with ethanol you get a zero-order process because you've more than saturated the metabolic enzyme, and that's a much simpler adaptation than a few a PBK, you know, additional requirement. It does require one equation, but it's not as onerous as a PBK.

DR. HEERINGA: Okay. I'd like to move on to question 2D at this point. Dr. Salice, if you would read it into the record, please.

DR. SALICE: Question 2D - Quantitative results of new date. The agency has presented individual and combined impacts of the new data sets on avian acute mortality predictions in and around a carbofuran-treated use site, using the TIM framework.

EPA believes that the new data do provide the limited means to further quantify the range of possible risk estimates based on different model inputs or assumptions concerning avoidance of carbofuran-treated feed, toxicity of carbofuran in different feed matrices, and carbofuran carry-over exposure between feeding events.

However, the results of additional probabilistic modeling, using the TIM framework, with incorporation of the newly submitted data produce mortality estimates to birds that are comparable to those reported in the agency's 2006 Reregistration Eligibility Science Chapter for Carbofuran, Environmental Fate and Effects Chapter and do not alter EPA's avian risk conclusions.

Does the SAP agree that these new data when considered together do not significantly alter the agency's overall probabilistic estimates of carbofuran's risk of mortality to avian species in and around a carbofuran-treated use site? Please provide a basis for your conclusions.

DR. HEERINGA: Dr. Delorme, more airtime.

DR. DELORME: Yeah. But there's light at the end of the tunnel; maybe my bladder will

survive. The additional data developed by the registrant, although beneficial, provide limited resolution to previously identified SAP concerns.

The data were limited for a number of reasons that we've already discussed, and from a scientific perspective, and, again, going back to one of the consistent themes, there is a concern that they were not representative of the wide range of species which could be affected by the various processes. Given the limitations of the data, integrating the result into the model is problematic. Furthermore, interactions among these metrics and those already in the model are currently undefined or unknown.

Taking into consideration the limitations of the data and using their preliminary result as a point of departure to do what if analysis, i.e. taking a leap of faith that they're reasonable, their inclusion by EPA in the models provide insight into how risks may vary in relation to the specific issues addressed. Given this, it's our conclusion that the risk estimate based on these models and the scenarios used are not significantly altered.

And then I had some following comments from some of the group members. EPA's analysis of each of the studies independently is appropriate. However, I

do not think the aggregate approach where EPA changed all the variable simultaneously is justified. EPA is justified in considering the implications of cholinesterase inhibition recovery study and the food matrix studies. Whatever the limitations of these studies on their own, they raise additional questions that suggest that incorporating them in an aggregate, into a model may not be warranted.

If one accepts the importance of food matrix on toxicology, then other variables based on aqueous bolus dose methods including recent AChE recovery studies should be reexamined. While we know of no data to evaluate this, the result of the food matrix study itself suggested it might not be reasonable to apply both the correction from the food matrix study and the cholinesterase recovery into a single model. Specifically, the fact that the timed onset of symptoms was longer with the food dose approach suggested that time quotes of cholinesterase inhibition might be different.

Likewise, the study notes that recovery of birds that did not die could take over seven hours, indicating a delayed cholinesterase recovery with this dosing method is a plausible hypothesis.

Likewise, the uncertain effect of the gorge

feeding scenario of the matrix study were, according to the registrant, up to 50% of the daily feed in a single delivery is then applied for low level consistent feeders modeled in the liquid param. The effect of the matrix study may or may not be replicated in a study where birds are provided small dishes of food over a long period rather than a single gorge dose. With that, I'll open it up to the associate discussants.

DR. HEERINGA: Dr. McCarty.

DR. MCCARTY: I don't have anything to add, but I did want to point out that captured in our comments was some information I got from a side conversation with Dr. Larry Brewer. He's the one that pointed out to me that by his estimate about 50% of the daily food intake of the birds was incorporated in that food bolus dose, and then he also clarified for me, in the raw data it indicates some birds took 24 hours to recover.

But he indicated that was a function of birds being given a dose in the morning, still showing effects at the end of the working day, people going home and not checking the birds until 24 hours later. So it's uncertain, but that was a side conversation and it influenced the decision.

DR. HEERINGA: Thank you, Dr. McCarty.

That's the appropriate way to handle that. Dr. Hill.

DR. HILL: I believe that my thoughts on this were covered. I'm happy with it.

DR. HEERINGA: Dr. Sample.

DR. SAMPLE: My comments are generally captured. I think the one thing that I really want to emphasize is taking into account what are the interactions of applying all of these adjustments simultaneously without knowing how they can relate with each other.

Approaching this from a risk assessment side, when we do our screening we're constantly, you know, focusing on compound conservatism by taking multiple conservative estimates that will get you a high estimate of risk. And there is the potential that then some of this may be leading to a compound liberalism in that since we do not know exactly how they respond. And I think it's also important to, as the modeling moves forward, that the interactions between not just these parameters but the other parameters be explained and integrated into the model so that if there are covariant parameters, they are allowed to co-vary in the model runs.

DR. HEERINGA: Thank you, Dr. Sample. Comments from other members of the panel on this item,

2D. Any additional comments at this point on any of the aspects of the question 2, which pertained to the new studies submitted by the registrant and their application in the modeling process or their appropriate use by the EPA in the modeling process? Dr. Brimijoin.

DR. BRIMIJOIN: This may be more of a question than a comment, but I understood I heard from Dr. Salice that the half-life estimate that we've settled on using is at the high end of the experimentally determined range, namely 4. something hours, and not the 12-hour step that we had originally built into the TIM 1 model.

If that's the case, I think that's fair, although it's still undoubtably somewhat conservative. Given that high end half-life, it would apply only to the birds that were consuming a near lethal dose in the initial phase. And so for the more crucial issue of, or more common issue of birds consuming sublethal amounts but repetitively, most likely the effect of recovery half-life would be much shorter. So I think even that reduced estimate from 12 down to 4 is still probably too conservative.

DR. HEERINGA: Dr. Salice.

DR. SALICE: Yeah. I just want to

clarify. The 4.4 and this may reflect my misunderstanding of the question or comment, but the 4.4 hour half-life was used in both models and adjusted to fit if you will this 12-hour time step in TIM 1 and the one-hour time step in TIM 2, just to clarify. And it's also, to sort of capture the range with possible responses, we did use the 1.1 hour half-life to see the impact that would have on risk projections looking at only that aspect of the model.

DR. HEERINGA: Dr. Sparling, did I see you? At this point I think what I'd like to do is to call a short break. Dr. Salice, I'll turn to you before I do that. Are you satisfied with the response of the panel to the charge question? And I don't want to get into extensive sort of reconsideration of issues, but make sure that everything is clear with regard to the panel's response.

DR. SALICE: Yes, we're satisfied.

DR. HEERINGA: Okay. Thank you very much. Let's take a 15-minute break and return at 10 minutes after 3:00.

(WHEREUPON, a break was taken.)

DR. HEERINGA: We'll wait just a second for Dr. Hill to return and also to get our designated federal official. We'll start with the designated

federal official. Just a quick note, again, Dr. Isom is on the telephone. For those of you, you have a pair of mics, if you could move the cups or the receivers on these closer together because some of you faded out for him, and I think it's appropriate to him join us. I want to make sure that he hears all the proceedings, and if you do hear a voice from above, it is Dr. Isom. And we will, in fact, acknowledge him at an appropriate time.

Before we move to question three, Dr. Delorme had one final comment that he wanted to add in response to charge question number two, and you can do that, Peter.

DR. DELORME: Peter Delorme. One of the things that we had discussed in the group -- and the other thing I want to do is I want to acknowledge the input that I got from the group. We had a lot of discussion. We had a lot of analysis going on, and it really helped us clarify things being able to bounce ideas off one another.

I'd like to thank the group for putting up with me when we were doing this. But one of the things we discussed is the need for some sort of framework for interpretation of the modeling results, and FMC did present something. I think that it's something that

EPA is going to have to look at because not everything is going to come out with this one. You need to have something in the future that helps both the registrants, the public, and the risk managers understand the information that we're presenting.

DR. HEERINGA: Again, just another administrative reminder to everyone, speak into the mic carefully. Even I guess within the room here, we have some people in the very back who can't pick us up.

Dr. Montgomery, you had something else to add on charge two?

DR. MONTGOMERY: Just a very small addition. The way I thought we were having these discussions is as a communication tool what would be the probabilistic equivalent of a LOC? When you have something that shows such acute toxicity, you can say, well, you know, it came down X percentage and it's still, you know, 50% too high. But going down the road, if we're using this as an approach, we need to be able to put this in context for people so that -- I know it's probabilistic in these error bars, but people still need to zoom in on something to ground them and that's what we were discussing.

DR. HEERINGA: Dr. Sample.

DR. SAMPLE: And just a followup on the

example that was in the registrant's material's it provided, we were talking percents, sort of showing you then the two dimensions and risk ranges on this particular level.

DR. HEERINGA: Just to, for the panel members, we have, during the break, received two additional documents. One of them is 10G protected, but it's the meta-analysis of benchmark doses for acute oral exposure to carbofuran, and I guess this is -- three documents. I can't start to talk without a new document arriving.

We did have also a one-sheet document as a response to a question raised by the FIFRA panel. It pertains to the geometric standard deviations from Dr. Carlson. And then the third document is also the response to questions raise, and that one is also from Dr. Carlson of FMC. So I would encourage all of the panel members to review these documents in the course of the new few time periods so we have a chance again to reflect that information as well.

Now I'd like to, at this point in time, go to charge question number three. And if I could ask Dr. Salice to read that into the record, please.

DR. PANGER: Melissa Panger is going to be reading that one.

DR. HEERINGA: Thank you, Melissa. I think I called you Pranger yesterday. I did know a Pranger at one time.

DR. PANGER: I've been called worse so that's fine.

DR. HEERINGA: I think it's been a couple of things, but please.

DR. PANGER: Okay. Thank you. So Melissa Panger, question number three, interpretation of incident reports. Since 2000, the Agency has observed a decrease in the number of reported wildlife incidents for pesticides as a whole based on data in the agency's Ecological Incident Information System, which is the EIIS version 2.

This decline corresponds to a decline in state-sponsored wildlife incident monitoring programs, which was in the Avian Incident Monitoring System Final Report that was provided to you. Incidents associated with carbofuran also have followed this trend, with a decrease in the number of wildlife incidents reported in the last several years.

Please comment on the Agency's conclusion that the decrease in recent reported wildlife mortality incidents associated with carbofuran is likely related to an associated reduction in monitoring and/or

reporting and does not provide affirmative evidence that the use of carbofuran, as currently registered, does not continue to cause a risk to wildlife, specifically birds. Please provide a basis for your conclusions.

DR. HEERINGA: Dr. Grue is our lead discussant on this question. Make sure we get both mics together, Chris.

DR. GRUE: Relative to the response of this question, I'm not necessarily speaking on behalf of all of the discussants and would be looking to them to provide their interpretations of my conclusions if, in fact, if they'd like to augment.

The agency's conclusion here is compounded by the fact of at least three factors, label changes, improved stewardship, and a reduction in state monitoring efforts due to funding limitations, and a change in the regulatory requirements under FIFRA for the reporting of incidents by registrant may account for the observed decline in incident reports.

Each of these factors were discussed in the agency's supporting documents and presented to the SAP by Dr. Panger. The agency dismissed the possibility that the reduction in reported incidents may be associated with restrictions in the use of carbofuran

and associated changes in the labels for these uses in 1998 as well as improved stewardship by the registrant and applicators. The agency rejected this possibility based in part on avian incident data associated with the use of carbofuran on grapes in California; that is one incident pre 1992, 27 incidents between '92 and '93, and no incidents thereafter.

However, this use was mitigated shortly after these incidents occurred. One would hope that the history of concerns associated with the use of carbofuran, coupled with increases in pressures for improved stewardship within the industry, contributed to the observed decline. And just as a side note here, I'd be interesting to know if the abrupt decline in carbofuran related incidents, beginning in 1994, was associated with restrictions in the use of granular formulations after 1992.

A visual comparison of the frequency of the histograms presented by the agency for carbofuran and non-carbofuran related incidents may support this conclusion that the decline began in the late 1990's for both groups of incidents, and the number of carbofuran incidences appeared to drop off sooner and more rapidly. The fact that the majority of the avian incidents associated with the use of carbofuran since

1998, 90% according to FMC, 60% to 95% according to the US EPA depending on what the fate of 60 un-determinates were associated with misuse also supports this conclusion.

One could argue, an this argument was made earlier today, that the distinction between mortality resulting from label uses and misuse are not important because the efficacy of a pesticide in illegally killing birds is a reflection of its toxicity to birds and reflects the availability of the product and it's capability to use it for legal purposes. At a minimum, the data on misuse indicate that the toxicity of carbofuran diverts high and that the necessary safeguards need to be in place, label and stewardship, to reduce the potential for incidents irrespective of motivation.

Similarly, one cannot argue that reductions in funding or reporting requirements for the registrants are not responsible for the decline in avian incident reports with carbofuran and other pesticides. The agency changed it's reporting requirements for registrants in 1998. At the same time, new restrictions and labels for existing uses of carbofuran were initiated. The potential effects of these new reporting thresholds on the number of

incidents reported and the quality of the reports, irrespective of the pesticide involved, are significant, and these were presented this morning by Dr. Mark. As a result of this action, coupled with funding limitations for incident reporting by state agencies, and I would argue the extent of this is really not clear. It's difficult to determine the cause of the decline of carbofuran related avian incidents.

And I'd like to just step back and be a little philosophical at this point and a take a little liberty here. Given the need for environmental surveillance as the only means by which false negatives can be identified in the agency's current regulatory paradigm, it is difficult to understand why reporting requirements would be relaxed and funding for the most comprehensive incident reporting database, referring to AIMS here, reduced, thereby compromising if not eliminating one of the three lines of evidence used by both the agency and the registrant in the current regulatory decision as well as others in the future.

I would argue that without targeted field studies and effective environmental surveillance, the utility of the modeling approach that we're discussing here that are undoubtedly going to be emphasized in the

future, are going to be severely compromised.

DR. HEERINGA: Thank you, Dr. Grue. I'd like to turn to the first associate discussant and that's Donald Sparling.

DR. SPARLING: Donald Sparling from Southern Illinois University. Dr. Grue reflected many of my ideas. I just would like to add a few things here. As Dr. Grue indicated, several factors relating to the time they reported incidents of mortality, they are independent of actual biopsy..

Dr. Michael Fry of the American Bird Conservancy said that the changes reported criteria substantially altered the number of incidents that were reported in the ICE database. Specially mentioned and as indicated by the agency, that the increase to 200 birds of a flocking species, 50 birds of a non-flocking species, and five predatory birds would have made a substantial difference in AIMS database gone from 2575 records to 130 incidents, a decline of about 95%. So it appears that the change in the regulatory nature of reporting certainly could have had an effect on what we have seen since 1998.

It is also well documented, I believe, at the federal level in the past several years, funding has been reduced or stable, and even fixed costs or fixed

budgets from one year to another with reduced operational costs for discretionary projects such as monitoring, and may have lead to reduced monitoring by federal agencies. States are much more variable. I would testify that in the state of Illinois, for example, the Illinois Department of Natural Resource budget has declined about 20% over the past five years. Again, if monitoring had been an element, many programs were eliminated.

I would also, just in the sake of fairness, take a look at Dr. Panger's report, slide number 28. It should be noted that between 1972 and 2000, 21 of 31 of registered use deaths occurred in the alfalfa. If this crop was removed from registration as proposed, as I understand it, there may be a decrease in deaths under registered use practices, but that only accounts for a minority of the total deaths anyway. The decrease in state monitoring activities is further accentuated by Dr. Odenkirchen's statement that the State of California, which was number two on the list of states reporting incidents is no longer, they are not reporting anymore. Okay. I think that's it.

DR. HEERINGA: Thank you, Dr. Sparling. Dr. Clark.

DR. CLARK: I agree principally with

what Dr. Grue had said, and I just want to add one brief comment. The type of reporting in terms of incidents, for example, in the avian incident monitoring system from about 1990 or so is relatively constant, and then decreases, as has been pointed out, around 2002.

Yet the carbofuran use has been declining since the 1990s to that point. So the point behind this comment is that if there were a one to one correspondence, you would expect to see it, but for some part you see no reporting and use of carbofuran relationship. And then later in the history you see a concordant decrease in both reporting and use of carbofuran. So the point behind it is that if you selectively slice out the data, no matter which way it goes, whether they are co-varied or not, you can make any of the arguments as Dr. Grue pointed out. It's compounded with a variety of other factors.

So attributing causality based on the incident monitoring system, whether it's the EIS or the AIMS is quite difficult, and to give it weight per se as an individual argument I think is problematic.

DR. HEERINGA: Dr. Hill.

DR. HILL: I think Dr. Grue and so forth have really covered most of the issues here, but I did

have a question. This is kind of directed toward the agency; in fact, it is. I either missed it or let it slip past me, but when the granular formulation was phased out, were those particular uses substituted for with the flowable, or were they just cancelled out, zip; they were no longer used?

DR. BRADBURY: Dr. Bradbury. If I could ask to get back to you on that just to make sure I've got accurate information 'cause I'm not confident for sure right now, but we'll get back on that question shortly.

DR. HEERINGA: Thank you very much, Dr. Bradbury.

DR. HILL: Because that really does seem to be the important issue that I hadn't thought of, and if I missed it I apologize to the board members. But it seems to me that if it was a simple substitution, then that would be one issue, but if the granulars were simply omitted from use, then that would substantially reduce the amount of carbofuran used over that period of time, which could partially explain for this, this particular issue that seems rather abrupt.

DR. PANGER: Well while they're looking for numbers, what we do know is that when the granular was brought down to 2500 pounds per acre, that when the

granular went down, flowable use did go up. I don't know specifically what crops were substituted for what, but we do know that there was that, you know, decline in granular, arise in flowable.

DR. HILL: But not necessarily a simple change in formulation in a particular use?

DR. PANGER: There was no change in formulation.

DR. HILL: I know, but I mean from the granular to the flowable?

DR. PANGER: Yeah.

DR. HILL: That didn't happen?

DR. PANGER: I don't know about the specific uses. I just know an overall use, granular went down --

DR. HILL: Yeah.

DR. PANGER: -- flowable went up.

DR. HILL: Because when flowable was pulled back in the 70s and substituted for the granular, it was just the simple one for one, and of course mortality persisted. But that was the days when they thought flowable was bad and the granular was a good substitution.

DR. HEERINGA: Dr. Bradbury, where do you want to go with this?

DR. BRADBURY: With about 85% to 95% confidence on that, when the granular changes happened, rice would be an example of a use that didn't carry over, otherwise flowable and granular were similar sources. That make sense? Okay.

DR. HEERINGA: Dr. Hill, any additional. Dr. McCarty?

DR. MCCARTY: John McCarty. Well I'm a big fan of monitoring systems. I think they're really important, and one of my colleagues has already mentioned this. But what we've got here isn't a monitoring system, it's a reporting system, obvious flows, the chain of unlikely events to get something in the database, unlikely events that we don't quantified estimates of how unlikely they are to be changing etcetera, etcetera, so that the events here are useful only in a one tail context; that is that they provide evidence that events occur.

Now we've been discussing this apparent decline in recent years and the three hypotheses, and my opinion is, you know, FMC has suggested data on, I believe, sales of carbofuran shown a decline. They've talked about their stewardship efforts, and this is responsible for the decline. As a personal opinion, I hope they're right. I think that's this type of

proactive attitude that we need to promote. ABC and ETA have shown data showing the decline is consistent with the change in FIFRA reporting.

I fully support that. It's a shame that, that change was made, but it is consistent with the observations that, that's responsible. I think a good argument has been made that the cuts in state budgets are plausible and consistent. I think the EPA presented data showing an almost identical decline in all reporting events, not just carbofuran, which strengthens their case. But I guess if I'm going to look at the two questions that were given up there, I'll take the second one first, does not provide affirmative evidence that the use of carbofuran is currently registered, does not continue to cause a risk to wildlife, specifically birds.

If I'm interpreting all the negatives in that statement correctly, I'd say I agree. Yeah. There isn't evidence that carbofuran has stopped killing birds. But to take the first question, carbofuran is likely, that the decrease is associated with reduction in monitoring and/or reporting, I've got to say I don't agree with that.

The data, it's plausible but they can't confirm it. Now at the same time I have to say the

same thing about FMC's hypothesis that it's declines due to reduction in stewardship. The data aren't there. They're being used inappropriately to go beyond what this idea that they just demonstrate that mortality occurs, and we can't assign causality with this database.

DR. HEERINGA: Thank you very much, Dr. McCarty and the other discussants. Any additional comments from other members of the panel. Dr. Brimijoin. Make sure you get the mics close to you. You're one of the silent ones.

DR. BRIMIJOIN: I think I agree with what I'm hearing on the expert eco side of the panel, but I just would like to comment that it seems to me that you have one hard piece of evidence in all of this. The reporting of bird kills is problematic at best.

Stewardship is impossible to quantify. I think FMC deserves some credit for at least speaking to this issue, but things are either impossible to quantify or hard for us to rely on and so affirmative evidence is hard to come by. As such, unless I grossly misunderstood the presentations so far, we've heard that there has been a drastic reduction in the amount of carbofuran use, drastic reduction, not small. And

the proposed continuation would be for still further reduction for current model.

It talks of being phased out, and this reduction will amount to greater than 90%. So it stands to reason that we might be faced with a situation if use were to continue that, yes, there would continue to be bird death and no amount of stewardship is going to prevent it. But they can probably with decline find more than one magnitude, and since the EPA will have to balance the benefits, I think that fact deserves to be acknowledged.

DR. HEERINGA: Dr. McCarty.

DR. MCCARTY: I think just to clarify in addressing the question, you're right. I would agree with you about the decline in carbofuran and that it's plausible, absolutely plausible that bird deaths have declined, but we don't have evidence of that in this database. And my other clarifying point would be I am not comfortable using proposed possible changes that haven't been implemented, haven't gone through the regulatory system.

Great if it happens, but I don't see that as a basis for making decisions until the regulatory system continues to go forward. But I certainly agree that it's plausible that bird deaths have declined.

DR. HEERINGA: Dr. Brimijoin.

DR. BRIMIJOIN: So all I mean is that to assume that they haven't declined would mean that current practices are exposing birds to dramatically higher risks of death from substantially smaller amount of the compound. So the remaining limited uses have got to be, would have to be associated with orders of magnitude greater bird kills for, for them not, deaths not to have declined. And it seemed to be highly probable.

DR. HEERINGA: Dr. McCarty.

DR. MCCARTY: This is also though a matter of scale. Our discussions have been focused on a field by field analysis.

DR. BRIMIJOIN: Yes.

DR. MCCARTY: And that's not changing or presumably. I mean, again, you can make an argument that, that has changed. So I think it's important to remain clear, the local effects versus continental scale effects.

DR. HEERINGA: Individual versus population averaged. Dr. Clark.

DR. CLARK: I agree with the basic tenant that you're proposing. It seems, stands to reason that we decrease the quantity of material that

we're putting out there on a spatial scale, that there would also be a proportional decrease in, in the number of mortality events.

I think the point that we're trying to make is that there's, well least what I was trying to make, is that given the data that we do have, if you take a look, for example, carbofuran use, even if isn't monitoring incident reporting. Actually prior to 2002, there's no relationship between use and incident reporting, and then after there's a concordant relationship.

So that's really the question, is the monitoring system sensitive enough to pick up those things. It is reasonable to assume what you just said, but based on the data structure we can't make that assessment.

DR. HEERINGA: I turn to you, Dr. Salice, or Dr. Panger, make sure that your satisfied. And I think it's a pretty clear statement, but I will let you judge.

DR. PANGER: We're fine. Thanks.

DR. HEERINGA: I'd like to -- Dr. Grue.

DR. GRUE: Maybe I could just ask a question to you in terms of procedure. Since that issue has been brought up and we didn't really, or

didn't have the opportunity to look at that relative to the -- which I should have. I should have; that's a very good point. Do I have the opportunity to --

DR. HEERINGA: Absolutely. Right.

DR. GRUE: -- since it's been brought up to include in the -- okay.

DR. HEERINGA: Yeah. It's been our policy in these meetings that any point, and I will give everyone an opportunity at the end of the day. We've got today and tomorrow to revisit these. And if you need time tonight and you have something that you find tonight that you'd like to present, you'll always have the opportunity. So simply because I move on from one question to the next doesn't mean that you're forbidden from ever revisiting it again.

DR. GRUE: That's was necessary additional presentation. Then that's the week that to look at them.

DR. HEERINGA: You can look at them and come back and just say --

DR. GRUE: Include them in the written documentation.

DR. HEERINGA: absolutely, and applies to any question. Obviously the very last question you have a very short time to do that, but that's -- let's

turn to question number four, Dr. Panger.

DR. PANGER: Melissa Panger, question number four, interpretation of field studies and monitoring efforts. In the 2006 Reregistration Eligibility Science Chapter for Carbofuran, Environmental Fate and Effects Chapter, pages 106 to 130, the agency discussed certain State-conducted carbofuran monitoring studies and available field studies on the effects of carbofuran.

The agency concluded that the state-conducted monitoring studies were flawed and provided only limited insight into the effects of carbofuran, and that overall the available field studies support the conclusion that carbofuran use causes a risk to wildlife, specifically birds. Question four, does the SAP concur with the agency's conclusions regarding the state-conducted monitoring studies and the available field studies on the effects of carbofuran? Please provide a basis for your conclusion.

DR. HEERINGA: Dr. Clark.

DR. CLARK: I'll start with what all the panelists have agreed upon, and then we had some individual comments to make as well. We're in agreement that the EPA's assessment that carbofuran can and does cause avian mortality does occur. They

concluded that the state-conducted studies were flawed and only supplied with limited insight into the effects of carbofuran treatment with agricultural fields. You also have to recognize that conducting field studies that adhere to after our conditions of study design are difficult even under the best conditions.

So for example many of the state studies, the 1989 study for example, refer to plots not treated with carbofuran as control plots, but because these plots were treated with other pesticides, they're not in the true sense a control and the analysis is not strictly speaking testing carbofuran treatment against a known condition, which is one of the other assumptions under the test.

The tests are really comparisons of known carbofuran treatments versus not treated with carbofuran and with some other factors that might be contributing to mortality. In this sense the EPA is correct that a strict carbofuran effect is difficult to attribute for a variety of reasons that have been mentioned throughout the proceedings.

The panel agrees that the inferences based on these sorts of studies in terms of attributing effects should be highly constrained and conditional statements should be made. And Dr. McCarty has a couple of

comments that he wants to make, and then I'd like to return to my individual comment as well.

DR. HEERINGA: Dr. McCarty.

DR. MCCARTY: First I'm going to preface this again with these field studies, we had a hard time accessing, and I've relied on information from Dr. Lou Best to clarify some points that have influenced my decision; and sorry but I need to run through these quickly. Concerns that came up were about the censusing (sic) that was done on live birds, and he noted that different areas were searched for live birds versus dead birds; but he clarified that it was standardized to area. He also gave me some more information about search efficiency and how that was determined, that they put out dead chicks randomly and used dogs at all the sites to find these birds. And I believe that's the information he provided outside the context of the regular question.

A big issue in the way these studies are being used, and I think Larry is going to touch on this as well, but it's being used by both groups is trying to use these estimates to quantify an absolute number of birds that are dead as opposed to a relative number, as opposed to higher in one field than in another. To do that we need to know in excruciating detail recovery

efficiency, and the placing dead birds is a good start. It's a good way, especially when these were done 20 some years ago to start to approach this, and they're to be commended, these studies, for having attempted to quantify this.

These approaches though of seeding an area with dead birds and then trying to find them, this is going to help for comparing, for example, search efficiencies between different field workers, and that's a big issue, not everybody is good at finding dead birds, possibly to compare efficiency in different sites. Another thing Dr. Best mentioned is, you know, the difference between trying to find a dead bird in a cornfield versus waist-high alfalfa fields, and it's a good way to quantify that. What these studies aren't sufficient to demonstrate is that searchers are going to find natural kills and certainly not at the same rate that they're finding seeded dead birds.

A key unknown in this is the propensity of impaired birds to either leave the study site or most importantly to hide. There's a paper, Berger et al, 2002, noting that one of the observed effects of cholinesterase in addition may be hiding. This is a study on captive European starlings.

They were exposed to a different inhibitor.

Somebody's going to have to help me with the pronunciation here, chlorfenvinphos; is that right? That the birds that were dosed would move away and hide after exposure to the pesticide, and that's Friday et al, 1996. One of the things, to give you an idea, even in this simplified captive aviary, the researchers noted they had trouble finding the birds in the aviary.

Now this study wasn't conducted with carbofuran. It does suggest that simple seeding of birds isn't sufficient to mimic the difficulty of locating dead birds in the field. Another line of evidence, anybody, I've done this, anybody whose radio-track small birds and then tried to find the birds that die. The only way you can find them is we literally get down on our hands and knees with an antenna in the grass trying to find the signal of the bird that's died. Now this is outside the scope of our charge, but there are techniques that could help to overcome this program in future studies.

This includes the application of statistical sampling approaches that have become virtually mandatory for bird surveys in the past decade to estimate detectability. Things like distant sampling, observer sample, got a list of references, Burnham et al, 1980; Bucklin, 1993; Nichols, 2000; etcetera, and

these have been applied to a situation at least once. So a paper, Rivera Milan et al, 2004. This was done to estimate detectability of dead birds in a study in South America.

Previous SAPs have also noted the possible value of applying radiotelemetry technology to these studies, technology that's been around and used with small birds since the 70s. So it was available when the 1980 studies were done. Lots of ways to get around this.

My other comments are going to be on the searches conducted in the mid 90s that failed to recover any birds. I'd point to a couple of things of why I don't, for lack of a better word, I don't trust that result. The search is conducted in the fields in the late 80s that I just got done talking about. Discovered birds before the pesticide events and in controls, and this suggests that a well conducted thorough search should find birds regardless of whether there's pesticide related mortality. The failure of the studies in the mid 90s to find anything raises questions about the ability of those field workers to find an event.

My final point on this, the registrant claims that if significant mortality were occurring due to the

pesticides, this would be obvious to field biologists, the public etc, and this is debatable. Now dramatic die-offs of large concentrations of birds catch people's attention. The story of the geese flying and falling away and falling dead out of the air, fine. If that was happening all the time, it would get people's attention.

A more typical scenario might involve relatively low densities of secretive birds and even complete mortality of these small songbirds would more closely mimic the scenario of a single bird death, which FMC acknowledges are easily missed on page 19 of their report. Then the concentrations of, concentrated carcasses of large flocking birds. Deaths of small territorial breeding birds are unlikely to be noted by the public or field researches, and they're unlikely to be reported.

And I'm going to toss out some numbers to try to emphasize this. USGS bird banding, putting numbered bands on birds; 2001, 689,019 non-game birds were banded in North America; 8057 were recaptured, recited, or recovered during this time, and this is typical. It suggests that less than 1.2% of these non-game birds that died were discovered. Small birds it's even more unlikely. In that same time period, 131,110 birias and

warblers were banded; 89 were recovered, 0.07%.

What these data suggest is that, well, birds are dying all around you and you don't notice, and that bird deaths don't attract attention. It's not reasonable to assume that the additional mortality of these small birds, especially in agricultural areas with relatively few people would be noticed.

DR. HEERINGA: Dr. Clark, are we back to you?

DR. CLARK: Just to point out, I'm in slight disagreement on bird banding data. The bird banding lab doesn't require people that originally band the bird to report self, their own bands that are caught. So that's actually an underestimate of recapture. Now back to my other point.

There are a couple of statements that have been made, and I don't necessarily disagree with either interpretation. One statement is that the absence of mortality doesn't mean that mortality doesn't occur, and I completely agree with that given the detectability issues that we have along this. However, it doesn't preclude the opposite that the absence of mortality sometimes just means that; that there's no mortality. I think there are some very legitimate issues that Dr. McCarty pointed out in terms of the

ability to detect that mortality have to be taken into consideration, but I think we need to be fair that we have to admit all possible outcomes along those lines; and we can use other weights of evidence to assess whether or not one is more likely than that other.

Another concern I have is that we're using items or descriptions about search efficiencies and given all the caveats, and there seems to be numerous of sources of variation that would contribute to estimators of the efficiency that is being captured for a particular circumstance, ecological situation, or whatever. And as Dr. McCarty pointed out, we're using that to predict the magnitude effect that not only in terms of individual studies. And you say today where we were looking at possible reporting in terms of the mortality adjustment figures, but we're also using that.

It exacerbates the problems when we try to parameterize the models, not only in terms of the structure types of recoveries but we're using it to set the bounds by which we sample in terms of the distributions, and that's a cause of concern too if we have that magnitude of uncertainty here; our estimates in terms of the model is going to be fairly large itself, and I think we need to acknowledge that because

we're relying on independent lines of evidence which aren't completely independent. We use the model plan to justify the fact that we don't have field studies that are providing accurate data, but some of the components of the model are based on the balance of the distributions that the field data might give us.

And as a final thought, and Dr. McCarty pointed this out, is that a known effects approach would have been more productive, and that really, what I'm talking about that is telemetry. You can start with a small number of birds, and nowadays with GPA technology, you can get a larger species. You can figure out which fields they've been and do the actual time budget on a very fine scale resolution and get these sorts of issues. So the technology nowadays certainly, and certainly during the time, of course, that these studies were conducted from a VHF type of telemetry point of view has existed, and we could have addressed these issues; but that's should have, would have, could have.

The other issue that was brought up that FMC brought up, and I think it is an important point, when we're measuring the level of risk and we're talking about the probability of a cohort experience and some sort of mortality event, I think we do need to put it

into the context -- again, Dr. McCarty pointed this out -- in terms of what species are we talking about and essentially what is the population level effect. Because what we are asking really is what's the impact on the various bird species, and I think that just needs to be put into consideration when we're making these sorts of judgments. And it may be that some species are more sensitive to any mortality event, and some proportion of the species might be a little bit more robust in their ability to sustain incidental harvest.

DR. HEERINGA: Other associate discussants? Dr. Sparling.

DR. SPARLING: Dr. Clark and Dr. McCarty steal a lot of my thunder. However, I just want to add one thing here in regards to risk. I am sure that from a regulatory perspective, risk has a specific meaning. From an ecological perspective, I think we have to ask at what level is the avian fauna being at risk. Clearly carbofuran provides risk to individual birds, but to provide risk to a population is something that none of the studies that I've seen are robust enough to truly answer. The field studies and incident reports do not show a population effect.

To show a true population effect, a study

would have to show that mortality was additive not compensatory. In other words, if the number of birds that died from carbofuran or from any given pesticide would have been in addition within a given time period to the birds that would have died from other factors such as disease or predation. It's a big difference to say that bird died because of carbofuran would have survived otherwise, than to say well if it didn't die from carbofuran, it would have died from a fox, from predation.

The other aspect of trying to define what it means from an ecological perspective is that as we talked about last night, any group of birds in a field are composed of essentially two groups if you will, probably more than that. But there's the nesting territorial birds, songbirds, and then there's another cadre of birds, which are floaters and non-breeders through the population.

From a lot of ecological theory and results, it shows that the birds that are actually breeding are by far more important to the population in that given year than are the non-breeders. So in order to truly answer if there's going to be a population effect, the studies need to be a lot more rigorous, and we need to follow some very specific guidelines to develop

protocols.

I echo the sediments of Dr. McCarty and Dr. Clark with regards to using telemetry. I would also add to that, that trying to band all the breeding birds in an area that's destined for spray would be a very important aspect of the study so you could distinguish between those birds that are breeding and those birds that are floaters.

The other thing that I would like to add too is that all the studies and all the estimates that are probably, as far as mortality have occurred, are very conservative because almost all the studies have examined direct kills or very, very quick immediate kills from the pesticide. It could be argued that a large proportion of birds, as Dr. McCarty suggested, are never found and may not even be subjected to direct mortality from the pesticide but may be subjected to indirect effects from becoming more abundant due to the pesticide and then being picked off by predators, by disease, by weather factors. And so when we actually see birds in the field, that's probably the tip of the iceberg. Thank you.

DR. HEERINGA: Thank you, Dr. Sparling. I'll turn now to Dr. Hill.

DR. HILL: Well I'm certain that they've

covered everything I could have thought of, and so I'll let it go at that right now.

DR. HEERINGA: Additional comments before we move on? Dr. Grue.

DR. GRUE: I would like to add just a few quick comments. First of all, in an earlier life, I did, with collaborators look at band recovery data, working with the bird banding lab in Laurel, Maryland relative to recovery rates with the idea of getting some insights as to recoveries of carcasses and so on. The comments that were made here actually were born out; the larger the species and body size, the higher the probability of recapture.

A couple other comments. I think we have to put these studies kind of in a historical context, and I think it's in part unfair to evaluate them under our current, what we might consider to be today's criteria. Having been, and I'm not sure I'm the only one here, but a standing member of the Avian Effects Dialogue Group which met from the late 80s into the early 90s to actually discuss the improvement of methods to assess the effects of pesticides on birds.

The studies were actually, many of them conducted at the time those discussions were actually taking place, and these studies bear some of the

deficiencies that the group actually identified. It's also important to recall that at that time field studies were really divided into two types. There was a screening designation and a definitive designation, and until you really reach the definitive designation, you weren't incorporating technology such as radiotelemetry and so on.

The emphasis of the screening studies was really to determine whether exposure was occurring and did that exposure result in mortality. The definitive studies then would go on to actually assess the impact of the magnitude of that response and it's effects on reproduction in the population.

I think another important point is, and one that, again, I've raised in the past; I'm going to raise again here because I think it's pertinent is the fact that we are lacking current studies that have had the opportunity to actually employ many of the recommendations that the other discussants have already measured, and that's really a reflection of a change in the regulatory paradigm. And I would argue, again, that as long as we're not moving or there's not motivation to conduct these studies, we as a group are going to be faced with the same difficulties as we move forward with decisions associated with pesticide

regulation in the future.

DR. HEERINGA: I'll turn to Dr. Panger and see if there are any --

DR. PANGER: We're fine.

DR. HEERINGA: Okay. I think they're pretty clear statements. I appreciate them. At this point then I'd like to turn to our fifth and final question in the environmental part, and that is Dr. Panger if you would be willing to read it into the record, please.

DR. ODENKIRCHEN: Actually Ed Odenkirchen, Dr. Odenkirchen is going to read that.

DR. HEERINGA: Okay.

DR. ODENKIRCHEN: Okay.

DR. HEERINGA: Get a little airtime.

DR. ODENKIRCHEN: Get my last airtime for the day. My chocolate donut has worn off. It will be slower. Number five, the risks of mortality to birds in and around a carbofuran-treated use site. Consistent with the EPA's Ecological Risk Assessment Guidance, the ecological risk assessment that supports the 2006 IRED, as well as the draft Notice of Intent to Cancel, uses multiple lines of evidence to assess risks of mortality to birds in and around a field treated with carbofuran.

These lines of evidence include results from deterministic risk estimates, probabilistic risk estimates, field studies and wildlife mortality incident reports. The agency incorporated SAP-reviewed methods and models in developing and evaluating these lines of evidence.

Since the IRED was published, new avian data were provided by the registrant for consideration as alternate model inputs to estimate the probability of mortality risks to birds. As discussed in EPA's draft Notice of Intent to Cancel and supporting documents, EPA did not find that these new data alter EPA's previous probabilistic risk assessment conclusions.

Having heard the EPA presentations and the public comments on EPA's proposed action, has the information provided in this meeting, taken as a whole, caused the panel to reach a conclusion contrary to EPA's assessment that carbofuran poses a significant risk of mortality to numerous avian species in locations where carbofuran is used? If so, please provide the basis for that conclusion.

DR. HEERINGA: And Dr. Montgomery is the lead discussant for this.

DR. MONTGOMERY: I finally get to speak too. I didn't have a chocolate donut though so. This

last question I tried to summarize not only what we just heard in the discussions here, but the discussants, the associate discussants on this question as myself are the leads on the other questions. So I did speak with them prior to sitting down and trying to incorporate their comments. So I will do my best to present that synopsis, and then if I have missed anything or people would like to clarify, feel free to jump on at the end.

We came to the meeting with voluminous data, and they were summarized in the US EPA's IRED draft Notice of Cancellation and supporting documents, all of which used multiple lines of evidence to assess impacts to birds in and around carbofuran treated fields. Charge questions asked the SAP to look at both the risk assessment and to examine both the quality of the new data and its impact on the probabilistic risk assessment and the preclusions.

If we go back to some fundamentals of eco risk, the presence of receptors, a complete or potentially complete exposure pathway to a chemical of concern is taken in conjunction with toxicological properties to determine risk.

We were asked to look at three lines of evidence. The first line was a deterministic risk

assessment. The second was the probabilistic risk assessment and the third line of evidence I grouped our last charge questions together which includes field studies of wildlife mortality incidents reports. I think everyone agreed in the deterministic risk assessment, this was a conservative screening and it indicated risk for carbofuran to birds.

One of the debates entered was the probabilistic risk assessment. The first question dealt with model versions. The panel felt that the agency demonstrated sufficient bridging of the older and newer models to show that the risk calculations were now significantly alternated when calculations were repeated using newly submitted data with newer models.

Consequently, the panel concurs with the agency, namely that that the results of modeling continues to support the conclusion that there is risk for avian mortality in an around carbofuran treated fields.

Regarding the charge question dealing with new data, the panel commended FMC for their efforts in generating new data in an attempt to move things forward. It found that the limitations in the data due to study design introduced uncertainties and confounded

its utility in the risk assessment. The consequence of these uncertainties was that the panel agreed that the risk assessment conclusions drawn by the agency would not be altered because of these new data.

The third line of evidence grouped together to include wildlife mortality incidents in field studies. Part one of this third line of evidence developed by mortality incidences we just, we heard quite recently.

The panel concluded that given the information provided, they did not believe that definitive conclusions could be drawn from these data. Variables such as effects of labor use changes, improved stewardship, reduction in state monitoring efforts, and the change in the regulatory requirements for reporting were all happening at the same time, and it was difficult to separate the variables.

Part two of this third line of evidence, the field studies. The panel acknowledges that field studies are extremely difficult to structure and manage. However, they can and these studies have provided some useful information regarding the probabilities in the field for avian mortality.

Some concern that the data was used for both sides of an argument was raised by panel members, for

example, and we just heard this discussion, a lack of dead birds doesn't mean they weren't there, but conversely not finding them doesn't mean that they weren't there either. This is the severe limitation in, in field data, and is one of the many confounding factors that is often found.

But in summary, the SAP agreed that the monitoring studies provided useful information that a more systematist approach to collecting it and interpreting it needed to be developed before it could be used quantitatively in risk assessments.

In final conclusion, the conclusion of the SAP and much of the discussion centered around data quality issues and concerns that study designs have a variety of design features that introduced uncertainty, which is a utility of the data. There was also concern expressed at various points in the discussions that the studies and models were developed outside of public forum peer review process.

Well having said this, FMC was to be commended for the efforts that they have made to advance these areas. Our charge asked us to use the results of multiple lines of evidence, that is the deterministic risk assessment, the probabilistic risk assessment, wildlife mortality and field studies to

determine whether the panel felt that a conclusion contrary to EPA's assessment that carbofuran poses a significant risk of mortality to numerous avian species did exist.

Using multiple lines of evidence, the SAP does not believe that the new data supports changing EPA's conclusion regarding this risk, but the probabilistic models, while they are a useful path to take, models are only models and we need to verify the operating parameters and assumptions with a reality check and actual field data.

DR. HEERINGA: Thank you, Dr. Montgomery. I'll turn to the associate discussants, Dr. Delorme if you want to add to that.

DR. DELORME: Yeah. I think Dr. Montgomery has done a good job of summarizing the previous discussions. I don't think there's any doubt that carbofuran can convert. I think we can't lose sight of the fact that there are other organisms out there to be considered as well, although we've focused on the birds. There are, you know, indications of potential for effects on aquatic ecosystems and potential for effects on target mammals, amphibians and whatnot.

From a personal point of view, I struggle

with what constitutes a significant risk. The modeling suggests a potential risk exists as do the historical incident reports and field studies, and there is some uncertainly associated with all these lines of evidence, sometimes considerable, and also with respect to the various interpretations that have been presented.

Actual risk is dependent to a certain extent on the conditions at the time of application, and I think that there are times when the conditions are right; and you will see mortality and the results of the models and the other things will be realized.

The frequency that, that occurs and the magnitude of those effects, I think, is not clear. So I struggle with it. Is it from a scientific statistical perspective or is it from an ecological perspective, so just to throw that out there.

DR. HEERINGA: Dr. Grue?

DR. GRUE: I think the previous discussant covered much of what I would include in this. I just want to emphasize something that Dr. Warren mentioned and that is the magnitude of risk and what is going to be considered acceptable in terms of magnitude of risk. And, again, to emphasis the fact that the environmental scenarios is really important to

dictating. It's probably very important in dictating the risk that's going to be present.

DR. HEERINGA: Dr. Clark.

DR. CLARK: I guess I will parrot the last three comments in terms of magnitude of risk. I think that's a critical factor, and I know it's outside the charge of this particular panel; but I think it's an extraordinarily important factor to consider. I know, again, also outside the charge of the panel, the hazard mitigation often for, you know, things that even have high risk is very important, and I don't know what opportunities there would be to explore in the sorts of mitigating processes.

DR. HEERINGA: Thank you very much to the assigned discussants on this question. Comments from any of the other members of the panel? Dr. Sparling then
Dr. McCarty.

DR. SPARLING: This is again reflecting a personal attitude, I think. I don't disagree with anything that has been really said or included here from a scientific perspective, but from a personal perspective, and again this is outside of our charge, I am concerned about the lack of alternatives for certain crops and what are individual farmers going to do that

are dependent upon those crops. So that's just my personal attitude and reflection of concern.

DR. HEERINGA: Dr. McCarty and then Dr. Montgomery.

DR. MCCARTY: Well several people, I think starting with Don, and Larry, and Peter have brought up the issue of what's unacceptable, and I'd certainly echo that I'd much rather answer that statistically than ecologically for the reasons that have been suggested; that birds do die all the time. Larry's agency kills them on purpose. Sorry I forgot about being recorded.

DR. CLARK: Under authorized --

DR. MCCARTY: Yeah, under authorized. But that focuses the discussion, and it's easy to focus our discussion on abundant birds. We do toxicology on abundant birds because we don't want to kill rare things. We work on redwing blackbirds, mallards. You know, lots of people in America purposely killed mallards, and Larry used the sustainable harvest analogy; and that's difficult. Fish and Wildlife Service struggles with how many ducks can hunters kill and maintain the population.

At the other extreme we have endangered species, and that's been explicitly put outside our

purview. It's being considered elsewhere. Different standard if there are, I forget what the exact count, 174 whooping cranes in the entire world and you kill 17 of them in a single event; that's bad at least in my opinion. The world isn't divided into endangered species and super abundant species. We've got to continue them, and that makes this even more difficult. I feel it's incumbent upon us when we're thinking about the magnitude of risk to think about species that don't have large populations.

There are species of significant conservation concern that aren't listed under the endangered species act, that have the potential to be exposed to carbofuran. Henslow's Sparrow. I don't have the exact numbers. I can get them. I believe since 1965 Henslow's Sparrow populations in North America dropped by 95%. This is a bird that breeds in conservation reserve program land, and the center of it's range is the corn belt of North America. I'm very disturbed to think about carbofuran being sprayed on CRP land where Henslow's Sparrows are breeding, but even if it's used on crop fields adjacent, there's the potential for exposure and risk.

Throughout the Midwest and Great Plains, American Golden Clovers are a species of conservation

concern. I know from my own work, they spend time in crop fields during migratory stopover. A little further west I don't know if there are the people here yesterday who raise sunflowers that have this on their land, but certainly in the area we have mountain clubbers. It's not on the endangered species list, but it's been discussed and they breed in farm fields.

These are not species listed under ESA, so they're not going to be discussed in the panel that discusses endangered species acts, but they're small, and they're declining populations of birds that I think we need to consider carefully what the impact of excess mortality is going to be in this situation, which is going to be much different than considering excess mortality in redwing blackbirds, or mallards, or what have you.

Now I'm not saying there is risk to these species. What I want to put on the record is in everything we've done and everything I've seen we've discussed, no one has considered whether there was risk to this other group of species, and I think I'll end that there.

DR. HEERINGA: Thank you, Dr. McCarty. Dr. Montgomery.

DR. MONTGOMERY: This is a personal

observation that strays a bit from where the discussion has been and the recent responses. And I mean this is a scientific context, but as we progress through these complex models that have increasingly larger and larger demands for data and input, we as scientists need to come up with some way of not having to have a real piece of data for input parameter. We need to be able to bridge and correlate between databases and bodies of data, and that's a very complicated issue. And I know that, you know, we've talked about models.

Models are only as good as the input. And it's a thorny issue, but I think that it's one as scientifics we need to give thought to because it's easy to say, oh, well let's just go do a field study, and let's do another tox study, and let's do another this; and then you have to do five species and you have to -- I mean, it goes on and on. And while these are nice numbers to have and in the purest sense of science it's a wonder, it's the best road to go.

Practically speaking, we as scientists need to give thought to this issue of combining data pools so that we get power from what we have and really go in and fill in the gaps that we really need to have filled but we can't fill with the data that we currently have. And I think that's an extremely complicated and

difficult task, but I think it's one as scientists we need to give thought to, to the point where it becomes something that can be implemented into these, these very complex assessments that we're not starting to do.

DR. HEERINGA: Thank you, Dr. Montgomery. Dr. Kehrer.

DR. KEHRER: Jim Kehrer. This answer this charge question has dealt with, the risk of mortality where carbofuran is used, but it doesn't ever talk about how carbofuran is used. And my understanding is some of the methodology that is being used, for example, burying it in the furrow with the potatoes should dramatically decrease the risk and to me would almost certainly lead to a conclusion contrary to EPA's assessment, at least in that particular methodology.

DR. HEERINGA: Dr. Delorme.

DR. DELORME: It's always dangerous to sit here and listen to other people talk 'cause it gets my brain going. I think that with respect to the conclusions made that we have to be aware of the limitations, particularly with respect to the modeling results. There's a construct there that we're using. We're making some assumptions and just a couple of issues. One, it's done on a field scale, okay, and we

have to be aware of whether or not that scale is appropriate and whether it is for the organisms we're trying to protect. And the other consideration is the scale abuse, the scope of use of the product and how that factors into significant risk. I'm not sure how to do that, but, you know, I think definitely there's got to be some way of looking at that.

DR. HEERINGA: Dr. Sample.

DR. SAMPLE: That was actually a nice lead-in for what I was writing down here. And this sort of strays a bit from our charge, but needing to look at the use and evaluation on the scales beyond the single field; and also because we have a set of tools that are being used in the agroecosystems systems, it's a variety of chemicals that had the same mode of action. And as we have seen from the field studies that were used as part of the risk evaluation, they can have confounding effects, and those multiple impacts can have significant implications.

The burdens that we're concerned with aren't restricted to individual fields. They use multiple fields on a broader landscape, so we needed to have an integrated approach. In aquatic systems, we have basically 10 DL's where we have maximum loads for so many different contaminants that are managed on a

watershed basis, and that gives us a way of getting a larger evaluation and integrating what's being evaluated.

And I would like to propose for consideration that a terrestrial equivalent be considered for investigating a way to manage total exposure with cholinesterase inhibiting pesticides within a given agroecosystem. This could be used to manage the application and balance the use of different pesticides and different combinations that would be appropriate for the habitats that are present, receptors that are present, and the crops, and, you know, what makes sense for the pests that would be present there.

DR. HEERINGA: Additional comments? I'd like to turn to Dr. Odenkirchen to see whether --

DR. ODENKIRCHEN: No. That about answers our question, and we thank the panel for all it's time and efforts today.

DR. HEERINGA: Okay. Before we move on, I'd like to -- and this is something that I promised to do with the panel and that is given the panel an opportunity to introduce any other scientific issues of relevance to the current review and material that they feel should be brought forward. We addressed a very broad range of topics in our response to the charge

questions, but is there anything remaining of scientific important that the panel would like to introduce at this point in time?

Again, as I told Dr. Grue, if a thought occurs to you tonight, or if you have a chance to check back with the publication. Dr. McCarty sounds like he must be an voluminous reader of the literature on Earth, and actually I admire that. But in any case, if something does come up, we will have a chance to revisit before the closure of this meeting. I'm going to take just a moment to confer with the DFO, and I'll be back.

Okay. What I'd like to do at this point is I'd like to adjourn for the day to make up for yesterday. I think that I very much appreciate having participated along with my other members of the FIFRA panel in a number of these meetings with the way and the efficiency with which you've addressed the charge questions, and the issues, and for your obvious preparation. My thanks to you on that. And also I guess I'll turn to Dr. Odenkirchen on any last comments or Dr. Bradbury.

DR. BRADBURY: No. I think we're done from our perspective too, and I appreciate the hard work by the panel. I know it's been an intense several

days already, and we look forward to tomorrow's discussions. So thank you.

DR. HEERINGA: Okay. And, again, we will convene again tomorrow morning at 8:30, and we will move immediately into the human health effects. Panel members, if you would please just take a moment to convene next door in our breakout room just for a quick administrative note.

(WHEREUPON, the **SESSION** was adjourned at 4:30 p.m.)

CAPTION

The foregoing matter was taken on the date, and at the time and place set out on the Title page hereof.

It was requested that the matter be taken by the reporter and that the same be reduced to typewritten form.

Further, as relates to depositions, it was agreed by and between counsel and the parties that the reading and signing of the transcript, be and the same is hereby waived.

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AT LARGE:

I do hereby certify that the witness in the foregoing transcript was taken on the date, and at the time and place set out on the Title page hereof by me after first being duly sworn to testify the truth, the whole truth, and nothing but the truth; and that the said matter was recorded stenographically and mechanically by me and then reduced to typewritten form under my direction, and constitutes a true record of the transcript as taken, all to the best of my skill and ability.

I further certify that the inspection, reading and signing of said deposition were waived by counsel for the respective parties and by the witness.

I certify that I am not a relative or employee of either counsel, and that I am in no way interested financially, directly or indirectly, in this action.

CHARLES DAVID HOFFMAN, COURT REPORTER / NOTARY

SUBMITTED ON FEBRUARY 7, 2008

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