

FIFRA SCIENTIFIC ADVISORY PANEL (SAP)

OPEN MEETING

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

U.S. ENVIRONMENTAL PROTECTION AGENCY
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U.S. ENVIRONMENTAL PROTECTION AGENCY

FIFRA SCIENTIFIC ADVISORY PANEL (SAP)

OPEN MEETING

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



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

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

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

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

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

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

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

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

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

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

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

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

3 **DR. HILL:** Elwood Hill. I'm a wildlife
4 toxicologist, expertise is primary in organophosphorus
5 carbamate and mercury toxicology.

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

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

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

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

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

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

1 risk assessment.

2 **DR. MACDONALD:** Peter MacDonald.

3 Professor of mathematics and statistics at McMaster
4 University in Canada. I have general expertise in
5 applied statistics.

6 **DR. LU:** Alex Lu from Rollins School of
7 Public Health at Emory. My research interest in using
8 biomarker for human exposure to pesticides and the
9 health effect. **DR. KEHRER:** Jim

10 Kehrer. Dean of the College of Pharmacy at Washington
11 State University, molecular toxicology.

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

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

19 **DR. BUNGE:** Annette Bunge. Department of
20 Chemical Engineering at the Colorado School of Mines
21 with expertise in dermal absorption and risk
22 assessment.

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

1 cholinesterases.

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

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

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

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

1 **DR. FRY:** Great. Thank you very much
2 for giving me the opportunity to comment. I have
3 prepared written comments. In those written comments I
4 did not talk about the probabilistic risk assessments.
5 I thought that you guys would have pretty ugly sessions
6 for a couple of days on that and more of it probably
7 wouldn't be useful. I will say that I did serve on the
8 2004 science advisory panel on probabilistic risk
9 assessment that was referred to by Dr. Moore yesterday,
10 and I have a completely different recollection of the
11 panel recommendation and responses than were expressed
12 by Dr. Moore yesterday.

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

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

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

6 The agency is conservative in its approach.
7 It should be. After all, the name of the agency is
8 Environmental Protection Agency. Tim's also largely
9 confirmed the deterministic approach, the RQ approach,
10 although it's much less sensitive. Let's please
11 remember in this whole effort here that the agency is
12 not trying to cancel all pesticides. They have over
13 1100 pesticides registered, but they should be trying
14 to get rid of obsolete chemistry, these meat axes kind
15 of pesticides like dieldrin, monochromophos, or
16 carbofuran.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 controls used chloropyrophos and killed a lot of birds.

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

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

16 Previous to that, of course, you have both
17 granular and flowable incidents included. I've
18 included on this chart both the number of cases in the
19 AIMS database and the number of birds effected, largely
20 killed. More of this large number here with more than
21 20,000 represents the deliberate abuse case that we
22 heard about in Illinois in 2000. But my point is here
23 that the cases of carbofuran go up all the way to where
24 we terminated, maybe interrupted, the data input in
25 2005 when the grant we had to establish this database

1 ended.

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

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

14 Not all these cases have land use reported.
15 We just reported what we got from the agency. So there
16 are 444 of these that do not have land use, but 151
17 records for corn, 95 for agricultural areas. This are
18 88 cases for vineyards represents 39 separate incidents
19 going back into the 70s all the way to 1994. We don't
20 have vineyard cases after 1994. I will say that I
21 inadvertently left out alfalfa on this list. Alfalfa
22 is about in the middle.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 Dr. Pranger also brought up the drop in
12 incident reports in her EIIS database. The AIMS
13 database shows exactly the same thing. Since the year
14 2000, there have only been 15 to 23 reports in the EIIS
15 database for birds since 2000. Previous to that the
16 greatest number we had was 2001, but it was increasing
17 all over the 90s.

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

25 We have gone through the AIMS database and

1 did an analysis of the reporting requirements for the
2 2575 cases, and there would only be 130 cases total if
3 the reporting requirements were as they are now. So we
4 think the incident reporting system is broken. We're
5 working with the agency to try and fix this, and I
6 would very much like to see that fixed.

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

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

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

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

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

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

14 **DR. FRY:** Yep.

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

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

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

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

12 **DR. HEERINGA:** Dr. Clark.

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

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

25 But, you know, we have our own quality

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

6 **DR. CLARK:** Just as a followup.

7 **DR. FRY:** Yeah.

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

11 **DR. FRY:** Yeah.

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

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

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

20 **DR. FRY:** Yeah.

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

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

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

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

11 **DR. FRY:** The Birds in Agricultural
12 Area.

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

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

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

1 **DR. FRY:** Sure.

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

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

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

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

13 **DR. HEERINGA:** Thank you very much, Dr.
14 Fry.

15 **DR. FRY:** Thank you.

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

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

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

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

14 It's fed to cattle. It's harvested at a high
15 moisture basis. There's a misprint on the cover for
16 the Furadan root worm. It's actually 6-19 instead of
17 6-9. On June 19th, my agronomist, Brian Bresnahan,
18 which is here today to speak as well, noted a corn root
19 worm infestation throughout my whole field. He
20 contacted me immediately to treat it with Furadan.
21 Right away I contacted the aerial applicator. The next
22 day it was applied to the whole field, except a strip
23 between the middle of the field.

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

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

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

15 In this one is the yield data that we had on
16 our test plants with the treated and the non-treated,
17 178.6 bushels per acre to 224.7 bushels per acre; 26%
18 increase. And this one is a spreadsheet of the
19 difference between the two dollars. As a first year
20 farmer in a competitive situation, a \$24,000 loss
21 severely impacts, could impact my future in farming.

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

25 I just want to point out that without the

1 rescue, it would make my first year stressful without
2 those extra dollars to proceed onto the next year.

3 Farming is a very expensive business. As a first time
4 farmer, I cannot afford to take a hit. Finally, I had
5 no idea that Furadan would have this big of an impact
6 on my field. Thank you, guys.

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

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

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

17 **DR. HEERINGA:** Thank you very much, Mr.
18 McLean.

19 **MR. MCLEAN:** Thank you guys.

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

1 supersede anything you received prior to that.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 **DR. HEERINGA:** Thank you very much,
2 Dr. Sass. Questions for Dr. Sass for clarification?
3 Dr. Brimijoin?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 programs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 increase the use of insects on potatoes.

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

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

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

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

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

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

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

20 **DR. HEERINGA:** Thank you Mr. Sklarczyk.

21 Dr. Sample has a question.

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

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

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

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

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

17 **MR. SKLARCZYK:** I'm sorry. I didn't
18 understand.

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

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

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

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

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

15 **DR. HEERINGA:** Good morning, Mr.
16 Horrall.

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

1 Indiana Vegetable Growers Association Executive Board.

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

9 Furadan helps us control our risks by
10 controlling mobile pests and allowing us to take
11 advantage of some profitable early markets. Furadan is
12 effective in helping us control nematodes, which are
13 the microscopic worms that live in the soil and feed on
14 plant roots. Often nematodes are not discovered in the
15 field until the plants are suffering from their feeding
16 on the roots. In 2006 we had a field that was infested
17 with nematode and would have cost us approximately
18 \$8000 if we had not had Furadan to use. Also Furadan
19 helps us in controlling wireworms.

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

1 Furadan also helps us control seed corn
2 maggots, which the flies fly into the area and lay an
3 egg by the plant, and then a larvae grows and feeds on
4 your small plant. If seed corn maggots and wireworms
5 kill the seedlings in the field, then you'd have to
6 walk individually down each row and plant them by hand
7 instead of mechanically, and that would cost you about
8 10 times the expense as doing it mechanically.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8 **DR. MONTGOMERY:** Mm-hmm.

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

10 **DR. MONTGOMERY:** Right.

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

16 **DR. MONTGOMERY:** Okay. Thank you.

17 **DR. HEERINGA:** Thank you very much,
18 Mr. Horrall.

19 **MR. HORRALL:** Thank you.

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

25 **MR. BRESNAHAN:** I would like to thank

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

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

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

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

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

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

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

1 applied in the furrow by the corn planter itself.

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

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

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

25 Those black bands you see in that picture,

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

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

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

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

1 there.

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

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

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

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

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

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

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

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

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

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

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

25 I sat through Tuesday's session when we were

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

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

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

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

25 **DR. HEERINGA:** Thank you very much, Mr.

1 Bresnahan.

2 **MR. BRESNAHAN:** Thank you.

3 **DR. HEERINGA:** Questions? Yes, Dr.

4 McCarty.

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

8 **MR. BRESNAHAN:** It is.

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

12 **MR. BRESNAHAN:** Yes.

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

15 **MR. BRESNAHAN:** yes.

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

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

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

3 **DR. MCCARTY:** Mm-hmm.

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

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

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

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

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

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

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

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

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

1 GM?

2 **MR. BRESNAHAN:** No.

3 **DR. MCCARTY:** Are they using carbofuran
4 in planting?

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

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

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

19 **MR. BRESNAHAN:** Mm-hmm.

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

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

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

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

25 Then your soybean acres become your root worm

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

8 **DR. HEERINGA:** Dr. MacDonald quickly.

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

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

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

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

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

8 **MR. BRESNAHAN:** Okay. Thank you.

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

11 **MR. BRESNAHAN:** You're welcome. Thank
12 you.

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

22 **(WHEREUPON, a break was taken.)**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 rootworm control is not always adequate.

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

9 **DR. HEERINGA:** Thank you very much,
10 Mr. Schertz.

11 **MR. SCHERTZ:** Are there any questions?

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

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

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

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

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

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

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

3 **DR. HEERINGA:** We do.

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

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

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

25 I have been involved in the biotech arena

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

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

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

25 This shows that the IRM program is working.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 So if a grower wishes to use aldicarb, his

1 ability to take advantage of early pressure process
2 markets of July and August are lost due to that long
3 PHI. That missed market could be a value from \$1.00 a
4 hundredweight to \$2.50 a hundredweight, on which I grow
5 200 acres at 500 hundredweight ranges from \$100,000 to
6 \$250,000 loss of market.

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

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

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

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

15 In summary, one might want to ask the
16 question, is there a replacement for Furidan's pest
17 coverage including insect control of nematode
18 suppression? And my response is, first, only if taming
19 for aldicarb has a 150-day PHI restriction reduced to
20 120 days.

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

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

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

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

13 **MR. HANKS:** Temic, cholic, right.

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

16 **MR. HANKS:** Yes.

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

20 **MR. HANKS:** In that part of Idaho.

21 **DR. MONTGOMERY:** -- with the pest
22 pressure?

23 **MR. HANKS:** Because of the short growing
24 season.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12 Well to be sure, why would we have a version
13 2.1 if there weren't some changes. So what really did
14 change between version 2.0 and 2.1? There were some
15 slight changes to the polo algorithm. We had an
16 introduction of a routine that allowed for variable
17 volumes into the puddle as recommended by the SAP in
18 '04. There was the addition of the ability to assess
19 multiple applications.

20 You will recall from yesterday's
21 presentations with regard to liquid param is the
22 ability to assess multiple applications. Well under
23 2.1 we can do that. We haven't done that for the
24 purposes of our comparisons here because our previous
25 models could not do that. We felt that would be sort

1 of piling on in terms of the risk comparisons.

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

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

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

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

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

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

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

1 see here is a representation of what happens in the
2 2.0, 2.1 model with regards to that bimodal pattern and
3 how it relates to the concept of gorge feeding and the
4 changing in the patterns and how those patterns relate
5 to what the SAP has said in the past would be
6 appropriate things to consider.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 allometric canal, residents in that allometric canal.

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

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

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

25 What new FMC data did we not consider? Well

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

7 It's not going to eat it versus I'm too sick
8 to eat. Well why did we not consider that? Well the
9 available study methodology could not differentiate the
10 effects of behavioral biases not pesticide related from
11 the effects potentially attributable to carbofuran.

12 That was our position. I believe there was a number of
13 questions with regards to that. FMC has asserted that
14 there is no bias. Well that was one of the big issues.

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

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

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

4 The number of birds that six out of six times
5 selected one side in preference to the other, 15 birds
6 on the left, 15 birds on the right for a total of 43%
7 of the birds that are very obvious and super strong
8 preference for one side or the other. A very strong,
9 in terms of five out of six, again another 27% of the
10 birds and a somewhat strong four out of six, which I'm
11 going to leave out of the rest of the analysis, another
12 14% of the birds.

13 So we finally came to the conclusion was that
14 70% of the birds demonstrated a strong preference in
15 the side of the cage where they fed, and it was not
16 related to chemical presence or to dosage level.
17 Something going on there, and it's not entirely related
18 to the presence or absence of carbofuran in the diet.

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

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

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

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

25 So should we be confident in food ingestion

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

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

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

25 So the other thing that we notice also in

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 So the take-home message with regards to this



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12 **DR. ODENKIRCHEN:** The maximum body
13 burden?

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

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

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

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

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

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

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

1 I guess, as a bird feeding.

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

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

18 **DR. HEERINGA:** Dr. Bailey and then
19 Dr. Hattis.

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

24 **DR. ODENKIRCHEN:** Yes.

25 **DR. BAILEY:** What was that?

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

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

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

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

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

19 **DR. HEERINGA:** Dr. Hattis.

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

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

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

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

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

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

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

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

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

21 **DR. HEERINGA:** Okay. Dr. Clark.

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

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

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

11 **DR. CLARK:** Right.

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

20 **DR. CLARK:** I understand that.

21 **DR. PANGER:** Okay.

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

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

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

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

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

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

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

3 Thank you everybody.

4 **DR. HEERINGA:** Welcome back everybody.

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

12 **DR. ISOM:** Yes. Can you hear me?

13 **DR. HEERINGA:** Very well.

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

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

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

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

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

1 those comments.

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

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

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

16 **DR. SALICE:** Indeed, yes.

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

25 **DR. SALICE:** All right. Good afternoon.

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

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

16 In the period of time between these two
17 versions of TIM, the probabilistic risk assessment for
18 carbofuran was initiated. At that time TIM version 1
19 was the only fully functional avian PRA model
20 available. Subsequent to the SAP review of TIM version
21 2 and the release of the carbofuran IRED in August of
22 2006, the agency has conducted modeling for subset
23 carbofuran scenarios using TIM version 2.1, the version
24 that incorporated the 2004 SAP recommendations to
25 ascertain the extent to which the updated model version

1 would offer carbofuran risk conclusions.

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

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

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

20 I also wanted to clarify that we interpreted
21 the charge question as focusing primarily on the
22 comparison between the application of TIM 1.0 and TIM
23 2.1 models and their suitability for estimating risk to
24 birds based on the exposure to pesticides.

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

1 2.1, and liquid param represent a large step forward in
2 environmental risk assessments from the sole reliance
3 on deterministic approaches.

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

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

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

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

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

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

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

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

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

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

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

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

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

25 **DR. HEERINGA:** Our next associate

1 discussant is Dr. Delorme.

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

5 **DR. HEERINGA:** Dr. Grue.

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

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

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

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

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

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

25 **DR. HEERINGA:** Thank you, Dr. Grue.

1 Dr. Montgomery.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 **DR. HEERINGA:** Thank you, Dr. Hattis.

16 Dr. Edler.

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

25 I think defining them and then actually

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

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

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

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

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

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

4 **DR. HEERINGA:** Dr. Sample.

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

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

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

25 **DR. HEERINGA:** Dr. Delorme anything to

1 add to that?

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

4 **DR. HEERINGA:** Dr. Grue.

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

16 **DR. HEERINGA:** Dr. Montgomery.

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

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

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

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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



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

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

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

10 **DR. HEERINGA:** At this point, Dr.
11 Portier.

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

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

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

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

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

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

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

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

14 **DR. HEERINGA:** Dr. Bailey.

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

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

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

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

10 **DR. HEERINGA:** Dr. Sparling and then
11 Dr. Sample.

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

25 **DR. HEERINGA:** Dr. Sample, did you have

1 a comment? Dr. Bailey.

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

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

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

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

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

4 **DR. SALICE:** One at a time. Okay.

5 Question number two, analysis of new data impacts.

6 Between April and June of 2007 the agency received four
7 studies from FMC. These studies were intended to
8 provide data to address uncertainties in the avian risk
9 assessment which were identified by the 2001 SAP. The
10 agency has reviewed these studies and evaluated the
11 extent to which these data would alter the agency's
12 carbofuran risk conclusions. The following questions
13 relate to the results of EPA's review and analysis of
14 each study and their overall impact on risk
15 conclusions.

16 2A - Avoidance of pesticide treated feed.

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

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

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

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

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

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

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

7 2A.I - In light of the limitations of the FMC
8 study methodology, please comment on EPA's decision to
9 use this study only as a screen for potential avoidance
10 behavior. Please provide a basis for your conclusions.

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

14 **DR. DELORME:** All three.

15 **DR. HEERINGA:** All three. Please,
16 Dr. Salice.

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

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

1 incorporate these data appropriately into TIM version
2 1, which has a time step that is more consistent with
3 the observation times and the data provided? Please
4 provide a basis for your conclusion.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 determine which is driving any change in consumption.

2 Okay.

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

11 Okay.

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

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

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

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

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

25 I put a couple figures on the computer there,

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

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

10 **DR. HEERINGA:** Dr. Sample.

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

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

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

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

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

25 And just a point that I would like to make,

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

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

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

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

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

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

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

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

6 Moving on to the third part of this sub-
7 question, given that the data on food consumptions
8 based on daily measurements, did EPA incorporate these
9 data appropriately into TIM 1, which has a time step
10 that is more consistent with the observations times
11 than the data provided? Please provide a basis for
12 your conclusion. I went back to the SAP results from
13 2001 and 2004, and I just want to read something that
14 was in the report. "A time step model as presented by
15 the agency is reasonable as a tier-2 approximately."

16 This is from the 2001, so this referenced to TIM 1.

17 "And should produce credible out put provided pesticide
18 intake does not affect the continued rate of intake,
19 i.e. no avoidance, either conditioned diversion or
20 post-ingestional feed incapacity, or avoidance occurs
21 too late relative to an intake commensurate with
22 lethality."

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

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

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

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

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

24 **DR. HEERINGA:** Thank you, Dr. Delorme.

25 Dr. McCarty is our next associate discussant.

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

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

17 **DR. HEERINGA:** Dr. Hill.

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

22 **DR. HEERINGA:** Thank you. Dr. Sample.

23 **DR. SAMPLE:** I concur. My comments have
24 been captured.

25 **DR. HEERINGA:** Dr. Clark has comments.

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

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

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

1 some flavor characteristic?

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

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

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

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

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

15 **DR. HEERINGA:** Thank you, Dr. Clark.

16 Dr. Hill.

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

25 If they don't have the control option

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

8 **DR. HEERINGA:** Dr. Grue.

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

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

25 The work that I've done personally and the

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

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

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

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

1 -- okay. Dr. Bailey.

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

9 **DR. HEERINGA:** Dr. Edler.

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

19 **DR. HEERINGA:** Dr. Portier.

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

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

6 **DR. HEERINGA:** Dr. Delorme.

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

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

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

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

12 **DR. HEERINGA:** Dr. Grue and then
13 Dr. Montgomery.

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

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

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

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

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

16 **DR. HEERINGA:** Dr. Montgomery.

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

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

1 seems to me that if we're looking for a more
2 universally applicable model, you have to have some way
3 of taking this model and adjusting it between 1 and 12.
4 And having to pick one model because you're closer to
5 12 and you're closer to 1 is not the best thing when
6 we're trying to design a more universally applicable
7 model.

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

14 **DR. HEERINGA:** Dr. Sample.

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

1 **DR. HEERINGA:** Dr. Bailey.

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

9 **DR. HEERINGA:** Dr. Odenkirchen.

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

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

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

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

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

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

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

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

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

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

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

25 **DR. ODENKIRCHEN:** Mortality, percentage

1 of mortality at the mean levels, what's presented.

2 We're trying to look, calculate is how many birds out
3 of any given set cohort are dying and what's the
4 frequency and magnitude of those projections.

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

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

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

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

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

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

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

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

25 2BI - Do you concur with the agency's

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

5 2BII - Given the limitations in the food
6 matrix studies, did EPA employ a technically sound
7 approach to use the data from these studies as inputs
8 to the TIM version 1 and TIM version 2.1 model to
9 evaluate the potential for food matrix effects to alter
10 mortality risk estimates. Please provide a basis for
11 your conclusions.

12 **DR. HEERINGA:** Dr. Delorme again is
13 going to lead.

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

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

1 future as well.

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

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

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

1 people would certainly like that for using less birds.

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

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

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

19 **DR. CHAMBERS:** Thank you. Dr. Hill.

20 **DR. HILL:** I believe mine have been
21 captured too.

22 **DR. CHAMBERS:** Okay, Dr. Sample.

23 **DR. SAMPLE:** My comments have been
24 captured.

25 **DR. CHAMBERS:** Okay. Any followup from

1 any other -- okay. Dr. Grue.

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

7 **DR. HEERINGA:** Dr. Portier.

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

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

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

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

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

23 **DR. HEERINGA:** Dr. Delorme.

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

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

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

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

22 **DR. HEERINGA:** Dr. Hattis.

23 **DR. HATTIS:** Yes. I think that's well
24 taken. I think on the other hand if you've found this
25 3.9 fold factor for one of your two tests and you

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

14 **DR. HEERINGA:** You touched your mic off.
15 Dr. Montgomery.

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

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

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

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

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

1 recognition that we can return to a summary of question

2 2. So

3 Dr. Salice, if you would be willing to.

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

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

25 For these reasons, EPA believes there is

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

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

11 2C-II - Given the limitations in the
12 acetylcholinesterase inhibition and recovery studies,
13 did EPA employ a technically sound approach to use the
14 data from these studies as carbofuran carry-over
15 exposure estimates in the TIM version 1 and version 2.1
16 models to evaluate the potential for alternative
17 mortality risk estimates? Please provide a basis for
18 your conclusions.

19 **DR. HEERINGA:** Dr. Delorme, lead again.

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

1 recovery for young fully grown northern bobwhite.

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

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

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

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

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

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

1 **DR. HEERINGA:** Dr. Salice, can you
2 answer?

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

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

13 **DR. SALICE:** Longer than?

14 **DR. DELORME:** Yeah.

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

17 **DR. DELORME:** They were your half-lives,
18 okay.

19 **DR. HEERINGA:** Dr. McCarty, associate
20 discussant on this.

21 **DR. MCCARTY:** My comments have been
22 captured.

23 **DR. HEERINGA:** Dr. Hill.

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

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

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

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

1 particular project been discussed a little more widely,
2 gotten a little more input, that I think people would
3 have recommended phasing it down because, really, using
4 300 animals to come up with this information is
5 nonsensical in my estimation; that's my perspective and
6 not necessarily represents the other people in the
7 group.

8 **DR. HEERINGA:** Dr. Sample, go ahead.

9 **DR. SAMPLE:** My comments have been
10 captured.

11 **DR. HEERINGA:** Comments from other
12 members, Dr. Grue.

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

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

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

12 **DR. HEERINGA:** Dr. Hattis.

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

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

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

5 **DR. HEERINGA:** Dr. McCarty. Dr. Schlenk
6 first and then Dr. McCarty.

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

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

1 actually were first-order processes.

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

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

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

1 patterns.

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

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

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

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

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

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

17 **DR. HEERINGA:** Dr. McCarty.

18 **DR. MCCARTY:** I just want to follow up
19 on something Dr. Grue mentioned in hopes of
20 inappropriate bird ecology not being perpetuated from
21 SAP to SAP. He mentioned the evening hiatus, and I
22 just want to remind people before this gets
23 incorporated that, first of all, the tests were done in
24 8-hour light, 16-hours dark, which caught my attention
25 but I'm told it's standard operating procedure.

1 The birds that are going to be exposed are
2 more likely to be encountered in the 16-hour light
3 period, so keep that in mind. And secondly, a lot of
4 birds feed at night, including some waterfowl,
5 shorebirds, things like that, so maybe there's always
6 an evening hiatus. So I just wanted to put that on the
7 record.

8 **DR. HEERINGA:** Thank you very much. Dr.
9 Hattis.

10 **DR. HATTIS:** Just briefly, I think that
11 Dr. Schlenk's suggestion of a zero order process is
12 quite, quite likely in fact. Essentially with ethanol
13 you get a zero-order process because you've more than
14 saturated the metabolic enzyme, and that's a much
15 simpler adaptation than a few a PBK, you know,
16 additional requirement. It does require one equation,
17 but it's not as onerous as a PBK.

18 **DR. HEERINGA:** Okay. I'd like to move
19 on to question 2D at this point. Dr. Salice, if you
20 would read it into the record, please.

21 **DR. SALICE:** Question 2D - Quantitative
22 results of new data. The agency has presented
23 individual and combined impacts of the new data sets on
24 avian acute mortality predictions in and around a
25 carbofuran-treated use site, using the TIM framework.

1 EPA believes that the new data do provide the limited
2 means to further quantify the range of possible risk
3 estimates based on different model inputs or
4 assumptions concerning avoidance of carbofuran-treated
5 feed, toxicity of carbofuran in different feed
6 matrices, and carbofuran carry-over exposure between
7 feeding events.

8 However, the results of additional
9 probabilistic modeling, using the TIM framework, with
10 incorporation of the newly submitted data produce
11 mortality estimates to birds that are comparable to
12 those reported in the agency's 2006 Reregistration
13 Eligibility Science Chapter for Carbofuran,
14 Environmental Fate and Effects Chapter and do not alter
15 EPA's avian risk conclusions.

16 Does the SAP agree that these new data when
17 considered together do not significantly alter the
18 agency's overall probabilistic estimates of
19 carbofuran's risk of mortality to avian species in and
20 around a carbofuran-treated use site? Please provide a
21 basis for your conclusions.

22 **DR. HEERINGA:** Dr. Delorme, more
23 airtime.

24 **DR. DELORME:** Yeah. But there's light
25 at the end of the tunnel; maybe my bladder will

1 survive. The additional data developed by the
2 registrant, although beneficial, provide limited
3 resolution to previously identified SAP concerns.

4 The data were limited for a number of reasons
5 that we've already discussed, and from a scientific
6 perspective, and, again, going back to one of the
7 consistent themes, there is a concern that they were
8 not representative of the wide range of species which
9 could be affected by the various processes. Given the
10 limitations of the data, integrating the result into
11 the model is problematic. Furthermore, interactions
12 among these metrics and those already in the model are
13 currently undefined or unknown.

14 Taking into consideration the limitations of
15 the data and using their preliminary result as a point
16 of departure to do what if analysis, i.e. taking a leap
17 of faith that they're reasonable, their inclusion by
18 EPA in the models provide insight into how risks may
19 vary in relation to the specific issues addressed.
20 Given this, it's our conclusion that the risk estimate
21 based on these models and the scenarios used are not
22 significantly altered.

23 And then I had some following comments from
24 some of the group members. EPA's analysis of each of
25 the studies independently is appropriate. However, I

1 do not think the aggregate approach where EPA changed
2 all the variable simultaneously is justified. EPA is
3 justified in considering the implications of
4 cholinesterase inhibition recovery study and the food
5 matrix studies. Whatever the limitations of these
6 studies on their own, they raise additional questions
7 that suggest that incorporating them in an aggregate,
8 into a model may not be warranted.

9 If one accepts the importance of food matrix
10 on toxicology, then other variables based on aqueous
11 bolus dose methods including recent AChE recovery
12 studies should be reexamined. While we know of no data
13 to evaluate this, the result of the food matrix study
14 itself suggested it might not be reasonable to apply
15 both the correction from the food matrix study and the
16 cholinesterase recovery into a single model.
17 Specifically, the fact that the timed onset of symptoms
18 was longer with the food dose approach suggested that
19 time quotes of cholinesterase inhibition might be
20 different.

21 Likewise, the study notes that recovery of
22 birds that did not die could take over seven hours,
23 indicating a delayed cholinesterase recovery with this
24 dosing method is a plausible hypothesis.

25 Likewise, the uncertain effect of the gorge

1 feeding scenario of the matrix study were, according to
2 the registrant, up to 50% of the daily feed in a single
3 delivery is then applied for low level consistent
4 feeders modeled in the liquid param. The effect of the
5 matrix study may or may not be replicated in a study
6 where birds are provided small dishes of food over a
7 long period rather than a single gorge dose. With
8 that, I'll open it up to the associate discussants.

9 **DR. HEERINGA:** Dr. McCarty.

10 **DR. MCCARTY:** I don't have anything to
11 add, but I did want to point out that captured in our
12 comments was some information I got from a side
13 conversation with Dr. Larry Brewer. He's the one that
14 pointed out to me that by his estimate about 50% of the
15 daily food intake of the birds was incorporated in that
16 food bolus dose, and then he also clarified for me, in
17 the raw data it indicates some birds took 24 hours to
18 recover.

19 But he indicated that was a function of birds
20 being given a dose in the morning, still showing
21 effects at the end of the working day, people going
22 home and not checking the birds until 24 hours later.
23 So it's uncertain, but that was a side conversation and
24 it influenced the decision.

25 **DR. HEERINGA:** Thank you, Dr. McCarty.

1 That's the appropriate way to handle that. Dr. Hill.

2 **DR. HILL:** I believe that my thoughts on
3 this were covered. I'm happy with it.

4 **DR. HEERINGA:** Dr. Sample.

5 **DR. SAMPLE:** My comments are generally
6 captured. I think the one thing that I really want to
7 emphasize is taking into account what are the
8 interactions of applying all of these adjustments
9 simultaneously without knowing how they can relate with
10 each other.

11 Approaching this from a risk assessment side,
12 when we do our screening we're constantly, you know,
13 focusing on compound conservatism by taking multiple
14 conservative estimates that will get you a high
15 estimate of risk. And there is the potential that then
16 some of this may be leading to a compound liberalism in
17 that since we do not know exactly how they respond.
18 And I think it's also important to, as the modeling
19 moves forward, that the interactions between not just
20 these parameters but the other parameters be explained
21 and integrated into the model so that if there are
22 covariant parameters, they are allowed to co-vary in
23 the model runs.

24 **DR. HEERINGA:** Thank you, Dr. Sample.

25 Comments from other members of the panel on this item,

1 2D. Any additional comments at this point on any of
2 the aspects of the question 2, which pertained to the
3 new studies submitted by the registrant and their
4 application in the modeling process or their
5 appropriate use by the EPA in the modeling process?

6 Dr. Brimijoin.

7 **DR. BRIMIJOIN:** This may be more of a
8 question than a comment, but I understood I heard from
9 Dr. Salice that the half-life estimate that we've
10 settled on using is at the high end of the
11 experimentally determined range, namely 4. something
12 hours, and not the 12-hour step that we had originally
13 built into the TIM 1 model.

14 If that's the case, I think that's fair,
15 although it's still undoubtably somewhat conservative.
16 Given that high end half-life, it would apply only to
17 the birds that were consuming a near lethal dose in the
18 initial phase. And so for the more crucial issue of,
19 or more common issue of birds consuming sublethal
20 amounts but repetitively, most likely the effect of
21 recovery half-life would be much shorter. So I think
22 even that reduced estimate from 12 down to 4 is still
23 probably too conservative.

24 **DR. HEERINGA:** Dr. Salice.

25 **DR. SALICE:** Yeah. I just want to

1 clarify. The 4.4 and this may reflect my
2 misunderstanding of the question or comment, but the
3 4.4 hour half-life was used in both models and adjusted
4 to fit if you will this 12-hour time step in TIM 1 and
5 the one-hour time step in TIM 2, just to clarify. And
6 it's also, to sort of capture the range with possible
7 responses, we did use the 1.1 hour half-life to see the
8 impact that would have on risk projections looking at
9 only that aspect of the model.

10 **DR. HEERINGA:** Dr. Sparling, did I see
11 you? At this point I think what I'd like to do is to
12 call a short break. Dr. Salice, I'll turn to you
13 before I do that. Are you satisfied with the response
14 of the panel to the charge question? And I don't want
15 to get into extensive sort of reconsideration of
16 issues, but make sure that everything is clear with
17 regard to the panel's response.

18 **DR. SALICE:** Yes, we're satisfied.

19 **DR. HEERINGA:** Okay. Thank you very
20 much. Let's take a 15-minute break and return at 10
21 minutes after 3:00.

22 **(WHEREUPON, a break was taken.)**

23 **DR. HEERINGA:** We'll wait just a second
24 for Dr. Hill to return and also to get our designated
25 federal official. We'll start with the designated

1 federal official. Just a quick note, again, Dr. Isom
2 is on the telephone. For those of you, you have a pair
3 of mics, if you could move the cups or the receivers on
4 these closer together because some of you faded out for
5 him, and I think it's appropriate to him join us. I
6 want to make sure that he hears all the proceedings,
7 and if you do hear a voice from above, it is Dr. Isom.
8 And we will, in fact, acknowledge him at an appropriate
9 time.

10 Before we move to question three, Dr. Delorme
11 had one final comment that he wanted to add in response
12 to charge question number two, and you can do that,
13 Peter.

14 **DR. DELORME:** Peter Delorme. One of the
15 things that we had discussed in the group -- and the
16 other thing I want to do is I want to acknowledge the
17 input that I got from the group. We had a lot of
18 discussion. We had a lot of analysis going on, and it
19 really helped us clarify things being able to bounce
20 ideas off one another.

21 I'd like to thank the group for putting up
22 with me when we were doing this. But one of the things
23 we discussed is the need for some sort of framework for
24 interpretation of the modeling results, and FMC did
25 present something. I think that it's something that

1 EPA is going to have to look at because not everything
2 is going to come out with this one. You need to have
3 something in the future that helps both the
4 registrants, the public, and the risk managers
5 understand the information that we're presenting.

6 **DR. HEERINGA:** Again, just another
7 administrative reminder to everyone, speak into the mic
8 carefully. Even I guess within the room here, we have
9 some people in the very back who can't pick us up.

10 Dr. Montgomery, you had something else to add
11 on charge two?

12 **DR. MONTGOMERY:** Just a very small
13 addition. The way I thought we were having these
14 discussions is as a communication tool what would be
15 the probabilistic equivalent of a LOC? When you have
16 something that shows such acute toxicity, you can say,
17 well, you know, it came down X percentage and it's
18 still, you know, 50% too high. But going down the
19 road, if we're using this as an approach, we need to be
20 able to put this in context for people so that -- I
21 know it's probabilistic in these error bars, but people
22 still need to zoom in on something to ground them and
23 that's what we were discussing.

24 **DR. HEERINGA:** Dr. Sample.

25 **DR. SAMPLE:** And just a followup on the

1 example that was in the registrant's material's it
2 provided, we were talking percents, sort of showing you
3 then the two dimensions and risk ranges on this
4 particular level.

5 **DR. HEERINGA:** Just to, for the panel
6 members, we have, during the break, received two
7 additional documents. One of them is 10G protected,
8 but it's the meta-analysis of benchmark doses for acute
9 oral exposure to carbofuran, and I guess this is --
10 three documents. I can't start to talk without a new
11 document arriving.

12 We did have also a one-sheet document as a
13 response to a question raised by the FIFRA panel. It
14 pertains to the geometric standard deviations from Dr.
15 Carlson. And then the third document is also the
16 response to questions raise, and that one is also from
17 Dr. Carlson of FMC. So I would encourage all of the
18 panel members to review these documents in the course
19 of the new few time periods so we have a chance again
20 to reflect that information as well.

21 Now I'd like to, at this point in time, go to
22 charge question number three. And if I could ask Dr.
23 Salice to read that into the record, please.

24 **DR. PANGER:** Melissa Panger is going to
25 be reading that one.

1 **DR. HEERINGA:** Thank you, Melissa. I
2 think I called you Pranger yesterday. I did know a
3 Pranger at one time.

4 **DR. PANGER:** I've been called worse so
5 that's fine.

6 **DR. HEERINGA:** I think it's been a
7 couple of things, but please.

8 **DR. PANGER:** Okay. Thank you. So
9 Melissa Panger, question number three, interpretation
10 of incident reports. Since 2000, the Agency has
11 observed a decrease in the number of reported wildlife
12 incidents for pesticides as a whole based on data in
13 the agency's Ecological Incident Information System,
14 which is the EIIS version 2.

15 This decline corresponds to a decline in
16 state-sponsored wildlife incident monitoring programs,
17 which was in the Avian Incident Monitoring System Final
18 Report that was provided to you. Incidents associated
19 with carbofuran also have followed this trend, with a
20 decrease in the number of wildlife incidents reported
21 in the last several years.

22 Please comment on the Agency's conclusion
23 that the decrease in recent reported wildlife mortality
24 incidents associated with carbofuran is likely related
25 to an associated reduction in monitoring and/or

1 reporting and does not provide affirmative evidence
2 that the use of carbofuran, as currently registered,
3 does not continue to cause a risk to wildlife,
4 specifically birds. Please provide a basis for your
5 conclusions.

6 **DR. HEERINGA:** Dr. Grue is our lead
7 discussant on this question. Make sure we get both
8 mics together, Chris.

9 **DR. GRUE:** Relative to the response of
10 this question, I'm not necessarily speaking on behalf
11 of all of the discussants and would be looking to them
12 to provide their interpretations of my conclusions if,
13 in fact, if they'd like to augment.

14 The agency's conclusion here is compounded by
15 the fact of at least three factors, label changes,
16 improved stewardship, and a reduction in state
17 monitoring efforts due to funding limitations, and a
18 change in the regulatory requirements under FIFRA for
19 the reporting of incidents by registrant may account
20 for the observed decline in incident reports.

21 Each of these factors were discussed in the
22 agency's supporting documents and presented to the SAP
23 by Dr. Panger. The agency dismissed the possibility
24 that the reduction in reported incidents may be
25 associated with restrictions in the use of carbofuran

1 and associated changes in the labels for these uses in
2 1998 as well as improved stewardship by the registrant
3 and applicators. The agency rejected this possibility
4 based in part on avian incident data associated with
5 the use of carbofuran on grapes in California; that is
6 one incident pre 1992, 27 incidents between '92 and
7 '93, and no incidents thereafter.

8 However, this use was mitigated shortly after
9 these incidents occurred. One would hope that the
10 history of concerns associated with the use of
11 carbofuran, coupled with increases in pressures for
12 improved stewardship within the industry, contributed
13 to the observed decline. And just as a side note here,
14 I'd be interesting to know if the abrupt decline in
15 carbofuran related incidents, beginning in 1994, was
16 associated with restrictions in the use of granular
17 formulations after 1992.

18 A visual comparison of the frequency of the
19 histograms presented by the agency for carbofuran and
20 non-carbofuran related incidents may support this
21 conclusion that the decline began in the late 1990's
22 for both groups of incidents, and the number of
23 carbofuran incidences appeared to drop off sooner and
24 more rapidly. The fact that the majority of the avian
25 incidents associated with the use of carbofuran since

1 1998, 90% according to FMC, 60% to 95% according to the
2 US EPA depending on what the fate of 60 un-determinates
3 were associated with misuse also supports this
4 conclusion.

5 One could argue, an this argument was made
6 earlier today, that the distinction between mortality
7 resulting from label uses and misuse are not important
8 because the efficacy of a pesticide in illegally
9 killing birds is a reflection of its toxicity to birds
10 and reflects the availability of the product and it's
11 capability to use it for legal purposes. At a minimum,
12 the data on misuse indicate that the toxicity of
13 carbofuran diverts high and that the necessary
14 safeguards need to be in place, label and stewardship,
15 to reduce the potential for incidents irrespective of
16 motivation.

17 Similarly, one cannot argue that reductions
18 in funding or reporting requirements for the
19 registrants are not responsible for the decline in
20 avian incident reports with carbofuran and other
21 pesticides. The agency changed it's reporting
22 requirements for registrants in 1998. At the same
23 time, new restrictions and labels for existing uses of
24 carbofuran were initiated. The potential effects of
25 these new reporting thresholds on the number of

1 incidents reported and the quality of the reports,
2 irrespective of the pesticide involved, are
3 significant, and these were presented this morning by
4 Dr. Mark. As a result of this action, coupled with
5 funding limitations for incident reporting by state
6 agencies, and I would argue the extent of this is
7 really not clear. It's difficult to determine the
8 cause of the decline of carbofuran related avian
9 incidents.

10 And I'd like to just step back and be a
11 little philosophical at this point and a take a little
12 liberty here. Given the need for environmental
13 surveillance as the only means by which false negatives
14 can be identified in the agency's current regulatory
15 paradigm, it is difficult to understand why reporting
16 requirements would be relaxed and funding for the most
17 comprehensive incident reporting database, referring to
18 AIMS here, reduced, thereby compromising if not
19 eliminating one of the three lines of evidence used by
20 both the agency and the registrant in the current
21 regulatory decision as well as others in the future.

22 I would argue that without targeted field
23 studies and effective environmental surveillance, the
24 utility of the modeling approach that we're discussing
25 here that are undoubtedly going to be emphasized in the

1 future, are going to be severely compromised.

2 **DR. HEERINGA:** Thank you, Dr. Grue. I'd
3 like to turn to the first associate discussant and
4 that's Donald Sparling.

5 **DR. SPARLING:** Donald Sparling from
6 Southern Illinois University. Dr. Grue reflected many
7 of my ideas. I just would like to add a few things
8 here. As Dr. Grue indicated, several factors relating
9 to the time they reported incidents of mortality, they
10 are independent of actual biopsy..

11 Dr. Michael Fry of the American Bird
12 Conservancy said that the changes reported criteria
13 substantially altered the number of incidents that were
14 reported in the ICE database. Specially mentioned and
15 as indicated by the agency, that the increase to 200
16 birds of a flocking species, 50 birds of a non-flocking
17 species, and five predatory birds would have made a
18 substantial difference in AIMS database gone from 2575
19 records to 130 incidents, a decline of about 95%. So
20 it appears that the change in the regulatory nature of
21 reporting certainly could have had an effect on what we
22 have seen since 1998.

23 It is also well documented, I believe, at the
24 federal level in the past several years, funding has
25 been reduced or stable, and even fixed costs or fixed

1 budgets from one year to another with reduced
2 operational costs for discretionary projects such as
3 monitoring, and may have lead to reduced monitoring by
4 federal agencies. States are much more variable. I
5 would testify that in the state of Illinois, for
6 example, the Illinois Department of Natural Resource
7 budget has declined about 20% over the past five years.
8 Again, if monitoring had been an element, many programs
9 were eliminated.

10 I would also, just in the sake of fairness,
11 take a look at Dr. Panger's report, slide number 28.
12 It should be noted that between 1972 and 2000, 21 of 31
13 of registered use deaths occurred in the alfalfa. If
14 this crop was removed from registration as proposed, as
15 I understand it, there may be a decrease in deaths
16 under registered use practices, but that only accounts
17 for a minority of the total deaths anyway. The
18 decrease in state monitoring activities is further
19 accentuated by Dr. Odenkirchen's statement that the
20 State of California, which was number two on the list
21 of states reporting incidents is no longer, they are
22 not reporting anymore. Okay. I think that's it.

23 **DR. HEERINGA:** Thank you, Dr. Sparling.
24 Dr. Clark.

25 **DR. CLARK:** I agree principally with

1 what Dr. Grue had said, and I just want to add one
2 brief comment. The type of reporting in terms of
3 incidents, for example, in the avian incident
4 monitoring system from about 1990 or so is relatively
5 constant, and then decreases, as has been pointed out,
6 around 2002.

7 Yet the carbofuran use has been declining
8 since the 1990s to that point. So the point behind
9 this comment is that if there were a one to one
10 correspondence, you would expect to see it, but for
11 some part you see no reporting and use of carbofuran
12 relationship. And then later in the history you see a
13 concordant decrease in both reporting and use of
14 carbofuran. So the point behind it is that if you
15 selectively slice out the data, no matter which way it
16 goes, whether they are co-varied or not, you can make
17 any of the arguments as Dr. Grue pointed out. It's
18 compounded with a variety of other factors.

19 So attributing causality based on the
20 incident monitoring system, whether it's the EIS or the
21 AIMS is quite difficult, and to give it weight per se
22 as an individual argument I think is problematic.

23 **DR. HEERINGA:** Dr. Hill.

24 **DR. HILL:** I think Dr. Grue and so forth
25 have really covered most of the issues here, but I did

1 have a question. This is kind of directed toward the
2 agency; in fact, it is. I either missed it or let it
3 slip past me, but when the granular formulation was
4 phased out, were those particular uses substituted for
5 with the flowable, or were they just cancelled out,
6 zip; they were no longer used?

7 **DR. BRADBURY:** Dr. Bradbury. If I could
8 ask to get back to you on that just to make sure I've
9 got accurate information 'cause I'm not confident for
10 sure right now, but we'll get back on that question
11 shortly.

12 **DR. HEERINGA:** Thank you very much,
13 Dr. Bradbury.

14 **DR. HILL:** Because that really does seem
15 to be the important issue that I hadn't thought of, and
16 if I missed it I apologize to the board members. But
17 it seems to me that if it was a simple substitution,
18 then that would be one issue, but if the granulars were
19 simply omitted from use, then that would substantially
20 reduce the amount of carbofuran used over that period
21 of time, which could partially explain for this, this
22 particular issue that seems rather abrupt.

23 **DR. PANGER:** Well while they're looking
24 for numbers, what we do know is that when the granular
25 was brought down to 2500 pounds per acre, that when the

1 granular went down, flowable use did go up. I don't
2 know specifically what crops were substituted for what,
3 but we do know that there was that, you know, decline
4 in granular, arise in flowable.

5 **DR. HILL:** But not necessarily a simple
6 change in formulation in a particular use?

7 **DR. PANGER:** There was no change in
8 formulation.

9 **DR. HILL:** I know, but I mean from the
10 granular to the flowable?

11 **DR. PANGER:** Yeah.

12 **DR. HILL:** That didn't happen?

13 **DR. PANGER:** I don't know about the
14 specific uses. I just know an overall use, granular
15 went down --

16 **DR. HILL:** Yeah.

17 **DR. PANGER:** -- flowable went up.

18 **DR. HILL:** Because when flowable was
19 pulled back in the 70s and substituted for the
20 granular, it was just the simple one for one, and of
21 course mortality persisted. But that was the days when
22 they thought flowable was bad and the granular was a
23 good substitution.

24 **DR. HEERINGA:** Dr. Bradbury, where do
25 you want to go with this?

1 **DR. BRADBURY:** With about 85% to 95%
2 confidence on that, when the granular changes happened,
3 rice would be an example of a use that didn't carry
4 over, otherwise flowable and granular were similar
5 sources. That make sense? Okay.

6 **DR. HEERINGA:** Dr. Hill, any additional.
7 Dr. McCarty?

8 **DR. MCCARTY:** John McCarty. Well I'm a
9 big fan of monitoring systems. I think they're really
10 important, and one of my colleagues has already
11 mentioned this. But what we've got here isn't a
12 monitoring system, it's a reporting system, obvious
13 flows, the chain of unlikely events to get something in
14 the database, unlikely events that we don't quantified
15 estimates of how unlikely they are to be changing
16 etcetera, etcetera, so that the events here are useful
17 only in a one tail context; that is that they provide
18 evidence that events occur.

19 Now we've been discussing this apparent
20 decline in recent years and the three hypotheses, and
21 my opinion is, you know, FMC has suggested data on, I
22 believe, sales of carbofuran shown a decline. They've
23 talked about their stewardship efforts, and this is
24 responsible for the decline. As a personal opinion, I
25 hope they're right. I think that's this type of

1 proactive attitude that we need to promote. ABC and
2 ETA have shown data showing the decline is consistent
3 with the change in FIFRA reporting.

4 I fully support that. It's a shame that,
5 that change was made, but it is consistent with the
6 observations that, that's responsible. I think a good
7 argument has been made that the cuts in state budgets
8 are plausible and consistent. I think the EPA
9 presented data showing an almost identical decline in
10 all reporting events, not just carbofuran, which
11 strengthens their case. But I guess if I'm going to
12 look at the two questions that were given up there,
13 I'll take the second one first, does not provide
14 affirmative evidence that the use of carbofuran is
15 currently registered, does not continue to cause a risk
16 to wildlife, specifically birds.

17 If I'm interpreting all the negatives in that
18 statement correctly, I'd say I agree. Yeah. There
19 isn't evidence that carbofuran has stopped killing
20 birds. But to take the first question, carbofuran is
21 likely, that the decrease is associated with reduction
22 in monitoring and/or reporting, I've got to say I don't
23 agree with that.

24 The data, it's plausible but they can't
25 confirm it. Now at the same time I have to say the

1 same thing about FMC's hypothesis that it's declines
2 due to reduction in stewardship. The data aren't
3 there. They're being used inappropriately to go beyond
4 what this idea that they just demonstrate that
5 mortality occurs, and we can't assign causality with
6 this database.

7 **DR. HEERINGA:** Thank you very much,
8 Dr. McCarty and the other discussants. Any additional
9 comments from other members of the panel. Dr.
10 Brimijoin. Make sure you get the mics close to you.
11 You're one of the silent ones.

12 **DR. BRIMIJOIN:** I think I agree with
13 what I'm hearing on the expert eco side of the panel,
14 but I just would like to comment that it seems to me
15 that you have one hard piece of evidence in all of
16 this. The reporting of bird kills is problematic at
17 best.

18 Stewardship is impossible to quantify. I
19 think FMC deserves some credit for at least speaking to
20 this issue, but things are either impossible to
21 quantify or hard for us to rely on and so affirmative
22 evidence is hard to come by. As such, unless I grossly
23 misunderstood the presentations so far, we've heard
24 that there has been a drastic reduction in the amount
25 of carbofuran use, drastic reduction, not small. And

1 the proposed continuation would be for still further
2 reduction for current model.

3 It talks of being phased out, and this
4 reduction will amount to greater than 90%. So it
5 stands to reason that we might be faced with a
6 situation if use were to continue that, yes, there
7 would continue to be bird death and no amount of
8 stewardship is going to prevent it. But they can
9 probably with decline find more than one magnitude, and
10 since the EPA will have to balance the benefits, I
11 think that fact deserves to be acknowledged.

12 **DR. HEERINGA:** Dr. McCarty.

13 **DR. MCCARTY:** I think just to clarify in
14 addressing the question, you're right. I would agree
15 with you about the decline in carbofuran and that it's
16 plausible, absolutely plausible that bird deaths have
17 declined, but we don't have evidence of that in this
18 database. And my other clarifying point would be I am
19 not comfortable using proposed possible changes that
20 haven't been implemented, haven't gone through the
21 regulatory system.

22 Great if it happens, but I don't see that as
23 a basis for making decisions until the regulatory
24 system continues to go forward. But I certainly agree
25 that it's plausible that bird deaths have declined.

1 **DR. HEERINGA:** Dr. Brimijoin.

2 **DR. BRIMIJOIN:** So all I mean is that to
3 assume that they haven't declined would mean that
4 current practices are exposing birds to dramatically
5 higher risks of death from substantially smaller amount
6 of the compound. So the remaining limited uses have
7 got to be, would have to be associated with orders of
8 magnitude greater bird kills for, for them not, deaths
9 not to have declined. And it seemed to be highly
10 probable.

11 **DR. HEERINGA:** Dr. McCarty.

12 **DR. MCCARTY:** This is also though a
13 matter of scale. Our discussions have been focused on
14 a field by field analysis.

15 **DR. BRIMIJOIN:** Yes.

16 **DR. MCCARTY:** And that's not changing or
17 presumably. I mean, again, you can make an argument
18 that, that has changed. So I think it's important to
19 remain clear, the local effects versus continental
20 scale effects.

21 **DR. HEERINGA:** Individual versus
22 population averaged. Dr. Clark.

23 **DR. CLARK:** I agree with the basic
24 tenant that you're proposing. It seems, stands to
25 reason that we decrease the quantity of material that

1 we're putting out there on a spatial scale, that there
2 would also be a proportional decrease in, in the number
3 of mortality events.

4 I think the point that we're trying to make
5 is that there's, well least what I was trying to make,
6 is that given the data that we do have, if you take a
7 look, for example, carbofuran use, even if isn't
8 monitoring incident reporting. Actually prior to 2002,
9 there's no relationship between use and incident
10 reporting, and then after there's a concordant
11 relationship.

12 So that's really the question, is the
13 monitoring system sensitive enough to pick up those
14 things. It is reasonable to assume what you just said,
15 but based on the data structure we can't make that
16 assessment.

17 **DR. HEERINGA:** I turn to you, Dr.
18 Salice, or Dr. Panger, make sure that your satisfied.
19 And I think it's a pretty clear statement, but I will
20 let you judge.

21 **DR. PANGER:** We're fine. Thanks.

22 **DR. HEERINGA:** I'd like to -- Dr. Grue.

23 **DR. GRUE:** Maybe I could just ask a
24 question to you in terms of procedure. Since that
25 issue has been brought up and we didn't really, or

1 didn't have the opportunity to look at that relative to
2 the -- which I should have. I should have; that's a
3 very good point. Do I have the opportunity to --

4 **DR. HEERINGA:** Absolutely. Right.

5 **DR. GRUE:** -- since it's been brought up
6 to include in the -- okay.

7 **DR. HEERINGA:** Yeah. It's been our
8 policy in these meetings that any point, and I will
9 give everyone an opportunity at the end of the day.
10 We've got today and tomorrow to revisit these. And if
11 you need time tonight and you have something that you
12 find tonight that you'd like to present, you'll always
13 have the opportunity. So simply because I move on from
14 one question to the next doesn't mean that you're
15 forbidden from ever revisiting it again.

16 **DR. GRUE:** That's was necessary
17 additional presentation. Then that's the week that to
18 look at them.

19 **DR. HEERINGA:** You can look at them and
20 come back and just say --

21 **DR. GRUE:** Include them in the written
22 documentation.

23 **DR. HEERINGA:** absolutely, and applies
24 to any question. Obviously the very last question you
25 have a very short time to do that, but that's -- let's

1 turn to question number four, Dr. Panger.

2 **DR. PANGER:** Melissa Panger, question
3 number four, interpretation of field studies and
4 monitoring efforts. In the 2006 Reregistration
5 Eligibility Science Chapter for Carbofuran,
6 Environmental Fate and Effects Chapter, pages 106 to
7 130, the agency discussed certain State-conducted
8 carbofuran monitoring studies and available field
9 studies on the effects of carbofuran.

10 The agency concluded that the state-conducted
11 monitoring studies were flawed and provided only
12 limited insight into the effects of carbofuran, and
13 that overall the available field studies support the
14 conclusion that carbofuran use causes a risk to
15 wildlife, specifically birds. Question four, does the
16 SAP concur with the agency's conclusions regarding the
17 state-conducted monitoring studies and the available
18 field studies on the effects of carbofuran? Please
19 provide a basis for your conclusion.

20 **DR. HEERINGA:** Dr. Clark.

21 **DR. CLARK:** I'll start with what all the
22 panelists have agreed upon, and then we had some
23 individual comments to make as well. We're in
24 agreement that the EPA's assessment that carbofuran can
25 and does cause avian mortality does occur. They

1 concluded that the state-conducted studies were flawed
2 and only supplied with limited insight into the effects
3 of carbofuran treatment with agricultural fields. You
4 also have to recognize that conducting field studies
5 that adhere to after our conditions of study design are
6 difficult even under the best conditions.

7 So for example many of the state studies, the
8 1989 study for example, refer to plots not treated with
9 carbofuran as control plots, but because these plots
10 were treated with other pesticides, they're not in the
11 true sense a control and the analysis is not strictly
12 speaking testing carbofuran treatment against a known
13 condition, which is one of the other assumptions under
14 the test.

15 The tests are really comparisons of known
16 carbofuran treatments versus not treated with
17 carbofuran and with some other factors that might be
18 contributing to mortality. In this sense the EPA is
19 correct that a strict carbofuran effect is difficult to
20 attribute for a variety of reasons that have been
21 mentioned throughout the proceedings.

22 The panel agrees that the inferences based on
23 these sorts of studies in terms of attributing effects
24 should be highly constrained and conditional statements
25 should be made. And Dr. McCarty has a couple of

1 comments that he wants to make, and then I'd like to
2 return to my individual comment as well.

3 **DR. HEERINGA:** Dr. McCarty.

4 **DR. MCCARTY:** First I'm going to preface
5 this again with these field studies, we had a hard time
6 accessing, and I've relied on information from Dr. Lou
7 Best to clarify some points that have influenced my
8 decision; and sorry but I need to run through these
9 quickly. Concerns that came up were about the
10 censusing (sic) that was done on live birds, and he
11 noted that different areas were searched for live birds
12 versus dead birds; but he clarified that it was
13 standardized to area. He also gave me some more
14 information about search efficiency and how that was
15 determined, that they put out dead chicks randomly and
16 used dogs at all the sites to find these birds. And I
17 believe that's the information he provided outside the
18 context of the regular question.

19 A big issue in the way these studies are
20 being used, and I think Larry is going to touch on this
21 as well, but it's being used by both groups is trying
22 to use these estimates to quantify an absolute number
23 of birds that are dead as opposed to a relative number,
24 as opposed to higher in one field than in another. To
25 do that we need to know in excruciating detail recovery

1 efficiency, and the placing dead birds is a good start.
2 It's a good way, especially when these were done 20
3 some years ago to start to approach this, and they're
4 to be commended, these studies, for having attempted to
5 quantify this.

6 These approaches though of seeding an area
7 with dead birds and then trying to find them, this is
8 going to help for comparing, for example, search
9 efficiencies between different field workers, and
10 that's a big issue, not everybody is good at finding
11 dead birds, possibly to compare efficiency in different
12 sites. Another thing Dr. Best mentioned is, you know,
13 the difference between trying to find a dead bird in a
14 cornfield versus waist-high alfalfa fields, and it's a
15 good way to quantify that. What these studies aren't
16 sufficient to demonstrate is that searchers are going
17 to find natural kills and certainly not at the same
18 rate that they're finding seeded dead birds.

19 A key unknown in this is the propensity of
20 impaired birds to either leave the study site or most
21 importantly to hide. There's a paper, Berger et al,
22 2002, noting that one of the observed effects of
23 cholinesterase in addition may be hiding. This is a
24 study on captive European starlings.

25 They were exposed to a different inhibitor.

1 Somebody's going to have to help me with the
2 pronunciation here, chlorfenvinphos; is that right?
3 That the birds that were dosed would move away and hide
4 after exposure to the pesticide, and that's Friday et
5 al, 1996. One of the things, to give you an idea, even
6 in this simplified captive aviary, the researchers
7 noted they had trouble finding the birds in the aviary.

8 Now this study wasn't conducted with
9 carbofuran. It does suggest that simple seeding of
10 birds isn't sufficient to mimic the difficulty of
11 locating dead birds in the field. Another line of
12 evidence, anybody, I've done this, anybody whose radio-
13 track small birds and then tried to find the birds that
14 die. The only way you can find them is we literally
15 get down on our hands and knees with an antenna in the
16 grass trying to find the signal of the bird that's
17 died. Now this is outside the scope of our charge, but
18 there are techniques that could help to overcome this
19 program in future studies.

20 This includes the application of statistical
21 sampling approaches that have become virtually
22 mandatory for bird surveys in the past decade to
23 estimate detectability. Things like distant sampling,
24 observer sample, got a list of references, Burnham et
25 al, 1980; Bucklin, 1993; Nichols, 2000; etcetera, and

1 these have been applied to a situation at least once.

2 So a paper, Rivera Milan et al, 2004. This was done to
3 estimate detectability of dead birds in a study in
4 South America.

5 Previous SAPs have also noted the possible
6 value of applying radiotelemetry technology to these
7 studies, technology that's been around and used with
8 small birds since the 70s. So it was available when
9 the 1980 studies were done. Lots of ways to get around
10 this.

11 My other comments are going to be on the
12 searches conducted in the mid 90s that failed to
13 recover any birds. I'd point to a couple of things of
14 why I don't, for lack of a better word, I don't trust
15 that result. The search is conducted in the fields in
16 the late 80s that I just got done talking about.
17 Discovered birds before the pesticide events and in
18 controls, and this suggests that a well conducted
19 thorough search should find birds regardless of whether
20 there's pesticide related mortality. The failure of
21 the studies in the mid 90s to find anything raises
22 questions about the ability of those field workers to
23 find an event.

24 My final point on this, the registrant claims
25 that if significant mortality were occurring due to the

1 pesticides, this would be obvious to field biologists,
2 the public etc, and this is debatable. Now dramatic
3 die-offs of large concentrations of birds catch
4 people's attention. The story of the geese flying and
5 falling away and falling dead out of the air, fine. If
6 that was happening all the time, it would get people's
7 attention.

8 A more typical scenario might involve
9 relatively low densities of secretive birds and even
10 complete mortality of these small songbirds would more
11 closely mimic the scenario of a single bird death,
12 which FMC acknowledges are easily missed on page 19 of
13 their report. Then the concentrations of, concentrated
14 carcasses of large flocking birds. Deaths of small
15 territorial breeding birds are unlikely to be noted by
16 the public or field researches, and they're unlikely to
17 be reported.

18 And I'm going to toss out some numbers to try
19 to emphasize this. USGS bird banding, putting numbered
20 bands on birds; 2001, 689,019 non-game birds were
21 banded in North America; 8057 were recaptured, recited,
22 or recovered during this time, and this is typical. It
23 suggests that less than 1.2% of these non-game birds
24 that died were discovered. Small birds it's even more
25 unlikely. In that same time period, 131,110 birias and

1 warblers were banded; 89 were recovered, 0.07%.

2 What these data suggest is that, well, birds
3 are dying all around you and you don't notice, and that
4 bird deaths don't attract attention. It's not
5 reasonable to assume that the additional mortality of
6 these small birds, especially in agricultural areas
7 with relatively few people would be noticed.

8 **DR. HEERINGA:** Dr. Clark, are we back to
9 you?

10 **DR. CLARK:** Just to point out, I'm in
11 slight disagreement on bird banding data. The bird
12 banding lab doesn't require people that originally band
13 the bird to report self, their own bands that are
14 caught. So that's actually an underestimate of
15 recapture. Now back to my other point.

16 There are a couple of statements that have
17 been made, and I don't necessarily disagree with either
18 interpretation. One statement is that the absence of
19 mortality doesn't mean that mortality doesn't occur,
20 and I completely agree with that given the
21 detectability issues that we have along this. However,
22 it doesn't preclude the opposite that the absence of
23 mortality sometimes just means that; that there's no
24 mortality. I think there are some very legitimate
25 issues that Dr. McCarty pointed out in terms of the

1 ability to detect that mortality have to be taken into
2 consideration, but I think we need to be fair that we
3 have to admit all possible outcomes along those lines;
4 and we can use other weights of evidence to assess
5 whether or not one is more likely than that other.

6 Another concern I have is that we're using
7 items or descriptions about search efficiencies and
8 given all the caveats, and there seems to be numerous
9 of sources of variation that would contribute to
10 estimators of the efficiency that is being captured for
11 a particular circumstance, ecological situation, or
12 whatever. And as Dr. McCarty pointed out, we're using
13 that to predict the magnitude effect that not only in
14 terms of individual studies. And you say today where
15 we were looking at possible reporting in terms of the
16 mortality adjustment figures, but we're also using
17 that.

18 It exacerbates the problems when we try to
19 parameterize the models, not only in terms of the
20 structure types of recoveries but we're using it to set
21 the bounds by which we sample in terms of the
22 distributions, and that's a cause of concern too if we
23 have that magnitude of uncertainty here; our estimates
24 in terms of the model is going to be fairly large
25 itself, and I think we need to acknowledge that because

1 we're relying on independent lines of evidence which
2 aren't completely independent. We use the model plan
3 to justify the fact that we don't have field studies
4 that are providing accurate data, but some of the
5 components of the model are based on the balance of the
6 distributions that the field data might give us.

7 And as a final thought, and Dr. McCarty
8 pointed this out, is that a known effects approach
9 would have been more productive, and that really, what
10 I'm talking about that is telemetry. You can start
11 with a small number of birds, and nowadays with GPA
12 technology, you can get a larger species. You can
13 figure out which fields they've been and do the actual
14 time budget on a very fine scale resolution and get
15 these sorts of issues. So the technology nowadays
16 certainly, and certainly during the time, of course,
17 that these studies were conducted from a VHF type of
18 telemetry point of view has existed, and we could have
19 addressed these issues; but that's should have, would
20 have, could have.

21 The other issue that was brought up that FMC
22 brought up, and I think it is an important point, when
23 we're measuring the level of risk and we're talking
24 about the probability of a cohort experience and some
25 sort of mortality event, I think we do need to put it

1 into the context -- again, Dr. McCarty pointed this out
2 -- in terms of what species are we talking about and
3 essentially what is the population level effect.
4 Because what we are asking really is what's the impact
5 on the various bird species, and I think that just
6 needs to be put into consideration when we're making
7 these sorts of judgments. And it may be that some
8 species are more sensitive to any mortality event, and
9 some proportion of the species might be a little bit
10 more robust in their ability to sustain incidental
11 harvest.

12 **DR. HEERINGA:** Other associate
13 discussants? Dr. Sparling.

14 **DR. SPARLING:** Dr. Clark and Dr. McCarty
15 steal a lot of my thunder. However, I just want to add
16 one thing here in regards to risk. I am sure that from
17 a regulatory perspective, risk has a specific meaning.
18 From an ecological perspective, I think we have to ask
19 at what level is the avian fauna being at risk.
20 Clearly carbofuran provides risk to individual birds,
21 but to provide risk to a population is something that
22 none of the studies that I've seen are robust enough to
23 truly answer. The field studies and incident reports
24 do not show a population effect.

25 To show a true population effect, a study

1 would have to show that mortality was additive not
2 compensatory. In other words, if the number of birds
3 that died from carbofuran or from any given pesticide
4 would have been in addition within a given time period
5 to the birds that would have died from other factors
6 such as disease or predation. It's a big difference to
7 say that bird died because of carbofuran would have
8 survived otherwise, than to say well if it didn't die
9 from carbofuran, it would have died from a fox, from
10 predation.

11 The other aspect of trying to define what it
12 means from an ecological perspective is that as we
13 talked about last night, any group of birds in a field
14 are composed of essentially two groups if you will,
15 probably more than that. But there's the nesting
16 territorial birds, songbirds, and then there's another
17 cadre of birds, which are floaters and non-breeders
18 through the population.

19 From a lot of ecological theory and results,
20 it shows that the birds that are actually breeding are
21 by far more important to the population in that given
22 year than are the non-breeders. So in order to truly
23 answer if there's going to be a population effect, the
24 studies need to be a lot more rigorous, and we need to
25 follow some very specific guidelines to develop

1 protocols.

2 I echo the sediments of Dr. McCarty and Dr.
3 Clark with regards to using telemetry. I would also
4 add to that, that trying to band all the breeding birds
5 in an area that's destined for spray would be a very
6 important aspect of the study so you could distinguish
7 between those birds that are breeding and those birds
8 that are floaters.

9 The other thing that I would like to add too
10 is that all the studies and all the estimates that are
11 probably, as far as mortality have occurred, are very
12 conservative because almost all the studies have
13 examined direct kills or very, very quick immediate
14 kills from the pesticide. It could be argued that a
15 large proportion of birds, as Dr. McCarty suggested,
16 are never found and may not even be subjected to direct
17 mortality from the pesticide but may be subjected to
18 indirect effects from becoming more abundant due to the
19 pesticide and then being picked off by predators, by
20 disease, by weather factors. And so when we actually
21 see birds in the field, that's probably the tip of the
22 iceberg. Thank you.

23 **DR. HEERINGA:** Thank you, Dr. Sparling.
24 I'll turn now to Dr. Hill.

25 **DR. HILL:** Well I'm certain that they've

1 covered everything I could have thought of, and so I'll
2 let it go at that right now.

3 **DR. HEERINGA:** Additional comments
4 before we move on? Dr. Grue.

5 **DR. GRUE:** I would like to add just a
6 few quick comments. First of all, in an earlier life,
7 I did, with collaborators look at band recovery data,
8 working with the bird banding lab in Laurel, Maryland
9 relative to recovery rates with the idea of getting
10 some insights as to recoveries of carcasses and so on.
11 The comments that were made here actually were born
12 out; the larger the species and body size, the higher
13 the probability of recapture.

14 A couple other comments. I think we have to
15 put these studies kind of in a historical context, and
16 I think it's in part unfair to evaluate them under our
17 current, what we might consider to be today's criteria.
18 Having been, and I'm not sure I'm the only one here,
19 but a standing member of the Avian Effects Dialogue
20 Group which met from the late 80s into the early 90s to
21 actually discuss the improvement of methods to assess
22 the effects of pesticides on birds.

23 The studies were actually, many of them
24 conducted at the time those discussions were actually
25 taking place, and these studies bear some of the

1 deficiencies that the group actually identified. It's
2 also important to recall that at that time field
3 studies were really divided into two types. There was
4 a screening designation and a definitive designation,
5 and until you really reach the definitive designation,
6 you weren't incorporating technology such as
7 radiotelemetry and so on.

8 The emphasis of the screening studies was
9 really to determine whether exposure was occurring and
10 did that exposure result in mortality. The definitive
11 studies then would go on to actually assess the impact
12 of the magnitude of that response and it's effects on
13 reproduction in the population.

14 I think another important point is, and one
15 that, again, I've raised in the past; I'm going to
16 raise again here because I think it's pertinent is the
17 fact that we are lacking current studies that have had
18 the opportunity to actually employ many of the
19 recommendations that the other discussants have already
20 measured, and that's really a reflection of a change in
21 the regulatory paradigm. And I would argue, again,
22 that as long as we're not moving or there's not
23 motivation to conduct these studies, we as a group are
24 going to be faced with the same difficulties as we move
25 forward with decisions associated with pesticide

1 regulation in the future.

2 **DR. HEERINGA:** I'll turn to Dr. Panger
3 and see if there are any --

4 **DR. PANGER:** We're fine.

5 **DR. HEERINGA:** Okay. I think they're
6 pretty clear statements. I appreciate them. At this
7 point then I'd like to turn to our fifth and final
8 question in the environmental part, and that is Dr.
9 Panger if you would be willing to read it into the
10 record, please.

11 **DR. ODENKIRCHEN:** Actually Ed
12 Odenkirchen, Dr. Odenkirchen is going to read that.

13 **DR. HEERINGA:** Okay.

14 **DR. ODENKIRCHEN:** Okay.

15 **DR. HEERINGA:** Get a little airtime.

16 **DR. ODENKIRCHEN:** Get my last airtime
17 for the day. My chocolate donut has worn off. It will
18 be slower. Number five, the risks of mortality to
19 birds in and around a carbofuran-treated use site.
20 Consistent with the EPA's Ecological Risk Assessment
21 Guidance, the ecological risk assessment that supports
22 the 2006 IRED, as well as the draft Notice of Intent to
23 Cancel, uses multiple lines of evidence to assess risks
24 of mortality to birds in and around a field treated
25 with carbofuran.

1 These lines of evidence include results from
2 deterministic risk estimates, probabilistic risk
3 estimates, field studies and wildlife mortality
4 incident reports. The agency incorporated SAP-reviewed
5 methods and models in developing and evaluating these
6 lines of evidence.

7 Since the IRED was published, new avian data
8 were provided by the registrant for consideration as
9 alternate model inputs to estimate the probability of
10 mortality risks to birds. As discussed in EPA's draft
11 Notice of Intent to Cancel and supporting documents,
12 EPA did not find that these new data alter EPA's
13 previous probabilistic risk assessment conclusions.

14 Having heard the EPA presentations and the
15 public comments on EPA's proposed action, has the
16 information provided in this meeting, taken as a whole,
17 caused the panel to reach a conclusion contrary to
18 EPA's assessment that carbofuran poses a significant
19 risk of mortality to numerous avian species in
20 locations where carbofuran is used? If so, please
21 provide the basis for that conclusion.

22 **DR. HEERINGA:** And Dr. Montgomery is the
23 lead discussant for this.

24 **DR. MONTGOMERY:** I finally get to speak
25 too. I didn't have a chocolate donut though so. This

1 last question I tried to summarize not only what we
2 just heard in the discussions here, but the
3 discussants, the associate discussants on this question
4 as myself are the leads on the other questions. So I
5 did speak with them prior to sitting down and trying to
6 incorporate their comments. So I will do my best to
7 present that synopsis, and then if I have missed
8 anything or people would like to clarify, feel free to
9 jump on at the end.

10 We came to the meeting with voluminous data,
11 and they were summarized in the US EPA's IRED draft
12 Notice of Cancellation and supporting documents, all of
13 which used multiple lines of evidence to assess impacts
14 to birds in and around carbofuran treated fields.
15 Charge questions asked the SAP to look at both the risk
16 assessment and to examine both the quality of the new
17 data and its impact on the probabilistic risk
18 assessment and the preclusions.

19 If we go back to some fundamentals of eco
20 risk, the presence of receptors, a complete or
21 potentially complete exposure pathway to a chemical of
22 concern is taken in conjunction with toxicological
23 properties to determine risk.

24 We were asked to look at three lines of
25 evidence. The first line was a deterministic risk

1 assessment. The second was the probabilistic risk
2 assessment and the third line of evidence I grouped our
3 last charge questions together which includes field
4 studies of wildlife mortality incidents reports. I
5 think everyone agreed in the deterministic risk
6 assessment, this was a conservative screening and it
7 indicated risk for carbofuran to birds.

8 One of the debates entered was the
9 probabilistic risk assessment. The first question
10 dealt with model versions. The panel felt that the
11 agency demonstrated sufficient bridging of the older
12 and newer models to show that the risk calculations
13 were now significantly alternated when calculations
14 were repeated using newly submitted data with newer
15 models.

16 Consequently, the panel concurs with the
17 agency, namely that that the results of modeling
18 continues to support the conclusion that there is risk
19 for avian mortality in an around carbofuran treated
20 fields.

21 Regarding the charge question dealing with
22 new data, the panel commended FMC for their efforts in
23 generating new data in an attempt to move things
24 forward. It found that the limitations in the data due
25 to study design introduced uncertainties and confounded

1 its utility in the risk assessment. The consequence of
2 these uncertainties was that the panel agreed that the
3 risk assessment conclusions drawn by the agency would
4 not be altered because of these new data.

5 The third line of evidence grouped together
6 to include wildlife mortality incidents in field
7 studies. Part one of this third line of evidence
8 developed by mortality incidences we just, we heard
9 quite recently.

10 The panel concluded that given the
11 information provided, they did not believe that
12 definitive conclusions could be drawn from these data.
13 Variables such as effects of labor use changes,
14 improved stewardship, reduction in state monitoring
15 efforts, and the change in the regulatory requirements
16 for reporting were all happening at the same time, and
17 it was difficult to separate the variables.

18 Part two of this third line of evidence, the
19 field studies. The panel acknowledges that field
20 studies are extremely difficult to structure and
21 manage. However, they can and these studies have
22 provided some useful information regarding the
23 probabilities in the field for avian mortality.

24 Some concern that the data was used for both
25 sides of an argument was raised by panel members, for

1 example, and we just heard this discussion, a lack of
2 dead birds doesn't mean they weren't there, but
3 conversely not finding them doesn't mean that they
4 weren't there either. This is the severe limitation
5 in, in field data, and is one of the many confounding
6 factors that is often found.

7 But in summary, the SAP agreed that the
8 monitoring studies provided useful information that a
9 more systematist approach to collecting it and
10 interpreting it needed to be developed before it could
11 be used quantitatively in risk assessments.

12 In final conclusion, the conclusion of the
13 SAP and much of the discussion centered around data
14 quality issues and concerns that study designs have a
15 variety of design features that introduced uncertainty,
16 which is a utility of the data. There was also concern
17 expressed at various points in the discussions that the
18 studies and models were developed outside of public
19 forum peer review process.

20 Well having said this, FMC was to be
21 commended for the efforts that they have made to
22 advance these areas. Our charge asked us to use the
23 results of multiple lines of evidence, that is the
24 deterministic risk assessment, the probabilistic risk
25 assessment, wildlife mortality and field studies to

1 determine whether the panel felt that a conclusion
2 contrary to EPA's assessment that carbofuran poses a
3 significant risk of mortality to numerous avian species
4 did exist.

5 Using multiple lines of evidence, the SAP
6 does not believe that the new data supports changing
7 EPA's conclusion regarding this risk, but the
8 probabilistic models, while they are a useful path to
9 take, models are only models and we need to verify the
10 operating parameters and assumptions with a reality
11 check and actual field data.

12 **DR. HEERINGA:** Thank you, Dr.
13 Montgomery. I'll turn to the associate discussants,
14 Dr. Delorme if you want to add to that.

15 **DR. DELORME:** Yeah. I think Dr.
16 Montgomery has done a good job of summarizing the
17 previous discussions. I don't think there's any doubt
18 that carbofuran can convert. I think we can't lose
19 sight of the fact that there are other organisms out
20 there to be considered as well, although we've focused
21 on the birds. There are, you know, indications of
22 potential for effects on aquatic ecosystems and
23 potential for effects on target mammals, amphibians and
24 whatnot.

25 From a personal point of view, I struggle

1 with what constitutes a significant risk. The modeling
2 suggests a potential risk exists as do the historical
3 incident reports and field studies, and there is some
4 uncertainly associated with all these lines of
5 evidence, sometimes considerable, and also with respect
6 to the various interpretations that have been
7 presented.

8 Actual risk is dependent to a certain extent
9 on the conditions at the time of application, and I
10 think that there are times when the conditions are
11 right; and you will see mortality and the results of
12 the models and the other things will be realized.

13 The frequency that, that occurs and the
14 magnitude of those effects, I think, is not clear. So
15 I struggle with it. Is it from a scientific
16 statistical perspective or is it from an ecological
17 perspective, so just to throw that out there.

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

19 **DR. GRUE:** I think the previous
20 discussant covered much of what I would include in
21 this. I just want to emphasize something that Dr.
22 Warren mentioned and that is the magnitude of risk and
23 what is going to be considered acceptable in terms of
24 magnitude of risk. And, again, to emphasis the fact
25 that the environmental scenarios is really important to

1 dictating. It's probably very important in dictating
2 the risk that's going to be present.

3 **DR. HEERINGA:** Dr. Clark.

4 **DR. CLARK:** I guess I will parrot the
5 last three comments in terms of magnitude of risk. I
6 think that's a critical factor, and I know it's outside
7 the charge of this particular panel; but I think it's
8 an extraordinarily important factor to consider. I
9 know, again, also outside the charge of the panel, the
10 hazard mitigation often for, you know, things that even
11 have high risk is very important, and I don't know what
12 opportunities there would be to explore in the sorts of
13 mitigating processes.

14 **DR. HEERINGA:** Thank you very much to
15 the assigned discussants on this question. Comments
16 from any of the other members of the panel? Dr.
17 Sparling then
18 Dr. McCarty.

19 **DR. SPARLING:** This is again reflecting
20 a personal attitude, I think. I don't disagree with
21 anything that has been really said or included here
22 from a scientific perspective, but from a personal
23 perspective, and again this is outside of our charge, I
24 am concerned about the lack of alternatives for certain
25 crops and what are individual farmers going to do that

1 are dependent upon those crops. So that's just my
2 personal attitude and reflection of concern.

3 **DR. HEERINGA:** Dr. McCarty and then
4 Dr. Montgomery.

5 **DR. MCCARTY:** Well several people, I
6 think starting with Don, and Larry, and Peter have
7 brought up the issue of what's unacceptable, and I'd
8 certainly echo that I'd much rather answer that
9 statistically than ecologically for the reasons that
10 have been suggested; that birds do die all the time.
11 Larry's agency kills them on purpose. Sorry I forgot
12 about being recorded.

13 **DR. CLARK:** Under authorized --

14 **DR. MCCARTY:** Yeah, under authorized.
15 But that focuses the discussion, and it's easy to focus
16 our discussion on abundant birds. We do toxicology on
17 abundant birds because we don't want to kill rare
18 things. We work on redwing blackbirds, mallards. You
19 know, lots of people in America purposely killed
20 mallards, and Larry used the sustainable harvest
21 analogy; and that's difficult. Fish and Wildlife
22 Service struggles with how many ducks can hunters kill
23 and maintain the population.

24 At the other extreme we have endangered
25 species, and that's been explicitly put outside our

1 purview. It's being considered elsewhere. Different
2 standard if there are, I forget what the exact count,
3 174 whooping cranes in the entire world and you kill 17
4 of them in a single event; that's bad at least in my
5 opinion. The world isn't divided into endangered
6 species and super abundant species. We've got to
7 continue them, and that makes this even more difficult.
8 I feel it's incumbent upon us when we're thinking about
9 the magnitude of risk to think about species that don't
10 have large populations.

11 There are species of significant conservation
12 concern that aren't listed under the endangered species
13 act, that have the potential to be exposed to
14 carbofuran. Henslow's Sparrow. I don't have the exact
15 numbers. I can get them. I believe since 1965
16 Henslow's Sparrow populations in North America dropped
17 by 95%. This is a bird that breeds in conservation
18 reserve program land, and the center of it's range is
19 the corn belt of North America. I'm very disturbed to
20 think about carbofuran being sprayed on CRP land where
21 Henslow's Sparrows are breeding, but even if it's used
22 on crop fields adjacent, there's the potential for
23 exposure and risk.

24 Throughout the Midwest and Great Plains,
25 American Golden Clovers are a species of conservation

1 concern. I know from my own work, they spend time in
2 crop fields during migratory stopover. A little
3 further west I don't know if there are the people here
4 yesterday who raise sunflowers that have this on their
5 land, but certainly in the area we have mountain
6 clubbers. It's not on the endangered species list, but
7 it's been discussed and they breed in farm fields.

8 These are not species listed under ESA, so
9 they're not going to be discussed in the panel that
10 discusses endangered species acts, but they're small,
11 and they're declining populations of birds that I think
12 we need to consider carefully what the impact of excess
13 mortality is going to be in this situation, which is
14 going to be much different than considering excess
15 mortality in redwing blackbirds, or mallards, or what
16 have you.

17 Now I'm not saying there is risk to these
18 species. What I want to put on the record is in
19 everything we've done and everything I've seen we've
20 discussed, no one has considered whether there was risk
21 to this other group of species, and I think I'll end
22 that there.

23 **DR. HEERINGA:** Thank you, Dr. McCarty.
24 Dr. Montgomery.

25 **DR. MONTGOMERY:** This is a personal

1 observation that strays a bit from where the discussion
2 has been and the recent responses. And I mean this is
3 a scientific context, but as we progress through these
4 complex models that have increasingly larger and larger
5 demands for data and input, we as scientists need to
6 come up with some way of not having to have a real
7 piece of data for input parameter. We need to be able
8 to bridge and correlate between databases and bodies of
9 data, and that's a very complicated issue. And I know
10 that, you know, we've talked about models.

11 Models are only as good as the input. And
12 it's a thorny issue, but I think that it's one as
13 scientific we need to give thought to because it's
14 easy to say, oh, well let's just go do a field study,
15 and let's do another tox study, and let's do another
16 this; and then you have to do five species and you have
17 to -- I mean, it goes on and on. And while these are
18 nice numbers to have and in the purest sense of science
19 it's a wonder, it's the best road to go.

20 Practically speaking, we as scientists need
21 to give thought to this issue of combining data pools
22 so that we get power from what we have and really go in
23 and fill in the gaps that we really need to have filled
24 but we can't fill with the data that we currently have.
25 And I think that's an extremely complicated and

1 difficult task, but I think it's one as scientists we
2 need to give thought to, to the point where it becomes
3 something that can be implemented into these, these
4 very complex assessments that we're not starting to do.

5 **DR. HEERINGA:** Thank you, Dr.
6 Montgomery. Dr. Kehrer.

7 **DR. KEHRER:** Jim Kehrer. This answer
8 this charge question has dealt with, the risk of
9 mortality where carbofuran is used, but it doesn't ever
10 talk about how carbofuran is used. And my
11 understanding is some of the methodology that is being
12 used, for example, burying it in the furrow with the
13 potatoes should dramatically decrease the risk and to
14 me would almost certainly lead to a conclusion contrary
15 to EPA's assessment, at least in that particular
16 methodology.

17 **DR. HEERINGA:** Dr. Delorme.

18 **DR. DELORME:** It's always dangerous to
19 sit here and listen to other people talk 'cause it gets
20 my brain going. I think that with respect to the
21 conclusions made that we have to be aware of the
22 limitations, particularly with respect to the modeling
23 results. There's a construct there that we're using.
24 We're making some assumptions and just a couple of
25 issues. One, it's done on a field scale, okay, and we

1 have to be aware of whether or not that scale is
2 appropriate and whether it is for the organisms we're
3 trying to protect. And the other consideration is the
4 scale abuse, the scope of use of the product and how
5 that factors into significant risk. I'm not sure how
6 to do that, but, you know, I think definitely there's
7 got to be some way of looking at that.

8 **DR. HEERINGA:** Dr. Sample.

9 **DR. SAMPLE:** That was actually a nice
10 lead-in for what I was writing down here. And this
11 sort of strays a bit from our charge, but needing to
12 look at the use and evaluation on the scales beyond the
13 single field; and also because we have a set of tools
14 that are being used in the agroecosystems systems, it's
15 a variety of chemicals that had the same mode of
16 action. And as we have seen from the field studies
17 that were used as part of the risk evaluation, they can
18 have confounding effects, and those multiple impacts
19 can have significant implications.

20 The burdens that we're concerned with aren't
21 restricted to individual fields. They use multiple
22 fields on a broader landscape, so we needed to have an
23 integrated approach. In aquatic systems, we have
24 basically 10 DL's where we have maximum loads for so
25 many different contaminants that are managed on a

1 watershed basis, and that gives us a way of getting a
2 larger evaluation and integrating what's being
3 evaluated.

4 And I would like to propose for consideration
5 that a terrestrial equivalent be considered for
6 investigating a way to manage total exposure with
7 cholinesterase inhibiting pesticides within a given
8 agroecosystem. This could be used to manage the
9 application and balance the use of different pesticides
10 and different combinations that would be appropriate
11 for the habitats that are present, receptors that are
12 present, and the crops, and, you know, what makes sense
13 for the pests that would be present there.

14 **DR. HEERINGA:** Additional comments? I'd
15 like to turn to Dr. Odenkirchen to see whether --

16 **DR. ODENKIRCHEN:** No. That about
17 answers our question, and we thank the panel for all
18 it's time and efforts today.

19 **DR. HEERINGA:** Okay. Before we move on,
20 I'd like to -- and this is something that I promised to
21 do with the panel and that is given the panel an
22 opportunity to introduce any other scientific issues of
23 relevance to the current review and material that they
24 feel should be brought forward. We addressed a very
25 broad range of topics in our response to the charge

1 questions, but is there anything remaining of
2 scientific important that the panel would like to
3 introduce at this point in time?

4 Again, as I told Dr. Grue, if a thought
5 occurs to you tonight, or if you have a chance to check
6 back with the publication. Dr. McCarty sounds like he
7 must be an voluminous reader of the literature on
8 Earth, and actually I admire that. But in any case, if
9 something does come up, we will have a chance to
10 revisit before the closure of this meeting. I'm going
11 to take just a moment to confer with the DFO, and I'll
12 be back.

13 Okay. What I'd like to do at this point is
14 I'd like to adjourn for the day to make up for
15 yesterday. I think that I very much appreciate having
16 participated along with my other members of the FIFRA
17 panel in a number of these meetings with the way and
18 the efficiency with which you've addressed the charge
19 questions, and the issues, and for your obvious
20 preparation. My thanks to you on that. And also I
21 guess I'll turn to Dr. Odenkirchen on any last comments
22 or Dr. Bradbury.

23 **DR. BRADBURY:** No. I think we're done
24 from our perspective too, and I appreciate the hard
25 work by the panel. I know it's been an intense several

1 days already, and we look forward to tomorrow's

2 discussions. So thank you.

3 **DR. HEERINGA:** Okay. And, again, we
4 will convene again tomorrow morning at 8:30, and we
5 will move immediately into the human health effects.
6 Panel members, if you would please just take a moment
7 to convene next door in our breakout room just for a
8 quick administrative note.

9 **(WHEREUPON, the SESSION was adjourned at 4:30 p.m.)**

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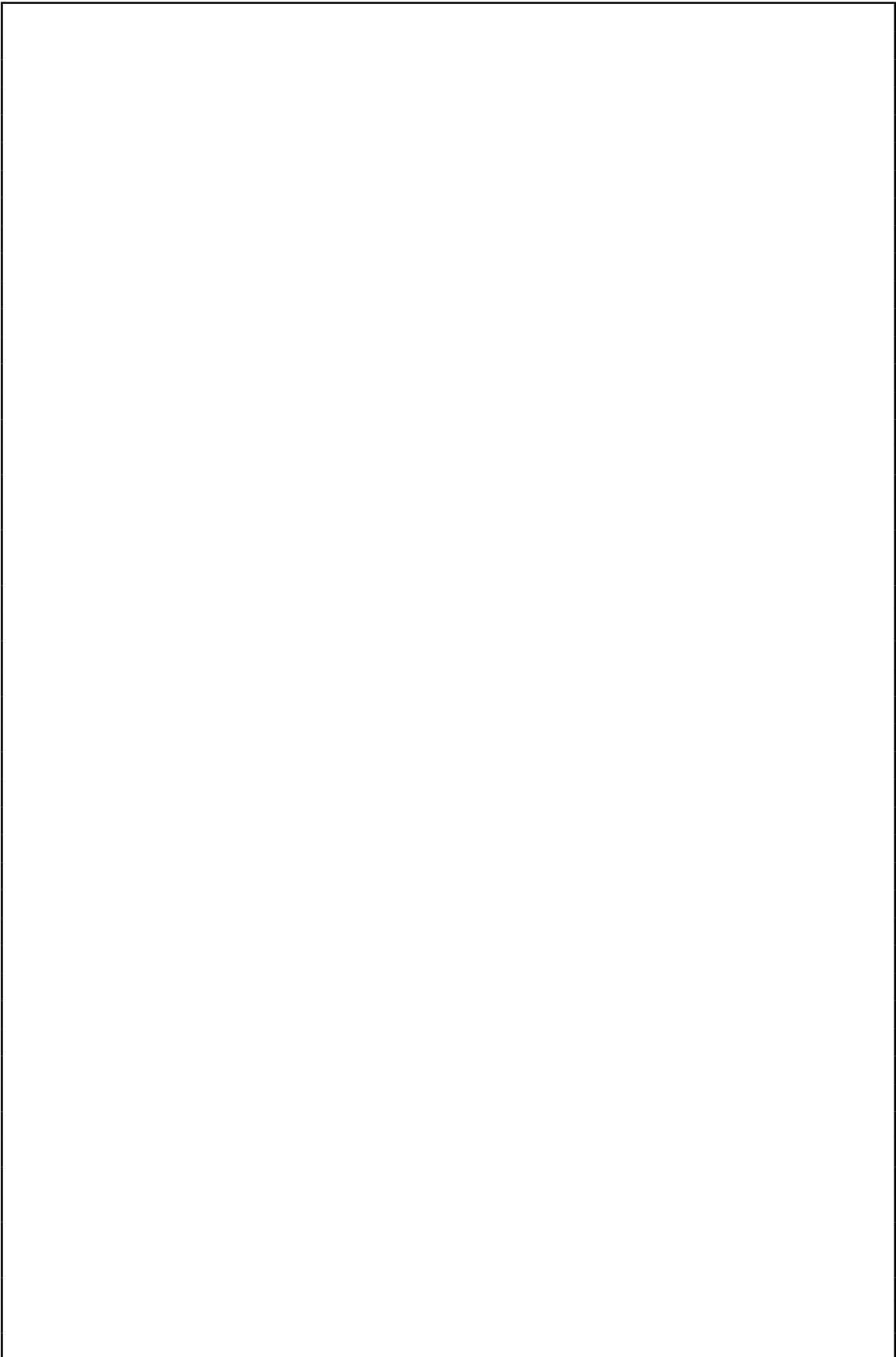
I certify that I am not a relative or employee of either counsel, and that I am in no way interested financially, directly or indirectly, in this action.

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SUBMITTED ON FEBRUARY 7, 2008



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0	100% 34:23 37:16, 19 112:20, 20, 22	1965 256:15
0.07% 238:1	1024 14:12	1967 139:1
0.12 112:1, 1	106 231:1	1972 220:12
0.88 123:1, 1	10g 213:1	1976 14:25 51:22
00 100:1 200:1	11 11:1 14:23 111:1 211:1	1977 85:16
0002 2:1	1100 9:13	1980 235:25 236:1
0003 3:1	113 12:1	1981 139:1
0004 4:1	11:00 71:21	1982 39:25
0005 5:1	12 12:1 59:18 112:1, 1 166:1 177:1, 1	1989 13:1 111:22 112:10 120:17, 17 232:1
0006 6:1	1250 27:11	1990 139:1 221:1
0007 7:1	127 17:1	1990's 216:21
0008 8:1	12:00 125:1	1990s 221:1
0009 9:1	13 13:1 57:1 113:1 213:1	1991 17:16
01 101:1 201:1	130 21:1 219:19 231:1	1992 216:1, 17
02 102:1 202:1	1300 11:23	1993 235:25
03 103:1 203:1	131,110 237:25	1994 13:13 14:19, 20 114:16 216:15
04 94:18 104:1 204:1	135 161:1	1995 13:13 68:22
05 105:1 205:1	14 14:1 112:1 114:1 147:21 214:1	1996 235:1
06 106:1 206:1	14% 105:12	1998 216:1 217:1, 22 219:22
07 107:1 207:1	15 15:1 20:14 64:1 105:1, 1 115:1 186:15 215:1	1999 80:1
08 108:1 208:1	15-minute 210:20	19th 27:17
09 109:1 209:1	150 85:20 88:15	1:00 125:1
1	150-day 87:19	2
1 128:1, 18 129:1, 25 130:15 132:1, 11, 24 147:1 152:16 153:20 154:1 156:1 163:23 165:1, 16 166:10 177:1, 1 179:14 182:22 183:1 192:15 201:20 209:13 210:1	151 14:16	2 21:1 115:16 128:21 130:15 132:11 145:21, 25 147:18 148:1 191:1 201:1, 20 209:1 210:1 214:14
1.0 94:11 95:1, 14 113:16 116:1, 1 117:10 121:19 129:22 131:1 132:17 174:1	16 16:1 112:1, 1 116:1 121:1 216:1	2.0 93:24 94:10, 14 95:13 96:24 97:1 100:1, 10 116:1 117:10 118:1 128:13 148:22 187:1
1.1 195:1 202:1 210:1	16-hour 203:1	2.1 93:16 94:10, 13, 14, 23 95:1, 13 96:24 97:1 100:1, 10 128:23 129:1, 23 130:1, 15 132:1, 18, 24 135:1 143:23 148:22 152:17, 21 173:24 174:1, 18 175:1 182:22 183:1 192:15
1.2% 237:23	16-hours 202:24	
10 10:1 15:1 53:1 64:1 72:20 110:1 139:16 147:21 186:15 198:1, 1 210:1, 20 260:24	1600 46:1	
10% 99:18 148:1	168 15:16	
10,000 15:13	17 17:1 117:1 217:1 256:1	
10-minute 71:20	174 256:1	
10.5 42:19	178.6 28:17	
	18 18:1 118:1 218:1	
	19 19:1 119:1 219:1 237:12	
	190 47:1	



2.1a 202:1	207:17, 22 224:1	37 37:1 137:1 237:1
20 12:10 18:1 20:1	25 18:1 25:1 71:21	37.5 45:16
72:12 73:1 75:17	125:1 225:1	38 38:1 138:1 238:1
79:1 120:1 180:1	2500 222:25	39 14:18 39:1
220:1 234:1	2575 10:17 21:1	139:1 239:1
20% 80:11 98:1 220:1	219:18	3:00 210:21
20,000 13:21	26 26:1 126:1 226:1	
200 20:19 86:1, 21	26% 28:17	4
219:15	27 27:1 127:1	4 20:1 145:21, 25
2000 13:22 14:25	216:1 227:1	209:11, 22
20:14, 15 22:22	27% 105:1	4.4 194:24 195:1,
214:10 220:12	28 28:1 128:1 220:11	1 198:17 199:21
235:25	228:1	210:1, 1
2001 20:16 22:13	29 29:1 129:1 229:1	4.6 42:14
95:13 128:1	2a 151:16 181:17	40 40:1 140:1
131:1 142:1	2a.i 153:1	193:1 240:1
151:1 165:13, 16	2a.ii 153:17	400,000 10:19
181:24 191:12	2a.iii 153:24	41 41:1 141:1 241:1
237:20	2b 181:20, 23 185:1	42 42:1 142:1 242:1
2002 34:1 160:1	2bi 182:25	43 43:1 143:1 243:1
221:1 229:1 234:22	2bii 183:1	43% 16:21 105:1
2004 8:1 94:1	2c 190:25 191:1	44 44:1 144:1 244:1
96:22 97:15, 16	2c-ii 192:11	4437 15:17
100:12, 18, 21	2d 181:15, 17	444 14:16
128:14, 24 129:1	203:19, 21 209:1	45 45:1 60:15
131:1 134:16		145:1 245:1
135:11 137:1	3	46 46:1 146:1 246:1
165:13 201:1 236:1	3 161:1 181:20	47 47:1 147:1 247:1
2005 13:25 22:16	3-hydroxy 202:11	48 48:1 148:1 248:1
23:1	3.4 46:23	48% 85:11
2006 52:1, 16 55:1	3.6 46:1	49 49:1 149:1 249:1
80:16 128:22	3.9 187:1 188:25	498 12:13 14:1, 11
138:18 151:18	198:14	16:21
191:1 204:12 231:1	3.9x 21:10	4:30 263:1
246:22	30 15:1 20:1 30:1	
2007 27:1 39:10	92:12 130:1 169:17	5
85:10, 12 151:1,	230:1	5 20:22
23 182:1 191:16	300 196:1 197:1	50 20:21 33:13
2008 2:1	200:1	50:1 150:1
202 15:15	31 31:1 131:1 220:12	219:16 250:1
2021 179:14	231:1	50% 33:13 52:21,
21 21:1 121:1 220:12	32 32:1 132:1 232:1	23 80:11 194:18
221:1	33 33:1 133:1 233:1	207:1, 14 212:18
21% 82:15, 16	33h27 27:11	500 86:1
216 16:21	34 34:1 132:17 134:1	50th 180:1
22 22:1 122:1 222:1	234:1	51 51:1 151:1 251:1
22,000 12:1 15:18	348020 143:10	52 52:1 152:1 252:1
224.7 28:17	35 35:1 135:1 235:1	53 53:1 153:1 253:1
23 20:14 23:1	350 12:1	54 54:1 154:1 254:1
123:1 223:1	36 36:1 136:1 236:1	540,000 15:12
24 24:1 124:1		

55 55:1 155:1 255:1		abcbirds.org 10:17
555 12:12	8	ability 43:1 60:1
56 56:1 156:1 256:1	8 87:1	62:1 83:1 86:1
56% 85:13	8% 82:15, 16	94:18, 22 109:19
57 57:1 157:1 257:1	8-hour 202:24	110:23 138:10
57% 112:22	80 80:1 180:1 193:1	158:23 159:14
57:26 178:24	80% 40:1	193:19 236:22
58 58:1 158:1 258:1	80's 86:1	239:1 241:10
59 59:1 159:1 259:1	8057 237:21	a2 163:20
5th 180:1	80s 236:16 244:20	able 15:24 40:19
	81 81:1 181:1	49:11 51:18 54:19,
	82 82:1 182:1	21 58:1 61:17
6	83 83:1 183:1	66:16 88:19 94:1
6 2:1 87:1	84 84:1 184:1	100:13 121:14
6-19 27:16	85 85:1 185:1	123:1 133:19
6-9 27:17	85% 146:1 224:1	138:25 148:12
60 60:1 160:1	86 86:1 186:1	166:23 169:1
217:1 260:1	87 87:1 187:1	175:18, 24
60% 217:1	87% 112:19	211:19 212:20
61 61:1 161:1 261:1	88 14:18 88:1 188:1	258:1
62 62:1 162:1 262:1	89 89:1 116:1	academic 47:1
63 63:1 163:1 263:1	120:1 123:1	academics 8:21
64 64:1 164:1	189:1 238:1	accentuated 220:19
65 65:1 165:1	8:30 263:1	accept 80:1
66 66:1 166:1		acceptable 34:13
67 12:1 67:1 167:1	9	140:12 253:23
68 68:1 168:1	90 90:1 190:1	accepted 80:1 92:1
689,019 237:20	90% 66:17 148:1	139:25
69 69:1 169:1	217:1 227:1	accepting 160:10
	90s 20:17 69:12	accepts 206:1
7	236:12, 21 244:20	access 14:1 35:1
7 2:1	91 91:1 191:1	38:1 90:1
70 70:1 170:1	92 92:1 192:1 216:1	accessed 25:19
70% 105:14	92% 80:23	accessing 233:1
700 11:24 15:23	93 93:1 193:1 216:1	accidents 72:21
70s 14:19 223:19	94 94:1 194:1	acclamation 105:21
236:1	94% 80:21	107:1 108:1
71 71:1 171:1	95 14:17 95:1 195:1	accomplish 100:10
71% 112:20, 22	95% 217:1 219:19	according 46:21 47:1
72 72:1 172:1	224:1 256:17	111:1 207:1 217:1,
72% 74:10	95th 180:1	1
73 73:1 173:1	96 96:1 196:1	account 33:24
74 74:1 174:1	97 97:1 197:1	101:17, 19, 22
75 75:1 175:1	98 98:1 198:1	189:1 192:1
75% 112:22	99 99:1 199:1	208:1 215:19
76 76:1 176:1		accounted 149:14, 15
77 77:1 177:1	A	accounting 109:25
78 78:1 178:1	abate 108:1	accounts 220:16
79 79:1 179:1	abbreviated 186:25	accuracy 75:18
7:00 2:10, 19	abc 14:25 225:1	108:22 109:23
		accurate 222:1 240:1

acetylcholinesterase 103:1, 15 167:1
 191:1, 16, 23
 192:1, 1, 12,
 22, 25 195:1
abrupt 216:14 222:22
ache 206:11
achieve 112:19
 156:25 175:19
achieved 193:1
absence 34:22
 52:21 105:18
 238:18, 22
absolute 233:22
absolutely 227:16
 230:1, 23
absorbable 116:21
absorbed 35:1 37:18,
 19
absorption 5:23 6:21
 34:24 36:1 37:16
**absorption/
 desorption** 184:23
abundance 64:18
abundant 243:18
 255:16, 17 256:1
abuse 10:24 11:12
 13:21 22:24 260:1
abused 11:16
acknowledge 155:23
 165:25 211:1, 16
 239:25
acknowledged 227:11
acknowledges
 130:18 237:12
 250:19
acknowledging 129:15
adapt 45:1
adaptation 203:15
adapter 126:1
add 40:1 47:1
 48:1, 13 88:1
 115:1 133:24
 134:1, 1, 1 144:1,
 1, 1, 17 185:18
 207:11 211:11
 212:10 219:1 221:1
 241:15 243:1, 1
 244:1 252:14
added 64:1
adding 183:18

addition 94:18 133:1
 136:1 138:21
 139:21 155:16
 161:1 182:15 184:1
 185:11 193:21
 212:13 234:23
 242:1
additional 71:1,
 18 77:17 89:23
 91:23, 23, 23
 121:12 124:21
 126:17, 24
 129:17 130:16
 131:22 133:24
 145:17, 19
 154:13 160:20
 184:1 200:23
 203:16 204:1 205:1
 206:1 209:1
 213:1 224:1
 226:1 230:17 238:1
 244:1 261:14
additions 128:1
 135:10
additive 242:1
address 30:15
 51:18 61:1 64:1
 71:1 90:1 133:1,
 18 151:1, 21
 165:24 179:22
 183:25
addressed 128:13
 129:1 131:14 157:1
 205:19 240:19
 261:24 262:18
addressing 30:19, 21
 128:10 227:14
adds 35:11
adequate 33:10 47:11
 77:1 172:1 177:24
adequately 135:1
 155:1 163:25
acre 28:17, 17
 83:20, 22 86:20
 112:1 123:16, 19
 222:25
acreage 15:10 77:17,
 21, 21
acres 15:1, 12, 13
 46:1 51:1, 21
 55:14 57:18, 19,
 21 60:21, 24 61:15

63:22 69:21, 22,
 25 70:1, 1 75:25
 81:12, 12 82:10
 84:1 85:1, 10,
 14 86:1, 21
across 18:1 23:1
 62:21 64:10 69:1
 80:1, 1 96:19
 100:1, 1 108:24
 111:1 112:18
 113:12, 12
 114:15 118:1,
 21, 25 119:13,
 15 142:11 163:17
 180:12 185:13
 198:25, 25
adhere 232:1
act 256:13
acting 4:21
action 2:1 13:1 51:1
 62:1 169:25
 191:13, 19, 21
 218:1 247:15
 260:16
actions 45:1 58:24
activate 125:24, 25
active 40:21 78:11
 112:1, 1
actively 74:18
activities 40:25
 135:21 220:18
activity 66:20
 103:1, 15 107:1
 191:15 193:17
acts 257:10
actual 25:1 98:24
 100:20 109:23
 134:17 146:1
 156:20 168:1
 184:15 198:1
 219:10 240:13
 252:11 253:1
actuality 147:11
actually 27:16 29:15
 36:1 58:1, 12, 19,
 23, 25 59:1, 10,
 21 60:1 63:1
 64:1 65:23 66:1, 1
 68:22, 24 72:25
 73:1, 1, 22, 24,
 25 74:20 75:16
 76:23 78:1 82:1

89:22 92:13 96:1
 98:1, 15, 20
 106:21 108:15
 110:17 112:11
 115:1 140:1
 141:18, 25
 144:1, 11 147:1
 149:1 157:18
 168:11 172:14
 173:11, 14, 23
 183:15 184:20
 188:17 196:25
 199:1, 11, 12, 13,
 15, 21 200:1, 17
 201:1 229:1 238:14
 242:20 243:20
 244:11, 21, 23, 24
 245:1, 11, 18
 246:11 260:1 262:1
acute 16:1 83:13
 128:1 135:18
 181:24 182:1, 1,
 11 203:24 212:16
 213:1
adjacent 256:22
adjourn 262:14
adjourned 263:1
adjust 123:25 124:1,
 1 145:1 198:15
adjusted 122:23
 210:1
adjusting 7:15
 112:17 152:22
 177:1, 1
adjustment 174:1
 177:20, 23, 25
 178:23 239:16
adjustments 208:1
adm 80:1
administrating 72:15
administrative 212:1
 263:1
admire 262:1
admit 239:1
admittedly 98:1
ads 182:14
adult 100:19, 22
 101:10 137:1, 1,
 18, 22 140:1, 14
adults 137:1, 21
 139:24 140:13
 193:1
advance 251:22
advances 130:1, 13
advantage 52:11 54:1
 86:1 130:1
advantageous 39:14
adverse 112:1 116:12
adversely 113:24
adversities 38:25
advertise 10:11
advice 91:25 130:21
advisor 57:11
advisory 2:1, 1 3:1,
 16, 19 8:1 39:16
 49:16 51:19 72:1
 89:20 126:1
 127:1 128:1
advocate 162:15
affairs 39:24
affect 107:23 165:18
 176:11 184:1
affected 205:1
affects 164:25
affirmative 215:1
 225:14 226:21
afford 29:1
aerial 27:21 67:1
 72:1, 1, 1, 11
aerially 66:11 68:1
ag 27:1 74:10
against 51:1 55:1
 84:1 232:12
age 96:19
agencies 22:20 218:1
 220:1
agency 2:1 4:23 5:25
 9:1, 1, 1, 11
 10:21, 22 14:15
 16:14 21:1 22:1
 23:21, 22 24:1,
 1 30:25 104:17
 106:13 108:24
 128:22 134:23
 135:1 142:1, 20
 145:22 151:1, 10
 165:15 182:1
 194:12 203:22
 214:10 215:23
 216:1, 19 217:21
 218:20 219:15
 222:1 231:1, 10
 247:1 249:11, 17
 250:1 255:11
agency's 2:1 31:1,
 1, 14 32:1 34:12
 128:1, 15 142:12
 151:11 182:25
 192:1 204:12, 18
 214:13, 22 215:14,
 22 218:14 231:16
agent 36:13 170:1
aggregate 195:1
 206:1, 1
aftermath 28:1
afternoon 7:25 21:22
 26:20 95:18 98:1
 99:11 117:1
 125:1 127:25
 147:10
ago 10:10 12:24,
 24 48:1 52:22
 61:13 120:18
 167:20 234:1
ahead 3:13 60:1
 126:10 127:1 196:1
 197:1
agreed 16:18 22:12
 231:22 249:1 250:1
 251:1
agreeing 15:1
agreement 106:1
 129:17 151:1
 231:24
agricultural 10:1
 11:19, 22 14:17
 15:1 16:1 25:11
 91:10 128:1
 232:1 238:1
agriculture 16:16
 45:1 48:1
agroecosystem 261:1
agroecosystems
 260:14
agronomist 27:17
 57:1 69:1
aiding 128:12
aims 11:20 12:1,
 10 13:12, 19 14:1,
 1 16:21, 23 17:1
 20:12, 25 218:18
 219:18 221:21
air 74:1 132:23
 160:12 237:1
aircraft 74:10

airplane 73:13, 18 75:15	153:21 183:1 204:14, 17 247:12	105:1 126:13 222:20 226:24 227:1, 1 228:1
airtime 192:21 204:23 246:15, 16	alterations 33:1 altered 193:15, 19 205:22 219:13 250:1	amounts 209:20 and/or 214:25 225:22 amphibians 252:23 ample 139:17 169:11 193:1
al 120:17, 17 139:1 157:1 160:1 234:21 235:1, 25 236:1	altering 129:1 131:18	animal 149:21 150:1 155:1 169:18 175:22 184:25 194:17 196:14
aldicarb 85:20, 25 87:19	alternate 86:12 87:23 247:1	animals 33:14 155:1 169:1 170:24 189:10 193:14 194:1 196:12, 16, 23 197:1
alex 6:1	alternated 249:13	annette 6:19
alfalfa 14:21, 21, 23 15:1, 1 19:1 78:1 110:1 112:1 120:1 220:13 234:14	alternative 42:24 47:20 55:13 56:15 142:17 156:15 192:16 194:11	announce 39:1 annual 50:1, 1 80:15
algorithm 94:15 98:12	alternatively 140:1	anorexia 103:21 108:12 109:10, 22 110:1 156:22 157:1 158:14, 16, 18, 20, 21 164:1, 24 176:1
allometric 103:1, 1	alternatives 43:23 55:21 56:12 254:24	anorexic 108:13 109:1, 1 171:15
allow 21:24 37:1 40:25 73:12, 16 77:15 133:16, 18 174:20 184:17 185:13 193:24	alters 148:1	answer 22:1 64:23 92:24 175:11 183:15 195:1 241:23 242:23 255:1 259:1
allowed 45:1 80:14 94:16 176:24 208:22	altricial 100:19, 22 137:1 140:10	answers 9:1 81:10 189:1 261:17
allowing 49:17 52:10 109:1, 1	analogy 115:16 255:21	antenna 235:15
allows 35:22 74:1 75:1 150:11 166:18	analyses 91:1 131:12	anthony 84:19
am 3:20, 20 22:11 72:1 75:24 113:1 181:15 187:1 227:18 241:16 254:24	analysis 7:1 16:25 21:1 31:10, 15 91:1 93:20 103:17 105:11 113:16 116:1 121:16 143:1, 1 147:1 149:1 151:1, 13 160:1, 10, 12, 20 161:1, 18 164:1, 1 165:1 176:15 186:1 198:17, 19 199:15 200:1 205:16, 24 211:18 228:14 232:11	anticholinesterase 36:10
almond 17:22 18:10, 19	analyzes 91:1 131:12	apart 36:1
alone 110:10	analyzed 119:1	anxiously 84:10
amended 85:1	analyzed 32:17 46:19	anybody 190:18 235:12, 12
america 19:17 65:11 236:1 237:21 255:19 256:16, 19	analyzing 154:20	anymore 220:22
american 4:1 7:23 10:1 219:11 256:25	among 96:18 121:1, 1 122:1 148:17, 20 149:1 163:1 167:1 196:14 205:12	anyone 190:1
already 62:17 67:17 81:1, 1, 22 135:1 197:19 205:1, 12 224:10 245:19 263:1	amount 3:1 19:14 26:1 34:1 70:19 73:1 89:1, 23 98:1	anything 13:1 23:1 30:1 56:1 117:1 143:25 167:21 168:21 200:1 207:10 236:21 248:1 254:21 262:1
alter 102:23 143:24 151:11		

anyway 57:11 60:1
 74:17 77:1 89:15
 200:22 220:17
anywhere 55:22
aphid 41:14 42:18
 43:14 44:1, 11
 48:24
aphids 42:14 43:1,
 11 48:24 85:19
 86:16
apologies 89:12
apologize 38:22
 222:16
apparent 158:1, 1
 164:1 188:1 224:19
apparently 160:1
 202:13
appear 99:19 116:1
 182:10
appeared 216:23
appears 108:1
 113:10, 19
 116:1, 1 137:25
 139:23 145:23
 146:1 154:23
 160:14 164:1
 219:20
applicable 101:13
 172:23 177:1, 1
application 41:1
 44:1 45:1, 1, 25
 47:1 48:1, 1, 1
 49:1, 1, 13
 50:1, 1, 1, 1,
 14 55:1 73:1
 78:1 82:23 87:1
 95:1, 1 110:1
 112:1 113:24
 129:22 143:15,
 17 146:17, 18
 209:1 235:20 253:1
 261:1
applications 43:1
 76:10 88:1
 94:19, 22 101:25
 143:19
applicator 27:21
 57:12 67:1 72:1,
 1, 12 77:1 88:1
applicators 66:10
 216:1
applied 6:1 7:1
 27:22 43:1 47:1
 49:24 54:15
 58:19 59:1, 10
 60:1 66:11 73:1
 85:1 146:1
 166:12 189:1 207:1
 236:1
applies 134:24 139:1
 230:23
apply 45:10 56:1
 68:1 75:13
 81:19, 21, 25
 82:1, 20 86:1
 162:1 177:19, 20
 206:14 209:16
applying 46:24 65:16
 208:1 236:1
appreciably 13:12
 21:19
appreciate 7:11
 36:16 38:15 57:1
 77:1 78:24 246:1
 262:15, 24
appreciated 89:1
appreciation 2:13
 3:1 7:15
approach 9:1, 1, 1
 22:1 31:14, 19
 32:16 33:1, 15, 18
 82:1 83:1 87:22
 128:1, 15 130:1,
 12 134:17 138:13
 142:12 153:1, 1,
 19 163:22 164:1
 166:1, 1, 1 172:20
 174:12 183:1
 185:1, 1, 1
 188:1 192:13
 194:1, 13 200:1,
 24 206:1, 18
 212:19 218:24
 234:1 240:1
 251:1 260:23
approached 156:13
approaches 130:1
 156:1 174:17 194:1
 234:1 235:21
approaching 83:22
 208:11
appropriate 3:15
 30:20 31:12
 92:21 97:1 126:1
 133:1 164:10
 166:16 172:17
 176:13 181:25
 187:1 194:1, 1
 200:1 201:1 205:25
 208:1 209:1 211:1,
 1 260:1 261:10
appropriately 37:1
 154:1 165:1 169:12
 171:13
approximate 186:24
approximately
 52:17 165:15
approximation 176:10
april 151:1 191:16
area 3:25 5:12,
 19, 23 25:12 29:13
 50:25 52:1 53:1
 67:1 76:1 80:11,
 12, 13 85:23
 114:1, 1, 1 125:15
 233:13 234:1 243:1
 257:1
areal 66:10
areas 10:1 14:17
 58:12 66:12
 84:22 96:16 118:10
 233:11 238:1
 251:22
aren't 169:1 226:1
 234:15 240:1
 256:12 260:20
arena 79:25
argue 134:10
 172:1, 15 186:18
 217:1, 17 218:1,
 22 245:21
argued 243:14
argument 217:1
 221:22 225:1
 228:17 250:25
arguments 221:17
arise 223:1
arises 124:23
aquatic 4:14
 252:22 260:23
aqueous 21:11 206:10
asada 55:1
ascertain 128:25
army 133:13
arriving 213:11

arrow 73:23 75:1
arrows 75:1
artifact 110:21
 162:1
at-plant 58:1, 25
at-planting 57:25
ate 92:12
aspect 65:23
 177:18 179:11
 210:1 242:11 243:1
aspects 133:1
 155:1 209:1
assault 169:24
assay 34:1
assemblages 42:1, 18
assembled 3:17
asserted 104:13, 16
assess 94:18, 22
 136:14 157:15
 166:19 239:1
 244:21 245:11
 246:23 248:13
assessed 191:14
assessing 31:12 33:1
assessment 4:22
 5:13, 16 6:1,
 14, 18, 22 8:1, 19
 34:11 35:1, 12
 76:21 90:1, 1, 23,
 24 93:11 95:1 96:1
 128:1, 17 130:1,
 1, 14 143:22
 151:1, 18 154:25
 155:1, 1 157:14,
 25 162:15 163:19
 194:21 208:11
 229:16 231:24
 246:20, 21 247:13,
 18 248:16, 18
 249:1, 1, 1, 1
 250:1, 1 251:24,
 25 252:1 259:15
assessments 8:1
 93:12 130:1, 11
 133:1 136:12, 15
 182:1 188:1 251:11
 259:1
assessor 155:24
 187:22
assign 226:1
assigned 254:15
assist 88:19
assistant 4:17
associate 5:22
 133:25 166:21,
 25 169:18 195:19
 207:1 219:1 241:12
 248:1 252:13
associated 2:1 11:22
 17:22 18:16
 45:18 95:1
 132:23 134:14
 135:22 142:18
 171:23 182:18
 187:1 196:1 197:15
 214:18, 24, 25
 215:25 216:1, 1,
 10, 16, 25 217:1
 225:21 228:1
 245:25 253:1
associates 5:12
 154:1
associating 170:1
association 17:21
 51:24 52:1
 78:21, 22 79:1, 12
associations 14:1
assume 37:16 88:14
 148:1 228:1 229:14
 238:1
assumed 101:22
 137:11 142:13
 179:1
assuming 142:25
assumption 137:12,
 25 138:1 139:1,
 21, 24 140:13
 142:17 143:1
 178:13, 22 179:1
 202:1
assumptions 95:1
 114:22 121:10, 23,
 24 136:20
 137:16, 22
 140:21 141:1 188:1
 189:12 204:1
 232:13 252:10
 259:24
assurance 23:16
assured 84:1
atlanta 4:1
audience 2:14 3:1
 56:21 71:25 89:1
audra 5:21
augment 215:13
august 86:1 128:21
attachment 85:1
 87:1, 11
attachments 87:10
attempt 249:23
attempted 234:1
attend 169:12
attention 97:24
 139:19 165:1
 202:24 237:1, 1
 238:1
attitude 225:1
 254:20 255:1
attract 238:1
attractive 69:20
attributable
 104:11 107:1
attribute 164:14
 232:20
attributed 112:1
attributing 221:19
 232:23
avail 126:14
availability 55:15
 93:16 130:1 133:10
 188:14 217:10
available 10:16
 24:10 26:1 32:1
 40:19 46:1 57:24
 58:1 82:22 83:1
 84:17 91:25 92:1
 93:17, 18, 25
 104:1 128:20 131:1
 156:11 159:14,
 16 164:1, 12 171:1
 183:1 184:1
 185:1 200:19
 231:1, 13, 17
 236:1
atv 113:1
average 80:22
 113:1 118:25
averaged 228:22
avian 10:1, 11,
 14, 15 48:13, 16
 76:1, 1, 21
 90:13 128:19 129:1
 131:1, 20
 142:18, 19

151:1, 24	152:12	baby 20:1	206:10	214:12
164:1, 24	182:1,	bachelor's 27:1	216:1	221:19
20	191:22	background 5:15	229:15	232:22
204:15,	19	30:17	66:1	240:1
214:17	216:1, 24	backing 178:25	basic 228:23	
217:20	218:1	bacteria 40:1	basically 18:1,	15
231:25	241:19	17, 25	61:19	64:19
244:19	247:1, 19	bad 223:22	73:15	74:22
249:19	250:23	bag 58:20	75:10	80:12
252:1		59:11	120:10	136:16
aviary 235:1,	1	bailey 7:1,	145:1	158:11
authorities 37:1		119:18,	260:24	
authority 37:1		20, 25	basin 65:1	
authorized 255:13,	14	120:1	basing 33:18	131:10
		144:20,	basins 65:24	66:1,
authors 105:19		21, 21,	23	
automobile 18:25		21	basis 26:1	27:15
awaiting 84:10		145:10,	31:12	50:1, 1,
aware 46:1	80:18	10, 14	10	90:23,
149:15	188:12	15	129:11	137:1
259:21	260:1	150:1,	143:1	147:19
away 18:20	27:21	1, 1,	148:16	150:13,
66:1	235:1	173:1,	152:24	153:10,
avoid 62:10	66:11	1	22	154:1
74:16	151:22	180:19	163:23	164:15
158:23	162:13	181:1	165:11	168:25
163:1		bailey's 179:20	183:1,	10
avoidance 38:1		baiting 106:21	191:14	192:1,
104:1,	1, 1	balance 172:10	204:21	215:1
106:1	107:1	175:23	227:23	231:19
109:10,	16, 18,	240:1	247:21	261:1
114:25	115:1,	261:1	bay 61:20	
122:1	140:21	bald 17:1,	bean 62:13	
141:23	151:16,	1, 1, 11	bear 244:25	
24	152:1,	balls 64:1	became 69:16	
10,	18	ban 30:13	become 34:1	46:1
18,	21	band 238:12	61:1	62:1
156:22		243:1	81:1	83:1
157:1,	1, 12,	244:1	141:1	188:1,
20		banded 237:21	235:21	
158:14,	19, 20	238:1	becomes 49:14	
163:15,	21	banding 237:19	53:19	66:1
164:1,	1, 11,	238:11,	67:18	77:25
17,	24	12	83:12	148:12
165:19,		244:1	259:1	168:13
20	166:1,	bands 59:25	becoming 243:18	
12		237:20	bedding 24:22	
168:1,	1	238:13	beet 41:14	42:13,
169:1,	15	baptista 138:18	beetle 42:19	18
170:1	171:15	barely 99:18	53:16,	22
173:11,	15, 17	barry 17:17	54:19	85:19
178:15	181:1,	bars 167:10	beetles 41:15	
1		212:21	42:14	44:1,
204:1		b2 185:1	53:15,	23
awful 97:25	110:1	base 40:10	54:1,	13
axes 9:14		190:19,	86:16	
		20		
		based 24:25		
		32:1		
		33:12		
		37:1		
		42:12		
		70:11		
		91:19		
		116:16		
		122:24		
		123:1		
		124:10		
		129:1,		
		24		
		132:1,		
		1		
		135:1		
		139:1		
		142:24		
		143:10		
		150:21		
		152:19		
		153:25		
		163:1		
		165:1		
		167:14		
		169:1		
		191:18		
		199:1		
		204:1		
		205:21		

B

beets 15:13
begin 102:1 106:23
 125:1, 1 178:20
 179:12
beginning 84:20
 99:22 188:13
 216:15
behalf 215:10
behavior 99:19
 100:1, 17 101:1,
 10 109:20 136:24
 137:13, 17
 139:17 141:23
 142:19 148:1 150:1
 152:1 153:10
 155:1, 10 166:1,
 14 171:1 193:15
behavioral 62:1
 104:10 128:12
 193:13
behaviors 25:25
 140:22
behind 64:1 69:22
 169:23 221:1, 14
believe 7:24 24:17
 29:24 33:16 51:1
 77:1 80:21 93:15
 104:12, 22, 23
 110:24 121:21
 134:13 171:16,
 20 172:1 182:16
 185:20 196:19
 201:17 208:1
 219:23 224:22
 233:17 250:11
 252:1 256:15
believes 104:17
 152:1 156:24 190:1
 191:25 204:1
belongs 43:18
belt 62:22 75:25
 80:1 256:19
benchmark 31:10,
 15 32:22 33:13
 213:1
benedict 27:1 57:1
 65:1
beneficial 43:11
 47:14 205:1
benefit 72:20 133:21
benefits 47:19 91:1,
 14 227:10
bennet 157:1, 1
berber 160:1
berger 234:21
best 15:24 61:18
 64:15 134:15, 21
 149:1 156:1 169:22
 172:20 177:1 179:1
 226:17 232:1 233:1
 234:12 248:1
 258:19
better 45:1 70:17
 84:19 108:17
 157:21 173:23
 187:18 189:1
 236:14
beyond 72:17
 176:21 226:1
 260:12
b7 58:1
bia 16:23
bias 104:14, 15, 16,
 25 105:20 109:20
 153:1 168:14 189:1
biases 104:10
bifenthrin 68:1
bifurcates 91:11
biggest 39:1
 147:24 186:13
bimodal 95:12, 15,
 22 96:23 97:1
 100:14 115:17
bioavailability
 102:17, 23
biochemical 34:1
biological 102:1
biologist 4:1
biologists 110:1
 237:1
biology 4:1, 19
 5:1 6:25 166:10
 185:10
biomarker 6:1 191:15
biopsy 219:10
biostatistics 6:16
biotech 58:1, 1,
 13 59:1 61:1, 15
 62:17, 25 70:15
 79:25 80:1 84:1
biotechnology 70:21,
 25
bird 7:23 10:1, 1
 12:1, 18 15:21
 16:1, 24 22:23
 98:13, 19 99:1
 101:1 103:1, 20
 104:1, 1, 20
 112:1, 15, 24
 118:10, 12, 16
 119:1 123:1, 1, 19
 144:13 146:16
 148:1, 16, 19,
 23 150:1, 1, 1,
 13, 14, 16, 17
 151:23 162:22
 173:15 175:19,
 22 176:1 180:21,
 22 182:1, 17 191:1
 200:1 202:20
 219:11 226:16
 227:1, 16, 25
 228:1 234:13
 235:16, 22 237:11,
 19 238:1, 11,
 11, 13 241:1 242:1
 244:1 256:17
bird's 168:12
birds 5:1 10:19
 11:19, 22 12:11,
 15 13:1, 19
 15:1, 1, 16
 16:1, 1, 1, 16
 17:1, 1, 11, 24
 18:11, 14, 17,
 23 19:1, 1, 13,
 14, 20, 21, 25
 20:1, 10, 15 21:13
 25:11 64:1, 1,
 10 65:10 76:12,
 17, 19 96:1
 98:25 100:1, 19,
 22 101:1, 1, 15
 102:20, 21
 103:13 104:16,
 17 105:1, 1, 1, 1,
 10, 12, 14, 21
 106:21, 22 107:1
 108:1 109:1, 1,
 1 110:10 112:17,
 18 113:1 114:14
 115:15 117:22,
 25 118:1 123:10,
 18 128:1 129:24
 134:11 136:24
 137:1 138:1, 1, 1,

1, 10, 16, 22
 139:1, 11, 22
 140:1, 10, 14
 142:13 148:17, 21,
 21 151:22 152:1
 157:1 159:1, 1,
 17, 18, 19
 162:11 169:11
 170:1 171:1, 1
 175:17 180:1
 181:1, 13 185:1
 186:11, 16, 20
 191:23 192:1 193:1
 194:1 196:1, 10
 200:20 203:1, 1
 204:11 206:22
 207:1, 15, 17, 19,
 22 209:17, 19
 215:1 217:1, 1
 219:16, 16, 17
 225:16, 20 228:1
 231:15 233:10, 11,
 12, 16, 23
 234:1, 1, 11,
 18, 20 235:1, 1,
 10, 11, 13, 13
 236:1, 1, 13,
 17, 19 237:1, 1,
 14, 15, 20, 20,
 23, 24 238:1, 1
 240:11 241:20
 242:1, 1, 13,
 16, 17, 20
 243:1, 1, 1, 15,
 21 244:22
 246:19, 24
 247:10 248:14
 249:1 251:1 252:21
 255:10, 16, 17
 257:11
birias 237:25
birth 159:13
bit 16:1 37:17
 41:1 59:13 65:24
 69:1 72:11 79:14
 93:14 120:21
 146:25 148:1, 24
 158:11, 17 168:1
 176:1 196:1
 241:1 258:1 260:11
black 59:25 73:25
blackbirds 255:18
 257:15
bladder 204:25
blocks 18:1
blood 17:23 31:1,
 1 32:10 33:14 35:1
 200:13, 20
bloodstream 38:1
bloomington 72:10
bmd 33:13
board 3:17 51:24, 25
 52:1 222:16
bobwhite 193:1, 1
bodies 258:1
body 15:19 108:11
 117:1, 12 119:11
 142:19 148:11
 244:12
bolus 21:11, 11,
 17 149:19 206:11
 207:16
booth 120:16
born 244:11
bosit 56:13
bottom 14:13 73:13
 100:1 156:23
bounce 211:19
bounds 239:21
bouts 20:1 138:1
bracketed 194:25
brad 5:14 129:13
 134:1, 1 161:1
bradbury 7:1, 1,
 20 90:12, 15, 16
 222:1, 1, 13
 223:24 224:1
 262:22, 23
brady 90:12 127:1, 1
brain 31:1, 1, 10,
 21 32:21 33:13
 34:1 49:1, 1
 192:25 193:1, 11
 194:15, 17
 200:18 259:20
branded 143:19
break 71:15, 18, 20,
 22 73:1, 13
 93:24 124:25
 127:23 160:16
 210:12, 20, 22
 213:1
breakout 263:1
breed 176:11 257:1
breeding 237:15
 242:20 243:1, 1
 256:21
breeds 256:17
bresnahan 27:17
 56:23, 25 65:1, 1,
 1, 12, 15, 22 66:1
 67:1, 14 68:1,
 1, 19 69:1 70:13
 71:1, 10, 11, 15
brewer 207:13
brian 27:17 56:23
bridge 155:17 258:1
bridging 249:11
brief 67:11 92:1,
 1 142:21 159:1
 161:1 176:17 221:1
briefly 85:1 88:1
 90:19 203:10
brimijoin 6:23, 23
 12:24 29:1, 10
 36:1, 1 209:1, 1
 226:10, 12
 228:1, 1, 15
bring 9:23 71:1
 76:22 89:1 161:1
bringing 166:14
brings 52:1 60:25
 163:18
broad 36:14 261:25
broader 138:1 260:22
brochure 26:10
brochures 39:16
 44:22
broken 21:1
brood 19:25
brought 10:1
 16:11, 24 20:11
 78:10 91:1 95:14
 101:20, 21 159:1
 199:1 202:1 222:25
 229:25 230:1
 240:21, 22 255:1
 261:24
brung 102:11, 12
bt 80:21 81:1 83:1
bucklin 235:25
budget 138:22
 220:1 240:14
budgets 220:1 225:1
build 19:21 48:25

carry 88:1 101:14
 224:1
carry-over 191:1
 192:14 204:1
carrying 59:15
carryover 177:12
 194:10
carson 38:18
case 12:1 13:21
 14:10 48:24 49:1
 71:1 82:21 91:25
 96:1 98:1, 25
 99:1, 14, 18, 18
 101:11 107:1 122:1
 159:17 163:1
 173:14 176:13
 198:1 209:14
 225:11 262:1
cases 11:17 12:12,
 12, 13, 15
 13:11, 18, 23
 14:1, 12, 14,
 18, 20, 24 16:22
 17:1 21:1, 1
 22:22, 23, 24
 58:23 61:11
 62:19 63:1 64:13
 148:19 174:11
 188:1
casing 112:13
casings 112:21
cassin's 123:14
catch 18:18 146:1
 156:1 166:23 237:1
categorically 121:1
category 36:14
cattle 27:14
caught 147:1
 202:24 238:14
causality 221:19
 226:1
cause 12:19 13:1
 24:1 108:15 109:16
 116:12, 16 161:1
 163:18 170:1 175:1
 181:16 215:1 218:1
 222:1 225:15
 231:25 239:22
 259:19
caused 247:17
causes 16:1 231:14
causing 43:11
caveat 97:13
caveats 239:1
cedar 79:1 83:15, 16
 89:13
cell 4:1 31:1
 32:10 33:14
census 123:1, 1, 23,
 24 124:1, 1, 1
censuses 124:14
censusing 233:10
center 4:18 6:16
 75:10 93:1
 122:13 171:1
 256:18
centered 251:13
centers 17:20
central 72:10
 85:21 137:19
 139:22 140:1
 171:24 179:25
 180:11 185:1 189:1
certain 3:1 12:14,
 16, 22 23:24 76:19
 155:16 159:1 231:1
 243:25 253:1
 254:24
certainly 16:25
 157:1 158:1
 165:1 170:23
 183:17 185:1
 219:21 227:24
 234:17 240:16,
 16 255:1 257:1
 259:14
certainties 92:1
certainty 12:13,
 16 25:1
certified 57:11, 11
chain 224:13
chair 3:19 72:1
 126:22
chaired 8:24
chairman 38:24 78:23
challenge 84:1
challenging 2:16
chambers 3:23, 23
 185:15, 19, 22, 25
chance 26:23 27:1
 59:1 60:1 64:14
 77:1 138:18 181:17
 213:19 262:1, 1
change 22:1 81:18
 94:14 117:1, 10
 132:1, 1, 1
 141:1 159:1 215:18
 219:20 223:1, 1
 225:1, 1 245:20
 250:15
changed 132:15 206:1
 217:21 228:18
changes 62:1 93:1
 94:13, 15 107:1
 117:1 124:19
 132:1, 1 134:19
 215:15 216:1
 219:12 224:1
 227:19 250:13
changing 39:18, 18
 48:1 97:1 224:15
 228:16 252:1
chapter 151:19, 21
 191:1, 1 204:13,
 14 231:1, 1
characteristic 169:1
characteristics
 40:23 169:1
characterization
 156:1
characterize 118:13,
 14 154:12
characterized 164:25
 191:13
characterizing 149:1
charge 9:17 30:14,
 19, 21, 23 35:14
 71:1 89:22 90:1,
 1, 1, 15, 25
 91:13, 13 92:1, 21
 93:1 116:10
 117:1 125:1
 126:10, 25
 127:1, 1, 1, 20,
 22 129:21 131:15
 156:20 174:22
 176:20 184:15
 210:14 211:12
 212:11 213:22
 235:17 248:15
 249:1, 21 251:22
 254:1, 1, 23 259:1
 260:11 261:25
 262:18
charged 156:1, 12

chart 13:18
check 56:21 60:1, 16
 173:1 252:11 262:1
checking 207:22
chem 184:22
chemical 6:20
 38:11 105:1, 16
 107:1, 11, 13
 109:20, 20
 110:19 111:13
 158:19 182:1
 183:24 248:21
chemically 170:22
chemicals 111:1
 130:12 136:12,
 15 183:25 186:18
 202:1 260:15
chemist 5:12
chemistries 184:18
chemistry 9:14 39:19
 44:24 49:10
cheryl 5:10
chew 159:17
chicken 133:13
 190:21
chicks 233:15
children 31:13, 18
 32:12
chill 80:1
chlorfenvinphos
 235:1
chloropyrifos 120:1
chloropyrophos 12:23
 13:1, 1, 1, 1, 1
 18:1
chocolate 92:12
 246:17 247:25
choice 34:15 55:12
 104:1 118:23
 159:14 166:1 169:1
 171:1 185:1
choices 141:14
 194:25
cholic 88:13
cholinergic 31:23
 171:23
cholinesterase 12:17
 31:1, 1, 11, 16
 32:10, 21 33:1, 1,
 14, 17 36:18 160:1
 163:16 193:1,
 11, 15, 24
 194:1, 13, 16, 17,
 19 199:22 202:14
 206:1, 16, 19,
 23 234:23 261:1
cholinesterases 7:1
chonylgrackels
 171:19
choose 196:1
choosing 82:19
chosen 163:1
chris 4:24 175:14
 215:1
chronic 16:1
chug 121:1
cincinnati 4:1
circulation 35:1
circumstance 239:11
circumstances 81:24
citations 15:17
 138:19 157:1
cite 37:11 138:17
city 70:10
claims 72:21 236:24
clarification 36:1
 84:12 88:10 117:1,
 1 124:22 144:13
 157:17
clarifications
 126:24
clarified 171:12
 207:16 233:12
clarify 91:14
 117:1 129:20
 173:21 178:11
 179:18 195:1
 210:1, 1 211:19
 227:13 233:1 248:1
clarifying 227:18
clark 4:16, 16
 6:12 23:12, 13, 13
 24:1, 1, 12, 18,
 21 122:21, 22,
 22 123:11, 20,
 22 124:1 167:25
 168:1 170:15
 171:10 220:24,
 25 228:22, 23
 231:20, 21
 238:1, 10 241:14
 243:1 254:1, 1
 255:13
class 31:22 42:21
 44:1 86:10 186:18
classes 39:18
 43:18 44:24
 49:10 96:19
classification 23:23
clean 73:10, 17 74:1
 158:21 159:16
clear 67:1 71:20
 89:18 123:1, 1
 138:1 144:1
 146:1 160:1
 164:22, 23
 168:13 175:1 184:1
 198:1 210:16 218:1
 228:19 229:19
 246:1 253:14
clearance 118:1
 148:10 191:14
 201:18, 19
clearer 120:21
clearly 241:20
climb 83:23
clinic 6:24
clinical 6:17 173:12
cm2m 5:14
close 11:17 59:1
 71:1 89:1 99:22,
 24 174:1, 1
 179:1 226:10
closed 73:12, 17
closely 46:12 140:15
 237:11
closer 177:1, 1
 211:1
closure 262:10
clovers 256:25
clubbers 257:1
co-varied 221:16
co-vary 208:22
cockpit 74:21 75:10
cocktail 47:10
code 131:1 202:1
coefficient 143:20
 144:23 146:1
cohort 181:1 240:24
cohorts 181:13
cns 200:17
cold 54:1, 17
collaboration 46:18

collaborators 244:1
colleagues 224:10
collecting 251:1
college 3:24 4:1
 5:22 6:10 39:1
collisions 18:25
colorado 6:20
 41:15 42:13, 19
 44:1, 11 85:18
 86:16
colored 169:13
column 85:1, 10, 12
combination 50:1, 22
 81:15 86:19 180:1
combinations 261:10
combine 27:1 173:16
combined 203:23
combining 258:21
comes 59:11 64:21
 70:1 88:1 148:18
 178:1
comfortable 174:13
 227:19
coming 37:12 41:17
 61:1 70:15, 20
 75:1 76:17 99:23
 166:1 174:1 176:23
 183:20
commend 188:18
commended 139:18
 234:1 249:22
 251:21
commensurate 165:21
comment 3:13 7:1, 21
 8:1 16:11 21:1, 1,
 20 25:1 30:24 31:1
 32:1 68:25 69:1, 1
 72:1 74:1 89:10
 91:16 121:1
 126:11, 19 133:1
 136:22 145:19
 150:1 153:1 156:12
 158:10 159:1, 1
 160:1 162:16
 165:24 173:1
 197:13 209:1 210:1
 211:11 214:22
 221:1, 1 226:14
 233:1
commentor 7:22 26:17
 38:16, 20 51:1
 89:1
commentors 26:24
 71:1 126:16
comments 2:12 7:17
 8:1, 1, 15 9:18
 25:23 26:1 29:24
 30:1, 13 32:1
 35:15 38:15
 45:20 68:16
 71:19 79:1
 84:12, 15 91:1
 92:1 96:10 126:17,
 22, 24 127:1
 133:24 134:1, 1
 136:17 145:17
 154:15 155:1 156:1
 159:1 167:23, 25
 171:10 185:17,
 23 195:21 197:1,
 11 199:1, 1 205:23
 207:12 208:1, 25
 209:1 226:1 231:23
 233:1 236:11
 244:1, 1, 11, 14
 247:15 248:1
 254:1, 15 261:14
 262:21
committee 39:24
 172:10
committees 79:10
commodity 83:19
common 74:1 156:1
 209:19
commonly 43:19
communicate 141:13
communication
 89:23 212:14
communities 190:1
community 190:1
companies 61:25
 70:16 80:19
company 40:10 57:1
 58:19 59:11 69:1
comparable 204:11
comparative 33:17
compare 113:16, 18
 114:24 115:1
 119:16 135:1 180:1
 185:11 234:11
compared 21:11, 17
 114:21 145:1
 147:14 148:11
 180:12
comparing 119:1
 167:1 234:1
comparison 31:1
 94:11 114:24
 117:19 129:22
 132:11, 22
 180:14 216:18
comparisons 94:24
 95:1 101:21
 113:1 124:17
 130:23 200:15
 232:15
compelled 64:1
compensate 64:17
 109:1
compensation
 108:18 110:1
compensatory 164:1
 242:1
competence 167:13
competitive 28:20
complete 12:21
 14:1 26:12
 111:20 116:11, 15,
 20 187:1 237:10
 248:20, 21
completed 197:17
completely 8:10
 73:12 124:1 238:20
 240:1
completion 143:1
complex 81:1
 119:1, 1, 1 173:18
 201:15 258:1 259:1
complicated 154:10
 258:1, 25
compliment 150:25
complimentary 133:20
component 133:22
 150:1 177:17
 202:10, 13
components 142:1
 181:21 240:1
comport 114:24
composed 242:14
composition 184:1
compound 11:16
 108:11 147:14
 178:14 182:1
 208:13, 16 228:1
compounded 215:14

221:18	164:1 166:1 231:10	134:17 159:12
compounds 20:1	232:1 250:10	193:21 232:1, 1
158:12, 19	conclusion 28:22	253:1, 10
169:20 170:1	34:12 47:18 55:1	conduct 158:1 245:23
191:12	104:18 105:13	conducted 34:16
comprehensive 218:17	113:23 129:1 154:1	128:22 142:21
compress 122:10	163:23 164:21,	152:10 186:1
compromised 219:1	23 165:12 182:1	187:13 235:1
compromising 218:18	205:20 214:22	236:12, 15, 18
computation 189:1	215:14 216:21	240:17 244:24
computed 144:23	217:1 231:14, 19	conducting 31:15
computer 9:22, 22,	247:17, 21	152:14 232:1
24 94:1 160:25	249:18 251:12,	confer 262:11
concentrated 237:13	12 252:1, 1 259:14	confidence 107:23
concentration	conclusions 31:1,	109:24 224:1
12:19 144:1, 14	1 32:1 93:1, 1	confident 106:25
146:16 152:12	109:18 111:15	222:1
concentration-	115:24 116:1	confine 100:1
dependent 158:24	119:10 128:1	confined 158:1
concentrations	129:1, 11 131:1,	159:20
143:18 169:1	10, 16, 19 132:1	confines 108:20
200:19 237:1, 13	135:1, 1, 13	confirm 8:25 9:1
concept 40:1, 1 69:1	141:1, 10 143:24	225:25
95:11 97:1 156:25	151:12, 15	confirmation 35:1
concepts 45:1	152:10 153:10,	confirmed 9:1
conceptual 132:16	23 157:1 182:20	conflict 68:23
concern 36:18	183:1, 1, 11	confounded 249:25
37:20 38:1 70:1	192:1, 1, 10,	confounding
102:1 124:1 150:12	18, 22 204:15,	124:13, 18 157:1
159:15, 19 162:1	21 215:1, 12	251:1 260:18
184:11 194:23	231:16 247:13	conjecture 107:21
205:1 239:1, 22	250:1, 12 259:21	122:15
248:22 250:24	concordance	conjectures 96:21
251:16 255:1	113:11, 17	conjunction 86:1, 14
256:12 257:1	114:1, 11 116:1,	248:22
concerned 35:19	1, 1	consequence 250:1
50:20 76:1 181:1	concordant 221:13	consequences 42:11
254:24 260:20	229:10	45:14 84:1
concerning 36:1	concur 129:10 131:17	consequently 48:17
204:1	133:1 143:1, 1	50:25 131:10
concerns 36:1, 1	167:1, 18, 23	249:16
74:14 75:12	182:25 192:1	conservancy 7:23
106:1 109:23 135:1	231:16	10:1 219:12
136:1 178:20	concurred 183:16, 17	conservation 12:1
183:17 184:1	192:21	16:12 17:10
186:23 193:12	concurrent 166:13	79:10 256:11,
205:1 216:10 233:1	concurs 249:16	17, 25
251:14	condition 158:14	conservatism 208:13
conclude 137:20	232:13	conservative 9:1,
158:15	conditional 232:24	1 12:21 22:1
concluded 152:1	conditioned 165:19	142:15 163:1
	conditions 111:19	

208:14 209:15,
23 243:12 249:1
consider 33:11
45:1 66:1 76:1, 12
83:1 95:15 96:23
97:1 102:16 103:25
104:1, 1 106:18
113:20 139:11
154:17 156:15
202:1 244:17 254:1
257:12
considerable 32:14
89:23 156:21 253:1
considerably 76:12
consideration
102:1 115:1
116:1 164:1, 18
184:13 185:13
188:1 205:14 239:1
241:1 247:1
260:1 261:1
considerations 152:1
159:1 184:17
considered 102:1, 16
103:16 106:13
108:19 111:24,
25 130:22 133:1
157:13 172:1, 1,
13 174:11 185:12
186:1 193:14
204:17 252:20
253:23 256:1
257:20 261:1
considering 2:1
59:19 167:15
183:22 206:1
257:14
considers 98:12
consistency 23:1
40:24 82:16
130:11, 24 136:11,
15
consistent 23:1
117:24 130:12
137:21 154:1
165:10 191:20
205:1 207:1 225:1,
1, 1 246:20
consistently 138:1
157:25
constant 121:24
199:19, 22 221:1
constantly 48:1
139:25 208:12
constants 200:13
constitutes 253:1
constrained 202:1
232:24
constraints 73:1
155:11
construct 189:25
201:24 259:23
constructs 166:15
189:23
consultant 56:24
57:1, 1
consultants 61:12
75:23
consultation 187:13
consuming 28:11
149:21 209:17, 19
consumption 95:16
96:1 103:20 140:14
152:13, 15, 20, 24
153:1, 25 159:1
160:13 161:13,
14 168:12
171:14, 18, 22
consumptions 165:1
contacted 27:20, 21
container 87:1
containing 129:1
contaminants 260:25
contaminated 158:21,
23 162:13
contend 41:13
contest 102:11
context 150:17
157:25 212:20
224:17 233:18
241:1 244:15 258:1
contexts 189:10
199:1
continental 228:19
continuation 23:1
227:1
continue 2:11 7:20
23:10 35:19
67:10 70:23
71:24 161:1
162:1 215:1 225:15
227:1, 1 256:1
continued 165:18
176:11
continues 83:23
227:24 249:18
continuing 76:24
continuous 57:19
69:11, 23
contrary 83:1 247:17
252:1 259:14
contrast 13:10
contrasting 140:20
contribute 143:15
239:1
contributed 216:12
contributing 232:18
contribution 191:10
contributions 89:1
99:12 140:18
144:19
contributors 32:17
33:21
control 23:15 24:1
40:21, 23 41:1, 22
42:1, 1, 1, 13,
16, 22, 25
43:12, 17, 21
44:25 45:1, 23
47:11 52:1, 12
53:1, 11 58:1, 16,
22, 23 61:19 62:25
66:21 68:12 70:1
76:11 77:1 82:1
85:18 86:16 87:17,
22 120:1 160:13
162:1, 1 170:25
198:1, 1 232:1, 11
controlled 43:21
controlling 52:10,
19 53:15
controls 13:1
43:24 47:24 107:10
161:1 236:18
convene 263:1, 1
converge 115:23, 24
conversation 207:13,
23
conversations 76:1
conversely 251:1
convert 252:18
converted 14:1
convince 68:18
convinced 102:20

cookie 25:20	29:23 30:1	194:19 219:12
cooperative 4:25	38:18, 22 39:11,	244:17
5:18	14, 21 40:17	critical 137:24
copied 85:1	42:1 44:22	254:1
copies 24:16	council's 39:23	criticism 99:1
copout 121:1	count 123:1 256:1	criticisms 168:14
copy 24:15, 15	counter 13:1	crop 11:1 12:1, 20
corn 14:17 15:12, 16	country 23:1	40:18, 19 45:1
27:10, 18 28:1, 1,	county 74:25	47:16 56:24
1, 10 53:1, 1	couple 7:10 8:1	57:1, 1, 11
57:1, 16, 18,	10:10 37:12	61:12 62:13, 13
19, 20, 21, 22	49:22 61:1, 13	96:1, 1, 1 138:1
58:1, 1, 1, 1,	75:12 76:13	220:14 256:22
11 59:1, 14	92:15 95:11 120:18	257:1
60:1, 1 61:15,	134:1 141:22	crops 11:22 12:1
23 62:1, 13, 20,	154:10, 20	15:1, 15 16:1, 1
22 63:22 64:1,	160:25 171:10	19:1 41:1 45:1
21 65:14, 19 66:17	178:10 187:1 199:1	54:22 80:12
67:15 68:1 69:1,	214:1 232:25	81:17 223:1 254:25
1, 11, 12, 13, 13,	236:13 238:16	255:1 261:12
22, 23 70:1, 1, 1,	244:14 259:24	cross 130:11 184:16
18 75:24, 25 76:1,	coupled 216:11 218:1	cross-resistant 62:1
1, 14, 19, 20,	course 8:21 11:1	crossed 96:12 189:19
23 77:17, 19, 19	13:16 17:1 18:20	crp 16:14 256:20
78:1, 1, 1, 21	19:1, 1 30:13	crucial 209:18
79:1, 1, 1, 11,	90:25 91:1, 1	crux 168:24
11, 15, 17, 23	92:1, 1, 15, 18	crying 170:1
80:1, 1, 1, 21	96:21 97:12	cucumber 53:15,
81:1, 1, 13, 14,	99:13 102:24 108:1	16, 22, 23 54:1,
17 82:1, 10, 10,	121:12 137:21	13, 19 55:1 56:1
17 83:1, 1, 1,	138:23 140:1 171:1	cue 169:18
1, 10, 13, 17, 19,	175:18 176:20	cues 169:12
23 84:1 112:1	190:14 213:18	culture 40:1
120:1 256:19	223:21 240:16	cv 145:11, 15
cornerstone 81:1	covariant 181:1	cup 104:16 105:1
cornfield 234:14	208:22	cups 211:1
corporation 58:1	cover 27:15 54:11	curious 156:14
corps 59:16	117:11 118:10	current 3:19 20:19
correct 39:1	coverage 87:17	41:1 51:24 75:16
145:13 190:14	covered 87:1	113:24 158:12
201:14 232:19	176:18 208:1	174:22 201:1, 1,
correction 206:15	221:25 244:1	15, 16 218:14,
correctly 225:18	253:20	20 227:1 228:1
correlate 258:1	cranes 256:1	244:17 245:17
correspondence	create 40:14	261:23
221:10	created 39:14	currently 4:21
corresponds 214:15	creates 91:16	15:1 26:25 30:25
cost 40:24 47:24	creating 41:20 43:14	40:1 55:13 72:14
52:17 53:1 54:25	credible 165:17	94:1 110:1
55:1 86:22	176:10	111:16 126:1
costs 219:25 220:1	credit 226:19	156:11 205:13
council 26:19	criteria 174:13	

249:21
deals 115:17 148:1
dealt 249:10 259:1
dean 6:10
death 48:16 173:15
 194:19 227:1 228:1
 237:11
deaths 220:13, 15,
 17 227:16, 25
 228:1 237:14 238:1
debatable 237:1
debate 176:22
debated 117:17 155:1
debates 249:1
debating 172:16
debilitated 18:21
 19:1
decade 44:13 235:22
decades 70:12
decay 146:25
decide 44:24 174:1
decided 27:1 29:16
decision 42:1
 79:22 90:25 91:10,
 18 134:21 153:1
 156:1 207:24
 218:21 233:1
decision-making 92:1
decisions 35:13 37:1
 135:1 156:1 227:23
 245:25
decline 22:19
 45:18 214:15, 15
 215:20 216:13, 14,
 21 217:19 218:1
 219:19 223:1
 224:20, 22, 24
 225:1, 1 227:1, 15
declined 22:13, 17
 160:14 220:1
 227:17, 25
 228:1, 1
declines 226:1
declining 221:1
 257:11
decrease 23:1
 214:11, 20, 23
 220:15, 18
 221:13 225:21
 228:25 229:1
 259:13
decreased 68:22
 168:16
decreases 221:1
decreasing 161:24
defense 26:19
 29:23 30:1 68:20
defenses 49:1 51:1
defer 26:21
deficiencies 245:1
define 141:20 242:11
defined 101:10
 135:19
defining 141:25
definitely 109:15
 166:22 200:13,
 15 260:1
definitive 157:1
 245:1, 1, 10
 250:12
degradation 144:10
 146:20
degree 57:13 132:1
 152:1
delay 10:1
delayed 62:11 206:23
deliberate 10:24
 11:12, 12 13:21
deliberately 11:14
deliberations 7:16
 30:1 35:24 91:1
deliver 137:1
delivery 207:1
delorme 4:20, 21
 134:1, 1, 1 143:25
 144:1 153:11, 14
 154:1, 1 162:1
 166:24 173:20
 174:1, 1, 1 176:1,
 1 183:12, 14, 14
 186:1 187:23, 24
 192:19, 20 195:10,
 14, 17 204:22,
 24 211:10, 14,
 14 252:14, 15
 259:17, 18
demand 83:13, 23
demands 138:12, 13
 258:1
demonstrate 73:22
 111:18 151:24
 182:1 226:1 234:16
demonstrated 31:22
 87:1 105:14 138:10
 157:1 249:11
demonstrates 21:1
densities 111:24
 112:18 113:11
 122:24 124:19
 237:1
density 112:16
 113:1, 1, 21
 114:14 123:16, 18
departing 202:1
department 4:12 5:18
 6:16, 19, 24 17:16
 220:1
departmental 200:1
departure 30:23 31:1
 34:10 201:14, 16
 205:16
dependant 137:1
dependency 198:23
dependent 137:20, 24
 138:14 139:14
 158:16 168:20
 193:21 253:1 255:1
depending 80:11
 81:16 126:1 135:11
 171:1 217:1
depends 145:11 176:1
depictions 97:10, 12
depression 12:17
depth 7:12 75:23
 87:1, 10
derive 137:18
derived 139:22
 160:11
dermal 5:23 6:21
 34:11, 12, 13, 19,
 24 35:1 36:1
 37:16, 23 101:20
 115:19 128:10
dermally 35:1
described 25:10 68:1
 91:1 140:15 142:15
 160:1 171:13
describes 10:1
describing 144:1
description 132:20
 187:14 192:24
 193:1
descriptions

131:12 239:1
deserts 16:15
deserves 226:19
 227:11
design 7:1 163:24
 170:18 172:12,
 13 173:10, 18
 177:1 188:20
 193:23 232:1
 249:25 251:15
designated 2:24
 210:24, 25
designation 245:1,
 1, 1
designed 32:1
 37:18 156:24
 157:15 158:25
 162:1 167:1
designs 182:12
 251:14
desirable 157:21
desire 160:19
desktop 51:14
despite 171:1
destined 243:1
destroyed 187:20
detail 72:17
 131:15 233:25
detailed 190:1
details 167:1
detect 158:23 239:1
detectability 235:23
 236:1 238:21
determination
 34:10 129:10
 143:1, 1 187:1
determine 27:24
 159:1 193:1
 218:1 245:1 248:23
 252:1
determined 129:1
 142:23, 25 187:1
 209:11 233:15
deterministic 9:1
 93:1, 11 116:10
 130:1 188:1, 1
 247:1 248:25 249:1
 251:24
devastation 41:20
 43:1
develop 45:22 188:17

189:24 194:1 196:1
 242:25
developed 10:1
 40:1 44:13 45:19
 69:14 105:21 106:1
 128:1 133:12 136:1
 205:1 250:1
 251:10, 18
developing 8:18
 44:10, 12 45:14,
 21 50:15 105:20
 140:10 247:1
development 31:25
 33:1 91:24
 121:12 164:10
 172:1 201:1
developmental 4:1
 201:22
deviation 145:1,
 1, 1 167:10
deviations 213:14
devoted 18:1
dfo 262:11
diagnosis 194:19
diagram 132:16
dialogue 244:19
diana 38:17 56:21
 71:25 72:1 89:1
diapause 62:10 69:24
diazonon 18:1, 10
diced 111:23
dictating 254:1, 1
die 206:22 235:14
 242:1 255:10
die-offs 237:1
died 53:10 235:17
 237:24 242:1, 1,
 1, 1
dieldrin 9:15
dies 53:20 98:1
diet 105:18 115:12
 161:1 170:20
dietary 95:1 99:12
 102:17, 22, 22
 110:1 152:15
 181:23 182:1, 1,
 11
differ 136:21 156:1
difference 27:25
 28:19 29:15
 91:17 160:22

161:21 162:1 193:1
 219:18 234:13
 242:1
differences 94:10
 95:1 97:17
 102:22 103:10
 120:10 141:21
 156:10 175:1
 181:11 184:17
 197:16
different 8:10 12:1,
 1 14:1, 24 15:17
 50:25 51:1 56:1
 60:1 69:15
 73:14, 14 76:15
 93:1, 10 100:13
 102:24, 25
 103:12 104:1
 120:22, 24
 121:22 130:12
 133:1 137:14
 140:1, 21, 21
 141:18 142:11
 150:1, 1 156:1
 157:24 171:20
 176:23 184:1, 17
 186:16 189:1, 1,
 1, 10 204:1, 1
 206:20 233:11
 234:1, 11, 25
 256:1 257:14
 260:25 261:1, 10
differential
 133:17 156:11
 157:23 197:15
differentiate
 104:1 178:12
difficult 39:1 60:19
 135:1 218:1, 15
 221:21 232:1, 19
 250:17, 20
 255:21 256:1 259:1
difficulties
 125:17 189:11
 245:24
difficulty 173:13
 235:10
dig 59:22
digestion 35:1
digestive 35:1 38:1
digging 59:13
dimensions 213:1

diminished 13:12	155:15 196:1	diurnal 128:12
diminishing 134:24	212:23 218:24	138:16
dioxide 170:1	224:19	diversion 165:19
direct 31:1 35:1	discussion 7:12	diverts 217:13
38:1 152:22	75:13 76:1, 1	divide 90:1 101:1
243:13, 16	117:1 126:1, 15	divided 145:1
directed 222:1	156:21 168:1 175:1	245:1 256:1
direction 75:1, 1, 1	177:16 187:14	division 4:22 8:14
141:1	194:20, 23	dixocells 95:19
director 4:1, 17, 21	211:18 251:1, 13	139:15
disagree 31:16	255:15, 16 258:1	dl's 260:24
100:25 133:1	discussions 25:24	docket 84:17
196:24 238:17	135:24 154:1	document 15:21 18:24
254:20	171:11 177:11	95:23, 24 129:1
disagreement 238:11	190:1 212:14	142:24 143:10
disagrees 34:15	228:13 244:24	213:11, 12, 15
disbanded 111:1	248:1 251:17	documentation 230:22
disbursement 75:1	252:17 263:1	documented 11:24
discern 24:23	disease 53:17	15:15 32:18
discontinuous 161:1	70:23 242:1 243:20	33:22 169:19
discover 82:1	diseases 4:19 60:1	196:18 219:23
discovered 52:14	dishes 207:1	documenting 10:18
236:17 237:24	disk 120:18	documents 146:13
discretionary 220:1	dismissed 215:23	213:1, 10, 18
discrimination 169:1	disparate 135:12	215:22 247:11
discriminatory	dispense 73:11	248:12
163:1, 13	displacement 45:1	dogs 95:19 233:16
discuss 244:21	displays 87:1	dollars 28:19 29:1
discussant 127:19,	disproportionately	42:15, 20 45:17
21 129:12 134:1	16:20 17:1	46:1 47:1 83:18
154:1, 1 166:25	disruption 47:22	domestic 35:18
185:16 195:20	disruptive 43:25	dominants 148:1
215:1 219:1 247:23	disseminate 26:10	dominated 118:22
253:20	distant 235:23	don 5:17 39:1
discussants 166:21	distinction 144:12	127:1 255:1
207:1 215:11 226:1	147:24 217:1	donald 38:20
241:13 245:19	distinctions 91:15	219:1, 1
248:1, 1 252:13	distinguish 243:1	done 13:1 16:25 21:1
254:15	distribute 113:12	34:1 39:19 67:17
discussed 81:23	distributed 7:25	76:21 94:23
115:10 119:22	29:25 51:10 84:16	103:1 124:14
120:1, 1 129:15	distribution	157:18 166:1 170:1
155:1 163:1	100:24 132:14	171:25 188:1
174:1 183:16 197:1	133:1 137:1	196:1, 1, 20
205:1 211:15, 23	180:1 186:12,	201:20 202:23
215:21 231:1	13, 14	233:10 234:1
247:10 257:1, 1,	distributions 109:12	235:12 236:1, 1,
20	130:25 161:17	16 252:16 257:19
discusses 257:10	179:21 180:1	259:25 262:23
discussing 89:22	239:22 240:1	donut 92:12 246:17
138:1 154:20	disturbed 256:19	247:25

door 202:1 263:1	17 24:1, 1, 1, 11,	133:25 134:1, 1,
dormant 17:22	12, 14, 18, 20, 21	1, 1, 1 135:25, 25
dosage 105:16 135:20	25:1, 1, 1, 1,	136:1, 1, 17,
175:20 179:1, 1	1, 11, 13, 17,	18, 19 140:17, 18,
dose 11:1 31:10	23 26:1, 1, 1,	19, 20 141:15, 15,
32:1, 1, 14, 22	1, 1, 13, 13,	16, 17 142:1, 1,
33:13 35:1	15, 16, 17 29:1,	1, 1 143:1, 1,
106:1, 1 135:18	1, 10, 17, 20, 21,	1, 25, 25 144:1,
148:11 152:23	22 30:1 36:1, 1,	1, 1, 1, 16, 16,
158:15 161:1, 1,	1, 1, 1, 1, 17	17, 19, 20, 21
24 162:1, 1, 12,	37:14, 14, 15,	145:1, 1, 1, 1, 1,
21, 23 168:19	20 38:14, 15,	10, 13, 14, 17,
171:17 172:1 176:1	17, 18, 18	18, 19, 25, 25
177:19, 22, 22, 24	42:10, 15 45:13	146:1, 1, 10,
178:14, 18, 18	46:17 49:20, 21,	10, 12 147:1,
179:1 185:1 191:22	22 50:1, 12, 19	17, 23 148:14, 14,
198:15, 21 200:1	51:1, 12, 15	15, 20 149:10, 10,
206:11, 18	55:17, 18, 19	11, 12, 12, 25, 25
207:1, 16, 20	56:1, 10, 12,	150:1, 1, 19, 19
209:17	16, 17, 20, 21, 21	151:1, 1 153:11,
dose-dependent	63:1 64:25 65:1,	11, 14, 15, 16, 17
158:22 168:15	1, 1, 1, 13, 16	154:1, 1, 1
dosed 21:10 235:1	66:1 67:1, 10,	159:1 161:10,
doses 105:24 106:19,	23 68:1, 13, 14,	10, 11 162:1, 1
22 213:1	14, 15, 20 70:1,	166:24, 24, 25
dosing 21:1 206:24	1, 1 71:1, 1,	167:1, 17, 17, 18,
dot 170:1	13, 23, 25, 25	22, 22, 23, 25, 25
dotted 189:19	77:1, 12, 13,	168:1 170:15,
double 61:19	13, 14 78:18	15, 16, 17
doubt 146:21 147:1	79:1 82:14, 23	171:1, 1, 1, 10
252:17	84:11 88:1, 10,	172:24, 24
douglas 84:14, 14,	11, 14, 17, 21, 25	173:1, 1, 1, 1,
18, 19	89:1, 1, 1	10, 19, 19, 20, 20
doves 112:22 139:1	90:12, 12, 15, 16,	174:1, 1, 1
dow 58:1	16 91:1 92:1, 11	175:12, 12, 13, 14
downstairs 103:23	104:23 109:1	176:1, 1, 1, 1,
dr 2:1, 12, 19	116:24, 24	16, 16, 17 177:14,
3:1, 11, 12, 18,	117:1, 1, 12,	14, 15 178:1, 1,
23 4:1, 1, 11, 16,	14, 16 119:18, 18,	1, 1, 1, 10
20, 24 5:1, 1, 10,	19, 20, 24, 25	179:19, 20, 23
14, 17, 21, 24	120:1, 1, 1, 13,	180:19, 25
6:1, 1, 1, 12, 15,	16, 19, 19, 20	181:1, 1, 14,
19, 23 7:1, 1,	121:1 122:1, 1,	21, 23 183:12, 12,
1, 1, 1, 19, 19,	21, 21, 22	14 185:15, 16, 17,
22, 25 8:1, 1, 12,	123:1, 11, 12, 20,	19, 19, 20, 22,
23 9:1, 21, 23,	21, 22 124:1, 1,	22, 23, 25
25, 25 10:1	12, 21 125:1, 1,	186:1, 1, 1, 1, 1,
11:1, 1 12:23	10, 12, 13, 14, 21	1, 21, 21, 22
13:10 20:11, 18	126:1, 1, 20	187:23, 23, 24, 25
22:1, 1, 10, 10,	127:1, 1, 1, 1,	188:22, 22, 23
14, 15, 18 23:1,	10, 10, 12, 12,	189:14, 15, 16
1, 12, 12, 13,	13, 16, 17, 24, 25	190:24 191:1, 1
	129:12, 13, 14	192:19, 19, 20

195:1, 1, 1, 10,
 13, 14, 15, 17,
 19, 19, 21, 23,
 23, 24 197:1, 1,
 1, 11, 12, 13
 198:12, 12, 13
 199:1, 1, 1, 1, 1,
 1 201:1, 1, 1,
 17 202:1, 17,
 17, 18, 19
 203:1, 1, 10,
 11, 18, 19, 21
 204:22, 22, 24
 207:1, 1, 10,
 13, 25, 25
 208:1, 1, 1, 1, 1,
 24, 24 209:1, 1,
 1, 24, 24, 25
 210:10, 10, 12,
 18, 19, 23, 24
 211:1, 1, 10, 14
 212:1, 10, 12, 24,
 24, 25 213:1,
 14, 17, 22, 24
 214:1, 1, 1, 1
 215:1, 1, 1, 23
 218:1 219:1, 1, 1,
 1, 1, 11 220:11,
 19, 23, 23, 24, 25
 221:1, 17, 23, 23,
 24, 24 222:1, 1,
 12, 13, 14, 23
 223:1, 1, 1, 11,
 12, 13, 16, 17,
 18, 24, 24
 224:1, 1, 1, 1,
 1 226:1, 1, 1,
 12 227:12, 12,
 13 228:1, 1, 1,
 11, 11, 12, 15,
 16, 21, 22, 23
 229:17, 17, 18,
 21, 22, 22, 23
 230:1, 1, 1, 16,
 19, 21, 23
 231:1, 1, 20,
 20, 21 232:25
 233:1, 1, 1, 1
 234:12 238:1, 1,
 10, 25 239:12
 240:1 241:1, 12,
 13, 14, 14, 14
 243:1, 1, 15,
 23, 23, 24, 25
 244:1, 1, 1 246:1,
 1, 1, 1, 1, 11,
 12, 13, 14, 15, 16
 247:22, 22, 24
 252:12, 12, 14,
 15, 15 253:18, 18,
 19, 21 254:1, 1,
 1, 14, 16, 18,
 19 255:1, 1, 1, 1,
 13, 14 257:23, 23,
 24, 25 259:1, 1,
 1, 1, 17, 17, 18
 260:1, 1, 1
 261:14, 15, 16, 19
 262:1, 1, 21,
 22, 23 263:1
draft 246:22
 247:10 248:11
drafts 97:1
dramatic 21:13 237:1
dramatically 68:22
 70:1, 16 228:1
 259:13
drastic 148:1
 226:24, 25
draw 74:1 147:24
 157:1 180:1 189:22
drawings 117:15
drawn 17:12 250:1,
 12
draws 181:20
drepe 113:16
drew 157:1
drift 72:21 74:13
 101:22, 24, 25
 115:18 116:1
drinking 21:24 22:1,
 1 115:1
driving 159:1
 166:1 185:1
drop 20:11 99:1, 1
 216:23
dropped 70:1 256:16
drug 37:17
dry 28:1 73:1, 13
dual 125:1
duck 15:1
ducks 255:22
due 43:1 86:1
 95:18 151:17
 215:17 226:1
 236:25 243:18
 249:24
dug 28:12
duration 2:16 135:16
 153:1 175:25
 178:19 179:1 194:1
during 19:15, 19, 19
 31:25 34:20
 35:10 37:1 39:13
 41:12 43:1 73:19
 80:23 102:1 105:21
 107:1 124:15 139:1
 140:1 159:19
 160:22, 23 168:1
 193:12, 18 198:1
 213:1 237:22
 240:16 257:1
duty 72:15
dying 181:1 238:1
dynamic 178:13

 E

e.g 162:24
eagle 17:1
eagles 17:1, 1, 11
ear 60:1 87:23
earlier 59:1 96:10
 102:1 125:16 144:1
 159:1 171:11 175:1
 202:1 217:1 244:1
early 34:1, 20
 43:1 52:11 53:23
 54:1, 10, 10,
 20, 22 85:1 86:1
 95:18 99:10 121:19
 124:25 147:20
 175:21 189:1
 244:20
earth 262:1
ease 11:16
easier 14:1
easily 18:20 138:1
 237:12
east 44:18 71:1
easy 17:13 155:19
 177:1 255:15
 258:14
eat 19:11 76:17
 97:25 104:1, 1,
 1 106:22 109:1
 138:1, 1 139:24

159:1 170:24
eaten 60:1
eating 107:1
 138:11 147:21,
 22 155:10 164:1
echo 243:1 255:1
echoing 159:1
ed 155:13 246:11
ed-50 194:15
eco 163:19 226:13
 248:19
ecofriend 95:23,
 24 96:17 100:1
ecological 5:16
 30:21 87:1, 13
 90:1, 23 92:1
 111:15 126:10
 155:1, 1, 1, 1
 157:14 174:1, 14
 177:17 179:10
 186:10 214:13
 239:11 241:18
 242:12, 19 246:20,
 21 253:16
ecologically 255:1
ecologist 5:1
ecology 4:18 5:1
 166:15 174:10
 202:20
economic 42:11 45:13
 46:12, 19, 22
 82:21
economical 55:12
economist 42:10
economy 46:16, 21
 47:1 91:10
ecosystems 252:22
edge 112:21
edges 12:1
edler 6:15, 15
 141:16, 17 142:1
 173:1, 10
edwards 78:20, 23
 79:1, 1 84:11
efed 8:17 23:1
effect 6:1 46:15
 60:1 72:20 90:11
 95:1 102:17 107:13
 108:16 110:1
 122:1, 1 124:11
 145:21 158:1
 163:11 175:1
 182:10 185:1
 206:25 207:1
 209:20 219:21
 232:19 239:13
 241:1, 24, 25
 242:23
effected 13:19
 110:11
effective 52:12 74:1
 75:14 82:13
 112:1 182:1 218:23
effectively 74:18
 109:1
effectiveness 67:16
effects 8:14 19:1
 31:21, 21, 24
 32:23, 25 34:1
 90:14 93:1 104:10,
 11 107:11 109:1
 111:21 112:1
 116:13, 21
 121:23 122:13
 128:1 133:19
 151:20 155:17
 157:20 158:20
 162:23 163:17
 164:1 168:14
 171:23 181:1
 182:21 183:1
 185:13 188:1
 191:1, 10 193:20
 195:1 198:15
 204:14 207:21
 217:24 228:19,
 20 231:1, 1, 12,
 18 232:1, 23
 234:22 240:1
 243:18 244:19,
 22 245:12 250:13
 252:22, 23
 253:14 260:18
 263:1
efficacies 40:24
efficacy 217:1
efficiencies
 111:25 234:1 239:1
efficiency 233:14
 234:1, 11 239:10
 262:18
efficient 73:10
 90:17
effort 9:11 10:10
 102:14
efforts 95:25 215:17
 224:23 231:1
 249:22 250:15
 251:21 261:18
effusively 8:16
egg 53:1 190:21
eggs 62:11 159:10
eight 18:1 47:1
 59:17 124:25 153:1
 174:1 179:1
eis 11:1 13:10
 20:12, 14 22:19,
 24 214:14
eis 221:20
either 34:16 37:25
 50:1 81:23 82:21
 83:1 85:1 87:13
 102:1 122:1
 140:1 165:19 222:1
 226:20 234:20
 238:17 251:1
elaborate 196:1
elect 79:1
elected 78:22 152:16
element 149:13,
 20, 24 220:1
elementary 74:1
eligibility 151:19
 191:1 204:13 231:1
eliminate 107:11
eliminated 49:1
 220:1
eliminating 83:1
 218:19
elimination 119:13
 191:1 199:1, 18,
 20, 22
embedded 65:14
eloquently 101:1
emerged 136:22
 138:20
emergence 41:1, 1
emergent 149:18
emerges 137:13
emerging 163:14
else 34:17 89:1
 196:1 212:10
elsewhere 149:23
 256:1

encounter 118:1, 19 144:14	102:16 125:1 126:18 128:1 129:1 130:1 131:11, 17 139:18 142:25 146:13 151:23 152:1, 1, 10, 15, 16 153:1, 18, 25 160:10 163:21 164:1 165:1 166:1 167:14 172:12 182:15, 22 183:1 185:1, 11 186:1 187:11 191:19, 25 192:13 194:1, 21 204:1 205:18 206:1, 1 209:1 212:1 217:1 225:1 227:10 232:18 247:12, 14	212:15 261:1 equivocal 176:13 esa 257:1 erratically 18:19 erroneous 104:18 119:10 error 167:1, 10 178:1 212:21 et 120:16, 17 139:1 157:1 160:1 234:21 235:1, 24 236:1 eta 225:1 etcetera 101:1 111:25 115:20 118:1, 1 120:11 127:22 201:19 202:1 224:16, 16 235:25 especially 60:23 62:1, 20 64:13 65:18 95:1 136:20 234:1 238:1 ethanol 63:21 77:18 199:13, 19 203:12 essential 79:23 83:1 essentially 9:1 122:1, 1 135:17 203:12 241:1 242:14 establish 13:25 184:21 194:1 established 193:14 establishing 80:1 159:1 estimate 53:12 128:1 167:1 177:21 178:1 179:1, 16 180:21, 23 191:1 193:25 199:18 200:16, 18 205:20 207:14 208:15 209:1, 22 235:23 236:1 247:1 estimated 33:23 42:14, 15 46:1, 23, 25 54:21 132:24 178:1 192:1 estimates 33:13 45:13 124:10 142:13, 16
encouraged 135:20 203:1		
encourage 35:21 213:17		
encumbers 3:1		
elwood 5:1		
emory 6:1		
endangered 17:1, 1 255:24 256:1, 12 257:1, 10		
endpoint 198:1		
endpoints 34:1		
energy 51:1 96:14 108:13 138:12		
enforcement 22:21, 23		
emphasis 72:18 245:1 253:24	epa's 30:1 35:1 94:1 129:10 143:1, 1 151:13 153:1 164:1, 20 182:1 192:1 204:15 205:24 231:24 246:20 247:10, 12, 15, 18 248:11 252:1, 1 259:15	
emphasize 117:1 159:12 167:1 177:18 208:1 237:19 253:21		
emphasized 218:25		
employ 136:1 153:19 163:21 183:1 192:13 194:1 245:18	environment 150:10, 11, 18 151:20 environmental 2:1 4:12, 22 5:25 8:14 9:1 39:24 79:10 80:1 84:1 90:13 130:1, 1 154:25 157:14 191:1 204:14 218:12, 23 231:1 246:1 253:25 environmentally 55:12 environments 150:1, 1 enzyme 203:14 enzymology 6:25 equation 203:16 equipment 45:1 81:19 143:16 equitoxic 202:13 equivalent 179:1	
engineering 6:20		
enhanced 132:11		
enjoy 40:12 89:15		
ensure 74:18 83:24 164:12		
enter 23:18 25:1 89:25		
entered 24:1 249:1		
entire 2:15 37:1 98:19 118:1 256:1		
entirely 13:13 83:1 105:17 115:15		
entities 46:12		
entity 150:1		
entry 109:1		
epa 2:14 3:1 23:1, 21 25:16 30:12 32:13 34:15, 19, 23 35:16, 17 37:1, 1, 16 38:1, 12 79:22, 23 82:15, 25 90:1 94:1		

153:1, 22 180:1
 182:24 183:10
 189:1, 1 191:1, 18
 192:15, 17 194:10,
 12 199:1 204:1,
 11, 18 208:14
 224:15 233:22
 239:23 243:10
 247:1, 1
estimating 122:24
 129:23 181:1
estimation 157:16
 197:1
estimators 239:10
evaluate 152:1
 153:21 164:11
 182:19 183:1
 192:16 194:11
 206:13 244:16
evaluated 34:1
 108:20 151:10
 172:1 261:1
evaluating 31:18
 132:10 247:1
evaluation 131:1, 13
 133:23 152:14
 260:12, 17 261:1
evaluations 106:1
evening 75:14
 138:17, 24
 198:1, 1 202:21
 203:1
event 16:1 61:20, 21
 70:25 147:1, 11
 236:23 240:25
 241:1 256:1
events 58:1, 1, 1,
 13 59:1, 1 61:1,
 16 62:25 70:15
 123:25 124:1 204:1
 224:13, 14, 16, 18
 225:10 229:1
 236:17
everybody 71:19 72:1
 89:1, 12 93:22, 23
 95:1 125:1, 1
 150:25 234:10
everyone 2:20 3:12
 125:1 136:1
 212:1 230:1 249:1
everything 13:13
 189:1 210:16 212:1
 244:1 257:19, 19
european 234:24
evidence 30:25
 32:1 93:10
 133:22 215:1
 218:19 224:18
 225:14, 19 226:15,
 22 227:17 235:12
 239:1 240:1 246:23
 247:1, 1 248:13,
 25 249:1 250:1, 1,
 18 251:23 252:1
 253:1
evident 130:16
evolution 95:1 102:1
evolutions 190:15
evolving 91:22, 24
 130:1 155:1
exacerbates 239:18
exact 256:1, 14
exactly 20:13 26:1
 123:1 180:20
 208:17
examine 137:16 143:1
 184:18 248:16
examined 243:13
examining 156:25
example 17:14 32:20,
 25 44:1 99:1
 132:22 133:11
 143:17 144:14
 152:25 188:10
 213:1 220:1
 221:1 224:1
 229:1 232:1, 1
 234:1 251:1 259:12
examples 97:11, 14
 139:1
exceed 116:12
exceeding 96:1
exceeds 98:1
excel 14:1
excellent 86:15
 87:21 160:18
 192:24
except 27:22 57:1
 99:10
exception 42:1 43:22
excerpted 11:23
 15:23
excess 257:12, 14
excessive 86:19
 193:1
exchange 89:24
excruciating 233:25
excuse 82:1 125:1
executive 52:1
exercise 37:1
exhaust 74:23
exhaustive 16:25
exhibit 138:16
exist 172:1 252:1
existed 240:18
existence 65:17
existing 194:1
 217:23
exists 15:22 143:1
 150:1 175:16 253:1
eye 147:1
expand 79:13
expansion 129:18
expect 62:16 63:20
 146:24 148:18
 197:15 198:1, 1
 221:10
expected 39:1
 158:22, 24
expediency 134:23
expense 53:1
expensive 29:1
experience 27:1 63:1
 87:1 150:21 240:24
experienced 46:14
 47:1
experiment 27:24
 119:22 140:25
 158:1 170:21
 173:1, 1 178:1
 196:10
experimental 6:17
 160:14 182:13
experimentally
 209:11
experiments 7:1
expert 226:13
expertise 3:25 4:14,
 18 5:1, 1, 12,
 20 6:1, 21 73:1
 125:15
experts 33:1 37:24
explain 141:21
 202:15 222:21

explained 208:20 36:1 251:17 227:11 240:1
explanation 107:18 **expresses** 148:10 245:17 252:19
explanations 108:1 **extend** 7:14 176:21 253:24
explicit 133:1, 1 **extended** 62:1, 10 **factor** 21:23
explicitly 255:25 69:24 136:11 33:12, 19, 19,
exploitation 133:10 **extension** 82:24 20 115:10
exploration 201:1 **extensive** 130:19 145:21, 23
explore 106:13 142:1 210:15 146:1, 1 161:13
170:13 184:16 **extensively** 120:15 166:1 185:12
254:12 **extent** 25:14 122:14, 186:1, 14 188:25
explores 109:22 14 128:25 148:1 198:14 254:1, 1
exposed 19:25 151:11 155:16 **factors** 21:22
117:22, 25 162:18 182:23 107:1 124:13, 18
133:11 139:1, 12 218:1 253:1 141:20 143:14
146:16, 18 **external** 136:1 199:1 157:1, 13 173:1, 1
160:23 162:11, **extinction** 84:1 187:1 215:15, 21
12 171:19 185:14 **extra** 29:1 219:1 221:18
203:1 234:25 **extract** 167:12 232:17 242:1
256:13 **extraordinarily** 243:20 251:1 260:1
exposing 228:1 **facts** 135:13
exposure 6:1 16:1, 1 **faded** 211:1
31:24 33:1 34:18 **fail** 58:10 59:1
73:1 74:1, 1, 14 61:11
77:1 87:1, 13 **failed** 37:1 38:1, 12
101:20 102:1 106:1 58:23 62:18
111:20, 20 69:17 236:12
115:1, 13, 19, **failing** 31:20
19 116:11, 11, 16, 33:24 58:11
19, 20 117:24 **failings** 59:1
118:1, 1, 1, 1, 20 **fails** 32:22
128:11 129:24 **failure** 35:1
133:1 135:16, 19 159:25 160:1
148:1 152:15 153:1 163:25 236:20
157:1, 22 160:23 **failures** 82:1
161:22 163:1, 11 **fair** 68:15 72:25
165:1 168:1 175:1, 76:22 93:18 102:14
1, 1 177:12, 23 109:12 111:1
178:24 179:1, 1 209:14 239:1
181:10 184:1 186:1 **fairly** 98:1 113:19
191:10 192:15 120:15 183:15
193:18 194:10, 200:18 201:13
20 204:1 213:1 239:24
235:1 245:1, 10 **fairness** 103:1
248:21 256:23 136:14 220:10
261:1 **faith** 205:17
exposures 33:1 **falling** 237:1, 1
101:23 102:1 **falls** 84:20
115:10, 15 **false** 218:13
116:14 118:23 **families** 114:23
142:18 148:10 **family** 51:21
153:1 192:1 **fan** 224:1
expressed 8:11

F

face 24:1
faced 41:11 44:17
227:1 245:24
facility 158:1
fact 8:24 25:24 33:1
37:11 69:17
92:20 96:15, 17
131:1 135:16
137:12 141:1 155:1
169:15, 21
175:16 186:23
187:1 189:1
190:1 196:1, 13
199:21 203:12
206:17 211:1
215:13, 15
216:24 222:1

farm 46:14, 16	23 151:16, 25	19, 22, 23 28:22
51:21, 22 53:13	152:12, 12	29:1 52:15, 16, 23
54:1, 22 79:1	159:25 162:13	53:1 59:1, 12, 15,
257:1	165:20 170:22	17, 19 60:1, 10
farmer 26:23	175:24 203:1	64:16 66:15
28:20, 24 29:1	204:1, 1 207:1	93:1, 12 97:22
38:21 48:1 51:1	feedback 91:14	98:13, 15, 16, 18,
60:17 66:1 68:17	feeder 104:25 105:22	20, 24 99:1, 10
72:1 78:20	feeders 207:1	101:23 110:1, 1, 1
81:10, 25 82:1	feeding 19:12	111:19, 21, 22, 22
83:24, 25 84:15	20:1, 1 52:15	112:1, 1, 10, 19
farmers 41:11 48:1	53:22 59:1	113:1, 1, 1, 1,
60:20 75:22	95:12, 15, 17,	12, 23, 25
78:16 79:1 81:1,	22 96:1, 23, 24	114:1, 1, 1, 13,
18 82:18 83:1	97:1, 1, 10, 22,	18, 20 115:25
254:25	24 98:14, 24 99:1,	116:19, 21
farming 27:1 28:21	1, 1 100:24 102:24	118:1, 10, 11, 13,
29:1 48:14 60:23	104:1 105:1 107:1,	25 119:13, 21
70:11 85:16	1, 12 108:1, 18,	120:1 123:17 128:1
farther 147:11, 12	19, 25 115:17,	134:17 142:10, 14,
202:1	19 118:11, 21	20, 22, 24
fashion 130:14	119:1, 13 128:11	143:1, 1, 10,
faster 92:14	136:23 137:1,	16, 19, 21
fasting 138:11	13, 16, 18, 21, 22	146:1, 14 148:1, 1
fat 122:17	138:1, 13, 16, 23,	150:1 155:17
fate 8:14 151:20	24 139:1, 1, 14,	159:15, 22 162:10,
191:1 204:14 217:1	20, 22, 24	10, 19 169:1, 16
231:1	140:1, 21 146:23	170:1, 1, 1 171:1,
fattening 139:13	148:22, 23	1 180:1 183:22
fauna 241:19	158:16 166:10	184:1 188:10
favor 11:1 38:11	168:1 171:1 175:17	218:22 228:14,
126:1 158:21	185:10 198:1 204:1	14 231:1, 1, 13,
favoritism 105:22	207:1	18 232:1 233:1, 24
favors 55:14	feedings 139:1	234:1 235:11
fear 158:13	feeds 19:11 53:1	236:22 237:1, 16
feather 18:15	119:12, 12, 16	240:1, 1 241:23
feature 66:1, 1 67:1	feel 38:1 48:17	242:13 243:21
141:24	49:18 79:18 83:1	245:1 246:24 247:1
features 172:12,	118:12 173:1	249:1 250:1, 19,
13 251:15	196:25 248:1 256:1	19, 23 251:1, 25
february 2:1	261:24	252:11 253:1
fed 27:14 28:1	feeling 36:12 186:16	258:14 259:25
105:15 140:1	feet 18:11, 14	260:13, 16
federal 2:25	felt 64:1 94:25	fields 11:11 17:12
210:25 211:1	249:10 252:1	48:17 57:1 58:1,
219:24 220:1	females 107:14 161:1	15 62:20 63:1
feed 19:16, 18, 20	162:1	64:1, 1 65:14
20:1 52:13 54:1	fewer 13:1 20:23	66:14, 23 75:19
70:14 76:20 96:1	22:1 76:12 196:10	100:1 112:18
104:16 109:1	field 11:1 16:1,	114:15, 16
118:24 137:10, 19,	10 17:12, 25 20:1,	134:12 142:11
	1, 1 25:1 27:10,	143:12 232:1
		234:14 236:15

240:13 248:14	148:1, 1 171:10	251:20
249:20 256:22	178:11 183:15	fmc's 79:14 85:1
257:1, 1 260:21,	199:1, 15 200:24	134:10 226:1
22	201:18 202:1, 1,	floaters 242:17
fifra 2:1, 1 3:19	23 219:1 225:13,	243:1
72:1 213:13 215:18	20 233:1 244:1	flocking 20:20
225:1 262:16	248:25 249:1	124:15, 16
fifth 52:1 246:1	first-order 199:16	219:16 237:14
fighting 47:15	200:1	florida 52:1
figure 9:18 70:14	fish 4:25 5:1	flow 132:16
161:20 167:12	17:16 197:21	200:13, 20
178:17 194:24	255:21	flowable 13:14, 17
240:13	fit 106:11 108:21	14:24 110:1
figures 160:25	119:1 210:1	222:1 223:1, 1,
239:16	fitted 17:24	10, 17, 18, 22
file 167:12	fitting 73:21, 23,	224:1
filed 35:16	25 74:1	flows 224:13
fill 52:1 76:19	fittings 73:1, 10	fluctuations 141:1
188:1 258:23, 24	five 33:11 47:12	fly 18:19 19:12, 15,
filled 258:23	48:1, 1 51:14	17 53:1
final 35:12 138:19	78:24 83:18	flying 74:16 77:21
159:15 211:11	105:1 126:1 127:11	237:1
214:17 236:24	219:17 220:1	focal 157:22 166:10,
240:1 246:1 251:12	246:18 258:16	16 185:10
finally 15:1 29:1	five-minute 79:20	focus 36:14, 16
35:14 105:13	five-year 23:10	255:15
108:12 115:18	fix 21:1	focused 91:12 157:16
116:1 247:24	fixed 21:1 116:17	180:10 228:13
financial 53:12	132:13 219:25, 25	252:20
54:21 55:1 60:25	flare 43:1	focuses 3:21 255:15
financially 28:23	flare-ups 43:11	focusing 129:21
finding 59:18	flat 28:1	208:13
160:1 234:10, 18	flavor 169:1, 1	fold 188:25
235:1 251:1	flawed 231:11 232:1	folding 111:10
findings 75:19	flaws 163:25	foliage 19:24 45:11
81:1 84:10	flexible 100:1	foliar 41:1, 14 44:1
fine 12:1 214:1	101:12 139:20	50:1 55:1 56:1
229:21 237:1	flies 53:1	78:1 85:1 86:10,
240:14 246:1	fmc 21:1 29:12 68:21	25 87:25
finished 181:17	73:22 79:17 102:15	folks 141:13
finishing 93:21	103:25 104:13	followup 24:1 175:15
first 7:21 23:17	107:1 108:16	177:15 185:25
27:1 28:19, 24	111:22 117:1	187:24 212:25
29:1, 1 30:1, 22	120:14 123:1	food 21:10, 17, 24
45:1 57:20 60:17	151:1, 23 152:1	22:1, 1 33:19
73:1 80:1 81:13,	153:1 163:1	40:15 95:16
13 85:1, 1, 10, 16	182:1 188:18	96:1, 1, 1, 18
87:18 90:14 97:1	191:16 198:14	97:25 98:1, 16, 18
104:22 107:1	211:24 213:17	101:1, 1 102:1
110:25 118:20	217:1 224:21	103:19 105:1
121:21 125:1 128:1	226:19 237:12	106:1, 14, 25
138:1 146:23	240:21 249:22	

108:1, 1 115:1, 11	131:25 150:23	function 142:18
118:1, 17, 18	156:1 158:1 188:1,	148:1 150:10
119:15 137:1 140:1	14, 15, 19	152:15 207:19
142:23 143:11	189:20 208:19	functional 94:1
144:1, 15	227:24 245:25	128:19
149:19, 22	249:24 261:24	functionality 121:13
151:22 152:1,	263:1	189:21
14, 18, 20, 23	four-day 2:21	fundamental 34:25
153:18, 21, 24	fourth 68:17 85:1	fundamentals 248:19
157:17, 20 158:21,	fowl 131:1	funding 23:1
21, 23 159:13, 14,	fox 242:1	215:17 217:18
16 160:13	fractions 97:22	218:1, 16 219:24
161:14, 15	99:17	fungicide 39:17
163:21 165:1	fractures 98:24	fungus 70:23
166:1, 12, 13	framework 131:25	furadan 27:1, 16, 20
168:1, 1, 16, 20	133:1 203:25 204:1	28:22 29:1, 14
171:14, 17, 22	211:23	40:20, 22 52:1, 1,
175:22 182:20,	frankly 21:25 39:1	11, 18, 18, 21, 23
20 183:1, 1, 1	free 49:18 248:1	53:1, 11, 14, 22
184:1, 11 185:1	freed 140:1	54:1, 15, 18, 24
189:1 195:1 206:1,	freely 10:16	55:1, 10, 10,
1, 13, 15, 18	frequency 49:24 50:1	15, 25 60:10, 25
207:1, 15, 16	181:1 216:18	61:1, 1 63:1,
foot 17:23	253:13	12, 15, 18 64:1,
forage 19:1, 16	frequent 116:17	12 65:16 66:15, 16
foraging 12:1 19:1	118:1 128:11	69:1
100:17 101:1, 1	frequently 16:1,	furidan 73:1 77:1
135:21 137:19,	15 47:1 51:1	78:1 79:14
23 139:23 166:1,	119:12 138:1	82:11, 21 84:1, 25
13	fqa 33:18	86:13, 17, 19, 25
forbidden 230:15	friday 235:1	furidan's 87:16
force 68:10 172:21	frito 40:10	furrow 58:1 59:1
185:1	front 2:17 77:1	68:1, 10 259:12
forced 47:1, 15	fruit 53:21	furthermore 205:11
forces 46:13	fruits 19:1	future 28:21 40:15
foreign 80:19	frustrating 37:1	62:1 63:21 79:23
forever 187:1	fry 7:22, 25 8:1	102:1 133:1
forget 256:1	9:23, 25 10:1 11:1	165:1 184:1
forgot 255:11	22:14, 18 23:1, 17	212:1 218:21 219:1
form 97:17 115:22	24:1, 11, 14, 20	235:19 246:1
149:17 188:16	25:1, 1, 11, 17	fuzzy 180:14
formal 127:1	26:1, 1, 1, 14, 15	
formulation 222:1	102:1 219:11	G
223:1, 1	full 62:11 160:1	gain 148:15
formulations 216:17	185:1 191:23	game 17:17 38:1
forth 117:17 171:1	193:24	gaps 258:23
187:1 196:1 221:24	fully 128:19 193:1	gary 78:20 79:1
fortunately 202:1	225:1	125:10, 10, 14, 22
forum 251:19	fumigant 56:1 87:23	126:1
forward 7:13, 17	fumigants 86:1, 17	gatekeeper 111:1
30:1 35:23 76:1	fun 59:15	gather 101:1
90:11, 19 130:1		

gears 89:18 209:16 218:12
geese 19:1 237:1 225:12 229:1
gene 61:10, 11 62:18 238:20 239:1
general 6:1 17:1 242:1, 1, 21
36:1 49:23 106:1 250:10 261:1, 21
119:1 129:17 141:1 **gives** 60:11 96:1
154:14 161:23 261:1
generalize 170:1 **giving** 8:1 78:24
generally 11:1, 1, 86:21 119:23 149:1
10 12:14 167:18
208:1 **glad** 14:25 15:1
generated 193:1 16:17 125:19
generating 249:23 **gleaned** 15:16
generations 40:15 **gm** 68:1
genes 61:25 **gmo** 80:1, 13 82:1
genetic 80:1 **gmos** 78:17 83:10
150:1, 1 **goal** 134:22 156:25
genetics 27:11 **golden** 256:25
150:10 **golf** 64:1
geographically 17:21 **gpa** 240:11
geometric 213:14 **gone** 11:23 20:25
german 6:15 22:20, 21 24:1
germane 36:1 39:1 60:1 89:14
getner 42:10, 15 123:1 125:1, 1
46:17 219:18 227:20
getner's 45:13 **goodness** 106:11
gets 41:23 61:1 **gorge** 19:10, 12, 16,
122:12 181:19 18, 20 97:1, 24
202:22 259:19 171:1 206:25 207:1
getting 66:11 **gorging** 95:22, 23
68:23 80:1 98:16 96:1 99:19
117:22 121:1 **gotten** 179:14 197:1
150:14 166:14 **gps** 75:1
177:16 184:19 **graduated** 27:1
192:20 244:1 261:1 **grain** 76:19
given 9:1 37:17 **grains** 19:1
67:25 96:1 97:22 **granivorous** 19:1
98:1, 13 101:15 **grant** 13:25 23:1, 1,
113:1 118:24 121:1 1, 10
131:16 133:19 **granting** 16:14
134:14 135:20 **granular** 13:14, 17
137:24 142:10 50:1 68:10
146:16, 25 153:17, 81:19, 21 216:16
24 154:22 157:1 222:1, 24 223:1,
162:13 163:20, 1, 10, 14, 20,
24 164:1 165:1 22 224:1, 1
169:25 177:23 **granulars** 222:18
179:1, 1, 15, 16 **grapes** 216:1
180:1, 16 181:1 **graph** 110:15, 16
183:1 185:1 192:11 111:1 198:1
194:1 196:21 **grass** 235:16
205:1, 20 207:20 **grasshopper** 170:1

gray 74:24 126:1
great 8:1 34:1 65:25
69:1 70:1 80:1
83:1 114:11
180:1 227:22
256:24
greater 22:23 40:1
46:20 147:15 227:1
228:1
greatest 20:16
122:14
greatly 132:11
green 41:14 42:14,
18 44:1, 11 65:1
85:19
grip-free 87:12
gross 83:20, 21
grossly 226:22
ground 18:21 28:1,
10 56:1 173:1
212:22
group 90:11 129:15
154:16 160:13
183:16 186:19
197:1 205:24
211:15, 17, 21
242:13 244:20
245:1, 23 257:21
grouped 249:1 250:1
groups 30:12
159:18 196:23
216:22 233:21
242:14
grow 71:1 86:1
grower 46:24 79:1
85:25
growers 39:1, 17
40:17 41:10, 13,
21 42:1, 13
43:10 44:1, 1, 16,
18, 19, 20 45:1,
1, 10 46:1, 1, 1
47:1 51:23 52:1, 1
55:13 78:21
79:1, 11, 17
80:16, 17, 22,
23 84:1
growing 43:1, 13
44:14 48:16 55:1
88:23 137:24
grown 48:14 80:12
85:23 193:1

grows 53:1
growth 54:10 64:17
grue 4:24, 24
 25:1, 1, 13, 23
 26:1, 1 134:1
 135:25 144:1, 1
 145:18, 19, 25
 146:1 171:1, 1
 172:24 175:12, 14,
 14 186:1, 1
 197:12, 13
 202:19 215:1, 1
 219:1, 1, 1 221:1,
 17, 24 229:22,
 23 230:1, 16, 21
 244:1, 1 253:18,
 19 262:1
guess 38:1 90:10
 95:20 119:1 123:22
 142:1 147:17
 160:19 176:1
 180:19 187:10,
 15 190:25 195:10
 200:12, 14
 202:16 212:1 213:1
 225:11 254:1
 262:21
guidance 75:20
 246:21
guidelines 43:1, 1
 242:25
gulf 96:12
gulls 20:20
guy 60:23 66:1
guy's 67:21
guys 8:1 29:1, 19
 67:23 195:11

H

habit 133:10
habitant 114:10
habitat 114:12
 155:10
habitats 261:11
habits 105:21, 25
 106:1, 1
half 18:1 65:20 72:1
 83:18 121:1, 17
 122:1 147:1 194:20
half-life 103:16,
 17, 18 118:1, 1,
 16, 17, 22 119:14,
 14 121:22 122:1
 147:13, 15 148:1
 192:1 195:1, 16
 198:18, 22
 199:18 209:1,
 16, 21 210:1, 1
half-lives 195:11,
 17
hand 53:1 188:24
handed 30:1
handle 73:11 88:1
 208:1
handled 72:25 87:1
handling 73:1, 1
handout 27:1 51:1
 79:1
handouts 87:1
hands 235:15
handwerker 4:1, 1
 125:1
hang 37:1
hanks 84:14, 14, 15,
 18, 18, 19 88:1,
 10, 13, 16, 20, 23
 89:1
happen 50:22 52:25
 62:14 78:1
 106:21 108:1 109:1
 147:16 155:22,
 23 169:1 171:1
 199:1 223:12
happened 7:12 69:10,
 19 78:1 150:24
 224:1
happens 49:1 54:1
 97:1 168:15 227:22
happy 22:1 35:24
 64:23 190:1 208:1
hard 7:11 24:15,
 15 37:10 60:18,
 22, 23 78:1 160:19
 181:19 226:15, 21,
 22 233:1 262:24
harder 148:1
hardship 85:21
harvest 27:13
 28:10 88:15 241:11
 255:20
harvested 27:14 28:1
hasten 83:1
hat 37:1
hatch 62:12
hatches 62:1
hatching 62:11
hate 50:1
hattis 6:12, 12
 119:19 120:19,
 20 122:1 140:19,
 20 141:15
 188:22, 23 198:12,
 13 203:1, 10
haven't 16:25 24:1
 25:19 26:25 71:1
 94:23 101:17 102:1
 107:17 122:16
 158:1 227:20, 20
 228:1
having 10:1 28:23
 44:20 64:18
 135:1 146:25 158:1
 173:1 177:1 184:20
 212:13 234:1
 244:18 247:14
 251:20 258:1
 262:15
hawks 17:10, 18
 18:23, 24
hazard 135:19 254:10
he'll 19:11
he's 125:1 207:13
head 6:16 163:10
health 4:22 5:25
 6:1, 1 30:1, 18
 31:17 90:1, 24
 263:1
healthier 40:14
hear 125:12 126:1
 156:18 211:1
heard 13:22 81:1
 89:1 125:11
 141:19, 22 179:10,
 11 209:1 226:23
 247:14 248:1 250:1
 251:1
hearing 7:17 91:1
 102:14 173:22
 226:13
hears 211:1
heeringa 2:13, 19
 3:10, 11, 18
 7:1, 1, 19 8:24
 9:25 11:1 22:1
 23:12 25:1

26:13, 16 29:1,
 17, 20 36:1
 37:14 38:14, 22
 49:20 51:1, 15
 55:17 56:17, 20
 64:25 65:1 68:13
 70:1 71:1, 1,
 13, 23 77:1, 12
 78:18 79:1 84:11
 88:1 89:1 90:16
 91:1 116:24 119:18
 120:13, 19
 122:21 124:21
 125:1, 13, 21
 127:12, 17
 129:12 133:25
 134:1 135:25
 136:17 140:17
 141:15 142:1
 143:1, 25 144:1,
 16, 19 145:1, 1,
 17, 25 146:10
 148:14 149:10,
 25 150:19
 153:11, 15 154:1
 161:10 166:24
 167:17, 22, 25
 170:15 171:1
 172:24 173:1, 19
 174:1 175:12
 176:1, 16 177:14
 178:1, 1 179:19
 181:14 183:12
 186:1, 21 187:23
 188:22 189:14
 190:24 192:19
 195:1, 19, 23
 197:1, 11 198:12
 199:1 201:1 202:17
 203:1, 18 204:22
 207:1, 25 208:1,
 24 209:24
 210:10, 19, 23
 212:1, 24 213:1
 214:1, 1 215:1
 219:1 220:23
 221:23 222:12
 223:24 224:1 226:1
 227:12 228:1,
 11, 21 229:17,
 22 230:1, 1, 19,
 23 231:20 233:1
 238:1 241:12

243:23 244:1
 246:1, 1, 13, 15
 247:22 252:12
 253:18 254:1, 14
 255:1 257:23
 259:1, 17 260:1
 261:14, 19 263:1
heinous 98:22
held 117:23
help 36:15 39:15
 53:11 54:18
 55:23 70:21
 91:24 133:18
 188:19 234:1
 235:1, 18
helped 28:22 211:19
helpful 74:1 179:18
helping 32:1 52:12
helps 52:1, 19 53:1,
 14 54:1 189:1
 212:1
hence 153:1
henslow's 256:14,
 16, 21
herbicide 82:1
herbicides 39:16
herbivorous 19:1
herculex 58:1 61:21
here's 99:14, 21
 114:1
hesitancy 61:24
hiatus 198:1, 1, 1
 202:21 203:1
hide 20:1 234:21
 235:1
hiding 234:23
high 17:1 21:13
 27:14 58:1 59:13
 82:17 95:18
 98:23 106:19, 22
 107:23 112:24
 113:19, 21
 117:25 121:18
 145:15, 16
 160:21 161:25,
 25 166:23 178:17
 200:1 208:14
 209:10, 16
 212:18 217:13
 254:11
higher 21:25 74:11
 116:1 118:20

122:25 144:14
 146:16 149:19
 192:1 228:1 233:24
 244:12
highest 15:1
 105:24 106:1
 161:24 162:1, 1
 191:21 192:1
highlight 36:1
 85:1 96:17
highlighted 85:1
 96:22 135:1
highly 96:18
 159:18 228:1
 232:24
hill 5:1, 1, 15
 167:17, 18 170:16,
 17 185:19, 20
 186:21, 22 195:23,
 24 208:1, 1 210:24
 221:23, 24
 222:14 223:1, 1,
 12, 16, 18 224:1
 243:24, 25
histograms 216:19
historical 244:15
 253:1
histories 139:12
history 44:10
 58:11 76:1
 196:24 216:10
 221:12
hit 25:18 29:1
 167:19 190:18, 19,
 20
hits 181:19
hold 19:12 139:1
holders 130:20
holding 158:1
home 4:1 18:1, 12
 19:1 20:1 80:1
 109:16 115:22
 190:18 207:22
honestly 190:17
hoops 54:16
hope 2:18 49:17
 216:1 224:25
hoped 172:23
hopes 202:19
hoping 138:18
hopper 42:18 73:19

horrall 51:1, 16, 17, 20 55:18, 24 56:1, 11, 18, 19	35:24 38:16, 19 51:1, 17 56:20, 22 64:23 69:12 71:17, 24 72:1 78:19 84:13 90:10 92:1 100:20 124:24, 24 127:1, 1, 1 136:22 144:1 150:20 155:1, 12 163:1 171:1 172:25 188:17 190:25 203:18 210:11 211:21 213:21 216:14 218:10 219:1 225:18 229:22 233:1 236:13 246:1 255:1, 1 261:14, 20 262:13, 14	108:13 113:1, 1, 1 114:1 125:14, 16, 19 126:18 136:12, 13 138:18, 19 149:1, 15 150:1 156:18 172:11 176:1 177:1 180:17 181:15 187:16 192:20 202:1, 25 208:1 215:10 222:1 224:1 225:11, 17 226:13 233:1 237:18 238:10 240:10 243:25 244:18, 18 245:15 256:19 257:17 260:1 262:10
horrall's 51:11	i.e 158:14 165:19 166:1 184:1 205:16	i've 13:17 14:10 15:1 27:1 30:14 39:1, 22 40:16 47:1 48:14, 15 57:1, 1 63:18 64:1, 1, 1 75:11, 12 79:1 127:13 166:22 171:25 181:18 214:1 222:1 225:22 233:1 235:12 241:22 245:15 257:19
horrible 28:1	i'll 9:18 16:1 41:1 73:1 85:1 89:1 90:1, 1, 1 97:1 161:1 176:17 207:1 210:12 225:13 231:21 243:24 244:1 246:1 252:13 257:21 262:11, 21	ice 219:14 iceberg 243:22 idaho 41:21 43:1 46:18 84:19, 20, 22 85:1, 1, 13, 21, 22, 22 88:20 idaho's 42:1 idea 23:1 29:1, 10 48:18 109:1 171:1 186:17 187:16 196:24 226:1 235:1 244:1
horse 64:1	i'm 2:19 3:1, 18, 18, 23 4:1, 1, 1, 1, 1, 1, 1, 12, 14, 16, 16, 20, 21, 24 5:1, 1, 1, 10, 11, 12, 14, 17 6:12, 23 7:1, 12 15:22, 24 16:17 24:18 27:1, 1 30:1, 1, 1, 1, 1, 10, 11, 16, 17, 18, 19, 20 32:1 39:1 50:17 51:20, 22 57:1, 1, 11 60:1 65:1 66:1 68:23 72:14 77:1, 16, 22 79:1, 1 83:15 84:18, 19, 25 92:15 99:19 100:19 101:1 102:20 104:1 105:10 106:1 107:10, 16, 21	ideal 177:20 ideally 134:22 185:1 ideas 211:20 219:1 identical 197:21 225:1 identified 32:18 46:25 78:20 101:1 132:13 151:1 182:21 205:1
host 117:21		
hour 20:1 118:11 146:23 147:1, 1, 18, 19, 25 166:1, 10 174:1, 1 195:1 198:18 210:1, 1		
hour-to 146:22		
hourly 98:1, 24 152:22, 24 153:1 166:1 173:25 174:11 176:12 178:21, 22		
hours 121:1 138:1, 11 147:21, 21 153:1 175:23 178:25 179:1, 1 198:1, 1, 1 206:22 207:17, 22 209:12		
house 112:13, 20		
hsrb 37:24		
huddo 139:1		
huge 3:1		
human 6:1 30:18 90:24 107:1 170:1 200:14, 15 263:1		
hummingbirds 138:1, 1		
hundreds 21:14, 16		
hundredweight 86:1, 1, 1		
hunger 152:1		
hungry 109:1		
hunt 18:23		
hunters 255:22		
hydroponically 40:1		
hypotheses 224:20		
hypothesis 137:1 206:24 226:1		
hypothetical 97:14		
<hr/> I <hr/>		
i'd 7:1 22:1 25:1 26:16, 22 29:21		

218:14 245:1	111:1, 1, 12	incorporation 102:13
identify 31:20	122:18, 19, 19	135:22 154:12
175:18	214:12, 18, 20, 24	204:10
ifs 119:1	215:19, 24	incorrect 11:1
ignore 108:17	216:1, 1, 1, 15,	increase 28:18 47:24
illegally 217:1	20, 22, 25	48:1 60:15 70:17
illinois 5:19	217:15 218:1, 1	115:13 124:1
13:22 22:11 71:1	219:1, 13, 19	193:19 219:15
72:10, 10 82:24	220:21 221:1 249:1	increased 63:22 78:1
149:13 219:1	250:1	83:12 85:20 109:17
220:1, 1	incisiveness 150:25	increases 216:11
illness 170:1	include 130:20 133:1	increasing 20:16
illogical 106:18	152:1 161:1	130:1 144:11
illustrate 97:16	164:1 165:1, 1	increasingly 258:1
illustrated 102:1	168:24 169:1	incubating 159:10
imagine 16:13	230:1, 21 247:1	incumbent 58:14 66:1
101:1 110:1 147:12	250:1 253:20	256:1
150:15	included 10:1, 22	immediate 243:13
in-season 82:12	11:25 13:17, 18	immediately 27:20
inadequacy 33:1	14:1 15:1 35:15	87:1 263:1
inadequate 33:18	128:10 152:1 159:1	indeed 92:24
34:16 35:1	164:15 170:19,	102:23 105:20
inadvertently 14:21	20 172:14 254:21	107:12 108:1
inappropriate	includes 10:23 131:1	110:10, 21 113:10,
34:17 202:20	143:12 160:12	17 118:19 121:23
inappropriately	235:20 249:1	127:16 179:14
67:22 226:1	including 40:23	independent 61:12
incapacitation	42:16 46:17	219:10 240:1, 1
116:22	87:17 90:1	independently 205:25
incapacity 165:20	139:13 143:15	indiana 51:20, 23
inception 187:11	145:1 162:15 203:1	52:1, 1, 1
inch 65:20 87:1	206:11	indicate 134:10
inches 66:18	inclusion 132:23	158:1, 1 186:1
incidences 216:23	194:13 195:1	217:12
250:1	205:17	indicated 3:18 47:23
incident 10:1, 11,	income 28:1 83:21	91:1 108:16
14 12:12 20:12, 24	incomplete 160:1	117:1 134:1 145:20
21:1 22:12 25:14	inconsistent 152:24	181:24 193:1
93:13 111:1, 15	incorporate 32:22	195:12 207:19
116:18 214:10, 13,	33:24 34:1	219:1, 15 249:1
16, 17 215:20	102:15 134:15	indicates 12:16 16:1
216:1, 1 217:20	135:10 154:1 165:1	140:22 143:11
218:1, 17 221:1,	201:11 248:1	207:17
20 229:1, 1 241:23	incorporated 8:23	indicating 152:1
247:1 253:1	51:1 55:11 56:24	160:22 191:15
incidental 241:10	72:1 93:1 108:24	206:23
incidents 10:16,	128:24 130:22	indications 96:1
17 11:1, 1, 10,	165:1 181:10	252:21
10, 13, 15 13:1,	198:23 202:23	indicative 194:16
1, 17 14:18 93:1	207:15 247:1	indirect 243:18
110:1, 1, 1, 20	incorporating 34:1	individual 100:10
	206:1 245:1	

112:12 113:18
 116:1, 10 148:23
 159:20 168:11
 203:23 221:22
 228:21 231:23
 233:1 239:14
 241:20 254:25
 260:21
individually 53:1
individuals 20:19,
 21, 22 96:19 121:1
 161:15 167:1, 1
 198:25
induce 175:17
industries 40:13
 83:24 84:1
industry 39:12,
 15, 21 40:1, 13
 42:1 43:1 45:1, 16
 46:10, 20 50:11
 52:1 72:14 74:10
 216:12
ineffective 83:11
inexcusable 16:17
infants 31:13, 18
 32:12
infected 53:19
infection 40:1
inference 153:20
inferences 232:22
infest 60:1
infestation 27:19
 41:25 46:1 53:23
 83:1
infested 27:10
 46:1 52:16 83:1
 84:1
infield 149:14, 24
influence 105:25
 106:1
influenced 207:24
 233:1
influences 103:1
 107:20 109:20
 110:19
influencing 107:13
inform 93:1, 1
information 15:1
 24:10, 13, 15
 32:19 42:1 48:1
 80:20, 24 89:1
 92:1, 16 93:1,
 13 102:14 103:1
 119:21, 23
 121:20 126:13,
 14 131:16 132:21
 145:15 154:17,
 22 155:11 156:15
 157:19 158:1 163:1
 166:17 171:21
 187:1 197:1 207:12
 212:1 213:20
 214:13 222:1
 233:1, 14, 17
 247:16 250:11,
 22 251:1
informing 155:22
infrequent 50:14
 51:1
infrequently 50:22
impact 28:21 29:1
 46:15, 20, 25
 47:12, 13, 14
 48:11, 15 60:25
 61:1, 23 91:1 93:1
 109:1 113:24
 123:24 151:14
 152:1 157:1, 16,
 22 163:1 164:13
 174:25 175:25
 182:19 192:1 195:1
 210:1 241:1 245:11
 248:17 257:12
impacted 49:1, 1
impacting 43:10
impacts 28:21
 33:25 49:1 62:1
 109:25 151:1
 203:23 248:13
 260:18
impaired 234:20
impairment 116:22
imperative 137:15
implement 199:23
implemented 173:24
 227:20 259:1
implementing 40:1
implication 146:14
implications
 133:16 206:1
 260:19
import 35:17, 20
importance 39:19
 96:22 186:1 206:1
important 8:18
 15:1 40:20 41:1
 42:1, 1 43:15 45:1
 46:1 65:10 68:24
 74:11 77:1 79:18
 80:21 81:15 84:1
 85:14 92:1 94:1
 97:23 98:11
 103:1 106:16
 114:1, 22 134:22
 139:11 141:20,
 24 144:12 146:14
 148:12, 25
 152:17 162:19
 163:18 165:1, 25
 167:20 168:23
 169:15 173:1
 175:11, 15, 18
 178:1 183:19
 184:10 185:12
 188:1 198:1, 10
 208:18 217:1
 222:15 224:10
 228:18 240:22
 242:21 243:1
 245:1, 14 253:25
 254:1, 1, 11 262:1
importantly 234:21
imports 35:22
impossible 158:25
 226:18, 20
improved 215:16
 216:1, 12 250:14
improvement 244:21
improvements 135:10,
 15, 23
ingested 35:1
 105:1 149:17
ingestion 96:15 98:1
 106:1, 14, 25
 108:1, 1 109:24
 110:1 166:13
 177:21, 25
ingredient 40:22
 112:1, 1
inhalation 101:20
 115:19 128:10
inhaled 35:1
inherent 135:17
inhibited 193:15
 194:17

inhibiting 261:1
inhibition 32:11, 21
 33:1, 1 160:1
 163:16 191:17
 192:1, 12, 23
 194:1, 13 197:16
 202:14 206:1, 19
inhibitor 234:25
initial 25:24
 90:1, 13 132:17
 137:1 144:1 169:24
 197:16 209:18
initiated 128:18
 217:24
initiative 201:1
injected 87:1
input 9:1, 1 13:24
 46:13 86:22, 23,
 24 130:20 163:22
 166:22 192:1 197:1
 200:11 211:17
 258:1, 1, 11
inputs 86:21
 114:22 115:23
 132:1 182:22 183:1
 204:1 247:1
inquired 24:1
inquisitive 156:14
insect 41:11, 17,
 18, 25 43:1
 44:1, 25 45:12
 49:1 50:23, 23
 51:1 70:22 76:16
 80:1, 10, 15 81:1,
 1 83:12 84:1
 87:17, 24, 25
 109:12
insecticide 39:17
 42:21, 23 44:10,
 14 45:1, 10 47:1
 54:14 55:1, 1,
 1, 1 58:1 59:10
 61:16 62:10
 67:22 70:1
 81:19, 25 82:1,
 11, 20, 22 83:1
insecticides 42:1,
 24 43:18 54:12
 57:25, 25 58:11,
 18, 25 60:12 62:1,
 24 63:16 69:15
 82:1 86:10
insects 20:1 42:23
 43:11, 12 47:14,
 17 48:1 82:1, 20
 184:12
inseparable 193:1
insight 182:23
 205:18 231:12
 232:1
insights 244:10
instance 24:1 148:22
instant 111:18
instantaneously 94:1
instead 27:16 35:1
 53:1 62:12 69:23
 78:17 85:1
 135:20 152:1
insufficient
 109:19 182:13
intact 96:18
intake 109:1 157:17,
 20 165:18, 18,
 21 168:1, 1, 16,
 20 176:11 207:15
integrate 118:1
 133:1 158:1
integrated 42:1
 47:22 57:23
 63:14 82:1, 19
 83:1 208:21 260:23
integrating 205:10
 261:1
integrity 3:1
intended 151:1
intense 3:1 262:25
intensity 104:25
intensive 86:23, 24
intent 2:1 15:10
 246:22 247:11
intently 96:1 118:24
interaction 150:12
interactions
 205:11 208:1, 19
interest 6:1, 18, 25
 7:1 31:1 77:1
interested 7:1 24:18
 91:1
interesting 48:20
 65:22 100:1 103:21
 107:15 108:1
 141:19 142:1
 164:16, 22
 168:10 174:18
 184:16 216:14
interference 184:1
interior 114:18
interplanting 77:24
interpret 114:1
 155:17 157:22
 178:24 179:13, 15
interpretation 100:1
 111:1 113:1 115:25
 156:11 159:23
 182:14 183:19
 188:11, 20
 211:24 214:1 231:1
 238:18
interpretations
 99:20 215:12 253:1
interpreted 116:1
 129:20
interpreting
 225:17 251:10
interrupted 13:24
interval 85:20
 88:15, 18
intervals 47:1
 167:13 194:1
intimately 166:1
intoxication
 108:10 159:24
 162:24
intrinsically 168:1
introduce 125:11
 140:1 261:22 262:1
introduced 249:25
 251:15
introduction 3:16
 72:11 94:16
invading 41:1
invaluable 49:14
invasive 25:20
investigating 261:1
investigation
 128:1 133:16
 164:13
invite 26:17, 22
 29:21 56:22 72:1
 78:19 84:14
involve 16:22
 168:1 237:1
involved 10:21
 17:1 79:25 218:1

involves 168:1
involving 110:1
iowa 7:1 71:1
 78:21 79:1, 1,
 1, 1, 11 82:14
 83:15
ipm 39:16 43:1,
 15, 20, 25 44:21
 63:1
iraq 57:10
ired 128:21 246:22
 247:1 248:11
irm 80:1, 10, 18,
 21, 23, 25 81:1
 83:1 84:1
irregular 66:24
irrespective
 197:25 217:15
 218:1
irrigated 63:1 64:16
 66:15
irrigation 70:11
irritation 169:1
it's 2:25 9:10 10:16
 14:1 15:1 17:1,
 1 19:24 21:15
 23:24 24:17
 25:24 26:17 27:14,
 14, 16 28:13
 31:1 32:1 33:1
 35:12 37:11 38:1
 41:20 46:1 48:24
 49:13 50:1, 10,
 21, 24 51:1, 1,
 1 54:1, 1 55:11
 56:1 57:16 58:14
 59:14 60:22 61:1
 62:15 63:1, 1
 65:21 70:22, 24
 71:1, 16 73:14, 15
 74:11 78:13
 79:20 89:1, 15
 92:13 93:1, 18, 23
 95:24 97:23
 98:18 99:12 100:1,
 1 103:21 104:1
 105:17 106:16
 111:13 114:1
 115:15 117:18
 118:22 119:1, 1
 122:12 126:12
 138:1 139:11 141:1
 144:12 145:1
 146:21 147:25
 148:1, 20 149:1,
 15 150:18 154:11
 156:14, 25
 157:10 162:11,
 14 163:11, 15, 16,
 16 164:1, 1, 22,
 23, 25 165:1, 1,
 25 166:1, 15
 168:23 170:1, 1,
 11 173:1, 13
 175:17, 19
 176:1, 13, 25
 177:16, 19, 20
 178:18, 19
 183:24 184:1, 1,
 12, 23 188:19
 189:1, 17
 190:15, 16, 21, 22
 193:1 196:22, 22
 198:1, 16, 24
 199:15 201:15,
 16 202:13, 25
 203:17 205:20
 207:23 208:18
 209:15 210:1
 211:1, 25
 212:17, 21 213:1
 214:1 217:10, 21
 218:1 221:17, 20
 224:12 225:1, 24
 226:1 227:15, 25
 228:18 229:19
 230:1, 1 233:21
 234:1, 14 237:24
 238:1 242:1 244:16
 245:1, 12, 16
 254:1, 1, 1 255:15
 256:1, 1, 18, 21
 257:1, 1 258:12,
 12, 13, 19, 19
 259:1, 18, 25
 260:14 261:18
 262:25
isn't 36:21 85:1
 93:17 224:11
 225:19 229:1
 235:10 256:1
isom 125:10, 12, 14,
 14 126:1, 1 211:1,
 1
item 19:11 118:1,
 17, 18 144:20
 181:19 208:25
items 102:1 119:15
 142:23 143:12
 144:1 151:22
 184:1, 11 239:1
iteration 180:1
iterations 121:11
issue 36:1 45:1
 91:22, 24 111:1,
 14 136:1, 19 157:1
 164:24 184:16
 189:17 202:11
 209:18, 19 222:15,
 18, 22 226:20
 229:25 233:19
 234:10 240:21
 255:1 258:1, 12,
 21
issues 2:1, 16
 7:14 39:13 44:1
 90:1 91:1, 12
 92:1, 18 93:1
 104:14 110:14
 126:11 135:22
 148:10 150:22,
 23 155:1 177:12
 205:19 210:16
 221:25 238:21,
 25 240:15, 19
 251:14 259:25
 261:22 262:19

 J

jan 3:23
jennifer 26:18, 19
 29:22 30:1
jim 6:1 17:17
 117:1 259:1
job 55:1 114:20
 252:16
jobs 3:1
joe 42:10
john 5:1 160:1
 167:19 224:1
join 125:19 211:1
joining 125:10 126:1
joint 130:25
jorgensen's 12:25
jorgenson 113:15
 120:17
judge 229:20

judgment 25:1	kinetics 191:1, 21	113:1 130:1 237:1,
judgments 241:1	192:1	14 239:24 243:15
judicious 63:15	km 202:13	256:10
july 52:1 86:1	knee 58:1 59:12	largely 9:1, 1 13:19
jump 248:1	knee-high 67:12 68:1	24:1 99:23 110:1
jumping 147:19	knees 235:15	119:1
junction 148:25	knock 59:21	larger 14:1 17:1
june 27:17 67:12	knowledge 78:10	46:15 138:1
151:1 182:1	130:1	148:18, 20
justified 38:1	known 43:1 191:18,	162:20 240:12
157:11 164:1	20 232:12, 15	244:12 258:1, 1
167:15 199:20	240:1	261:1
206:1, 1		larks 112:22
justifies 160:10		larry 4:16 23:13
justify 37:17	L	122:22 158:10
139:1 240:1	lab 64:1 155:17	207:13 233:20
juvenile 33:14	238:12 244:1	255:1, 20
	label 43:24 63:10	larry's 255:11
	76:11 79:18, 18	larvae 53:1 59:17,
	85:1 88:1 215:15	20 76:11
K	217:1, 14	laser 97:1
kehrer 6:1, 10	labeled 63:1 79:15	last 15:11 21:1,
37:14, 15 117:1,	labeling 101:24	20 39:1 55:20 57:1
1, 1, 14 259:1, 1,	labels 55:22 216:1	63:19 68:18, 20
1	217:23	73:1 75:12 76:1
ken 4:1 146:12 176:1	labor 46:13 86:24	77:15, 20 78:1
kentucky 5:23	250:13	85:12 86:13 89:1
kevin 82:23	labor-proposed	91:16 92:15
key 41:13 44:1 45:11	134:19	95:11 96:21
80:1 136:24 137:13	laboratory 5:18	99:21 120:1 125:19
175:1 183:21	116:13, 17	138:25 154:10
234:19	lacito 139:1	164:21 172:11
kids 12:1 20:1, 1,	lack 32:1 36:25	173:1 199:13
1, 1	41:1, 22 60:1	214:21 230:24
kill 11:14 17:1 53:1	64:18 67:16 83:1	242:13 246:16
122:25 255:17,	110:22 135:1 138:1	248:1 249:1
22 256:1	151:17 162:13	254:1 262:21
killdeer 18:16, 18	164:1 236:14 251:1	lasts 139:16
109:11 114:25	254:24	late 8:15 54:1 69:12
killdeers 115:1	lacking 245:17	76:18 78:13
killed 12:11 13:1,	lame 125:1	82:22 165:21
20 15:1 52:21,	laminated 44:21	216:21 236:16
23 123:10 255:19	land 14:1, 14, 16	244:20
killling 217:1 225:19	67:1 96:16 256:18,	latent 40:1
kills 10:23 19:10	20 257:1	later 16:1 41:1 44:1
226:16 228:1	landing 74:24	71:1 76:13
234:17 243:13,	lands 16:14, 15	158:11 160:1
14 255:11	landscape 260:22	207:22 221:12
kinds 99:24 163:15	landscapes 65:10	latest 67:13
199:1 201:12	language 58:1	laurel 244:1
kinetic 193:25	large 13:20 16:1	lc-50 181:25
199:14, 14	17:1 60:20 96:1	law 22:21 134:24
200:25 202:15		

lay 40:10 53:1	less 9:1, 10 37:1	likewise 206:21, 25
laying 28:1 159:10	70:18 82:13 122:19	limit 159:13
161:12	143:21 156:24	limitation 38:1
ld 175:1	159:1 184:1	43:24 76:10 251:1
ld-50 135:17	185:1 237:23	limitations 64:21
149:19 181:25	lessons 44:17	92:1 152:18 153:1,
187:1	let's 9:10, 18	18 163:20 179:17
lead 28:1 47:25	11:1 71:20, 21, 23	183:1, 1 190:12,
127:19, 21	93:14 110:1	12 192:11 194:1
129:12 154:1, 1	111:1 112:10, 12	205:10, 14 206:1
183:13 192:19	127:17, 17 151:1	215:17 218:1
215:1 220:1 247:23	181:20 190:12	249:24 259:22
259:14	210:20 230:25	limited 26:1 31:20
lead-in 260:10	258:14, 15, 15	45:25 94:1 110:1
leader 4:24	lethal 209:17	131:1 155:10 164:1
leadership 72:13	lethality 12:19	182:12 204:1
leading 164:1 208:16	165:22 196:1	205:1, 1 228:1
leads 107:19 248:1	letter 82:15, 24	231:12 232:1
leaf 42:18	level 11:17 35:11	limits 109:24
leafhoppers 41:14	46:14 88:14 105:16	line 68:20 73:15
42:13	108:1 117:25 118:1	87:10 100:1 109:13
lean 45:20	177:23 179:1	156:23 189:22
leap 205:16	194:18 207:1 213:1	235:11 248:25
learn 88:1	219:24 240:23	249:1 250:1, 1, 18
learned 43:1 44:16	241:1, 19	linear 106:17
92:14	levels 101:25	lined 194:25
learning 168:1, 1,	106:1 111:20	lines 18:1 73:1 74:1
12, 21	116:12, 12, 16, 20	93:10 218:19 239:1
least 3:1 16:1 19:19	181:1 193:25 198:1	240:1 246:23
20:1 26:1 50:23	liberalism 208:16	247:1, 1 248:13,
55:1, 1 59:17 61:1	liberty 187:12	24 251:23 252:1
99:21 115:16	218:12	253:1
138:1, 21 182:15	lies 66:17 95:1	linkages 177:16
186:15 189:1, 11	life 101:13 111:17	linked 46:12 166:1
194:18 215:15	139:12 141:1	185:1
226:19 229:1 236:1	173:13 190:1	liquid 9:1 94:21
256:1 259:15	194:21 244:1	99:25 101:1 108:19
leave 29:11 54:16	lifted 87:14	109:1 113:1 114:1,
60:1 74:13	light 7:16 62:23	11, 19, 25
105:11 107:23	125:25 153:1	115:1, 12 116:1, 1
125:1 234:20	202:24 203:1	117:1 120:24, 25
leaves 82:16 139:17	204:24	121:1 122:1, 1
lecture 199:13	likelihood 176:22	130:1, 16 131:1, 1
led 105:22	likely 100:23	132:20 134:10,
legal 10:23 11:1, 17	137:1 139:1	18 135:1 136:21,
217:11	141:1 153:1	25 137:11, 14,
legislative 39:13	162:14, 19	25 139:1, 23
legitimate 238:24	182:17 193:1	140:1, 16 148:1
length 102:25 110:12	198:20, 24 199:1	154:23 156:18
120:1	203:1, 12 209:20	178:21 207:1
leslie 133:14	214:24 225:21	list 12:23 13:1
	239:1	14:21 220:20

235:24 257:1	114:1 138:12 140:1	lull 95:17
listed 12:23 56:22	154:10 178:17,	lunch 71:16 124:25
132:12 159:25	17 207:1 245:22	lutz 6:15
256:12 257:1	long-term 32:24 34:1	luxury 159:21
listen 59:1 259:19	longer 54:1 81:18	lying 28:10
listing 161:19	83:19 147:15	lymphatic 35:1
literally 235:14	195:12, 13	
literature 11:21	206:18 220:21	
15:20 17:1 169:11,	222:1	
19 171:21 196:1,	loose 92:22	
18, 21 197:19	lorsban 63:1, 1	
262:1	lose 54:20 252:18	
little 16:1 37:17	losing 84:1	
41:1 59:13 74:1	loss 18:24 23:1	
79:14 87:1 89:18	28:1, 20 42:11	
93:14 97:1 98:1	46:25 47:1, 16, 21	
99:16 120:21 142:1	53:12 54:1, 21	
145:21 158:11,	55:1 86:1	
17 160:22 168:1	losses 45:17	
176:1 178:13 187:1	46:14, 22, 24	
189:19 196:1	lost 86:1	
197:1, 1 201:21	lot 13:1 19:1	
218:11, 11 241:1	22:20 30:11	
246:15 257:1	37:10 59:19	
live 52:13, 20 65:23	64:1, 19 68:25	
233:10, 11	76:1, 16 77:16	
live-a 86:14, 20	92:15, 16, 23 96:1	
liver 35:1	97:25 101:1, 1	
lives 121:1, 17	104:1 106:10	
122:1 147:1	110:1, 1, 13	
living 83:20	111:23 119:1 131:1	
load 73:13	147:19 149:1	
loaded 26:25 94:1	154:17 175:1	
loading 11:1 73:20	180:21 187:13	
96:1, 1	203:1 211:17, 18	
loads 41:24 260:24	241:15 242:19, 24	
loafing 12:1	lots 106:10 108:21	
loc 212:15	236:1 255:19	
local 228:19	lou 233:1	
locating 235:11	loud 170:1	
location 12:1 19:20	love 65:25	
locations 247:20	low 32:1, 14 86:18	
locked 100:1	99:1, 17 112:1	
lodged 28:1	113:1, 20 118:1	
lodging 28:1	121:18 141:10	
logo 79:1	153:1 207:1 237:1	
lp 156:18 164:16	lower 122:1, 13	
166:1	143:23 153:1 175:1	
long 7:11 16:10 17:1	lu 6:1, 1 15:24	
18:1 81:17 85:1	68:14, 15, 20	
86:1 103:18	199:1	
	lucky 113:1	

M

ma 83:19

macdonald 6:1, 1
68:14 70:1, 1

machine 94:1

mad 95:19

maggots 53:1, 1

magnitude 32:16
33:22 134:13
135:16 138:1
178:18 181:1
197:16 227:1 228:1
239:13, 23
245:12 253:14, 22,
24 254:1 256:1

main 53:14 72:15, 18
75:20 80:20 84:24

mainly 52:1, 1 85:18
154:11

maintain 2:25
49:12 255:23

maintaining 55:15
178:14

major 57:17 85:22
175:1

majority 28:1
80:17 135:15
216:24

malaise 169:17 170:1
171:23

males 107:14
161:1, 20

mallard 163:1

mallards 140:12
162:20 255:18,
20 257:15

mammals 103:10
252:23

manage 83:1 89:19
250:21 261:1, 1

managed 260:25

management 2:15 4:23
35:12 39:20 42:1
43:25 44:19, 21

45:11 47:22, 23
 49:15 57:22, 23
 61:1 63:14 80:1,
 16 81:1 82:1, 19
 84:1 87:25 141:14
managers 212:1
managing 61:14
mandated 40:1
mandatory 235:22
manifested 99:12
manifests 98:14
 190:1, 13
manipulation 25:20
manner 73:1 77:1, 1
manual 93:21
manually 167:11
manufacturer 73:15
mapped 18:1
marine 59:16
mark 87:1, 13 218:1
marked 107:15 109:17
market 45:15 47:20
 52:1 54:20, 22
 69:1, 19 78:1, 1
 86:1, 1
marketable 40:20
markets 52:11
 54:1, 10 86:1
marking 86:14
marlin 82:14
Maryland 52:1 244:1
mass 59:23 66:17
 112:1 113:1
master's 57:12
material 20:1
 26:25 45:1 92:20
 116:1 117:1 124:22
 228:25 261:23
material's 213:1
materials 7:24 84:16
 131:11
mathematical 155:11
mathematics 6:1
matrices 204:1
matrix 102:17, 22,
 22 115:1, 11 122:1
 133:14 163:17
 181:24 182:1, 1,
 11, 20, 21
 183:1, 1, 1 184:1,
 1, 1, 22 185:1
 195:1 198:15
 206:1, 1, 13, 15
 207:1, 1
matrixes 102:24
 189:1
matten 2:1 3:12,
 18 9:21 51:12 89:1
 120:16 126:1, 20
matter 106:11
 118:1 141:1 166:13
 168:15 221:15
 228:13
matters 113:1 114:15
 141:12
maturities 201:22
mccarty 5:1, 1 65:1,
 1, 1, 13, 16
 66:1 67:1, 10,
 23 68:1 136:18, 19
 140:18 146:1 159:1
 166:25 167:1
 185:16, 17 195:19,
 21 199:1, 1
 202:17, 18
 207:1, 10, 25
 224:1, 1, 1
 226:1 227:12, 13
 228:11, 12, 16
 232:25 233:1, 1
 238:25 239:12
 240:1 241:1, 14
 243:1, 15 254:18
 255:1, 1, 14
 257:23 262:1
maximal 141:1
maximize 83:25
maximum 117:1, 12
 260:24
may 11:1 16:1
 17:12 19:20
 21:16 33:1 34:1
 54:1 65:19 74:1, 1
 91:1, 1 92:1
 96:1 98:1 100:1,
 1, 1, 1 101:12, 14
 102:21, 22, 23, 25
 103:11, 13
 107:20 109:21
 113:1 114:19
 115:13, 18 126:1
 139:12 140:15
 141:21 142:15
 146:1 149:22
 151:22, 23 152:1
 156:23 158:1
 159:20 160:1 168:1
 171:22 172:22
 174:11, 14
 175:22 177:24,
 24 182:1 185:1
 202:15 205:18
 206:1 207:1, 1
 208:16 209:1 210:1
 215:19, 24
 216:20 220:1, 15
 234:23 241:1
 243:16, 17
maybe 13:24 19:22,
 23 56:1 99:10
 103:12 121:15
 134:1, 1 141:1
 146:1 147:14
 163:11 174:1
 176:12 184:19,
 23 186:17 190:19
 203:1 204:25
 229:23
mayo 6:24
mclean 26:23 27:1,
 1, 1 29:1, 1,
 12, 18, 19 59:1
 74:25
mcmaster 6:1
meadow 112:21
mean 34:1 39:18 74:1
 76:13 78:1, 1,
 1, 13 106:15
 122:13, 20
 123:25 138:1
 145:1, 1, 11, 16
 147:1, 20 160:15
 169:1 181:1
 190:1 198:1
 223:1 228:1, 1, 17
 230:14 238:19
 251:1, 1 258:1, 17
meaning 241:17
means 20:1 34:1
 45:23 109:21
 111:13 204:1
 218:13 238:23
 242:12
meant 106:1 147:1
meanwhile 10:1

measure 34:1 58:16
 74:1 135:19
measured 135:17
 148:16 150:1
 171:16 245:20
measurement 31:1
measurements
 153:25 165:1
measures 58:10 61:19
 62:25 70:1 161:15
measuring 240:23
meat 9:14
mechanically 53:1, 1
mechanism 168:1,
 22 169:25
mechanistic 6:13
mediated 168:23
medicine 3:24 4:1
medium 121:18
meet 116:12
meeting 2:1, 1, 21
 3:1, 17 30:1 48:21
 60:13 61:12 72:1
 125:17 247:16
 248:10 262:10
meetings 230:1
 262:17
melissa 213:24
 214:1, 1 231:1
melon 51:1, 21,
 21, 23 52:1, 1
 55:14
member 4:1, 1, 1, 14
 51:24 110:24 126:1
 127:19 133:1
 194:15, 23 244:19
members 2:14, 14
 3:1, 1, 16 7:1, 24
 27:1 51:10 57:1
 78:24 125:1, 1
 126:1, 23
 127:13, 18
 129:18 133:24
 140:19 158:18
 159:1 162:17
 172:25 197:12
 205:24 208:25
 213:1, 18 222:16
 226:1 250:25
 254:16 262:16
 263:1
memory 121:21
mention 2:24 3:1
 19:13 83:15 138:20
mentioned 20:18
 42:17, 24 67:12
 86:11 126:1 139:16
 144:1 167:1 171:11
 202:19, 21
 219:14 224:11
 232:21 234:12
 253:22
mercury 5:1
merit 166:1 174:17
 185:1
message 19:1 94:1
 112:1, 25
met 244:20
meta-analysis 213:1
metabolic 203:14
metabolism 35:1 38:1
 141:23
metabolite 202:11
metal 76:25
meteorology 143:16
meter 75:18
meth 64:1
methamidophos 43:17,
 20, 23
methidathion 18:1
methiocarb 169:11,
 21
method 34:25 82:1
 145:1 206:24
methodologies 32:1
methodology 31:19
 104:1 109:19 153:1
 200:1, 23
 201:15, 16 259:11,
 16
methods 34:23
 41:22 48:1, 1
 92:1, 1 114:1
 130:1 143:18
 206:11 244:21
 247:1
methylbromide 56:1
metrics 132:23
 205:12
mexico 41:17
mic 189:14 212:1
michael 7:22 51:1,
 19 102:1 219:11
michigan 3:20
micromatic 73:16, 21
microphone 90:1
 125:1
microphones 125:22
microscopic 52:13
microtomography
 143:16
mics 211:1 215:1
 226:10
mid 67:12 86:1
 236:12, 21
midday 95:18, 20
middle 14:22 27:23
 57:1 65:14 75:24
 98:1 99:1, 1, 16
 122:12
midnight 154:19
midwest 44:18
 77:19 125:18
 256:24
midwestern 52:1
migrate 19:18 96:13
migrating 41:18
 138:11
migration 19:14,
 19 96:14 139:13
 159:1
migratory 12:1 257:1
milan 236:1
mile 18:1, 1
miles 18:1, 1
 64:1, 1, 1 65:23
 79:1
million 42:15, 19
 45:17 46:1 47:1
 75:25 83:17, 18
 161:22
mimic 140:15
 235:10 237:11
mind 22:1 119:1
 155:14, 20
 170:18 174:1
 202:10 203:1
minds 6:20 120:21
mine 57:1 185:20
 195:25
minimally 112:1
minimizing 168:20
minimum 198:22
 217:11

minnesota 52:1	19, 25 129:1	23, 23 115:16,
minor 20:23 136:1	131:13 132:1,	23 119:1, 1 120:22
minority 220:17	20, 25 133:12	121:17, 19, 25
minute 87:1	134:1 135:1, 1	122:1 129:23, 25
minutes 7:10 71:21	136:1, 22	130:1, 18 131:1,
78:25 92:12 124:25	137:11, 14 138:1	1, 24 132:12, 15
169:17 210:21	139:10, 20, 23	133:1, 1, 1, 1,
misprint 27:15	140:1, 22	14, 15, 20
mispronounced 38:23	142:12, 16	135:1, 10 136:1,
missed 30:1 86:1	143:22 145:1, 20	1, 21, 25 137:15
222:1, 16 237:12	148:17 149:1, 23	140:16 141:1,
248:1	150:1 152:11,	18, 21 142:1
mississippi 3:24	16, 16, 17	149:1, 1, 16
missouri 27:1	153:20 156:1, 10	154:11 155:1,
mistaken 65:1	157:1 162:16	13, 15 175:1
misunderstanding	164:1, 15, 16	188:14 192:16
210:1	165:1, 14 166:15	194:14 201:1,
misunderstood 226:23	168:25 170:12	12, 21 205:18,
misuse 10:24 11:1,	173:1, 1, 1, 1, 25	21 210:1 239:19
1, 12 22:24 217:1,	174:24 176:24	247:1 249:12, 15
1, 12	177:1, 1, 1, 1	251:18 252:1, 1, 1
mite 41:15 43:14	179:1, 24 180:1,	253:12 258:1,
mites 42:1 43:1	13, 16 181:10	10, 11
mitigated 216:1	182:23 183:1 190:1	moderate 40:24
mitigating 186:1	191:11 192:1	modernize 130:1
254:13	194:10 195:1	modes 45:1 62:1
mitigation 74:1	199:24 200:1	96:24 191:13
254:10	201:1, 24, 24	modifications 130:16
mixed 42:1, 17	204:1 205:11, 12	modified 80:1 132:1
mixes 47:10	206:1, 16	modify 189:25
mm-hmm 56:1 66:1	208:21, 23	modifying 182:1
67:1 68:19	209:13 210:1 227:1	moisture 27:15
mobile 52:10 159:18	239:24 240:1, 1	molecular 6:11
mode 51:1 169:25	247:1 249:10	molting 159:10
191:18, 20 260:15	modeled 149:22 207:1	moment 35:17
model 8:13 73:14	modeler 140:24	167:20 262:11
75:11 91:23	modelers 8:17, 22	263:1
93:1, 14, 20	139:18	monarchs 197:18
95:1 97:1, 15,	modeling 6:13 102:16	monday 117:1
16 98:1 99:1	128:1, 22 129:1	money 67:21
100:1, 13, 16	131:12, 18, 24	monitoring 10:1, 11,
101:12 102:15	133:1 147:18	14 20:1 23:1, 1
103:15 108:25	155:21, 21	93:13 116:18
109:14 112:10	166:18 177:17	214:16, 17, 25
113:25 115:1, 1,	185:1 198:20, 23	215:17 220:1, 1,
1, 13 116:1, 10,	204:1 208:18	1, 18 221:1, 20
14 117:20 119:1	209:1, 1 211:24	224:1, 12 225:22
120:25, 25	218:24 249:17	229:1, 13 231:1,
121:1, 12, 22	253:1 259:22	1, 11, 17 250:14
122:1, 1, 11	models 8:18 93:1, 1,	251:1
128:1, 1, 1, 1,	1, 1 94:25	monochromophos 9:15
	101:18 102:1, 1	monoculture 16:15
	103:1 114:21,	

monsanto 58:1 61:10 62:18	214:23 217:1 219:1 223:21 226:1 229:1	multiplier 46:15, 22, 24
monte 100:1	231:25 232:18	multiply 153:1
montgomery 5:10, 10, 11 55:18, 19 56:1, 10, 16 63:1	236:20, 25 237:10 238:1, 19, 19, 23, 24	multiplying 178:24 185:1
77:13 88:10, 11, 14, 17, 21, 25	239:1, 16 240:25	multitudes 47:10
104:23 136:1, 1	241:1 242:1	myself 24:19 66:1 248:1
144:16, 17	243:11, 17	
175:13 176:1, 16, 17 189:15, 16 212:10, 12	245:10 246:18, 24 247:1, 10, 19	N
247:22, 24 252:13, 16 255:1 257:24, 25 259:1	249:1, 19 250:1, 1, 23 251:25 252:1 253:11 257:13, 15 259:1	naive 146:1
month 12:1 15:11 19:23 20:1	morton 139:1	namely 87:22 152:19 209:11 249:17
moore 8:1, 12 9:1	motivation 217:16 245:23	narrow 43:23
morality 114:19 194:11	motor 193:17	narrowing 101:10
moreover 191:22	mountain 257:1	naruf 72:14
morning 2:1, 12 4:20 30:1 51:15, 17	move 3:12 15:1 25:1 38:19 39:1 51:13, 14 66:18 95:11 118:12 126:1 127:1, 20 140:1 142:1 150:20, 23 151:1 158:1 172:25 181:15 188:19 189:20 190:25 203:18 211:1, 10 230:13 235:1 244:1 245:24 249:23 261:19 263:1	nation 52:1 79:1 85:1
72:1 78:23 92:11 94:1 96:11 99:10 107:21 112:22 126:17 138:17, 24 147:10 164:20 175:25 199:24 207:20 218:1 263:1	movement 139:21	national 4:1, 17 26:18 29:23 38:21 39:11, 13, 20, 23 40:17 42:1 44:22 51:24 79:11 85:14
mortalities 10:18 112:1 113:12 116:1 122:23	moved 75:1 90:19 111:24 131:25 188:1	nationwide 72:19
mortality 15:1 16:1 110:1 111:17 112:1, 14, 20 113:1, 1, 18, 21 114:12, 15, 17 116:13, 16, 17, 21 120:10 122:1 123:14, 19, 25, 25 124:1, 10 128:1 129:1 131:19 133:17 134:11 135:21 140:23 141:1 153:22 180:25 181:1 183:10 191:22 192:17 194:16 196:1 203:24 204:11, 19	moves 208:19	natural 30:1 66:1 184:11 196:1 220:1 234:17
	moving 74:13 75:1 117:22 155:1 156:20 159:21 163:20 165:1 188:1 194:1 245:22	nature 120:1 143:18 156:13 179:1 219:20
	muddy 64:1	nearly 83:17, 22 98:18
	multiple 14:1, 1 20:1 47:1 62:1, 1 77:21 94:19, 22 127:14 133:1, 20 151:1 167:1 208:13 246:23 248:13 251:23 252:1 260:18, 21	neat 70:15, 20
		nebraska 5:1 27:1 52:1 57:1, 13, 17 58:12 65:1 69:1, 10 71:1
		necessarily 16:1 97:13 103:1 145:16 155:22 172:13 196:13, 17, 19 197:1 215:10 223:1 238:17
		necessary 16:11 81:19 87:24 194:1 217:13 230:16
		negate 106:1
		negative 21:21 48:15

62:1	nine 71:1	263:1
negatively 43:10	nitrogen 70:17	noted 27:18 131:1, 1
47:14	no-choice 170:20	137:1 193:23
negatives 218:13	noic 90:19	194:15, 18
225:17	non 109:19 110:18	220:12 233:11
neither 33:20 95:1	non-breeders 242:17,	235:1 236:1 237:15
nematode 52:17	22	notes 206:21
87:17, 22	non-breeding 193:1	nothing 33:16 56:1
nematodes 52:12,	non-calibrate 142:1	144:1, 17 163:1
14 56:1 85:17	non-carbofuran	185:18
86:1, 15	216:20	notice 2:1 15:10
neonicotinoid 44:1	non-concentrated	74:23 75:1 98:1
neonicotinoids	152:1	99:17 107:25
49:1 86:10	non-ecological	109:11 132:19
neophobia 158:12	140:24	146:22, 22 238:1
nervous 171:24	non-flocking 219:16	246:22 247:11
nest 101:1 102:1	non-game 237:20, 23	248:12
159:21	non-gmo 81:1 83:1	noticed 24:1 71:1
nesting 12:1 19:25	non-mobile 137:20	199:25 202:1 238:1
101:1, 1 102:1	non-nesting 115:15	noting 234:22
242:15	non-passerines 139:1	notion 178:1
nestling 115:19	non-rescued 28:1, 13	notorious 44:12
139:10, 16	non-treated 28:16	nowadays 240:11, 15
nestlings 100:23	noncholinergic 31:21	nozzles 87:12
137:1, 20 140:1	32:23	nrdc 32:13 34:15, 23
nests 20:1	none 36:24 98:1	nrdc's 35:15
net 46:1 49:1	152:1 241:22	nu-may 5:24
neurobehavioral	nonsensical 197:1	nuke 16:16
32:24 33:25	nor 33:21 164:1	numeral 142:1
neurocognitive 32:25	nork 175:1	numerical 132:1, 1
33:25	norm 77:25	numerous 239:1
neurodevelopment	normal 143:1	247:19 252:1
33:1	normally 62:13	nutritional 159:1
neurotoxicity 33:1	66:22, 24 163:1	nutshell 136:16
neurotoxicology	169:1	
125:16	north 65:11 84:20	O
newer 49:10 129:1	237:21 256:16, 19	o'connor 8:16
149:1 249:12, 14	northeast 79:1	obcd 172:15
newest 170:1	northern 41:19	object 170:1
newly 204:10 249:14	65:1 193:1, 1	occasionally 76:1
nice 26:12 196:22,	northwest 27:1 41:1,	occupational 39:25
23 258:18 260:1	1, 10 43:15	74:14
niche 52:1 78:1	44:1, 16, 19 45:1,	occur 33:1 45:14
niches 47:1	1 46:11, 21, 23	82:1 101:23 103:13
nichols 235:25	47:1	111:17 112:1
night 19:15 64:1	note 2:13, 13	114:16 130:14
138:25 164:21	26:24 47:1	141:1 149:22 152:1
175:23 203:1	129:25 133:1	162:18 169:1
242:13	154:24 163:1	170:11 176:19
nights 138:12 154:20	164:16 177:15	224:18 231:25
nighttime 198:1	198:1 211:1 216:13	238:19

occurred 114:18 23 75:1, 21 187:16 199:16
 178:1 216:1 220:13 77:13 78:13 79:1 233:23, 24
 243:11 88:25 89:17 107:13 **opposite** 75:1 238:22
occurring 15:15, 122:21 123:21 **optimal** 156:25
 16 42:17 236:25 142:1 151:1 155:1, **option** 37:1 61:19
 245:1 19, 23 156:17 63:11 170:25
occurs 107:16 165:20 159:1, 11, 22 **options** 63:1, 1
 168:21 169:17 163:17 165:24 64:20
 170:1 175:21 226:1 173:1 175:1 181:14
 253:13 262:1 184:12 185:22, **oral** 34:18 37:21, 23
observation 153:1 25 186:1 188:16 181:25 213:1
 154:1 258:1 195:18 203:18 **orally** 35:1
observational 107:1 210:19 214:1 **orchard** 18:10, 19,
observations 96:20 220:22 224:1 230:1 22
 152:19 165:10 246:1, 13, 14 **orchards** 17:22 18:14
 225:1 259:25 261:19 19:1
observer 235:24 262:13 263:1 **ord** 201:1
obsolete 9:14 **old** 48:1 59:16 64:1 **order** 19:16 130:1
obvious 28:13 **older** 149:1 249:11 138:1 157:24
 105:1 224:12 237:1 **omaha** 5:1 167:12 186:25
 262:19 **omitted** 222:19 188:1 192:1 193:25
obviously 30:17 31:1 **oncology** 6:17 202:1 203:11
 71:16 89:1 **one-hour** 210:1 242:22
 127:18 200:1 **one-sheet** 213:12 **orders** 228:1
 202:12 230:24 **onerous** 203:17 **oregon** 41:21 43:1
odenkirchen 92:1, 11 **ones** 56:1 73:1 140:1 84:23 85:1, 1, 13
 116:25 117:12, 140:10 140:10 **organ** 31:1 200:10
 16 119:24 120:1, 1 **organisms** 252:19
 121:1 122:1 127:1, 260:1
 11 147:1, 23 **organization** 39:11
 148:20 155:13 **organophosphate**
 178:1, 10 179:23 17:19 33:1 36:20
 180:25 181:1 **organophosphates** 37:11, 12 43:18
 201:1, 1 246:11, **organophosphorus** 5:1
 12, 12, 14, 16 31:23 34:1
 261:15, 16 262:21 36:19, 24 171:20
odenkirchen's 220:19 **organophosphorus** 5:1
odor 169:1 **origin** 165:25
offer 7:1 100:13 **original** 24:16
 129:1 143:22, 23
office 4:1 201:1 **originally** 209:12
officer 51:25 238:12
official 2:25 **oscillation** 148:1
 22:21 210:25 211:1 **others** 61:14 81:20
offsite 20:1 103:1, 12 112:15
offspring 101:1, 1 218:21
oh 124:12 258:14 **otherwise** 127:23
oil 74:22 143:1 178:1
okay 9:23 10:1 224:1 242:1
 12:1 26:21 56:16 **ought** 189:1 198:16
 71:1, 23 72:1, 152:17 184:1 **overall** 12:1 23:1

93:1 116:1
 124:20 133:22
 151:14 162:1 195:1
 204:18 223:14
 231:13
overcome 235:18
overcompensation
 108:1
overlaid 18:1
overlap 99:15
overlaps 11:20
overseas 35:20, 21
overview 90:12
overwhelm 108:13
 109:1
ours 66:11
outbreaks 43:14
outcome 33:1
outcomes 31:25
 32:1 239:1
outlandish 196:1
output 97:14 132:1
 180:1, 1
outputs 99:1
 103:16 135:1, 13
 164:14
outside 25:14
 36:21 129:16
 184:15 233:17
 235:17 251:18
 254:1, 1, 23
 255:25
owned 51:22
owner 5:11

P

pa 83:19
pace 130:1
pacific 41:1, 1,
 10 44:1, 16
 45:1, 1 46:11, 20,
 22 47:1
package 127:22
packaged 73:1 77:1
page 30:16, 22
 32:1 33:11 34:10
 85:1 237:12
pages 87:1 231:1
pain 24:17
pair 211:1
p.m 2:10 125:1 263:1

pamphlet 10:1
panel 2:1, 1, 14
 3:1, 1, 19 4:1, 1,
 10, 15 7:1, 10, 23
 8:1, 11, 13, 19,
 24, 25 9:1 10:1
 22:1 27:1 29:1, 25
 38:25 49:16 51:10,
 19 57:1 64:11
 68:17 72:1 77:12
 78:24 79:21 84:12,
 16 89:20 90:1
 92:10 110:24
 116:25 125:1
 126:1, 14, 20, 21,
 23 127:1, 13,
 18, 19 128:1
 129:16, 18
 130:18 133:1, 24
 136:18 140:19
 156:1, 23 158:1,
 1, 15, 18 159:1
 160:18 162:17
 164:1 172:25
 192:21 193:12,
 23 208:25 210:14
 213:1, 13, 18
 226:1, 13 232:22
 247:17 249:10, 16,
 22 250:1, 10,
 19, 25 252:1
 254:1, 1, 16 257:1
 261:17, 21, 21
 262:1, 17, 25
 263:1
panel's 210:17
panelist 71:14
panelists 231:22
panels 9:1
panger 123:1, 12, 21
 124:1, 12
 127:10, 13 213:24,
 24 214:1, 1, 1
 215:23 222:23
 223:1, 11, 13,
 17 229:18, 21
 231:1, 1, 1 246:1,
 1, 1
panger's 220:11
panhandle 69:1
pans 169:13
paper 12:25 13:1

25:1 167:1, 1,
 15 234:21 236:1
papers 11:23
 15:20, 23
paradigm 218:15
 245:21
paradigms 169:10
parallel 136:1
param 9:1 94:21
 99:25 101:1 108:19
 109:1 113:1 114:1,
 11, 19, 25 115:1
 116:1, 1 117:1
 121:1 122:1, 1
 130:1, 17 131:1, 1
 132:20 134:10,
 18 135:1 136:21,
 25 137:11, 14,
 25 139:10, 23
 140:1, 16 148:1
 154:23 156:19
 207:1
parameter 114:10, 20
 120:25 146:1
 168:25 170:12
 258:1
parameterization
 135:1, 1 136:20
parameterize 93:1
 164:1 239:19
parameterized
 134:1 135:12
parameters 8:19 9:1,
 1 100:17 120:24
 132:12 172:15
 200:20 208:20, 20,
 22 252:10
params 178:22
parathion 18:1
parents 138:13
 193:21
parrot 254:1
partially 222:21
participated 2:16
 89:20 262:16
particular 44:11
 75:11 114:18
 135:14 136:23
 144:20 161:19
 170:13 197:1 213:1
 222:1, 22 223:1
 239:11 254:1

259:15
particularly 24:19
 36:1 76:18 79:1
 132:19 196:17
 199:11 259:22
partners 80:1
pass 35:1 53:1 72:16
 75:20
passed 67:1
passerines 137:1, 19
 138:15, 22 139:15
passes 54:1
passive 96:1
past 51:22 59:1, 1
 64:14 67:15 76:1
 79:12 89:1 96:11
 97:1, 11 154:20
 188:1 219:24 220:1
 222:1 235:22
 245:15
path 252:1
pathway 248:21
pathways 111:20
 116:11, 15, 19
pattern 42:16 46:1
 95:12, 15, 22
 96:23 97:1, 1, 10,
 18, 19 98:1, 15,
 19, 21 99:1, 15
 100:1, 14, 15
 115:17 137:23
 138:16, 23
 139:1, 1, 1, 20
 140:1 148:22, 23
 168:12, 12 197:20,
 21, 22 199:14
patterns 40:25 48:19
 96:25 97:1, 1
 98:10 99:24 100:1,
 14, 15 128:12
 137:13 139:18,
 22 140:1, 14 201:1
pbk 200:1 201:1
 203:15, 17
pay 97:23
paying 139:19
pdf 167:12
peach 41:14 42:14,
 18 44:1, 11 85:19
peak 98:1 139:14
peaks 95:15 98:1, 22
 99:22 138:17, 24
pediatrics 4:1
peer 90:21 91:1
 130:19 136:1, 1
 251:19
pending 143:1
pens 152:1
people 3:1 11:13
 39:1 89:12 107:1
 110:17 154:25
 155:1 160:18 171:1
 176:18 185:1
 196:15 197:1, 1
 202:22 207:21
 212:1, 20, 21
 238:1, 12 248:1
 255:1, 19 257:1
 259:19
people's 237:1, 1
per 15:13 20:1
 28:17, 17 47:1
 59:17, 20 112:1
 123:16, 19
 161:22 221:21
 222:25
percent 114:17
 132:1, 1 133:19
 161:13
percentage 78:1
 132:1 180:25
 212:17
percentile 115:1
 180:1
percents 213:1
perfect 82:1 190:1
perfectly 201:1
perform 149:1
performance 83:1
 135:1, 1
performing 60:12
performs 55:25
perhaps 11:1 36:13
 108:16 120:25
 187:11, 15 194:1
 202:15
perimeter 114:12
period 3:13 7:1,
 21 16:10 72:1
 89:1, 10, 21
 90:1 96:1 105:22
 107:1, 1 128:16
 139:25 140:1
 154:18 160:23,
 24 178:15 193:18
 203:1 207:1 222:20
 237:25 242:1
periods 101:13
 139:14 159:1, 19
 213:19
permanent 4:1, 1,
 10, 15 32:24
 34:1 126:1
perpetuated 202:20
persisted 223:21
person 70:10
personal 45:20
 47:1 167:14 224:24
 252:25 254:20,
 22 255:1 257:25
personally 44:20
 171:19, 25 172:1
 183:23
perspective 155:24
 156:16 157:19
 174:1, 14 184:14
 186:10, 16
 187:21 197:1 205:1
 241:17, 18
 242:12 253:16,
 17 254:22, 23
 262:24
pertain 36:1
pertained 209:1
pertaining 35:14
pertains 69:1 213:14
pertinent 245:16
pest 4:23 40:21
 41:1, 1, 17
 42:1, 1 43:1, 22
 44:25 45:25 47:22,
 24 57:23 63:14
 70:22, 22 76:16
 82:1, 19 83:1
 87:16 88:21 160:1
pesticide 3:25
 5:25 10:24, 25
 11:1, 11, 14
 12:14, 18 16:13
 18:1 36:1, 10 41:1
 49:1 55:11 57:12
 70:25 88:1
 101:25 104:10
 111:1 128:1 131:25
 142:1, 21 143:1
 146:15, 17

151:16 165:17
 176:11 217:1 218:1
 235:1 236:17, 20
 242:1 243:14,
 17, 19 245:25
pesticide-induced
 171:14 176:1
pesticides 6:1 9:12,
 13, 15 10:20 12:1,
 11 22:1 31:23
 36:11, 18 37:1, 13
 60:10 70:11
 120:1 129:24
 139:1, 12 140:11
 155:25 184:16
 214:12 217:21
 232:10 237:1
 244:22 261:1, 1
pests 41:1, 11 42:1,
 25 43:21 44:1,
 13 47:11, 13 52:10
 53:12 56:1 57:17
 261:13
peter 4:20 6:1 167:1
 174:1 183:14
 211:13, 14 255:1
petitioning 30:12
petralophyra 68:1
pharmacokinetics
 199:13
pharmacology 6:24
pharmacy 5:22 6:10
phase 139:11, 16
 193:13 209:18
phased 56:1 222:1
 227:1
phases 139:11
phasing 197:1
phi 85:20 86:1 87:19
philosophical 187:10
 189:17 190:1, 22
 218:11
philosophically
 187:16
pick 53:20 112:13
 177:1 179:1
 180:1 212:1 229:13
picked 17:1 75:12
 243:19
picking 20:1
picks 67:1
pickup 44:23 78:12
picky 159:14
picture 27:1, 1, 12,
 25 28:11 53:21, 24
 59:25 73:21
 114:1 173:18
 184:14
pictured 28:1
pictures 59:1, 1, 23
 68:23
phone 125:20
pie 170:1
piece 226:15 258:1
pieces 80:22 153:12
pigment 170:10
piling 95:1
pill 60:18
pilot 66:1 72:12
 74:12, 15 75:1, 1
pilot's 75:1
phys 184:21
phys-chem 184:18
physiological 158:13
pipeline 47:21
pit 67:1
pivot 66:15 67:1
pivots 66:14, 24
placement 74:19
places 52:1 89:13
 94:1 103:22
placing 234:1
plagued 187:10
plain 81:20 84:21
plains 69:1 70:1
 256:24
plan 76:15 240:1
planning 61:25
plant 41:24 52:14
 53:1, 1, 1, 17,
 19, 21, 22, 25
 54:1, 1, 1, 13
 57:13 58:21 59:18,
 20 62:24 70:18
 87:13
planted 45:24 46:1
 65:19 69:21 70:1
 80:14
planter 59:1
 81:20, 21
planting 41:1
 44:1, 1 61:16
 67:24 68:1, 1,
 12 81:25 82:1 85:1
 86:14
plants 28:16 52:15
 53:10, 24 54:11,
 17 60:1, 1, 1
 61:23 149:18
 184:12
plastic 54:11, 15,
 18 55:25
plates 170:1
plausible 139:1
 206:24 225:1, 24
 227:16, 16, 25
play 119:1 148:18
 182:1
please 9:10 71:24
 125:11 129:10
 143:1 153:1, 10,
 15, 22 154:1
 163:23 165:11
 183:1, 10 192:1,
 17 203:20 204:20
 213:23 214:1, 22
 215:1 231:18
 246:10 247:20
 263:1
plenty 38:10 134:25
plethora 37:13
plot 29:14 112:21
 200:1
plots 112:1, 1, 14
 120:1 123:13
 232:1, 1, 1
plus 46:18 73:1
point 7:1, 20
 13:22 23:16 26:16,
 22 28:1, 25
 29:20 30:23 31:1
 34:10 38:15
 39:25 51:1 56:20
 58:24 67:17
 71:17 72:1 76:22
 78:16, 19 84:13
 87:11 89:1, 17, 25
 90:10 102:1 121:1,
 1 124:24 126:1
 127:1 134:1
 146:10, 13 149:1
 150:1, 15 156:1, 1
 161:1 162:12, 25
 166:14 167:20,
 21 168:1 169:23

172:11, 18, 24
 178:1 179:1 187:25
 188:15, 20
 189:21 190:10, 17,
 22, 24 193:16
 196:1 197:24
 198:1, 10, 18
 201:10 203:19
 205:15 207:11
 209:1 210:11
 213:21 218:11
 221:1, 1, 14
 227:18 229:1
 230:1, 1 236:13,
 24 238:10, 15
 240:18, 22
 245:14 246:1
 252:25 259:1
 262:1, 13
pointed 96:20
 137:1 164:20
 174:25 207:14
 221:1, 17 238:25
 239:12 240:1 241:1
pointer 97:1
pointless 63:10
 67:18, 20
points 31:24 155:1
 166:23 176:18
 180:1 186:13
 188:1, 10 233:1
 251:17
poisoning 10:15
 17:19
police 94:1
policy 136:13
 189:1 230:1
polo 94:15 138:17
pools 258:21
poor 58:22 106:11
 108:21
poorly 34:16
population 48:13, 16
 69:18 81:16 122:25
 124:10, 11, 19
 133:1, 14 146:1
 186:11 228:22
 241:1, 21, 24,
 25 242:18, 21,
 23 245:13 255:23
population-based
 3:21
populations 61:1
 62:15 256:10, 16
 257:11
portable 103:1
 108:23
portier 4:1, 1
 77:13, 14
 146:11, 12, 12
 147:17 173:19,
 20 186:1, 1 201:17
portier's 187:25
portion 115:12
 122:25 161:14
 180:10, 11
posed 127:1 131:1
poses 129:1 131:19
 134:11 247:18
 252:1
position 75:14, 17
 104:12 113:25
 181:12
positioning 75:19
positions 40:16
 72:13
positive 45:1
possibilities 106:14
 170:14
possibility 215:23
 216:1
possible 27:1
 31:20 32:23 61:1
 92:13 104:1 115:16
 141:1 146:15 149:1
 158:19 182:19
 204:1 210:1 227:19
 236:1 239:1, 15
possibly 173:23
 234:11
post 38:17, 18, 18
 56:21, 22 71:25
 72:1 82:22 89:1
 120:10 161:16
 168:1
post-application
 146:24
post-ingestional
 165:20
post-plant 85:1
post-planting 41:1
post-treatment 112:1
potato 38:22 39:1,
 11, 12, 14, 15,
 20, 21, 23 40:1,
 1, 1, 17 41:1, 10,
 15, 16, 16, 22
 42:1, 1, 13, 19
 43:1 44:1, 1, 1,
 11, 14, 18, 22
 45:1, 12, 16
 46:11, 20 48:14
 84:24 85:18 86:16
potato-producing
 84:22
potatoes 15:21 40:10
 45:24 46:1 48:1
 49:25 85:11, 22
 86:23 259:13
potency 202:14
potential 32:1 33:25
 38:1 40:1 46:1
 48:12, 22, 25
 50:24 76:1 87:12
 91:1 103:19
 104:1 109:1 133:11
 151:21 152:1, 1
 153:1, 21 157:22
 163:1 183:1 185:13
 186:1 189:1 191:10
 192:1, 16 194:11
 208:15 217:15,
 24 252:22, 23
 253:1 256:13, 22
potentially 38:1
 104:11 157:1
 175:24 248:21
pounce 55:1
pounds 112:1, 1
 222:25
power 258:22
ppm 161:1, 1
pra 128:19 191:1
 192:1
practical 74:1
practically 258:20
practice 48:19 78:14
 83:1
practices 220:16
 228:1
praise 15:1
praised 8:13, 16
pranger 20:11, 18
 214:1, 1
pranger's 13:10

pray 64:19	261:11, 12, 13	previous 13:16 18:13
pre 120:10 160:22	presentation 26:24	20:15 94:24
161:16 168:1 216:1	39:1 51:11 71:13	129:1 130:21
pre-harvest 85:19	79:20 88:1 109:1	131:18 139:19
pre-migration 19:19	117:1 124:23	157:1 236:1 247:13
pre-migratory 139:13	126:13 131:24	252:17 253:19
pre-plant 55:11 87:1	132:18 160:1 163:1	previously 39:22
pre-validated	164:20 167:1 201:1	41:18 205:1
34:22 35:10	230:17	prey 17:13 19:1, 11
precision 194:1	presentations 30:1	price 83:13 157:1
preclude 169:15	51:13 94:21 97:12,	primarily 3:21 57:24
238:22	15 102:1 116:1	68:11 73:1
precludes 35:1	226:23 247:14	129:21 148:21
preclusions 248:18	presented 22:1 23:19	primary 5:1 41:1
precocial 140:11	48:22 89:1 90:1	prime 74:1, 1
predation 162:24	101:1, 18 105:1	principal 5:11
193:20 242:1, 10	121:20 123:1	principally 220:25
predators 101:1	124:23 128:1	principals 57:24
243:19	130:24 132:17,	printed 85:1
predatory 20:22	24 134:18 143:10	prior 30:1 54:15
219:17	151:18 156:1 160:1	76:1, 23 229:1
predict 78:1 115:1	164:17 165:14	248:1
239:13	167:1 179:24 181:1	proactive 8:17 78:14
predicted 115:17	184:1 186:1	225:1
116:1	191:1 193:17 201:1	probabilistic 8:1, 1
prediction 137:1	203:22 215:22	93:1, 12 95:25
predictions 93:1	216:19 218:1 225:1	116:14 128:1, 17
95:1 113:25	253:1	142:12 151:18
116:1 140:22	presenting 93:19	152:11 155:1 182:1
181:12 203:24	212:1	188:1 204:1, 18
preexposure 108:1	presently 40:1 41:20	212:15, 21
preface 233:1	preserving 80:1	247:1, 13 248:17
prefer 37:1	president 39:10,	249:1, 1 251:24
preferable 31:1	23 51:1, 23	252:1
preferably 189:12	72:14 78:22 79:1	probabilities 250:23
preference 105:1, 1,	pressure 63:23 77:17	probability 130:25
14	86:1 88:22	135:20 147:1
preferences 185:1	pressures 216:11	240:24 244:13
preliminary 205:15	presumably 228:17	247:1
preparation 262:20	presume 34:23	probable 12:13,
prepared 2:20 8:1	pretend 118:10	15, 22 121:1
29:24 179:1	pretty 8:1 12:21, 21	228:10
presence 54:24	57:1 58:17	probably 8:1 63:20
105:16, 18 107:1	60:18, 24 106:11	67:14 71:15
149:16 248:20	114:20 148:12	72:24 74:11, 19
present 14:1 71:25	173:18 181:19	99:20 103:10 115:1
76:13 98:20	196:18 229:19	121:15 122:12, 15,
114:1 126:19	246:1	18 141:1, 10
129:19 160:1 164:1	prevent 49:11	169:13 176:25
211:25 230:12	80:10 81:1 227:1	187:10 189:1
248:1 254:1	preventing 110:23	198:16, 22
	prevents 53:23	201:12 209:23

227:1 242:15
 243:11, 21 254:1
problem 107:1 173:10
 186:13 187:10
problematic 34:1
 205:11 221:22
 226:16
problems 44:17 69:14
 81:1 239:18
procedure 35:11
 202:25 229:24
procedures 65:17
 132:1
proceed 29:1 181:20
proceedings 71:17
 211:1 232:21
proceeds 95:25
process 3:1 23:14
 34:1, 21 37:1
 53:11 73:20 85:1
 86:1 90:21 91:11
 126:12, 12 127:1
 136:1, 1 168:1, 1,
 22, 22 190:16
 198:1 199:15, 16
 203:11, 13
 209:1, 1 251:19
processes 46:13
 89:21 90:20
 91:11 132:1
 200:1 205:1 254:13
processing 41:24
 80:1 83:17
processors 46:1
produce 40:1 51:22
 60:1 62:1 70:18
 143:18 165:17
 204:10
produced 40:1
 85:1, 11, 14
producer 66:1
producing 85:15
 100:1
product 39:18 40:14,
 20 43:16 47:18, 21
 55:22 68:10
 73:1, 11 75:24
 76:1 77:1, 19 84:1
 87:21 88:18 146:20
 217:10 260:1
production 40:1,
 1, 1 46:11 52:1
 63:22 64:22
 69:1, 1 77:18,
 23 79:24 84:24
 85:11, 13, 23
productive 240:1
products 37:18 40:18
 42:1 43:21 44:1
 47:10 73:1 88:1
professional 77:1
professor 4:1, 12
 5:1, 22 6:1
 17:17 39:1
profitable 52:11
profits 83:25
program 16:12 20:1
 30:1 42:1 43:15,
 20 47:22, 23 49:15
 57:15, 23 58:14
 72:16, 19 78:11
 80:10, 25 81:1, 1,
 1 83:1 87:25
 144:24 145:15
 150:16 235:19
 256:18
programmed 87:22
programs 44:1 84:1
 110:21 214:16
 220:1
progress 258:1
project 197:1
projection 198:1
projections 181:1
 195:1 210:1
projects 23:1 220:1
promised 92:24
 261:20
promote 54:10
 89:22 225:1
promotion 51:25
pronounce 39:1
pronounced 39:1
pronunciation 235:1
propagation 160:13
propensity 234:19
proper 74:18
properly 75:15
properties 184:19,
 22 248:23
proportion 241:1
 243:15
proportional 229:1
propose 89:19 261:1
proposed 2:1 76:22
 220:14 227:1, 19
 247:15
proposing 35:18
 174:13 228:24
protect 54:1, 13, 19
 55:15 74:13
 173:1 260:1
protected 101:1
 213:1
protecting 51:1 55:1
protection 2:1
 5:25 9:1 33:10, 19
 40:18 45:1 48:25
 50:24 57:14
protective 31:17
 32:1 106:20 108:12
protocol 164:10
protocols 35:10
 172:17 243:1
prove 194:1
proven 48:24 109:21
provide 33:10
 57:15 91:14 129:10
 132:21 143:1
 145:22 151:1
 153:10, 22 154:1
 163:23 165:11
 180:1, 1 182:23
 183:1, 10 191:17
 192:1, 17 195:1
 204:1, 20 205:1,
 18 215:1, 1, 12
 224:17 225:13
 231:19 241:21
 247:21
provided 31:1
 36:22 86:15
 90:25 120:17 128:1
 129:1 131:11
 142:25 143:12
 151:23 154:1, 22
 158:17 160:1 163:1
 164:1 165:11, 17
 176:10 182:1 192:1
 207:1 213:1 214:18
 231:11 233:17
 247:1, 16
 250:11, 22 251:1
provides 31:11
 192:24 241:20

providing 90:22 240:1	1 86:1	24, 24 231:1, 1, 15 233:18 246:1
provisioning 100:23 137:1	<hr/> Q <hr/>	248:1, 1 249:1, 21 254:15 259:1 261:17
pseudocholinesterase 31:1	quail 140:12 197:22	
public 2:11 3:13 6:1 7:1, 15, 18, 21, 22 26:17, 24 38:16, 20 51:1 56:23 71:1, 18 72:1 81:1 89:1, 1, 10 91:1 93:17, 25 94:1 126:16 136:1 212:1 237:1, 16 247:15 251:18	qualitatively 184:1 189:11	questionable 108:22 187:15, 17, 19
publication 262:1	quality 23:15, 16, 25 33:19 45:18 47:25, 25 164:12 173:13 218:1 248:16 251:14	questions 9:1, 17 16:24 22:1, 1 29:1 30:14, 19, 21, 23 35:15 36:1 49:18, 23 55:18 57:1 64:23 65:1 68:13 71:1, 14 77:11, 12, 16 81:10 84:12 88:1 89:22 90:1, 1, 1, 15 91:1 92:1, 19, 20, 21, 23 104:13 106:1 110:1, 12, 15 116:10 117:1, 1, 1 124:21 125:1 126:10, 15, 25 127:1, 1, 20 134:25 151:12 160:16 175:1 206:1 213:16 225:12 236:22 248:1, 15 249:1 262:1, 19
publicly 26:1	quantified 224:14	
published 11:21 15:11 17:1 138:1 247:1	quantify 204:1 226:18, 21 233:22 234:1, 15	
puddle 94:17	quantitative 203:21	
puddles 149:17	quantitatively 151:21 251:11	
pulled 94:1 223:19	quantity 228:25	
pulling 161:11	quarter 66:25	
pumped 87:1	question 12:25 26:1 33:1 35:24 49:21 55:20 68:15 70:1 77:15 87:16 88:11 95:21 106:24 107:1 108:1 113:1 115:20, 23 117:17 123:22 124:1 127:1, 14, 22 128:1 129:1, 13, 16, 21 131:15 134:1, 14 140:19 146:1 150:20 151:1, 1 153:24 154:1, 11 156:21 160:11, 15 165:1 166:1, 11 172:1 173:21, 24 174:24 175:1, 10, 11, 16 176:1, 21 178:12 179:1, 12, 12, 20 180:20 183:21 185:10 191:1 195:10 203:19, 21 209:1, 1 210:1, 14 211:10, 12 213:13, 22 214:1 215:1, 10 222:1, 10 225:20 227:14 229:12, 24 230:14,	
pumps 74:22		
punch 27:11		
punctuated 96:1, 15		
purdue 56:13 125:14		
pure 70:1		
purely 122:15		
purest 258:18		
purported 163:1 191:17		
purporting 151:24 182:1		
purpose 21:23 140:13 193:1 196:1 255:11		
purposely 255:19		
purposes 94:24 217:11		
purse 70:1		
purview 256:1		
puts 51:1 67:1		
putting 67:22 187:17 211:21 229:1 237:19		
puzzled 200:1		
pyrethroid 42:23		
pyrethroids 43:1,		
		quorum 126:1, 1 quote 34:1 quoted 95:24 quotes 114:1 206:19

	rates 48:1 96:15	99:1 101:1 104:1
R	107:1 110:1 112:1,	106:19, 19
rachel 38:17	1, 17 113:19, 24	109:10 112:23,
radio 17:24 18:1, 16	137:18 153:1 191:1	23 113:1 114:22
235:12	198:25 199:1	117:18 118:24,
radiotelemetry 236:1	201:18 244:1	25 119:1, 1, 10
245:1	rather 14:1 77:25	122:10 125:18
rain 65:20	96:1 98:22 101:1	141:23 144:12
raise 81:1 206:1	127:21 157:16	148:1 149:1
213:16 245:16	162:20 185:1 196:1	156:1 157:15
257:1	201:15 207:1	160:19 165:23
raised 213:13 245:15	222:22 255:1	168:14, 24 171:1
250:25	rating 108:18	173:17 174:10,
raises 162:1	ratio 33:12, 17	24 178:1 184:10
202:12 236:21	rational 145:22	186:1 187:1 190:1,
raising 12:1 159:10	rats 34:13	21 197:1 199:14,
ran 95:1 103:15	raw 161:11 167:12	17 208:1 211:19
121:18	207:17	218:1 221:25
randomly 99:1 233:15	raymond 8:15	222:14 224:1
range 9:17 18:12	re 93:1	229:12, 25
67:16 113:18 138:1	reach 82:20 119:10	232:15 240:1 241:1
157:21 161:22	175:1 191:23 245:1	245:1, 1, 1, 20
163:17 182:17	247:17	253:25 254:21
183:22 204:1 205:1	reaches 24:22	258:22, 23
209:11 210:1	react 193:19	reapplied 23:1
256:18 261:25	reader 262:1	rearing 19:25
ranges 18:1 86:1	readily 184:1	reason 16:1, 1 36:19
185:14 213:1	reading 213:25	38:1 93:18 121:1
ranging 140:1	ready 27:1 201:11	178:11 227:1
rank 161:18	real 37:22 41:20	228:25
rapid 111:1, 10	61:1 64:21 86:13	reasonable 33:18
rapidly 112:19	107:13 141:1	62:16 118:12
137:24 216:24	173:17 179:12	137:1, 1 140:13
rapids 79:1 83:15,	197:22 200:1 258:1	157:1 165:15
16 89:13	reality 155:1, 1, 15	169:25 170:10
raptor 19:10	198:20 252:10	198:17 205:17
raptors 16:20, 22	realize 97:11 102:10	206:14 229:14
17:1, 12 19:1	106:16 112:19	238:1
rare 255:17	114:1 118:15, 18	reasons 61:1, 1
rarer 147:11	144:10 148:25	63:18 67:20 130:13
rat 180:14 193:16	189:21 190:10, 11	169:23 176:1
200:13, 15	realized 253:12	191:25 205:1
rate 82:16 98:1	realizes 39:21	232:20 255:1
103:1 106:1	realizing 69:18	reassessment 34:21
108:19, 25	really 17:11 20:10	recalculated 195:11
113:21 118:1, 21	22:1 25:17, 21	recall 94:1, 20
119:14 121:24	48:19 63:1 64:15	100:1 245:1
137:1, 10 141:22	70:15, 20 75:23	recap 90:18
165:18 177:21	76:11, 24 78:1, 10	recapture 238:15
199:18, 22	94:13 95:1 96:1,	244:13
201:19 234:18	13 97:17, 19	recaptured 237:21
		receive 48:1 80:22

90:21 162:22	166:1 203:1, 20	24 225:21 226:1,
received 30:1 89:1	213:23 246:10	24, 25 227:1, 1
111:11 151:1 176:1	257:18	250:14
213:1	recorded 255:12	reductions 107:1
receivers 211:1	records 11:21 12:1	110:19 217:17
receiving 192:1	14:1, 1, 12, 17,	redwing 255:18
recent 78:1 131:1,	23 15:17 16:21	257:15
14 132:1 133:15	17:1 24:1, 25 25:1	reed 5:24, 24
135:1 206:11	219:19	reexamined 138:1
214:23 224:20	recover 162:12	206:12
258:1	207:18 236:13	refer 36:19 232:1
recently 27:1	recovered 237:22	reference 160:1
48:21 197:17 250:1	238:1	referenced 40:11
receptors 133:11	recoveries 239:20	165:16
248:20 261:11	244:10	references 120:16
recited 237:21	recovery 103:1, 1	235:24
recognition 189:1	191:1, 17, 18, 21,	referencing 48:1
190:16 191:1	24 192:1, 1, 1,	referred 8:1
recognize 38:25	12, 23 193:1,	referring 77:1
130:1, 10 154:19	10, 13, 18, 24, 25	119:21 218:17
155:25 158:1 166:1	194:1, 14 195:1	refine 138:19 187:18
174:16 181:16	197:14, 18 198:1	reflect 8:18 22:24
182:1 185:1 189:10	199:1, 12 206:1,	126:25 131:23
232:1	11, 16, 21, 23	135:18 210:1
recognized 40:16	209:21 233:25	213:20
130:1	244:1, 1	reflected 25:1
recognizing 174:1	red 17:1, 18 18:1,	156:16 219:1
181:21 189:1	1, 1, 18 31:1	reflecting 254:19
recollection 8:10,	32:10 33:14 43:1	reflection 48:1
25 149:1	75:1	217:1 245:20 255:1
recommend 34:1	redeye 26:21	reflects 144:1 154:1
63:1 66:15 84:1	reduce 21:14, 18	217:10
132:1 200:1	40:1, 1 73:1 182:1	reforms 96:1, 11
recommendation	196:16 200:25	refuge 16:16
8:11 67:1	217:15 222:20	80:11, 12, 18
recommendations	reduced 31:1 72:21	81:1, 1, 11, 14,
8:20, 22 66:1	87:19 88:19 107:12	17 83:1, 1, 11, 11
128:1, 10, 13,	108:11 109:1	84:1, 1
24 129:1 131:1, 22	152:12, 14, 23	refuse 126:1
134:15, 21	209:22 218:18	regard 12:25 21:22
136:18 139:19	219:25 220:1, 1	71:1 89:11 92:22
140:18 172:19	reduces 109:1	94:1, 21 95:13, 21
245:19	reducing 21:23	101:18 106:1, 1
recommended 94:17	77:1 83:11 87:1,	110:19, 22
95:14 98:1	12	111:12 114:1
100:1, 12 197:1	reduction 21:10	118:17 149:16
recommending 34:23	47:25 74:1 86:22	178:23 179:23
37:15 66:22 84:1	103:19 106:14	201:1 210:17
200:23	107:1, 15 108:1	regarding 32:1 140:1
reconsideration	109:24 124:1	182:1 183:1 192:1,
210:15	171:14, 17, 22	1, 22 231:16
record 14:1 127:1	214:25 215:16,	

249:21 250:22
 252:1
regardless 105:1
 118:15, 16
 147:25 160:1
 168:13 236:19
regards 93:16
 96:11 97:1 99:1,
 15 104:13
 107:18, 21
 110:15 112:25
 179:11 201:1, 18
 241:16 243:1
region 31:20 65:1
 85:15
regional 32:23, 23
 33:15
regions 44:15
register 89:1
registered 9:13 15:1
 16:12 26:23
 55:21 88:1
 110:1, 1 111:16,
 19 215:1 220:13,
 16 225:15
registering 37:1
registrant 16:18
 21:25 22:1 38:12
 131:11 132:10
 134:18, 20 135:1
 136:1 137:1 143:13
 163:25 172:1
 176:22, 23 205:1
 207:1 209:1 215:19
 216:1 218:20
 236:24 247:1
registrant's
 199:10 213:1
registrant-
provided 152:25
registrants 25:15
 36:22 136:1
 212:1 217:19, 22
registrar 15:1, 1
registration 36:23
 38:11 44:14
 47:20 84:1 132:1
 220:14
regression 106:1,
 12, 17 108:20, 25
regressions 106:23
regular 164:15

233:18
regulated 190:1
regulation 138:13
 246:1
regulations 37:1
regulatory 4:23 13:1
 136:13 190:1
 215:18 218:14,
 21 219:20
 227:21, 23
 241:17 245:21
 250:15
reinforce 134:1
 172:10
reinforces 33:1
 186:1
rejected 41:25 216:1
rejoinder 181:18
relate 97:1 135:15
 151:13 155:1
 176:20 208:1
related 25:23 33:1
 50:12 91:1 104:10,
 25 105:16, 17
 106:1 107:1
 132:1 135:1 154:11
 214:24 216:15,
 20 218:1 236:20
relates 95:22
 97:1, 22 118:1,
 1 119:14
relating 219:1
relation 205:19
relations 184:18
relationship 40:12
 152:11 161:1
 168:16, 20
 184:21 185:1
 198:21 221:12
 229:1, 11
relationships 103:11
 152:23
relative 94:11 122:1
 161:14 165:21
 181:11 186:1 215:1
 230:1 233:23 244:1
relatively 60:24
 72:25 154:18 221:1
 237:1 238:1
relaxed 218:16
release 74:22 128:21
released 94:1

relevance 201:1
 261:23
relevant 64:11 71:16
 126:15 139:1
 141:13 151:17
 159:19 166:17
 176:1 189:1
reliable 34:22 37:22
reliance 31:16 32:20
 34:1 35:1 130:1
relied 42:1 201:19
 233:1
relies 101:1
rely 56:1 226:21
relying 240:1
remain 78:1 126:1
 159:21 228:19
remaining 2:11
 32:1 76:1, 22
 134:25 140:1 228:1
 262:1
remains 201:1
remedy 53:18
remember 8:15 9:11
 52:24 66:1 93:1
 97:24 100:12
 102:19 103:14
 108:21 110:25
 112:24 114:14
 118:1 125:23, 24
 194:22
remind 202:22
reminder 212:1
reminds 59:16 173:11
removal 109:16 115:1
remove 115:1
removed 45:15
 109:1 164:17
 220:14
rendered 46:1
repeatability 34:24
repeated 249:14
repeatedly 47:11
 95:10
repeating 178:1
repellency 105:24
 156:22 157:1, 1,
 15, 20 161:13
 164:1, 11, 24
 168:1, 1, 18
 169:14 171:15

repellent 169:22	163:1 184:10 205:1	5:1, 18 6:1, 16
repetitively 209:20	represented 16:20	29:14 36:21, 22
replace 47:1 54:1	17:1, 1 18:13	46:21 48:21 125:15
55:14	99:25 134:16	201:1
replaced 47:19	representing 7:23	researcher 48:21
replacement 87:16	14:23 26:18	187:22
replacing 83:1	29:23 38:17, 21	researchers 46:17
replicate 123:1	39:1, 12 78:21	47:1 235:1
replicated 207:1	98:18 153:1	researches 237:16
report 10:22 24:24	represents 10:15	reservations 136:10
71:16 93:19	13:21 14:18 24:1	reserve 16:12 256:18
97:16 110:23	98:16 112:1	reserves 19:21
111:11 138:19	114:1 197:1	residence 143:1
160:1 161:1 165:14	reproduction	resident 94:1
214:18 220:11	101:15 116:13,	residents 103:1
237:13 238:13	22 159:1 245:13	residue 10:21
reported 10:21	reproductive 76:14	12:14 18:12
14:14, 15 20:23	101:14 133:17	23:23 48:12 109:12
22:18 23:22 143:20	reputation 196:14	142:1, 14, 20,
160:1 204:12	request 24:10, 17	22 143:11 145:1
214:11, 20, 23	38:1, 1, 12 77:21	146:15
215:24 218:1	requested 17:17	residues 12:18 18:11
219:1, 12, 14	require 35:1 37:1, 1	21:24 22:1, 1
237:17	81:1 152:22 162:10	35:1, 1 118:18
reporting 20:19	177:24 202:1	119:15 133:10
21:1, 1, 1 24:1,	203:16 238:12	142:23 144:11
23 25:14 110:20	required 34:20	145:1, 1, 1
111:1 215:1, 19	requirement 20:19	resist 189:16
217:18, 21, 25	203:16	resistance 39:20
218:1, 15, 17	requirements 21:1, 1	41:1 43:25 44:1,
219:21 220:21,	80:18, 19 81:1, 18	10, 12, 13, 19, 21
22 221:1, 11, 13	83:1 96:1 108:13	45:11, 14, 19,
224:12 225:1,	109:1 215:18	21 47:12, 17, 23
10, 22 226:16	217:18, 22	48:23 49:1, 11, 15
229:1, 10 239:15	218:16 250:15	50:15, 20 51:1
250:16	requires 80:11 81:1,	61:1 62:1 69:15
reports 10:12 20:12,	11 137:22	80:10 81:1, 1
14 22:13, 16, 19	requiring 37:1	83:10, 12 86:12
23:14, 20, 20,	reregistration 34:21	resistant 44:17 49:1
20 24:16 48:1	35:10 151:19 191:1	61:1 69:18 80:1,
110:1 111:15, 18	204:12 231:1	15 81:1 84:1 87:24
164:1 214:10	rescue 29:1 46:1	resolution 205:1
215:20 217:20	49:12, 14 50:1	240:14
218:1 241:23 247:1	58:24 62:19, 24	resolve 173:14
249:1 253:1	63:1 64:13 68:1	resource 96:16 220:1
represent 17:11	69:16 76:11 77:24,	resources 26:19
96:25 97:17 102:21	25 79:15, 21	29:23 30:1 66:1
130:1 142:14	82:12, 22 83:1	110:23
155:1, 15 198:20	84:1	respect 32:11
representation 97:1	rescued 28:12	65:25 120:23 131:1
representative 29:13	rescuing 77:22	157:1, 12, 13
79:1 98:1 101:10	research 3:22 4:18	159:23 166:1

174:21, 23 185:1
 188:11 194:1 253:1
 259:20, 22
respond 39:1 201:1
 208:17
responded 121:22
responding 176:1
response 9:1 32:1,
 10, 15 87:18 109:1
 111:1, 10 115:1
 119:11 122:1
 126:25 135:18
 148:11 154:1, 15
 156:17 157:23
 158:13, 15
 160:21 161:1
 162:1, 1, 21
 163:24 171:17
 172:1 179:16, 19
 210:13, 17
 211:11 213:13,
 16 215:1 245:12
 261:25
responses 8:11 30:22
 108:13 161:1 162:1
 182:17 193:13
 210:1 258:1
responsibility
 2:25 3:1
responsible 77:1
 217:19 224:24
 225:1
rest 84:1 105:11
 114:12 140:1 146:1
 170:23
restrict 43:1
restricted 88:1
 260:21
restriction 87:19
restrictions
 215:25 216:16
 217:23
result 28:1 46:1
 47:21 48:11 49:1
 96:14 103:20
 108:11 111:21
 116:21 124:23
 130:25 132:1, 1
 135:21 142:15
 148:1 159:15
 164:18 193:1 196:1
 202:1 205:10, 15

206:13 218:1
 236:15 245:10
resulting 46:15
 50:14 130:21
 135:1, 13 217:1
results 21:16 35:1
 80:15 113:21
 129:1, 1 130:20,
 23 131:12, 17
 132:1 137:15
 140:20, 25 141:1
 143:22 151:13
 155:21 156:1
 157:1, 1, 16
 158:1, 1, 1, 1
 159:23, 24
 160:1, 1, 10
 164:1, 16 165:12
 167:1, 1 171:13
 172:1, 1, 22
 179:13 180:1
 182:15 184:1
 188:12 191:20
 203:22 204:1
 211:24 242:19
 247:1 249:17
 251:23 253:11
 259:23
retailer 72:1, 1
retain 126:1
retention 85:1
 134:19
retrieve 10:1
return 7:1 176:1
 181:21 191:1
 210:20, 24 233:1
returns 83:21 134:24
reuse 67:1
reveals 160:20
revenge 67:19 78:13
reverse 47:15 124:17
review 37:24 90:22
 91:1, 11 128:20
 129:1 130:19 131:1
 136:1, 1 137:1
 142:21, 25
 151:13 172:21
 213:18 251:19
 261:23
reviewed 48:18
 120:14 128:14
 137:1 151:10 152:1

191:19
reviewing 123:1
revisit 117:1 126:22
 230:10 262:10
revisiting 230:15
rewriting 202:1
rice 82:14 224:1
rick 56:13
rid 9:14
rights 184:25
rigorous 242:24
rinse 73:1 74:1
ripe 19:1, 1
risk 5:13, 16 6:1,
 13, 18, 21 8:1, 1,
 19 20:10 21:13, 18
 34:11 76:1, 1, 20,
 21 82:17 83:1,
 11 87:1 90:1, 1,
 14, 23, 24 95:1,
 1, 1, 25 109:17,
 25 115:18, 20
 126:10 128:1, 1,
 17 129:1, 1, 23
 130:1, 1, 1, 13
 131:19 132:1, 24
 133:1 134:11, 13
 135:19 136:12,
 15 141:14 143:24
 151:1, 12, 14,
 18 152:10 153:22
 154:12, 25
 155:1, 1, 24 156:1
 157:14, 25
 162:15 163:19
 164:18 179:21
 180:23, 23 182:20,
 23 183:10 187:22
 192:1, 17 193:22
 194:11 204:1,
 15, 19 205:20
 208:11, 15 210:1
 212:1 213:1
 215:1 225:15
 231:14 240:23
 241:16, 17, 19,
 20, 21 246:20,
 21 247:1, 1, 13,
 19 248:15, 17, 20,
 23, 25 249:1, 1,
 1, 1, 12, 18
 250:1, 1 251:11,

24, 24 252:1, 1
 253:1, 1, 1, 22,
 24 254:1, 1, 11
 256:1, 23
 257:17, 20
 259:1, 13 260:1,
 17
risks 31:13, 18
 32:11 34:14
 35:12 52:1 84:1
 115:1 128:1
 131:1 140:1 141:10
 189:1 205:18 228:1
 246:18, 23 247:10
river 43:1 84:21,
 21, 24
rivera 236:1
riverside 4:13
road 201:13 212:19
 258:19
roads 18:1
robust 31:1 35:1
 37:1 38:1 133:1
 152:1 180:10
 241:10, 22
rodents 34:17
role 63:1 181:23
roll 87:1 182:1
rollins 6:1
roman 142:1
room 72:24 212:1
 263:1
roosting 12:1 19:22
root 27:10, 12,
 16, 18 28:1, 1
 34:18 35:1 37:21
 57:16 58:1, 1,
 1, 11, 22 59:14,
 17, 20, 23 60:1
 61:1, 10, 17,
 20, 21 62:1, 15,
 20 63:23 64:17
 66:17, 21, 21
 67:17 69:13, 24,
 25 70:1, 1
roots 28:1, 1, 1, 1,
 11, 14 52:14, 16
 59:14, 22 60:1, 1,
 1 64:18
rootworm 76:10
 77:1 79:16 81:1,
 16 82:1, 10, 17
 83:1, 1, 10 84:1
rotate 45:1, 1
rotating 87:23
rotation 43:19 69:22
 86:17
rots 60:1
roughly 54:1, 23
 58:1
routes 128:11
routine 41:12 94:16
rq 9:1 21:12
row 53:1
rows 87:14
rqs 21:14
ruby 5:24
rule 111:21
rules 63:14
run 67:1 90:1 94:1
 95:1 98:21 99:1
 102:10 115:1
 117:20 121:25
 122:16 161:1
 190:18 233:1
running 67:1
 102:12 122:23
runs 93:23 132:1, 1,
 25 145:20 152:11
 208:23
rush 92:13
rushing 101:1 181:15
rusty 64:1

 S

sacrificed 134:23
safe 55:12 77:1
safeguards 80:1
 217:14
safely 77:1
safety 21:22, 23
 33:12, 20 72:18
 145:23 146:1
saint 84:19
sake 220:10
sales 13:1 224:22
salice 127:1, 1, 12,
 16, 24, 25
 142:1, 1 145:1, 1,
 1, 13 151:1, 1
 153:16, 17 181:22,
 23 191:1, 1 195:1,
 1, 13, 15
 203:19, 21
 209:1, 24, 25
 210:12, 18
 213:23 229:18
salice's 109:1
sample 5:14, 14
 49:21, 22 50:1,
 12, 19 102:1
 129:13, 14
 143:1, 1 149:11,
 25 161:10, 11
 162:1 167:22, 23
 177:14, 15
 182:13 183:17
 185:22, 23 193:1
 197:1, 1 208:1, 1,
 24 212:24, 25
 235:24 239:21
 260:1, 1
sampled 100:1
samples 17:23, 24
sampling 100:1 194:1
 235:21, 23
sap 2:1 34:1, 1
 38:25 91:1 94:17
 95:14 96:22 97:1
 98:1 100:12, 18,
 21 103:23 121:21
 128:14, 20, 24
 129:1 134:16
 135:11 137:1 142:1
 151:1 156:1 165:12
 172:20 176:1
 181:24 190:14
 191:12 201:18
 202:21, 21
 204:16 205:1
 215:22 231:16
 248:15 251:1, 13
 252:1
sap-reviewed 247:1
saps 91:17 130:21
 131:1 236:1
sass 26:18 29:21,
 22, 22 30:1, 1
 36:1, 1, 1, 17
 37:20 38:15
sat 63:25 117:23
satisfied 210:13, 18
 229:18
saturated 203:14
scalable 100:1

scale 97:24 128:1
 177:19 228:13,
 20 229:1 240:14
 259:25 260:1, 1
scales 260:12
scatter 106:10
 108:21
scattered 158:1
save 55:1, 1
saves 54:25
savings 86:20, 21
saw 51:13 70:1 73:16
 109:1 113:10, 14
 115:1
scenario 45:25
 63:12, 19 68:1
 132:1 162:14, 18
 198:1 207:1 237:1,
 11
scenarios 70:1
 128:23 130:24
 205:21 253:25
scheduled 2:21 38:20
scheduling 7:16
schertz 72:1, 1, 1
 77:10, 11 78:1, 19
schlenk 4:11, 11
 199:1, 1 202:1
schlenk's 203:11
school 6:1, 20 88:1
science 3:16, 19 8:1
 72:1 89:20 127:1
 151:19, 20
 156:1, 1, 12
 188:17 189:18
 190:22 191:1
 204:13 231:1
 258:18
sciences 4:13
scientific 2:1, 1, 1
 3:1 30:24 32:1
 34:25 49:16
 51:19 89:24
 90:1, 21 91:1,
 1, 12 92:1 125:1
 126:1 128:1 130:19
 156:16 157:19
 172:21 184:14
 190:1 205:1 253:15
 254:22 258:1
 261:22 262:1
scientifically 31:12

130:10
scientifics 258:13
scientist 30:1, 18
scientists 156:13
 189:18 258:1, 20
 259:1
scope 72:17 91:13
 235:17 260:1
scott 72:1
scout 57:16, 18
 58:1, 15 59:14
scouting 48:15
 58:1 59:12
 78:11, 15
scrape 83:20
screen 75:10 152:1
 153:1 157:11
screening 172:1
 208:12 245:1, 1
 249:1
se 221:21
seam 133:12
search 114:1, 1
 140:1 233:14 234:1
 236:15, 19 239:1
searched 233:11
searchers 234:16
searches 124:1
 236:12
season 41:12 43:1,
 13 55:1 76:18 82:1
 85:24 88:24
seasons 140:1
seats 125:1
seattle 61:13
second 42:16 57:20
 72:1 75:17 81:14
 87:21 95:16
 147:1 148:1 185:15
 194:1 210:23
 225:13 249:1
secondary 102:1
 162:23 193:19
secondly 23:1 171:17
 203:1
secretive 237:1
section 67:1
security 72:19
sediments 243:1
seed 27:11 40:1,
 1, 1, 10 53:1, 1

57:1 58:19, 19, 20
 59:11, 11 61:25
 69:1 80:19 81:22
 82:1, 1, 12
seed-applied 57:25
 58:18 59:1
seeded 234:18
seeding 234:1 235:1
seedlings 53:1 54:1
seeds 184:12
seeing 24:19 50:15
 76:25 113:1
 162:1 197:21, 23
seem 74:1, 1 108:1
 169:25 184:13
 222:14
seemed 138:20 170:18
 200:23 228:1
seemingly 196:1
seems 62:21 108:1
 123:1 140:24
 141:12 149:23
 170:20 177:1
 187:18 198:20
 222:17, 22
 226:14 228:24
 239:1
seen 19:1 20:1 44:20
 48:15 58:12
 59:1, 1 61:11
 62:14, 17 64:1
 72:20 77:20
 97:10 111:17
 123:23 130:15
 146:1 157:1, 1
 165:1 188:1 219:22
 241:22 257:19
 260:16
seiber 17:18
select 16:1 19:1,
 1 104:1
selected 30:23
 99:1 105:1
selecting 45:1
selection 25:25
 104:17, 25
selective 158:20
selectively 221:15
self 238:13
sense 60:11 173:16
 174:20 195:1 224:1
 232:11, 18

258:18 261:12
sensitive 9:10 93:24
 140:23 141:1
 163:1, 1, 12
 196:12 229:13
 241:1
sensitivity 93:20
 135:18 140:10
 180:1, 12 183:21
 185:12 198:17, 19
sensory 4:19
sent 80:1 82:14
separate 14:18
 94:1 109:19 200:10
 250:17
separation 142:1
september 52:1
sequence 29:22
 181:19
serious 38:1
 109:23 160:11
seriously 3:1 44:20
serve 8:1
served 34:1 39:10,
 22
serves 121:21
servi-tech 56:24
service 82:24 255:22
services 72:1
session 7:11 63:25
 125:1 263:1
sessions 8:1 39:1
 57:1
sets 95:1 142:22
 182:1 193:1 203:23
settled 209:10
setup 158:1
seven 14:24 47:12
 57:1 206:22
seventy-four 114:17
several 18:25
 52:22 56:1 68:13
 75:25 78:1 138:1
 157:12 168:10
 173:16 214:21
 219:1, 24 255:1
 262:25
severe 44:17
 116:18 251:1
severely 28:21 219:1
sexes 193:1, 10
shaded 114:1
shame 21:25 225:1
shape 66:25 106:12
shared 72:13 126:21
sharp 71:20
sharper 122:1
sheet 65:18 76:25
sheets 44:21
sheltered 101:1
shift 49:1 50:24
 89:18
ship 52:1
sic 108:10 233:10
sick 104:1
shoes 64:1
shorebirds 20:21
 139:1 203:1
short 71:18 85:23
 88:23 96:1 97:25
 103:17 139:25
 154:18 183:15
 186:25 210:12
 230:25
shorter 47:1 209:21
shortly 98:1
 141:17 216:1
 222:11
shovel 59:15
showed 168:19
showing 86:11 162:10
 207:20 213:1
 225:1, 1
shown 62:1, 1
 81:23 116:12 143:1
 169:14 190:15
 224:22 225:1
shows 11:15 20:13
 21:13 54:1 73:21
 75:11 80:16, 25
 82:15 114:11
 138:15 199:11
 212:16 242:20
sides 250:25
sift 59:22
sight 170:1 252:19
signal 235:16
significant 135:12
 161:1, 21 162:1
 173:1 218:1 236:25
 247:18 252:1 253:1
 256:11 260:1, 19
significantly 204:17
 205:22 249:13
signs 54:1 159:24
shuttles 87:1
silent 226:11
similar 42:22
 43:16 44:1 96:20
 114:21 130:24
 131:1 164:18
 171:18 172:1 182:1
 224:1
similarities 136:1
similarity 115:1
 131:1
similarly 217:17
simple 100:14
 113:1 177:20
 180:15 196:1
 222:17 223:1, 20
 235:1
simpler 203:15
simplified 235:1
simplifying 121:10
simply 36:25 63:11
 100:15 222:19
 230:13
simulation 186:15
 200:1
simultaneous 135:1
simultaneously 206:1
 208:1
single 16:1 34:1
 35:1 47:1 50:1,
 1 95:1, 1
 104:20, 24
 111:11 117:24
 140:25 141:1
 179:16 206:16
 207:1, 1 237:11
 256:1 260:13
sit 259:19
site 19:13 20:1
 129:1 191:14
 203:25 204:20
 234:20 246:19
sites 110:11
 131:21 182:18
 233:16 234:12
sitting 57:1 248:1
situation 28:20
 99:21 159:16 169:1

172:22 187:19
 227:1 236:1 239:11
 257:13
situations 98:1,
 19 116:18 141:1
 155:18 159:18
six 18:1 34:10 51:14
 57:1 59:20 66:17
 86:13 104:20
 105:1, 1, 1, 10
sixth 52:1
size 16:24 112:18
 142:19 183:18
 244:12
sizes 182:13
skin 37:19
skip 32:1
skipping 30:16
 202:10
sklarczyk 38:21,
 24 39:1 49:20
 50:1, 1, 17, 21
 51:1
slice 221:15
sliced 111:23
slide 28:1 55:20
 73:1 132:17 199:11
 220:11
slides 9:19, 21 11:1
 120:12
slight 94:15 238:11
slip 222:1
small 13:14 17:14
 51:20 53:1, 24
 54:1 60:24 65:13
 76:23 78:1
 139:15 182:13
 183:17 207:1
 212:12 226:25
 235:13 236:1
 237:10, 14, 24
 238:1 240:11
 257:10
smaller 28:14
 42:22 228:1
smallest 138:1
slope 197:15
slopes 187:1 197:14
slower 246:18
slowly 155:1
slows 18:22
snack 40:14
snake 84:21, 21
smoke 74:22 75:1
smokers 74:1
society 4:1
softer 49:10
soil 52:13, 20 54:24
 55:11 56:1 58:21
 59:21, 22 66:17,
 18, 19 85:1
 86:1, 18 87:1
soil-applied 86:25
sold 35:19
sole 31:16 32:20
 39:12 130:1
solely 167:14
solution 78:17 177:1
solutions 76:25
space 100:1
spacing 75:21
span 67:11
sparling 5:17, 17
 22:1, 10, 10, 15
 23:1 149:10, 12,
 12 210:10 219:1,
 1, 1 220:23
 241:13, 14
 243:23 254:17, 19
sparrow 112:13, 13
 123:14 256:14, 16
sparrows 112:20
 256:21
spatial 133:1, 1,
 1 229:1
somebody 9:20 104:21
 149:1
somebody's 235:1
somehow 106:20
 108:12
someone 11:1
somewhat 105:10
 209:15
somewhere 53:13
 150:16
songbird 20:21
songbirds 162:21
 237:10 242:16
sooner 216:23
speak 27:18 71:15
 78:25 125:23 212:1
 247:24 248:1
speaker 56:23 125:19
speaker's 72:1
speakers 81:1 125:1
speaking 79:1 187:25
 215:10 226:19
 232:12 258:20
special 6:18 7:1
 47:19 52:1 126:1
specialize 5:1
specially 219:14
species 10:20
 12:1, 1 14:1
 15:14, 15 16:1
 17:1, 1, 1, 1, 1
 19:1, 1, 18 20:22,
 23 25:25 41:1, 1
 62:1, 1, 21
 96:19 100:10
 102:20, 21, 21, 23
 103:1, 1, 12, 20
 104:1 108:24
 112:12 113:1, 1,
 1, 1, 13, 15,
 18, 20, 21, 22
 116:1 121:1 122:23
 123:13, 17 124:1
 129:1 131:20
 133:18, 19
 135:14 140:11
 141:1 151:24
 157:21, 23, 24
 158:1 162:20, 21
 163:1, 1, 1, 1,
 12, 13, 17 166:11,
 16 179:17 180:1
 182:1, 17
 183:20, 22
 184:11 185:10, 11,
 14 186:19 198:25
 204:19 205:1
 219:16, 17
 240:12 241:1, 1,
 1, 1 244:12 247:19
 252:1 255:25
 256:1, 1, 1, 11,
 12, 25 257:1, 1,
 10, 18, 21 258:16
specific 16:1
 36:25 44:19
 71:14 90:1
 113:15 122:23
 123:13 126:1

205:19 223:14	southern 5:19	85:16 86:1 90:17
241:17 242:25	22:11 149:13 219:1	156:1
specifically 30:14	southwestern 51:23	starting 60:1
36:15, 20 206:17	spoke 26:20	67:24 255:1 259:1
215:1 223:1 225:16	spots 18:15	starts 122:10
231:15	spotted 53:15	stasis 124:1
specimens 20:20	soybean 69:19, 21,	state 3:24 6:11
spectrum 40:23 42:1,	22, 25 70:1 77:24	7:1 22:20 27:1
22 43:17	soybeans 69:20 78:1	43:1, 1 57:1, 17
spectrums 43:24	spray 19:24 54:12	69:11 82:14
speed 75:1	55:1 74:12 243:1	111:1 125:23
spend 65:24 99:1	sprayed 18:10, 12,	159:24 215:16
101:1 138:11 148:1	14, 22 78:1 256:20	218:1 220:1, 18,
257:1	sprayer 87:11, 11	20 225:1 232:1
spending 121:1	sprays 17:23 55:1, 1	250:14
spent 110:1 111:23	86:10	state-conducted
149:1	spreadsheet 28:18	231:1, 10, 17
sophisticated 141:1	spring 140:1	232:1
sore 57:1	springtime 89:16	state-sponsored
sorry 10:1 30:1	square 18:1 67:1	214:16
50:17 125:16 233:1	stable 31:1 219:25	stated 68:21 79:1
255:11	stack 61:25 173:25	82:1, 13, 23 93:16
sort 9:17 10:10	staff 2:15 125:1	110:22 146:14
23:14 58:15	stage 59:13 76:14	statement 79:14
68:23 91:17	stages 34:20 101:15	93:15, 18 176:1
92:22 94:25 102:10	stake 130:20	220:19 225:18
129:14 132:21	staley 80:1	229:19 238:18
150:1, 12 165:1	stamps 141:22	statements 100:21
168:1 170:1 177:16	stand 189:18	126:18 151:1
184:21 195:1	standard 24:23	232:24 238:16
198:16, 21	145:1, 1, 1, 1	246:1
199:20 210:1, 15	167:1, 1 178:1	states 10:12 39:10
211:23 213:1	202:25 213:14	40:1, 11 41:19
240:25 260:11	256:1	45:16 77:18
sorts 60:1 62:14	standardized 177:1	79:24 85:12
68:11 132:18	233:13	96:13 220:1, 21
169:10 170:1	standing 65:21	static 100:15
232:23 240:15	244:19	statistic 144:22
241:1 254:12	standpoint 74:15	statistical 173:10
spider 41:15	106:20	235:20 253:16
sought 135:1	stands 227:1 228:24	statistically 255:1
sound 31:19 130:10	starlings 234:24	statistician 3:21
153:19 163:21	start 27:1 58:1	4:1
183:1 192:13, 24	112:12, 16	statistics 4:1
194:1, 12, 18	113:20 129:14	6:1, 1 7:1 187:1
sounds 262:1	146:23, 25	status 12:1 17:10
source 11:20 80:20	154:14 201:11,	87:25 120:22 159:1
sources 152:1	13 210:25 213:10	statutes 91:19, 20
224:1 239:1	231:21 234:1, 1	stay 2:18 19:15 48:1
south 19:17 236:1	240:10	66:1 67:1 90:1
southeast 85:22	started 26:1 52:22	181:16
		stays 71:19

steal 241:15 28:1 55:10 61:22 250:20
stefy 82:23 219:18 **struggle** 190:1
stensen 114:16 **substantially** 219:13 252:25 253:15
step 98:13 117:24 222:19 228:1 **struggles** 255:22
118:20, 20 **substituted** 222:1 **sugar** 15:13 92:13
120:13 130:1 223:1, 19 **suggest** 132:22 133:1
147:1, 1, 25 154:1 **substitution** 61:1 172:1 201:12 206:1
165:1, 14 166:1 222:17 223:23 235:1 238:1
170:10 175:15 **subsumed** 111:1 **suggested** 29:14
176:12, 23 **stop** 175:17 190:11 109:21 134:24
177:10 178:16, 21, **stopover** 12:1 257:1 135:11 142:1
22 179:1, 10 **stopped** 225:19 172:12 184:1
188:14, 15 **storage** 10:1 191:12 206:14,
189:20 209:12 **storm** 89:14 18 224:21 243:15
210:1, 1 218:10 **story** 27:1 97:20, 21 255:10
steps 95:12 98:1 237:1 **suggesting** 162:14
100:1, 1 104:20 **suggestion** 203:11
121:23 128:11 **suggestions** 48:18
191:11 50:13
stepwise 130:14 **suggests** 48:23
steve 3:18 6:23 7:1 116:19 171:21
stewardship 72:16, 18 111:13 215:16 236:18 237:23
216:1, 12 217:14 253:1
224:23 226:1, 18 **suitability** 129:23
227:1 250:14 **suitable** 19:1
stimulate 64:17 96:16 152:1
stinchcomb 5:21, 21 **stuart** 4:1
sub 144:20 165:1 **studies** 31:11
subject 35:1 34:17 35:1 36:1
135:23 160:12 48:12 91:23
subjected 243:16, 17 93:1, 12, 13
sublethal 19:1 110:1, 1 111:22,
162:11, 23 22 112:1, 1 113:23
170:19 209:19 114:1 120:1, 14
submit 38:12 126:20 123:1 137:1 138:1,
22 139:1 149:18
submitted 10:13 151:1, 1, 10
23:15, 21 152:1, 1 155:17
157:10 191:16 157:1 170:1 182:1,
204:10 209:1 10, 16, 21
249:14 183:1, 1, 1 186:24
submitting 136:1 187:1, 1, 1, 17
subpart 129:13 188:18 192:12,
14 193:1, 16
subparts 127:24 194:1, 1 197:17
subsequent 35:1 200:1 205:25
102:18 118:19 206:1, 1, 12 209:1
128:20 135:23 218:23 231:1, 1,
143:22 1, 11, 13, 17,
subset 43:22 76:1, 18 232:1, 1, 1, 23
23 128:22 233:1, 19 234:1,
substantial 15:19 15 235:19 236:1,

1, 21 239:14	168:1, 1, 1	221:1, 20
240:1, 17	sure 2:19 3:1 15:22,	224:12, 12 227:21,
241:22, 23	24 23:18 24:1,	24 229:13
242:24 243:10,	22 26:1, 25 57:1	systematically 90:1
12 244:15, 23,	79:21 92:16	systematist 251:1
25 245:1, 1, 11,	94:12 95:1 96:17	systemic 40:25 66:20
17, 23 247:1 249:1	99:19 100:19	87:21
250:1, 19, 20,	101:1, 1, 1 106:10	systemically 55:24
21 251:1, 18, 25	107:17, 22 108:14,	systems 73:17
253:1 260:16	23 117:1 126:1, 22	196:1 224:1
stuff 166:1 170:24	166:15 172:11	260:14, 23
200:14, 21	180:17 202:1	
summarize 248:1	210:16 211:1 215:1	T
summarized 248:11	222:1, 10 226:10	tab 143:1
summarizing 93:20	229:18 241:16	table 21:12
252:16	244:18 260:1	tactic 45:12
summary 84:15	surface 184:1	tactile 169:1
87:15 90:13 126:18	surprise 39:1	tail 15:1 17:10,
191:1 251:1	surprises 30:11	18 18:1, 18 67:1
summer 67:11 140:1	surveillance 218:13,	224:17
sun 95:20	23	tails 18:1 122:10,
sunflower 40:13	survey 74:10 80:16	11, 17
sunflowers 257:1	123:15, 16, 17	take-home 94:1
sunrise 95:16 98:1	surveyed 80:17	111:25 112:25
sunset 95:17	surveys 235:22	takers 83:12
style 70:10	survival 173:12	taking 115:1 124:1
styled 30:14	survive 162:23	140:25 177:1
super 105:1 106:19	169:24 205:1	178:23 187:12
256:1	survived 242:1	205:14, 16
supersede 30:1	surviving 191:23	208:1, 13 244:25
supplied 232:1	susceptibility	talk 8:1 10:1 16:1
suppliers 46:13	193:20	41:1 64:1 93:14
supplies 115:11	susceptible 20:1	102:1, 12 110:11
support 31:1, 14	suspect 77:18	125:1 129:19
33:1 129:1	89:14 103:1, 12	156:18 213:10
131:18 133:20	sustain 241:10	259:10, 19
142:24 216:20	sustainable 70:12	talked 21:1 60:1
225:1 231:13	255:20	61:1 75:23
249:18	swallow 60:18	103:22 104:22
supported 128:1,	switched 81:22	110:17 114:23
15 143:1	symptomless 40:1	127:13 180:21
supporting 137:1	symptoms 17:19 160:1	224:23 242:13
215:22 247:11	206:17	258:10
248:12	synopsis 92:1 248:1	talking 59:24 64:1
supports 30:25 217:1	synthetic 42:23 43:1	91:21 136:13, 14
246:21 252:1	system 10:1, 11,	146:1 147:1 150:13
suppose 200:1	14 21:1 38:1 66:21	155:20 169:1
supposed 58:20	73:12, 21 75:16	186:10 197:20
60:1 200:22	78:15 84:25	213:1 236:16
suppression 85:17	125:1 171:24	240:10, 23 241:1
86:15 87:18 158:16	214:13, 17	talks 227:1
		taming 87:18

tanks 87:1	95:1 102:25 103:17	140:17 141:15
target 31:1 191:14	105:1 115:11	142:1 144:24
200:10 252:23	117:16 124:18,	145:16 146:1
targeted 218:22	19 136:10 141:14	150:19 166:24
task 155:19 172:21	147:13 171:12	167:22 170:15
259:1	172:1, 16 178:13	172:23 185:15,
tasks 111:10	179:20 200:19	19 190:24 203:1
taste 169:1	201:22 202:13	207:25 208:24
team 111:1, 1, 11,	221:1 229:24	210:19 211:21
12	232:23 238:25	214:1, 1 219:1
technical 190:1	239:14, 15, 19,	220:23 222:12
technicality 125:22	21, 24 241:1	226:1 243:22, 23
technically 153:19	253:23 254:1	252:12 254:14
163:21 183:1	terrestrial 128:1, 1	257:23 259:1
192:13, 23	151:17 261:1	261:17 263:1
194:1, 12	terrible 125:18	thanks 162:1
technique 100:1	territorial 237:15	229:21 262:20
techniques 235:18	242:16	that's 15:21 17:13
technology 48:1	territories 159:1,	19:1 23:19, 22
130:1 236:1, 1	20	24:1, 1 25:1, 18
240:12, 15 245:1	test 28:16 34:22	26:1, 1 29:13,
ted 7:1 144:21, 21	105:21 151:17	16 36:22 40:1 41:1
145:10 148:15	153:18 163:1, 1	49:1, 1 52:24
150:1 173:1	169:1 170:11,	53:24 57:10 59:10,
telemetry 18:1, 16	13, 19 171:12	19 60:1, 18 61:18,
240:10, 18 243:1	172:1, 14 184:20	21 63:1, 13
telephone 211:1	232:14	67:12 69:14, 16
tellum 86:1	testable 137:1	77:18 79:18
temic 88:12, 13	testify 49:17 220:1	84:20 87:1 91:12
temperatures 95:19	testing 35:1 185:1	94:1 97:19 98:1
temporal 138:23	232:12	99:11, 25 100:25
139:1	tests 33:24 34:1	102:19 107:1, 22
temporally 17:22	41:14 86:18 171:16	108:23 114:22
temporarily 16:1	187:12 188:25	115:1 117:17
tenant 228:24	193:17 202:23	118:12 119:1 123:1
tenants 34:25	232:15	124:22 127:1
tend 150:22	texas 69:1	136:16 137:1
tended 58:22 89:21	thank 3:11 7:1, 1,	141:13, 23
tendencies 180:15	10, 18, 19 8:1 9:1	148:11 149:20,
tendency 179:25	26:13, 15 29:1, 1,	23 150:12 156:1,
180:11 185:1	17, 19 35:23	17 163:13, 18
tent 115:12	36:1 38:14, 24	164:19 165:1, 24
term 103:21	49:16, 20 51:1, 18	166:20 168:24
termed 109:1	55:16, 17 56:16,	174:14, 15, 24
terminate 15:1	17, 19, 25 64:25	175:1, 1 176:1
terminated 13:1, 24	65:1 71:1, 1, 11	183:23 187:20,
terminology 103:24	72:1 77:1 78:18	21 188:23 189:1
157:18	79:17 84:10, 11,	190:1, 1 196:18
terms 23:15 25:24	13 88:1, 1, 25	197:1, 22 198:1,
31:17 34:1 68:23	89:1, 1, 11	10 201:1 203:14
90:1, 22 92:1, 1	90:16 116:22, 24	208:1 209:14, 14
	125:1, 21 135:25	212:23 214:1 219:1
		220:22 224:25

225:1 228:16
 229:12 230:1,
 16, 17, 25
 233:17 234:10
 235:1, 16 236:1
 238:14 239:22
 240:19 243:1, 21
 245:20 254:1, 1
 255:1, 21, 25
 256:1 258:1, 25
thee 27:1
themes 163:14 205:1
themselves 41:23
 61:23 126:14
 137:10
theory 50:23 242:19
there's 15:19 22:1
 23:23 26:1 27:15
 36:25 42:21
 48:20 54:14
 61:23 64:1 70:20
 76:1, 1 77:16
 98:1, 1, 21, 22
 101:1 103:10
 108:21 124:1 131:1
 134:25 149:13
 161:25 166:1
 169:10 171:20
 174:20 181:17
 184:19 190:15
 193:1 197:18 203:1
 204:24 229:1, 1,
 10 234:21 236:20
 238:23 242:15, 16,
 23 245:22 252:17
 256:22 259:23
 260:1
thereafter 216:1
thereby 87:1 218:18
therefore 89:1
 101:13 115:1
 118:23 166:1, 12
 185:1
thermal 138:12
they'd 215:13
they'll 170:1
they're 10:1 17:1
 18:1, 18 19:23, 24
 20:1, 1 37:20
 44:24 61:15
 86:24 107:1 117:22
 139:14 155:21
 184:1 201:10
 205:17 222:23
 224:1, 25 226:1
 232:10 234:1, 18
 237:16 246:1
 257:1, 10, 11
they've 45:24
 61:17 67:25 224:22
 240:13 243:25
thicker 122:12, 12
thigh-high 67:15
 68:1
thiophosphates 49:1
thiophoxide 44:1
third 68:17 72:1
 87:24 165:1 213:15
 249:1 250:1, 1, 18
thorny 258:12
thorough 143:1
 236:19
thoughts 92:1
 134:1 208:1
thousands 21:14,
 16 60:20, 20 65:13
tie 92:22
tied 16:1 19:13 20:1
tier-2 165:15 176:10
threshold 33:1 59:19
 82:21 172:1 175:1,
 16 176:1
thresholds 60:13
 217:25
throughout 27:19
 39:1 40:1 43:13
 100:24 114:16
 137:1 232:21
 256:24
throw 70:24 93:22
 253:17
thrown 92:16
tight 90:18
thunder 241:15
thus 63:22
tim 93:16, 24 94:10,
 10, 11 95:13 96:24
 100:1, 10 101:12
 112:10 113:16
 115:16 116:1, 1
 117:10, 10 118:1
 121:19 128:1,
 13, 17, 18, 20, 23
 129:1, 1, 22,
 22, 25 130:15, 15,
 15, 18 131:1, 1
 132:1, 1, 11,
 11, 17, 18, 24
 136:21, 24
 137:15 140:15
 143:23 147:1, 18
 148:1, 22
 152:16, 17, 21
 153:20 154:1, 22
 156:1 163:22
 164:19 165:1, 16
 173:24 174:1, 18
 175:1 182:22, 22
 183:1, 1 192:15
 194:10, 14
 199:24 201:1
 203:25 204:1
 209:13 210:1, 1
tim's 8:23 9:1, 1
timeframe 169:17
timeframes 91:19
 194:1
tip 243:21
tired 121:1
tissue 40:1 200:18
tma 85:17
today 2:18 7:13
 27:18 39:1 48:1,
 10, 19 64:1
 68:22 79:1 87:1
 92:1, 1 94:1 102:1
 137:1 190:1
 217:1 230:10
 239:14 261:18
today's 244:17
tolerance 34:21
 35:17
tolerances 35:20
tomorrow 7:13 200:14
 230:10 263:1
tomorrow's 263:1
tonight 230:11, 12
 262:1
tool 41:1 43:15 63:1
 75:14, 18 78:17
 80:1 87:24 212:14
toolbox 40:21
tools 74:17 260:13
top 12:10 53:21
 66:17 73:25

74:23 82:1
topics 90:1 91:1, 21
 93:1 261:25
toss 237:18
total 14:11 17:1
 21:1 98:12 105:1
 114:19 123:1, 1,
 10 161:14, 17
 220:17 261:1
totality 119:1
totals 15:17
touch 233:20
touched 176:18
 189:14
toward 45:21
 105:22 222:1
towards 153:1
town 51:20
tox 258:15
toxic 11:13 103:20
 109:1, 10, 22
 156:22 158:14,
 16 191:15
toxica 157:1
toxicant 158:14
 169:24
toxicity 11:15
 16:1 21:10 31:1
 34:12 48:13 102:18
 181:24 182:1, 1,
 11 204:1 212:16
 217:1, 12
toxicological 248:22
toxicologist 5:1
 30:18
toxicologists 196:14
toxicology 4:1, 14
 5:1, 1, 15, 20
 6:11, 25 206:10
 255:16
track 149:1, 1
 181:16 235:13
tract 35:1
tractors 87:1
trade 76:1
trading 80:1
traits 62:17 80:10
transcripts 100:20
transferred 10:1
transformation
 200:10
transit 113:1
translated 14:11
translocated 58:21
transmitters 17:24
transplanting 54:16
transplants 52:22,
 23
travel 30:1 125:17
traveled 69:1
treat 27:20
treated 15:1 16:1
 20:1 28:16 60:16
 101:23 112:1, 14
 114:13 120:1 128:1
 129:1 131:20
 142:10 151:16
 161:14 170:22
 232:1, 10, 16
 246:24 248:14
 249:19
treatment 15:1 27:11
 46:1 49:13, 14
 59:20 63:1 67:19
 69:16 79:15, 21
 80:13 82:12 83:1
 84:1 85:1, 1 87:1,
 25 120:11 160:21
 167:1 170:1 232:1,
 12
treatments 50:10
 81:22 82:1, 13
 87:23 161:16, 18
 162:1 232:16
tremendous 48:11
 62:1 69:13 89:1
 126:13
trend 161:24 214:19
trials 173:12
tried 56:11 133:1
 166:22 179:1
 235:13 248:1
triggers 55:16
trip 57:1
trouble 62:1, 21
 66:13 235:1
troubled 187:1
troubles 187:1
truck 78:13
true 21:17 25:1 48:1
 232:11 241:25
truly 8:18 241:23
 242:22
trust 236:14
try 21:1 23:17 40:14
 47:12 61:20 64:15,
 16, 17 66:1
 68:18 73:1 104:1
 178:1, 16 196:15
 237:18 239:18
trying 9:12, 13 39:1
 43:12 77:22
 83:20 142:1 147:24
 155:16 165:23
 168:24 174:1, 1
 177:1 180:20, 23
 181:1 187:18
 190:20 201:23
 229:1, 1 233:21
 234:1, 13 235:16
 242:11 243:1 248:1
 260:1
tubers 41:23 46:1
tuberworm 41:16, 16,
 22 42:17 44:1
tuesday 64:1
tuesday's 63:25
tv 75:10
tunnel 204:25
tunnels 54:1
turn 2:12 3:1 61:1
 75:1 90:1, 1, 14
 92:1, 1 210:12
 219:1 229:17 231:1
 243:24 246:1, 1
 252:13 261:15
 262:21
turned 17:1, 19
 60:16 87:14
turns 139:10
tweak 200:1
tweaked 200:1
twice 63:19 107:16
two-spotted 41:15
type 76:11, 25
 103:11 119:1
 133:15 144:15
 150:11 162:1
 172:20 186:25
 200:1, 21 221:1
 224:25 240:17
types 54:12 132:14
 186:24 239:20
 245:1

179:24
variability 31:1
 118:13, 14
 119:15 120:23
 121:1 133:1
 142:13, 14
 143:24 144:23
 146:15 148:16,
 17 149:1 150:13,
 15 178:1 179:21,
 25 180:1, 22
 182:14 183:18
 198:24 199:1
variable 19:13 94:16
 96:18 115:15
 116:15 119:12
 122:16 137:13
 140:14 143:18
 148:1 160:11
 180:17 189:13
 199:1 206:1 220:1
variables 117:21
 119:1, 1 206:10
 250:13, 17
variance 142:10, 10,
 18, 20 143:1, 1,
 1, 11, 15 144:1, 1
 145:12, 16
 148:1, 24 160:21
 161:18, 25 167:1
 202:15
variances 147:13
variation 142:1
 143:20 149:14,
 24 162:1 239:1
variations 133:15
varied 120:22 121:1,
 1, 1
varies 81:16
variety 40:18
 96:25 100:15
 110:10, 11
 221:18 232:20
 251:15 260:15
various 31:24
 72:13 146:1 154:21
 186:24 205:1 241:1
 251:17 253:1
vary 100:1, 1, 1,
 1 121:17 122:1
 132:14 142:23
 146:24 148:23

182:24 205:19
varying 122:1, 1
vast 80:16
vector 53:16
vectoring 102:1
vegetable 52:1
verbal 79:1 144:13
verify 252:1
version 93:1
 94:12, 14 95:13
 128:1, 1, 13,
 18, 20, 23, 23, 25
 129:1, 1 131:1
 143:23 153:20
 154:1 163:23
 182:22, 22
 183:1, 1 192:15,
 15 202:1 214:14
versions 93:14
 101:19 128:17
 134:1 249:10
versus 24:24 60:16
 104:1 144:15 148:1
 158:18 167:1
 168:1, 1 178:16
 179:1 228:19, 21
 232:16 233:12
 234:14
vertical 75:1
veterinary 3:24
vetting 23:14
vhf 240:17
viable 55:21
vice 39:22
view 21:21 23:16
 39:25 75:1 168:1
 240:18 252:25
viewed 163:1 178:15
viewing 177:11
views 169:1
v9 67:15
vineyard 14:20
vineyards 14:18
virtually 235:21
viruses 40:1
visiting 61:14
visual 169:12 216:18
voice 39:12 211:1
volumes 94:17
voluminous 248:10
 262:1

voluntary 10:12
vortex 47:15

W

waist-high 234:14
wait 53:1 82:1 156:1
 210:23
walk 53:1 64:1
walking 18:21 57:1
 64:1, 1 65:21
 113:1
wallet 88:1
war 17:23
warblers 238:1
warm 41:18 89:15
warned 33:1
warranted 164:14
 174:12, 15 206:1
warrants 165:1
warren 253:22
washington 4:25
 5:1 6:10 30:1
 41:21 43:1 46:19
 79:19 84:23 85:1
washington's
 85:10, 13
wasn't 13:1 124:17
 166:23 200:1 235:1
wasting 67:21
watch 190:13
watching 121:1 149:1
water 21:24 22:1,
 1 64:15, 16, 18
 65:1, 18 66:1,
 1, 16, 21 67:1,
 1 70:18 115:1,
 10 149:20, 21
waterfowl 20:20
 110:1 203:1
watermelon 51:25
 52:1
watershed 261:1
wayne 175:1
ways 25:1 70:23
 83:24 134:15 236:1
we'd 15:24 132:1
 150:15
we'll 7:20 26:21
 90:1, 1, 17 91:1
 99:1 117:1 121:13,
 13 125:1 127:23

151:1 176:1 201:13
210:23, 25 222:10
we're 2:11 7:17
14:25 21:1 23:10
27:1 35:18 51:20
59:24 60:12
63:14 68:1, 11
89:17, 25 91:18,
21 93:19, 21 104:1
108:23 123:1, 1
124:1 138:1
146:1 147:1, 24
150:13, 14
154:13 155:15,
20 156:1 161:1, 20
168:18 177:1, 1,
11 181:1, 11, 17
183:20 186:1
188:1, 16
189:24, 25
190:1, 11, 18,
19 197:21, 23
198:1, 14 200:1,
14, 22 201:22,
25 208:12 210:18
212:1, 19 218:24
229:1, 1, 21
231:23 239:1,
12, 16, 20
240:1, 23, 23
241:1 245:22 246:1
256:1 259:1, 23,
24 260:1, 20
262:23
we've 11:23 19:1
22:20, 21 24:14
51:21 56:11
58:1, 12, 15
60:1 61:11
62:14, 17, 19
64:14, 15 80:1
92:23 102:13
115:22 123:1
154:19 157:1 170:1
179:10, 14
180:21 188:1, 1
190:1 196:17
201:20 205:1 209:1
224:11, 19
226:23 230:10
252:20 256:1
257:19, 19 258:10
weakness 119:1
weaknesses 133:21
154:24
weapon 68:18
wear 118:25
weather 41:18
54:1, 17 89:15
125:18 193:20
243:20
web 10:16
web-based 10:15
website 10:17 24:1
94:1
week 12:24 19:20, 23
64:1, 1, 1
136:22 199:13
230:17
weeks 18:13 54:1
61:13 76:13 123:15
weigh 84:1
weight 3:1 24:24
93:10 133:22
221:21
weights 239:1
weirdest 170:1
welcome 2:1 3:12
71:11 72:1 125:1
welfare 196:14
west 257:1
western 62:1, 20
wetland 66:13
wetlands 65:14,
18, 19
whatever 70:24
84:1 142:1 168:1
170:10 196:1, 16
206:1 239:12
whatnot 188:11
252:24
whenever 54:11
whereupon 71:22
210:22 263:1
whether 12:1 19:1
23:24 30:24 32:1
60:1 62:1 70:22,
24 71:1 75:13
77:24 93:1
98:12, 14 104:24
105:1, 25 108:23
110:18 113:1
115:11 117:18
141:1 147:25
149:20 162:1
163:15, 16, 16
170:23 174:1
184:12 188:19
197:14, 25 221:16,
20 236:19 239:1
245:1 252:1 257:20
260:1, 1 261:15
whole 9:11 27:19, 22
30:11 31:1 32:21
57:10 69:1
97:19, 21 117:21
118:22 119:1 155:1
164:24 175:1
186:18, 19
187:20 191:1
214:12 247:16
whooping 256:1
whose 235:12
wide 205:1
widely 9:17 26:10,
11 140:1 197:1
widen 122:11
wider 122:11 157:21
wife 69:1
wild 96:17 138:22
139:1 182:17
193:18
wildlife 4:17, 18,
19, 25 5:1, 1, 15,
18, 20 11:14 17:20
22:21 112:1 113:25
214:11, 16, 20, 23
215:1 225:16
231:15 247:1 249:1
250:1 251:25
255:21
willing 191:1 246:1
wilson 17:17
wilt 53:16, 17, 25
wilts 53:20
window 118:1, 1, 1
winter 138:12
wire 133:13
wireworm 45:24 46:1,
1
wireworms 52:19, 20,
21, 24 53:1 56:1
wish 81:20
wishes 85:25
withdraw 16:18

