

US EPA ARCHIVE DOCUMENT

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US EPA ARCHIVE DOCUMENT

UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE

COMMITTEE MEETING

April 22-23, 2009

Conference Center - Lobby Level

2777 Crystal Drive

One Potomac Yard South

Arlington, VA 22202

1 P R O C E E D I N G S

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3 MS. EDWARDS: Thank you very much for returning
4 on time this morning. I would like to get started pretty
5 quickly here so we can have a full three-hour session
6 with a lot of good input from all of you. One thing I
7 would like to request before we get started is that those
8 of you who are on the phone today, if you would please
9 mute your phone until the point at which you would like
10 to speak and then you, of course, need to unmute your
11 phone or we won't be able to hear you.

12 So, our first session today is Session 7, which
13 is a PPDC workgroup, a report on comparative safety
14 statements, with our session chair, Marty Monnell.

15 MS. MONELL: Good morning, everyone. As you
16 hopefully remember, this work group was charged with
17 delving into the feasibility of allowing comparative
18 safety statements or logos on pesticide product labels.
19 Heretofore, we have not permitted statements regarding
20 greenness or safety or the use of logos, except in a
21 certain, very limited circumstance.

22 So, there was a sense of this committee that

1 yes, this really should be pursued given the interest in
2 consumers and getting some information on products that
3 they may be making decisions about for purchasing. We've
4 approached this whole endeavor sort of with a three-
5 legged stool in mind; that is, the interest of the
6 consumer and getting some information about the product
7 that they're purchasing.

8 Obviously, the registrants are interested in a
9 marketing edge, so to speak, by allowing these statements
10 to be on their labels to help the consumers. But
11 probably, most importantly, from our perspective is that
12 we, EPA, have a statutory obligation to make sure that
13 anything that we do is not deceptive and it protects
14 human health and the environment. So, balancing all of
15 those three interests is sort of the umbrella under which
16 we have pursued our discussions.

17 Last October, we reported out that the work
18 group had begun its deliberation, that we had had a
19 threshold meeting where we had presentations from a
20 number of other groups that do reviews or permit
21 statements regarding greenness or energy efficiency or
22 organic status. So, everybody was operating sort of on a

1 level playing field in terms of having an appreciation
2 for what is already going on out there.

3 Since then, we've had several more meetings,
4 including meetings of subgroups as our work groupers want
5 to do. Initially, we were sort of fumbling because we
6 have a very large subgroup with a lot of different
7 interests. So, we broke out into three subgroups. One
8 was looking at the possibility of developing a system
9 regarding statements around or the use of a logo around
10 institutional and industrial pesticide products.

11 Another group looked into a framework for
12 allowing factual statements on pesticide products. In
13 other words, this is made out of natural ingredients or
14 the container is all recycled materials, and so forth.

15 Then, the third group looked into the
16 feasibility of developing a decision tree so that
17 whatever we pursued, we would have a flow chart of, you
18 know, if this, then we go to the next step; if not, then
19 it's a non-starter.

20 So, then we met again and heard all of the
21 recommendations from those three subgroups. We
22 ultimately decided that two projects were worthy of

1 further pursuit and then we would use a decision tree --
2 the process that was developed by the decision tree group
3 to help us flow the work from these two endeavors.

4 So, you're going to hear this morning about two
5 proposals that we as a work group would like to put forth
6 and would like some feedback on running a pilot. The
7 first one that you're going to hear about this morning
8 will be a pilot that would involve using our sister
9 organizations designed for the environment program to
10 take a look at -- this would be voluntary -- take a look
11 at initially some probably antimicrobial products -- but
12 I'll let them talk about their deliberations on this --
13 and to see if indeed they would pass the design for the
14 environment screen and thus be eligible for a logo to be
15 permitted on a pesticide product label. So, that's one
16 approach, one pilot that we've discussed.

17 The other would involve the use of factual
18 statements. That involves permitting certain statements
19 to be on pesticide labels with regard to not only the
20 product itself, but the packaging of that product. We've
21 done a lot of work on that. In both instances, there's
22 more work to be done. We acknowledge the fact that there

1 are some implementation issues to be addressed. But we
2 feel that they're both ripe enough to recommend to this
3 group that we do a pilot.

4 So, I'll turn it over to Michael and Clive.

5 MICHAEL: Thank you, Marty.

6 Briefly, when the first work group got
7 together, it was a discussion as to whether or not we
8 should have external or third party certification and
9 logos appearing on these products or whether or not we
10 ought to do something that was more owned by EPA.

11 We would refer to Energy Star, for example, and
12 the design from the environment program as examples of
13 EPA-run logo certification programs that seem to fit the
14 needs of the folks in the room. So, we were asked to
15 focus on an internal logo as opposed to an external
16 third-party certification. So, hence, the work group or
17 subgroup was formed on the DfE logo for different
18 sectors.

19 We're going to go over the background, the
20 previous products that may have been reviewed already by
21 the Design for the Environment Group. The issues that
22 arose, the draft facts to consider, and the next step.

1 Now, currently, products that make cleaning
2 claims are permitted to apply for the design for the
3 environment logo once they've completed their review.
4 Most of the antimicrobial hard, nonporous surface
5 disinfectants, those labels contain uses as pesticides
6 and as cleaners. So, in theory right now, you can have
7 an antimicrobial disinfectant that has disinfection
8 claims, sanitization claims, and cleaning claims. If
9 they were to remove all the claims except for the
10 cleaning and go over to DfE (audio problems).

11 So, OPP and the Design for the Environment
12 Group agreed to work together to determine the
13 feasibility of allowing products that have passed the DfE
14 review to submit a label amendment to OPP in order to
15 place the logo on pesticide products.

16 So, the previous products -- the Design for the
17 Environment Group sent over three products that they felt
18 may have dual use as disinfectants, although they passed
19 the DfE screen as cleaning products. OPP, in turn, sent
20 eight products over to the Design for the Environment
21 Group for review.

22 The products that we forwarded -- is it picking

1 up in the back -- so, what we wound up doing was sent
2 eight products over to the Design for the Environment
3 Group for review. We decided we would try to (audio
4 problems).

5 The products that we forwarded contained
6 different active ingredients (audio problems) at two
7 percent with acute tox 3, the same chemical X at eight
8 percent was acute tox 1. So, we sent it over to see if
9 it was going to make a distinction with their review,
10 depending on the AI and the acute tox classification.

11 The products also involved different use sites.
12 Some of the issues that arose was that OPP staff were
13 required to complete the TOSCA (phonetic) CBI training
14 before the Design for the Environment staff can provide
15 any records and do a cross sharing.

16 Similarly, the Design for the Environment staff
17 were required to complete FIFRA CBI training before we
18 could provide any records to them. So, we had to take a
19 pause and everyone had to get trained on both sides of
20 the house here so that we could share our records.

21 The OPP expanded participation to include the
22 Registration Division, the Biopesticide Solution

1 Provision Division, the Field and External Affairs
2 Division, and the Health Effects Division. Other issues
3 were that there was a question as to whether or not we
4 need to include the Environmental Fate and Effects
5 Division and whether or not we needed -- the new work
6 group members had to be brought up to speed.

7 So, there was some time, because we had been
8 doing this since the fall of 2008. Here we were with new
9 work group members who we had to bring up to speed in
10 terms of where we were thinking and what the direction
11 and the goals were.

12 We realized that we needed some draft facts or
13 criteria to consider when we did our review. So, we
14 thought, you know, maybe if something went through a DfE
15 review and it came over to OPP, what do we want to make
16 sure did not receive a logo? We didn't want it to be
17 false and misleading. We didn't want folks to think that
18 a logo was potentially a safety claim. So, what could we
19 do up front. We didn't want to make the situation more
20 confusing in the marketplace.

21 So, first of all, no carcinogens. Secondly, no
22 acute tox 1 or 2 products. We thought that if you have

1 to wear goggles and a face shield, you ought not have a
2 Design for the Environment logo on your product. So, if
3 you've got PPE issues, we didn't feel that those products
4 warranted this pilot.

5 You should not have any unresolved 6A2 issues
6 out there. So, if you've got 6A2, and this would really
7 echo around efficacy, then we don't want you to even
8 apply for this particular pilot.

9 No unresolved efficacy failures. If you had an
10 efficacy failure related to some state testing or post-
11 registration testing through the antimicrobial testing
12 program, you need to have that resolved before you come
13 in and apply for this pilot. The issue came up that we
14 did not want individuals to formulate down in order to
15 receive the DfE logo at the expense of compromising
16 efficacy in, say, a hospital setting. So, no unresolved
17 efficacy issues.

18 No current enforcement actions. If you're
19 currently under a stop fail or dealing with the Office of
20 Enforcement and Compliance Assurance on an issue, you
21 should not be applying for this pilot.

22 Also, only OPP approved statements could be

1 made regarding the logo. We sat down and thought about
2 many different ways the marketing folks could have at it
3 when they got a DfE logo on a pesticide label. So, we
4 were asked, you know, maybe you don't want to be
5 prescriptive in a list of claims. And we thought, well,
6 because of the pilot, perhaps that's exactly what we want
7 to do. We want to maybe list four, five, six, whatever
8 number we come up with, claims that can appear in
9 conjunction with the awarding of this logo so that we
10 could control a little bit more and then find out whether
11 or not we need to expand that list of claims.

12 We also said that no products with unapproved
13 inerts should be able to receive this logo. For folks
14 who aren't aware of the DfE program, they do a comparison
15 of each active ingredient, whereas we're looking at the
16 entire formulation. So, if it's an unapproved inert, we
17 want that to be cleared and approved before you start
18 this process.

19 No outstanding conditional registration data
20 issues. If you received an accepted with comments or
21 conditional registration and you still owe us data, you
22 need to get that data in here before you actually can

1 apply for this pilot.

2 No personal protective equipment should be
3 required on that product in order to get this logo
4 awarded.

5 This next issue came up as a discussion --
6 cross discussion with the factual statement group -- and
7 that is the term biodegradable is bandied about. If you
8 want to use the term biodegradable, the question came up,
9 well, then, maybe you ought to disclose all your inerts
10 on your label, not just say we're biodegradable, but list
11 exactly what inert ingredients are in your formulation
12 that yield the determination that you are in fact
13 biodegradable. That would help the consumer decide
14 whether or not he or she wanted to purchase that product.

15 Continuing, no developmental tox issues. The
16 complete product formulation would be reviewed,
17 individual components by DfE and the final formulation by
18 the Office of Pesticide Programs.

19 The next steps, OPP and DfE will review a
20 second round of products. We're also looking to refine
21 the factors to consider. And we're going to continue to
22 seek advice from the PPDC on the merits of the pilot.

1 So, for now, we have sent a second round of products
2 over. When the good folks at DfE are finished with their
3 evaluation, we will sit back down with OPP scientists and
4 regulatory staff to make sure that what they think over
5 in DfE would warrant a logo our science and regulatory
6 staff would also be in agreement with. So, it would not
7 be any issue in terms of us saying yes or they're saying
8 no or they're saying yes and our saying no.

9 Did you want to have questions now or go onto
10 the implementation?

11 What Marty is referring to is that Clive is
12 going to be talking about the implementation of a DfE
13 logo pilot. So, we just loaded that up on the screen for
14 you.

15 We started discussions about how would you
16 implement a pilot in the first place. So, we're going to
17 quickly go over the scope and duration of the pilot, the
18 application process, and conditions of labeling. Now,
19 these are all ideas that the subgroup came up with. Once
20 again, we're still waiting for feedback from the PPDC on
21 whether or not this idea has merit.

22 Scope and duration, the pilot would be opened

1 to all indoor hard nonporous surface products that do not
2 have outstanding FIFRA 6A2 issues or efficacy failures
3 and the other criteria that we discussed a minute ago.
4 The pilot would run for one year. If, at any time, the
5 agency determines not to continue the pilot, no new
6 production of labeling would be permitted that bore the
7 DfE logo for the pesticide product in question. The
8 agency would permit the limited sale and distribution of
9 products already in the channels of trade.

10 Now, what about the process? Registrants will
11 contact the Design for the Environment Group and complete
12 their process to obtain DfE certification. There are
13 data requirements that have to be submitted and reviewed
14 by contractors that work for DfE before you can actually
15 get their logo.

16 Upon receipt of a DfE certification, you would
17 then submit a pre-amendment to the corresponding
18 regulatory division within OPP. Quick pause right there.
19 It was discussed whether or not there should be a
20 notification, whether or not it should be considered a
21 fast track amendment, or would it be a PRIA amendment.

22 Well, there were varying opinions but the

1 overall consensus was that at least for the pilot, we
2 want to see some information being submitted. We're
3 going to have to review some of that information and
4 we're going to have to sit down with the science and
5 regulatory staff and work through the issues, if any,
6 that we might come up with DfE and OPP.

7 So, we thought that we did not want to make
8 that a notification because it can't be done in that time
9 frame. Also, there was concern that depending on which
10 division you're applying for, the fast track amendment
11 process has different time frames. So, the PRIA process
12 had a more reliable time frame in which we could operate.
13 So, you could feel relatively assured that you would get
14 a response by X date. So, we thought a PRIA submission
15 for an amendment would be adequate.

16 Clearly indicate on the cover page of a
17 submission that the actions related to voluntary DfE
18 pilot so as to not to be confused with other amendments.

19 Include five copies of a draft labeling that
20 include the DfE logo and the acceptable marketing claims
21 as defined by OPP. That would be a descriptive list yet
22 forthcoming.

1 The registrant also would include a
2 certification statement that makes reference to the
3 voluntary pilot and agrees with the provisions thereof.
4 OPP will review the acute tox classification of the
5 product. OPP will review the formulation to insure that
6 the active ingredients are not deemed chemicals of
7 concern. OPP would evaluate the marketing claims to make
8 sure that the claims that you're listing are in fact
9 those that we've already agreed upon. And the process
10 must be completed each time the formulation changes.

11 I know in the antimicrobial industry, it is not
12 uncommon to have one basic and 30 alternate formulations.
13 Well, that means that each one of your formulations would
14 have to go through the Design for the Environment Group
15 in order to receive that logo or you'd have to have a
16 separate registration with just that product on
17 formulation being reviewed.

18 Now, Clive is going to go over the steps to
19 obtain a DfE logo for a currently registered product.
20 Now, on your handout, the area in pink is going to be in
21 white so you're not going to be able to see that clearly.
22 We put it in pink for the overhead. So, look at the

1 screen if you're having difficulty viewing the area in
2 pink.

3 MR. DAVIES: Thanks, Michael.

4 So, just a little bit of an introduction on the
5 Design for the Environment Program I think might be
6 useful for folks. We are a voluntary program that is
7 part of the Office of Pollution Prevention and Toxics
8 which is the sister office of the pesticides office. The
9 OPPT, this office is the office (inaudible) and is
10 responsible for regulating new and existing chemicals.

11 What the Design for the Environment Program
12 does is that we look at or really we use the technical
13 tools and expertise of OPPT to look at products and
14 actually allow use of our logo on the products that are
15 safer in a given category of use.

16 Now, we don't just take a product and look at
17 that product as a whole. We break that product down into
18 the functional classes of ingredients that the product is
19 made up of, so that if we're talking about a safer
20 product, we think about that product in terms of the
21 surfactant, the solvent, the keylator (phonetic), the
22 colorants, the fragrance that are in that product. We

1 make sure that each of those ingredients is from among
2 the safest ingredient that's available for use in that
3 functional class.

4 Once we allow use of our logo on a product or
5 as part of that process, we ask the product manufacturer
6 to sign a partnership agreement with us that specifies
7 how the product will be formulated and any things that
8 can be done in terms of continuing improvement, research,
9 and so forth by that company, and then that agreement
10 lasts for three years. At the end of that three-year
11 period, we get back together with the company and examine
12 any improvements in the state of green chemistry and so
13 forth, and are there ways that that product could be
14 improved.

15 We just recognized our thousandth product a
16 couple months ago, so there is a substantial number of
17 products out there on the market with our recognition. A
18 very important part, we believe, of what we do is as we
19 move our program forward, we have a multi-stakeholder
20 engagement to think about where we're going, what we're
21 doing, what are the safe levels that we consider to be
22 reasonable to be allowed in products. So, NGOs, product

1 manufacturers, chemical manufacturers, retailers these
2 days are all very important parts of the folks that we
3 talk with.

4 Now, this flow chart, if you can take a look --
5 I hope you can read what it says here -- but basically,
6 this is the way that someone can come into our program.
7 What the applicant does here in this brown box, if they
8 want to come in and work with the DfE program, they
9 submit all of their ingredients to a qualified third
10 party.

11 We actually leverage our programs through third
12 parties that we have qualified with chemical and
13 toxicological ability to look at formulations and help us
14 by preparing a packet of information that looks at the
15 ingredients, the data that's available on those
16 ingredients, where data is not available on those
17 ingredients, any structural activity relationship work
18 that's needed to better understand those ingredients and
19 project their toxicology so that we're sure that what is
20 coming into our program are really the safest
21 ingredients.

22 Then, there's a loop back with the applicant

1 from that third party. They ask, okay, third party, this
2 is what we've come up with. Do you want us to go to DfE
3 now or would you like to potentially make some changes in
4 your formulation? So, then you go to the green boxes.
5 Those green boxes are DfE. This is where DfE would do a
6 quality assurance on what the qualified third party had
7 done in terms of preparing data and then make a decision
8 about whether we would allow the logo on the product. Of
9 course, this so far is all for non-pesticide labeled
10 products.

11 So, at the end of all that, we make a
12 determination about use of the logo and either sign a
13 partnership agreement with the manufacturer that would
14 allow use of the logo or we ask that additional changes
15 be made to the formulation.

16 Now, if we were to move forward in implementing
17 a pilot for pesticide labeled products, you see the light
18 blue box on the right-hand side here. What would happen
19 there is that once the DfE process was complete and once
20 DfE was okay, then there would be a loop with the
21 pesticides program for registration or amendment of
22 existing registration. At the end of all of that, there

1 might be a partnership agreement with DfE, with OPP, that
2 would allow use of the label.

3 MICHAEL: Finally, conditions of labeling. We
4 were trying to figure out exactly what kind of provisions
5 would we have on a pilot in terms of labeling. We
6 thought that no reference made in the marketing of this
7 product involving terms that violate 40 CFR 156.10(a)(5),
8 the false and misleading, the comparison statements,
9 things of that nature. No comparisons with other
10 registered products. Citation only of the DfE website
11 for pesticides, which is something we thought ought to be
12 created.

13 If you were to go out and look at the current
14 DfE website, there may be some terms about the DfE logo
15 that we may find in violation of some of the FIFRA
16 (inaudible). So, we may have to consider creating our
17 own website that's DfE for pesticides. ADOPP will
18 provide the only marketing statements permitted under the
19 pilot.

20 At any time a marketing violation occurs under
21 this pilot, the registrant would immediately issue a
22 voluntary recall of the volatile products or be found in

1 violation of FIFRA Section 12(a)(1)(B) and 12(A)(1)(E).

2 The Antimicrobials Division, the idea of the
3 pilot was that we heard a lot of concern from the
4 antimicrobial industry in terms of the INI folks that
5 they'd like to see something started with a pilot there.
6 So, we thought that we would look at the hard, nonporous
7 surface indoor products first, realizing that there may
8 be some folks in both the Biopesticides Division and the
9 Registration Division that also want to play in the
10 pilot. But the focus would be on internal antimicrobial
11 products first.

12 UNIDENTIFIED FEMALE: Would you say that again?

13 MICHAEL: There was a question as to whether or
14 not this pilot ought to be expanded already to our
15 division. By definition of a pilot, we were advised that
16 you couldn't exclude folks who actually wanted to
17 participate, but the focus was for indoor, hard,
18 nonporous surface disinfectant, which are your
19 antimicrobial products.

20 So, if somebody from the Registration Division
21 wanted to get involved in this pilot or somebody from the
22 Biopesticides Division, they would not be excluded and

1 their application would be considered on the merits.

2 UNIDENTIFIED FEMALE: (Inaudible).

3 UNIDENTIFIED MALE: A registrant, yes, yes.

4 MS. EDWARDS: Thank you, Michael.

5 Well, I was going to wait until after the
6 second group presented, but one of the -- Pat Quinn is
7 delayed. So, I think at this point what I'd like to do
8 is ask the PPDC a question, around which I'd like some
9 comments and any questions.

10 That is, what is your reaction -- are you
11 comfortable with the work groups' recommendation that we
12 proceed with this pilot to allow the use of a DfE logo on
13 pesticide product labels, as described, in a pilot
14 fashion, understanding that there are still some
15 implementation issues to be ironed out, not the least of
16 which is the decision on what do we want the actual
17 outcomes to be? What's the desired outcome of this
18 pilot, this particular pilot? How do we evaluate it at
19 the end of the pilot?

20 So, I'll entertain questions/comments at this
21 point. I'll start this time clockwise. Daniel? Just
22 indicate which panel member you might want to have a

1 question from.

2 DANIEL: (Audio trouble) -- secular trend in a
3 functional class as part of -- toward greater and greater
4 safety. Do the bars get raised for labels over time?

5 UNIDENTIFIED MALE: Yes. We consider ourselves
6 to be a green chemistry program. A very important part
7 of what we do is allow limited time for recognition of
8 products. At the end of the three-year partnership
9 agreement, we would get back with the company and talk
10 about improvements in green chemistry and require
11 improvements to the products.

12 UNIDENTIFIED MALE: Another sort of question
13 generally (inaudible) which seems to make sense for this
14 particular group of nonporous surface disinfectants.
15 Going forward with the pilot, are you doing so without a
16 firm commitment to -- if this works for this class of
17 products, to expand to all pesticide products? I mean,
18 at this stage, you're not (inaudible) pilot as an
19 evaluation -- a program that would, if successful, be
20 expanded universally, are you?

21 UNIDENTIFIED FEMALE: Actually, we've been
22 advised by counsel that we could not exclude other kinds

1 of products from participation in this pilot. So, the
2 underlying assumption would be if it works for
3 antimicrobial products, then we would consider expanding
4 it to other types of products.

5 UNIDENTIFIED MALE: So, in that vain, it
6 strikes me that the criteria that you've set for the
7 kinds of products that could be included -- that
8 registrants could apply for for the pilot, they're not
9 sufficient to address criteria for I think a more complex
10 set of products whose uses are a little less predictable,
11 nuanced in the field. So, in terms of answering your
12 question, do I think this is a good idea, I'm worried
13 about broader applicability to other pesticide products
14 after this pilot.

15 UNIDENTIFIED MALE: At this stage of the game,
16 they are still draft factors to consider. We realize
17 that one size will not fit all. So, there may be a
18 different set of criteria for those antimicrobial
19 products, a separate set of criteria for the products on
20 the provincial side of the house, and perhaps a third set
21 of criteria for the biopesticides side of the house. But
22 we haven't got to that level yet, which is why we're

1 still looking to reevaluate and tweak the factors to
2 consider. But, you're absolutely right.

3 UNIDENTIFIED FEMALE: So, basically you're
4 saying, just to follow on with that, that these factors
5 that you had listed here, you developed these for the
6 most part right now for hard surface disinfectants. So,
7 before you would open this pilot up to any other class of
8 products, all of this would be reviewed.

9 UNIDENTIFIED MALE: Yes.

10 UNIDENTIFIED FEMALE: And how are you going to
11 create the standards that would apply to different
12 classes of products, then, because it is a highly complex
13 issue? Even just the list of what you've got here for
14 just one class, disinfectants, how would you -- how would
15 a consumer ever understand what all of those different
16 factors were before you just had a logo on a package?

17 I guess part of it is, where's the education
18 part of this? I know we've talked about it in the work
19 group. But, as a member of the work group, some of the
20 stuff that you've presented here today we haven't
21 discussed in the work group yet. I know you guys have
22 done a lot of work going into this and bringing this to

1 the table today, but we haven't had a chance to talk
2 through all of these other factors to some degree that
3 you're bringing up right now.

4 So, I think still part of it is, where's the
5 educational component, even for a pilot project? What
6 happens as a result of the pilot project? Does somebody
7 get to put the logo on their label?

8 UNIDENTIFIED MALE: Several questions all in
9 there, so I'll try to knock some of them off one at a
10 time. Firstly, the factors to consider for the hard
11 surface disinfectants are not finalized. A lot of work
12 went into getting to where we are now with those factors.
13 So, that involved many meetings with DfE and the
14 pesticide staff.

15 That involved bringing more players to the
16 table to make sure that everybody in the Office of
17 Pesticides was okay with the factors as developed. So,
18 that took a few months, and we're not done yet. So, that
19 would have to take place for each sector, if you will, or
20 class of products that would undergo the DfE review and
21 then come over for pesticides.

22 Clive, I think, in previous meetings have

1 talked about their sector approach to how they actually
2 segregate the products in order to determine which ones
3 are greener for chemistry purposes, and safer. We
4 haven't done that yet. So, there's going to have to be a
5 process in which you sit down and talk about exactly what
6 a pesticide cluster or sector look like for this DfE
7 logo.

8 Then, the education component, what does it
9 mean? Part of the evaluation criteria that had been
10 discussed before was, you know, what are you trying to do
11 and are you going to influence the behavior of consumers
12 by having that logo on a product? So, some of the
13 subgroup members thought maybe we need to sit down and do
14 some market research before you put the logo on and find
15 out what people's patterns of behaviors are.

16 Then, during or subsequent to the pilot, do
17 another survey and find out if their behaviors were
18 changed or altered because they saw a logo on a product?
19 Do they think that it was safer? Do they think it was
20 better? Did they not buy other products because they did
21 not bear that logo?

22 So, we have not flushed that out. It's on a

1 to-do list.

2 UNIDENTIFIED FEMALE: (Inaudible).

3 UNIDENTIFIED MALE: Well, what we generally do
4 in this regard -- I think there were a number of
5 questions packed in and I think there is this idea that
6 you have to responsibly enter each sector with a good
7 understanding of the chemistries that can be used and the
8 alternatives that are available and being able to define
9 the red through the greener end of the spectrum so that
10 you are allowing the safer end in products that would
11 bear a label so that you have a basis for what you would
12 educate on and a good understanding -- a good broadly
13 understood and easily communicated approach.

14 In terms of communication, we take an approach
15 where we rely heavily on our partners to do communication
16 with us, the partners who label products. And we ask
17 them to do outreach associated with those products to
18 make information available on their web site since it
19 sends folks back to our web sites as appropriate.

20 We also do outreach and education with the
21 retailers who make information about our program more
22 broadly available.

1 MS. EDWARDS: Matt.

2 MATT: My first question was along the same
3 lines, and I think I just need a little more clarity.
4 How well do you understand the influence of the DfE label
5 on consumers in terms of their decisionmaking? What does
6 that actually mean to the -- not to the very well
7 educated consumer, necessarily, but, in fact, a consumer
8 who might look at a label and say, oh, well, this is
9 safe, this is great, I can use this. What exactly is the
10 impact and how well do you understand that?

11 Then, the second thing I would ask is, what
12 promises are actually made by the DfE label? What
13 literally does that constitute in terms of promises to
14 the product manufacturer? How are you guaranteeing the
15 safety of this product in any way? Are there
16 repercussions for EPA if, in fact, something unforeseen
17 happens down the road?

18 UNIDENTIFIED MALE: Well, first of all, in
19 terms of the significance of carrying the DfE logo on a
20 product, what we ask is that when a manufacturer puts the
21 logo on the product, they also put a statement on the
22 product that says that the product is recognized for

1 safer chemistry. That is what we recognize the product
2 for. We don't recognize it for qualities beyond being
3 made up of a safer set of chemicals. So, that's the
4 claim and that's what then is looked at on manufacturer's
5 web sites and on our web site to further explain what the
6 product means.

7 In terms of our level of understanding of the
8 impact of the product, we have not -- we, EPA, DfE --
9 have not conducted independent market studies to
10 understand as EPA exactly what consumers will take from
11 the logo. However, a substantial number of our partners
12 have done consumer focus groups and we've, being party to
13 those, seen the results and so forth.

14 Consumers take from the logo that the product
15 is safer, and they seem to understand the relationship
16 between the tag line that said safer chemistry and that
17 that is really what that logo is about. Also, the DfE
18 logo with EPA on it communicates well to folks and is
19 something that they have felt is trustworthy in their
20 view, just in terms of a quick reaction from consumers,
21 the kind of people who would pick a product up off a
22 shelf.

1 (Audio problems.)

2 UNIDENTIFIED MALE: Then it would be very
3 important to know what the points of evaluation are going
4 to be and what is the purpose of the pilot. If,
5 ultimately, there can be an expansion to other types of
6 pesticides, then not knowing much more about it, I would
7 think that the criteria for the pilot should include a
8 range of products, not just those that you're talking
9 about right now.

10 Also, just a weigh in from state-lead agency
11 perspective, because our primary view of the label is as
12 a tool for enforcement and for understanding and
13 instructions to users, we're very circumspect about
14 adding materials to the label that are not directly
15 associated with that purpose. We worry about clutter of
16 labels.

17 There's some discussion earlier -- Michael, I
18 think you mentioned that there would be some statements
19 that the antimicrobial division would need to -- only
20 their approved statements relating to the marketing
21 claims for logos would be included. I know there's going
22 to be a discussion about that later on, but I think it

1 would be very important if you actually do this pilot and
2 put products out in the market.

3 I'm wondering if this might be one where a
4 virtual pilot would be more appropriate. If you do that,
5 you're going to need to do a real lot of lifting with the
6 state-lead agencies to explain to them what the review
7 process is for these logos, what statements are
8 acceptable, and, you know, get us up to speed so that
9 there's not going to be confusion when states are
10 reviewing these labels independently.

11 UNIDENTIFIED FEMALE: We recognize the
12 potential impact of this, any kind of a pilot or program
13 of this type on states. We've had two state
14 representatives on the work group from New York and
15 California -- I think at your recommendation, actually.

16 Janine, are you on the line?

17 JANINE: Yes, I am.

18 UNIDENTIFIED FEMALE: Okay. Do you want to
19 make any comment about Dennis' observation?

20 JANINE: Well, yeah. We were speaking of that
21 before and we do have a lot of concerns with the channels
22 of trade and what's actually on the labels and consumers

1 just knowing what those logos mean. What Clive was just
2 saying about the recognized for safer chemistry and
3 that's what the logo means, that's a concern. That could
4 be almost misleading.

5 So, I don't know -- it's very difficult for us
6 to know where this is actually going to go until we see
7 more, you know, progress. Ultimately, we're the ones
8 that have to review the final labels to see how it looks
9 in printed form and how it's presented and whether or not
10 it's misleading and if people can actually read the label
11 directions that they're supposed to read and it's not
12 cluttered. So, that's a lot of our concerns.

13 UNIDENTIFIED FEMALE: One of the implementation
14 issues that we obviously still need to address is the
15 statements that would be permitted in conjunction with
16 the DfE logo on a pesticide product. That has still not
17 yet been totally fleshed out. That's what Michael was
18 referring to when he said that AD would be developing
19 those kind of acceptable statements. So, again, we
20 acknowledge that there is still implementation issues
21 that need to be addressed for sure. This discussion is
22 very helpful.

1 I don't want to cut short the other
2 presentation on the other potential pilot so can anybody
3 -- would you mind holding the remaining questions?

4 Caroline, you're waving at me. Yes, okay.

5 UNIDENTIFIED FEMALE: (Audio problems) who may
6 have other types of products not in a high (inaudible)
7 product that would like (inaudible) what their thoughts
8 are. That would be the most helpful (inaudible).

9 UNIDENTIFIED FEMALE: Okay. Do we have
10 someone --

11 UNIDENTIFIED MALE: Thank you. As a registrant
12 (audio problems). First of all, I apologize for being
13 late to all of you. It's good to see so many familiar
14 faces.

15 I think that one of the things that Marty did
16 at the start of this process that was very helpful was
17 she brought in the Energy Star program from the air
18 office. The history of these programs that attempt to
19 recognize technology leaders and environmentally
20 preferable products and then put that logo -- in fact, in
21 Energy Star's case, an EPA logo -- is given to whatever
22 product performs in the top 10 or 15 percent of that

1 niche, they're able to demonstrate very persuasively that
2 it drives consumer purchasing behavior, it drives
3 technology advancement, and they're able to qualify an
4 air program with some precision the kinds of pollutants
5 and greenhouse gas savings that they've, you know, been
6 able to accomplish through that kind of an effort. So, I
7 mean, just a generic comment I wanted to offer that.

8 MS. EDWARDS: Michael.

9 MICHAEL: I'm very interested to know what the
10 thousand products are now that carry this label, what the
11 universe of those products is and how they are
12 interpreted by the public in terms of, you know,
13 environmentally friendly. Then, is it probable that
14 consumers will look at these pesticide products with the
15 same environmentally friendly attitude that they're
16 looking at the others? Is there any tox classification
17 for any of the thousand products now carrying this logo?

18 UNIDENTIFIED MALE: Thanks for the question.
19 So, for the thousand products that we look at now, they
20 are largely cleaning products. They are detergents, hard
21 surface cleaners. We also have some other products in
22 the mix, things like conversion coating for aircrafts and

1 alternatives to road salts and chemicals that you can use
2 in truck tires instead of clip ons lead wheel weights.
3 So, there's actually a broad array of products that we
4 have allowed labeling for but with a distinct focus on
5 cleaners and detergents.

6 We have not used the tox classifications that
7 the pesticides program does. As a matter of fact, in
8 investigating some of the products that we have allowed
9 labeling for, we've seen some disconnects between the way
10 that the pesticides program would look at and the way
11 that we would look at them. But in terms of recognition,
12 allowing use of the logo on pesticide products, we would
13 have the most conservative view rule in both cases or in
14 the case of that recognition.

15 In terms of what consumers see and understand,
16 my understanding -- Pat's comment about the Energy Star
17 program I think is an important one. The Energy Star
18 program is a longer established program that has had
19 resources to look into the effects of what their logo
20 means. They have been able to show a correspondence
21 between the placement of that logo on products and
22 changes in consumer behavior and the consumer

1 understanding of and response to that logo.

2 We haven't been around that long, but we have
3 been party to or been shown the results of focus groups
4 and so forth that some of our partners who are
5 manufacturers of commercial products have done both
6 before and after they have labeled the product. So, they
7 have a good understanding that there is a good
8 communication from this logo and that the people see it
9 and find that to be an indicator of something that would
10 be better. I think we've seen movement in the
11 marketplace recently that shows on the ground that this
12 is the case.

13 The other thing that we've got here, I would
14 like to point out, is folks like Wal Mart and Home Depot
15 see DfE our program and the technical depth of our
16 program as a positive metric for sustainability and are
17 asking their suppliers who want to show an improved
18 sustainability footprint to work with us to come up with
19 safer products, which is, frankly, one of the most
20 important reasons that we are up over 1,000 products
21 right now.

22 We are at the place where we can document the

1 pounds of better chemicals that are used in the products
2 that we've labeled. That's up on our web site and is in
3 the hundreds of millions of pounds. We believe that
4 that's an important thing, too.

5 So, I hear, understand and agree with the -- I
6 think I've heard it at least three times of, you know,
7 what the consumers think of this mark. We're not where
8 we might be in an ideal world, but we do have a
9 reasonable understanding of what it conveys.

10 UNIDENTIFIED FEMALE: I'm going to stop the
11 questions right now. I have made a list of those with
12 their cards up, so you'll go first once we hear the
13 second presentation. You can ask questions of the first
14 group as well as Pat and Michael Fry, who are the leads
15 on our --

16 Michael, are you more comfortable staying there
17 or would you like to come up? Good point.

18 As I indicated at the outset, we have a second
19 pilot recommendation from the work group and this has to
20 do with factual statements being allowed to be made on
21 pesticide labels. Pat Quinn and Michael Fry are the co-
22 leads on this report.

1 MR. QUINN: Thanks, Marty. So, I will get
2 started. Michael and I have talked, at least just a bit,
3 previously and so we hope to complement each other here.

4 Alongside the logo discussions, there's been a
5 rather consistent interest on the part of particularly
6 antimicrobial registrants but consumer product
7 registrants in general in being able to say things that
8 are factually demonstrable about the environmental
9 characteristics of those products. So, this particular
10 group, Marty gave it the very catchy name of limited
11 factual statements and standards. That is really sort of
12 where we started.

13 So, the charge to the subgroup I think was
14 basically take a look at whether or not EPA could find a
15 basis for an expanded use of these factual statements.
16 Importantly, I think, the emphasis we were given is to
17 draw upon existing standards, existing test methods and
18 existing federal policy where available to base these
19 kinds of statements upon.

20 I think also at the outset, we were reminded to
21 keep two things in mind. One was that we were really
22 going to design this with an eye toward avoiding consumer

1 misunderstanding. We're also going to try and design
2 something that was not an overwhelming resource
3 commitment for the agency to review but something which
4 did preserve the integrity of the product review process.

5 So, we had a very diverse and I'm happy to say
6 a very active stakeholder group that worked on this. We
7 had EPA representatives, we had industry people, we had
8 NGOs, we had both California and New York represented and
9 within the agency quite a diverse participation from the
10 general counsel's office, the compliance office,
11 antimicrobial division -- Clive was quite active in the
12 group -- and others as well. And I think as a measure of
13 the level of engagement, we had virtually everybody
14 participate in at least one of the three group conference
15 calls.

16 So, we produced three sort of work products,
17 and here they are. One is simply a discussion of the
18 relevant statutory authority rules, label manual
19 guidance. We thought it was prudent at the start to
20 understand the four walls we're operating within so that
21 we did not go beyond what the law and the regs allow us
22 to do.

1 What I'm really going to focus on today is the
2 second bullet, which are the potential principles the
3 agency might base such a policy upon and representative
4 examples. Then we also, quite fortunately, found that
5 because these characteristics of products, because these
6 terms have such wide currency, there are a lot of federal
7 programs, a lot of standards, a lot of existing test
8 methods to base this upon.

9 So, I won't spend a lot of time on this. I
10 think everybody is familiar with this portion of FIFRA
11 that prohibits any kind of a statement that is false or
12 misleading. This one I've learned and forgotten because
13 I'm getting too old. Back in 1996, many of us worked on
14 the amendments to the act, which, from an antimicrobial
15 perspective, really focused on trying to convince
16 Congress that these products were somewhat different,
17 that they had different use patterns, they presented
18 different challenges, they ought to be treated a bit
19 differently.

20 It turns out that when you look at the statute,
21 there's a reference which is actually quite relevant to
22 this, which deals specifically with antimicrobial

1 products and says you can say things about the product
2 efficacy composition and container composition or other
3 characteristics. Now, I will say that is qualified by
4 the false and misleading prohibition, but it is rather
5 specific. And then we looked at the regulations and the
6 guidance, particularly PR Notice 9810, which is quite
7 related to what we're doing here.

8 So, I'm going to focus on three areas which the
9 subgroup talked about extensively as being areas where we
10 might have a policy based upon these principles and some
11 examples of what it might allow you to say. The first --
12 and, you know, forgive the murdering of the English
13 language here -- nonpesticidal factual statements
14 regarding product characteristics other than the
15 pesticide are presumptively acceptable. So, you might
16 say something about recycled content. You might say
17 something about soy-based ink.

18 You might -- I don't know whether we have eco
19 bottles on the table today but we should. You know,
20 you'll see frequently now water bottles that say made
21 with 33 percent less plastic than our previous bottle.
22 So, that's really what we have in mind here, something

1 that really goes to the packaging, the container itself.

2 The second area of interest, and quite a strong
3 interest by registrants, was being able to say something
4 about their other environmental commitments. So, these
5 would be efforts by a company that was interested in
6 climate change, in greenhouse gas reductions, in safe
7 drinking water in the third world, in drawing consumer's
8 attention perhaps by a web site link to that. If you
9 want to see more about what Clorox is doing to provide
10 safe drinking water in Africa, go to.

11 So, there's our example. I'd forgotten I'd put
12 this in here. But you might go to a web site that was
13 talking about the sustainability efforts by a company.
14 We'll talk about some concerns that were raised and
15 limitations placed on that.

16 Then, finally -- and we spent a lot of time on
17 this last third bullet -- we're talking about
18 characteristics here which involve the pesticides
19 themselves. Here, let's just focus on a couple of the
20 examples.

21 Fragrance free, dye free, not things that we've
22 been able to say up until this point, important to some

1 consumers who are making choices about products, fairly
2 easy to verify since you're only looking at a
3 confidential statement of formula. Either there's a
4 fragrance there or there's not.

5 Readily biodegradable in water, we're going to
6 talk in more detail in a moment about this. Contains X
7 percent of plant derived ingredients, the subgroup had
8 some vigorous discussion about this, as you can imagine.
9 We'll talk about that in a moment.

10 Then, an area that I think is increasingly
11 important to a lot of companies who are shipping product
12 where they can go to concentrates and really minimize the
13 effect on air quality and greenhouse gas emissions, again
14 something that's fairly easy to quantify.

15 Okay, so, this is really where we focused
16 within all of that. We focused on corporate commitments.
17 Here people had concerns. What we were doing was we were
18 reopening the familiar episode of the Red Cross logo.
19 We're really getting back into cause marketing. So, I'll
20 show you how we dealt with that in a moment.

21 Biodegradable, enormous help from particularly
22 DfE on this. They do a lot of biodegradability analysis.

1 There is, it turns out, an existing OPPTS guideline on
2 ready biodegradability in water. So, we were happy to
3 put our hands on that. There are OECD methods which are
4 widely accepted by everyone as being the appropriate
5 measure. There are some limitations because they're
6 ingredient specific. We need to come to grips with that.

7 Plant derived, here I want to give credit to
8 Bill Bailick (phonetic), ISSA, others in the group who
9 really drew our attention to what the farm bill did in
10 2001, 2002. They set up a bio-based product procurement
11 requirement. So, hopefully, EPA is now buying bio-based
12 cleaning products because they've been told to. They
13 have a rule that is final that lays out the
14 characteristics of these bio-based products.

15 There's a lot of language in the rule and in a
16 related executive order which talks about the value of
17 plant-based and bio-based products from the standpoint of
18 renewability and disposal. So, we tried to draw upon
19 that.

20 It turns out there's a method that involves
21 radio carbon dating and is again widely accepted. ASTM
22 owns it. You have to buy it. But it gives you an

1 objective measure of the degree to which a product is
2 plant-based.

3 Then, finally, in the options for
4 implementation, we won't spend a lot of time on this --
5 some people in the group felt that this was already well
6 policed by the FTC. That option was shredded by many
7 stakeholders as being inappropriate. We were told that
8 thanks very much, EPA and the states will do the
9 compliance.

10 So, I'll just go through these quickly.
11 There's you OPPTS guideline on radio biodegradability.
12 As I said, there are a series of USDA rules on bio-based
13 products. The cleaning product rule is cited there. The
14 OECD test methods and the ASTM method.

15 So, our recommendations are the following.
16 That OPP should begin to allow limited factual statements
17 for antimicrobial products. I want to say that many
18 members of the subgroup feel that these principles are
19 equally applicable to other consumer products; for
20 instance, lawn and garden. I want to also recognize that
21 we were made to understand that agricultural pesticides
22 do not have an interest in these types of statements and

1 want not to be a part of the process.

2 We also talked a bit about implementation.

3 I'll say more about that in a moment because a few of us
4 have had a chance to talk to Marty about how we might
5 initially implement all of this. Then, lastly, what we
6 said is in spirit, these statements need to be consistent
7 with whatever DfE logo program EPA might adopt.

8 These are not fixed in stone. They are the
9 product of only a couple of discussions that Michael,
10 Marty, Cleo, and a few of us have had about how this
11 might get rolled out. But the notion of a pilot
12 registered antimicrobial products, and I'm talking about
13 25B products to be clear here, we are not.

14 We were initially thinking 12 months, although
15 I have to say that I've had some feedback from members of
16 the subgroup who don't think that's long enough,
17 including Jeanine in New York who thinks that, you know,
18 probably correctly, it takes quite a while to get these
19 things through the states and maybe 18 months would be
20 more appropriate.

21 This would be done by amendment or new product
22 registration, not by notification, if the EPA folks feel

1 strongly, and the states do as well, if they want to see
2 all of the data and all of the documentation during the
3 pilot and then sort out what they want to see and what
4 they don't need to see if we go forward with full-blown
5 implementation.

6 June is just not fixed in stone at all. It
7 just seemed like a plausible possible launch time. We
8 intend to take public comment during the pilot and at the
9 conclusion of the pilot once we've kind of set up some
10 points of evaluation for it.

11 So, thank you.

12 MS. EDWARDS: Michael, do you want to add
13 something?

14 (Audio problems)

15 MICHAEL: All right, as you can imagine, I had
16 some questions about things such as green labels and bio-
17 based content and this kind of thing. I was very
18 gratified to see ASTM methods that can identify recent
19 carbon input into plants relative to ancient carbon
20 inputs into petroleum, for instance, and being able to
21 distinguish those with a hard science criterion of carbon
22 dating, carbon 14 content. So, I think that was very

1 nice.

2 Similarly, the biodegradability I think is very
3 important that there are established standards for these.
4 So, with those two things to be included in it, I have
5 much greater acceptance of the pilot.

6 Now, with regard to biodegradability, there is
7 a discussion within the subgroup. Some in the subgroup
8 were quite concerned that things like surfactants
9 (phonetic), which are active in the environment, they
10 must be biodegradable. But there was question as to
11 whether or not the active ingredient needed to be
12 biodegradable as well to have this biodegradability put
13 on the label.

14 I am extremely adamant in saying that all
15 ingredients in the product must be biodegradable for a
16 label to have biodegradability on it. In fact, if
17 anything, you know, it's particularly important to have
18 an active ingredient be biodegradable to have a
19 biodegradability label on the product, especially if this
20 is essentially a certification on the part of EPA.

21 So, with those caveats in here, I was quite
22 happy with the outcome of the subgroup and I was really

1 quite pleased at the, you know, the way the industry and
2 everybody here went forward with this.

3 I need to digress just slightly, and I haven't
4 discussed this with the subgroup at all because it came
5 up the day before yesterday. The Washington Post online
6 media talked about a new label that was approved by EPA
7 on the 23rd of January for a BASF product called
8 Headline. It's a fungicide pyroclostroban (phonetic).

9 The news release that came out of BASF said
10 that this fungicide EPA has approved plant health claims
11 on the label, a new precedent for the agricultural
12 community. The plant health claims benefits are improved
13 growth, efficiency, excellent disease control, enhanced
14 tolerance to stress conditions such as drought, heat,
15 cold, temperature and ozone damage even in the absence of
16 any damaging fungi.

17 This was really troubling that the EPA would
18 permit a label allowing this kind of marketing claim.
19 Apparently, my discussions with Bill Jordan on this, the
20 EPA does not evaluate the efficacy of a product, only its
21 safety. This is really bobby (phonetic) as far as I'm
22 concerned, to have a marketing claim sanctioned by the

1 EPA on plant health of a product that is presumably going
2 to be applied widely in commercial agriculture based not
3 on its fungicidal properties but on the fact that it's
4 "like a vitamin." I really don't like pesticide claims
5 as health claims. So, since we're in this factual
6 statement discussion today, I thought I need to bring
7 that up.

8 The letter from EPA approving this from Tony
9 Kish (phonetic) and John Boswin (phonetic) says that the
10 registrant must submit by June 15th an acceptable revised
11 master label for the subject product. Inasmuch as June
12 15th is before our next PPDC meeting, I thought it was
13 important to bring this up and kill this one just as
14 quick as possible.

15 Thank you.

16 MS. EDWARDS: Thank you, Michael.

17 I'm going to go back to the order that was
18 established previously and take care of those questions
19 or comments first.

20 Tom Green, you're first.

21 MR. GREEN: Thanks. I'm excited about this
22 program. I think it's really a good addition to the

1 signal words or reduced risk product classification, the
2 signal to less toxic to users. I have concerns about
3 25Bs being excluded and wasn't sure whether that's the
4 case with the DfE pilots. I'd hate to see this program
5 work to the detriment of those manufacturers who have
6 been developing 25B products that might be a disadvantage
7 on the shelf there without this label. There are more of
8 these products out there that are finding good effective
9 sets in the pest management programs.

10 Also wondering about your list of criteria,
11 whether that's on top of criteria that DfE already uses
12 and, if not, whether there's an opportunity to include
13 other issues like reproductive and developmental
14 toxicity, neurotoxicity, active ingredients on the toxic
15 release inventory, endocrine effects, and so forth.

16 Then finally, I had questions about
17 restrictions on marketing, no comparisons to other
18 products. Does that apply just to the label or does that
19 mean anywhere in the product literature or on the product
20 web site?

21 If that's a concern, I think you need to
22 anticipate that user groups are going to start making

1 those comparisons in their literature and on their web
2 site. For example, I can see a healthy hospital's
3 organization putting that comparison together and
4 question whether that restriction should be placed on the
5 manufacturers who might be in a better position to make
6 accurate comparisons rather than third parties.

7 UNIDENTIFIED MALE: With regard to the 25B
8 products, I think Marty alluded to earlier that under the
9 advice of counsel, we wouldn't be excluding anybody who
10 wants to actually participate in the logo implementation
11 portion of the pilot. So, to my knowledge, we would not
12 be excluding them. If they wanted to come through the
13 DfE screening and then the subsequent OPP review, they
14 could do so.

15 With regard to the expansion of the criteria,
16 much, if not all, of what you listed out there in terms
17 of neurotox, developmental tox, and the other issues are
18 already being discussed as part of the inherent criteria.
19 The question as to whether or not the DfE factors and
20 evaluation criteria are included, this would be in
21 addition to what the folks over at DfE are already doing.

22 So, as Clive alluded to earlier, this would be

1 the most conservative way that we could actually get a
2 product through and have a logo on it. So, you'd have to
3 satisfy both DfE's criteria and the additional criteria
4 that we would set if we felt that additional criteria
5 were warranted.

6 Did you have a third question that I missed?

7 MR. GREEN: That was on the marketing
8 limitations.

9 UNIDENTIFIED MALE: Okay, thank you. Right
10 now, if a company chooses to have a product registered
11 and make claims on their web site that differ from their
12 EPA-accepted label, then under 40 CFR 168-22 and the
13 FIFRA Section 12, we will go after that person because
14 you have now marketed a product with claims differ.
15 168-22 refers to advertising in claims. That includes
16 the internet, that includes mail outs and other things.
17 So, we have taken enforcement action with the Office of
18 Enforcement Compliance Assurance on those type of claims
19 that are on the web site.

20 One of the things we did discuss in a subgroup
21 was that if you wanted to actually go out and make a
22 claim right now, there's no requirement that you actually

1 come in and have that claim reviewed prior to doing so.
2 But you do so under your own peril if you go out there
3 and actually exceed the claim.

4 We have in the past asked registrants or told
5 registrants they need to remove a link from their web
6 site that did go to a hospital association that did say
7 we believe this product is environmentally preferable to
8 the others that are out there or we think this class of
9 chemicals is better than the others. We've said we may
10 not regulate that web site because they don't have
11 registered products, but you can't link to that site and
12 you can't reference that site in the sale and
13 distribution of your product. So, those principles and
14 laws and statutes and regs will still apply.

15 MR. GREEN: Okay, thanks. I think it would be
16 helpful for us if we could see the DfE criteria that
17 these criteria would be on top of.

18 MS. EDWARDS: I just want to clarify one
19 statement that Michael made about the 25B products. We
20 had a lot of discussion about the 25B products.
21 Essentially, because they are not registered and they
22 could conceivably pose a lot of issues with the states,

1 we decided that the initial outset for the pilot we would
2 not include them, although we didn't rule them out. They
3 just weren't going to be the focus of the initial pilot
4 because of the surrounding issues about them not being
5 registered. If you recall, one of our criteria to be
6 considered was that the product be a registered product
7 for the pilot.

8 UNIDENTIFIED MALE: One thing that I wanted to
9 say is that we have looked at at the actives and then
10 we've looked at the inerts with OPP about the endpoints
11 that we would consider and the endpoints that we would
12 consider for the actives are actually pretty well
13 harmonized already. And then, for the inerts, we would
14 use the set of endpoints that is used in the high
15 production volume, moderate production volume, challenge
16 that chemical manufacturers are initiating or are working
17 on now under the Champ (phonetic) program, if you're
18 familiar with that, under OPPT.

19 So, repro tox, mutagenicity (phonetic),
20 carcinogenicity, aquatic toxicity, a full range of
21 endpoints is included under DfE consideration. Actually,
22 we call it our general screen is on our web site and it

1 lists those toxicological considerations and thresholds
2 beyond which we consider there to be a level of concern
3 and wouldn't allow the ingredients. I'd be happy to go
4 through that whenever convenient for folks.

5 UNIDENTIFIED FEMALE: I think actually most of
6 my questions have been answered. My big one was just
7 answered one second ago.

8 So, I guess overall, then, I'd just like to say
9 that I generally support the project and I support going
10 in this direction. I would actually just like on the
11 next PPD to have more information. I'm not very familiar
12 with the Design for the Environment and I don't have
13 access to look at the web site now. I was concerned
14 about the CMR and PBT issue, the carcinogen/mutagen
15 reproductive toxin and (inaudible) toxic. But in your
16 last statement it sounds like you are considering those
17 things.

18 I also saw on my little Blackberry ability to
19 go on the web site that in 2007, your web site says that
20 you've reduced by 80 million pounds chemicals of concern
21 in those products, which is pretty significant. So, I
22 would support it with -- just that I want to go beyond

1 the acute toxicity endpoints. It sounds like you are.

2 And then, I would at some point like to put on
3 the agenda wherever it is appropriate this issue that
4 Michael brought up about claims made on labels that are
5 -- because this efficacy thing is going to be important
6 because some of the things that will get into your
7 program as green chemistry are getting in because you can
8 use less of the chemical because it's more potent or
9 longer lasting. That's a real toss-up issue that I'm not
10 very comfortable with. I think it does deserve a bit of
11 conversation.

12 UNIDENTIFIED FEMALE: I wanted to just say some
13 of the general things that I have said at most of the
14 work group meetings just for the benefit of everyone who
15 hasn't heard me a few times already. One is that I think
16 there is a really strong consumer demand for this kind of
17 program. I think it's really appropriate that EPA
18 recognize that consumer demand and try to meet it.

19 One of the things that I believe that
20 consumers, you know, really want in a program like this
21 is basically they want to be able to trust the program.
22 Most consumers don't want to have to do their own

1 independent evaluation of the ingredients in some
2 antimicrobial product, you know, or any pesticide
3 product.

4 So, to establish that trust, I think there's a
5 few things that are really important. Probably the most
6 important is that the criteria for the logo be really
7 transparent. I was actually impressed when I looked at
8 the DfE web site that it did feel to me like the criteria
9 were really clearly explained and really transparent and
10 that it was something that an ordinary person could look
11 at and understand.

12 I hope that if DfE and OPP are working
13 together, that there can be an equally transparent
14 explanation of how that process works and just how the
15 whole evaluation process will proceed so that people
16 really will have trust in this logo and it will provide
17 the kind of assurance that people are looking for.

18 One of the sort of flip sides about trust is I
19 think this example that Michael brought up that if -- at
20 the same time we're pursuing this logo for consumer
21 products, if at the same time EPA is approving label
22 statements that -- where the process is not very

1 transparent and there isn't -- there doesn't seem to be
2 the kind of background, unless there's something that
3 we're missing here, that's going to undermine the trust
4 and it's going to make it really hard for organizations
5 like the one I work for to be able to recommend to folks
6 that they use this DfE logo as a criteria for their
7 purchasing decisions.

8 UNIDENTIFIED MALE: I put my card up about an
9 hour ago. I don't remember what I put it up for, but I
10 kept it up because I didn't want to lose my place in
11 line.

12 I think there are two things I would like to
13 talk about. One is to maybe stress the urgency of this
14 issue and what I mean by that is there is a large group
15 of consumers, but particularly state and local government
16 agencies, that are demanding green products and services.
17 I think in the absence of some definitive action from the
18 government, EPA, other people are stepping into the
19 breach. I just urge you to act quickly to address that
20 consumer demand in the marketplace before somebody else
21 does and maybe doesn't do it as well as you're capable of
22 doing it.

1 According to Jay Leno last night, he said
2 everybody is looking for green products. He said even
3 Dick Chaney is looking for them, that he issued a press
4 release yesterday urging the government to only use
5 recycled water when they water board. I didn't make that
6 up. That's what Jay Leno said.

7 The second point I wanted to make, though --
8 and this is I think what I was -- when I put my card up
9 in the first place -- Michael, I think what I heard you
10 say is that OGC has said, well, though you're only
11 thinking about antimicrobials, did I understand you to
12 say that you can't discriminate against other types of
13 products?

14 MICHAEL: Yes. We were advised that we could
15 exclude others.

16 UNIDENTIFIED MALE: This is kind of a big point
17 for me. I think that fundamentally changes this whole
18 question in some big ways. The criteria that I think
19 you've done a good job of articulating for antimicrobials
20 may not necessarily be the right criteria for products
21 other than antimicrobials. I think there's a lot of us
22 that kind of checked out of this process at the point at

1 which the agency said, well, for the time being, we're
2 going to do a pilot that only involves consumer
3 antimicrobial products. I would like to suggest -- I
4 mean, I've got like about 20 questions.

5 When you said this might apply to things other
6 than antimicrobials, I started writing questions. I'm
7 not going to ask them all, but I'd love to see a
8 conference call or a meeting really soon -- I mean next
9 week even -- to talk about the question of whether those
10 criteria are the -- again, I'm not ranting on
11 antimicrobials. I think you did a great job. But are
12 those the right criteria for things that are conventional
13 insecticides?

14 AMY: The benefit here is I've now got two
15 pages of questions. The American Association of
16 Pesticide Safety Educators has -- which includes
17 pesticide safety, educator's firm extension, and also
18 state lead agency people, and private consultants. We
19 have some concerns about how this goes.

20 One of the things that is of most concern is
21 that moving the market to purchasing logo products -- and
22 I have no doubt that the logo programs that are currently

1 there or that marketers and manufacturers are finding
2 them that they are effective in moving the market toward
3 purchasing those logo'd products or safety statements
4 could -- or factual statements could, in some cases, do
5 the same kind of thing.

6 But moving people toward what you might
7 perceive as a better purchasing decision is not
8 necessarily the same as moving people toward a better use
9 decision and better use practices. In fact, it could be
10 quote at odds with fostering better use conditions. I
11 would say that it's not only not equivalent necessarily
12 but it could be even poorer.

13 If we don't know ahead of time what people are
14 doing -- these products that we're discussing now, it's
15 not just a matter of the green chemistry and the safer
16 chemistry. It's a matter of the use conditions, making
17 sure they're continued to be used on the right site for
18 the right pests at the right rates.

19 All of that information with the right re-entry
20 period, the right preharvest intervals, people have to
21 still keep reading all of the pesticide label to ensure
22 that they're using these products correctly and achieving

1 your goal which really surrounds protecting human health
2 and the environment better than just getting people to
3 buy a product with "green chemistry" and then
4 disregarding the rest of the label requirements.

5 So, that's a very, very great concern to us
6 because I think if you look at the impact down the road,
7 you might see some things occur that you had not
8 envisioned as a result of this. There still should be
9 ways to do it.

10 The second thing is the conventional pesticides
11 are very, very different from antimicrobials. The market
12 and the people who use them have different cultures of
13 education and backgrounds. I agree with Bob that this is
14 a very different thing.

15 When we first talked about a pilot program
16 starting out for just the antimicrobials and
17 disinfectants and sanitizers, that was a different thing
18 than talking about -- now that you've been advised by
19 your counsel that you can't restrict it should some
20 products that are conventional pesticides wish to get
21 into this program. It's not only, again, just a
22 criteria, but a pilot program to test how well the

1 program works for the sanitizers and disinfectants that
2 would not necessarily at all carry over to the evaluation
3 of how it would work for conventional pesticides.

4 So, I think if this could happen, I really
5 really think that you need to do two pilot projects or as
6 many as you need for the many different sectors that you
7 have. You might need one for consumer products, one for
8 ag products.

9 Then, Bob Rosenberg also mentioned the state
10 and local government pressure for green products. I
11 agree with that. That's something that we see with our
12 state-lead agencies, the concerns of where that would go
13 if you move the market so much that, for instance, the
14 organophosphates (phonetic), let's say, are no longer
15 logo'd products or their factual statements make them no
16 longer desirable products for people to use. How are you
17 going to resolve concerns about resistance development as
18 you move the market away from these kinds of products?

19 So, yes, we do want to accomplish all these
20 things but how do you make sure that you at least keep
21 the tools that you need and don't end up having state and
22 local governments and perhaps retailers, perhaps grocery

1 stores, saying that they really only want crops and foods
2 that have been grown with the logo'd products or the
3 factual statement products. So, these are just things
4 that you need to design into your evaluation first and
5 see how that's going to go.

6 Finally, on the eco bottles, I would really
7 stay away with any statements that say reduction because,
8 for instance, envision manufacturer A with 20 percent of
9 this better plastic in their product from the beginning
10 and manufacturers B with 75 percent. A 30 percent
11 reduction by manufacturer B would bring them down to 50
12 percent and they'd still be a far worse bottle to choose
13 than the bottle that started out with a better product to
14 begin with. But manufacturer A wouldn't be able to
15 advertise that. So, really be careful with your factual
16 statements. They can very well be misleading.

17 PAT: I appreciate those comments, Amy. With
18 regard to the last one, and I think it may be a larger
19 point, I think what you're -- to me what you're trying to
20 encourage if you're the agency and you're embarking on
21 any of this, is directional change. So, while not
22 everybody's environmental practices may be as good as

1 others, if you can encourage directionally everybody who
2 is manufacturing a bottle to use 33 percent less than
3 they did a month ago, that's desirable.

4 I'm not sure that the consumer is really going
5 to be confused to a point where we need to be terribly
6 concerned. I mean, that's really the reason to do this,
7 is the success that we've seen in other areas with these
8 kinds of logo programs, particular when the logo is
9 backed by this agency and the trust that the people have
10 in the agency. That to me is really the point here.

11 AMY: I disagree, Pat, that if a product
12 already has 10 percent versus a product that is now down
13 to 50 and you're now forcing -- now consumers are going
14 to go buy the one that's got 50 instead of the one that's
15 got 10 percent. That's my only point in the wording
16 there.

17 UNIDENTIFIED FEMALE: And those are criteria
18 that we're still working on.

19 I have a sense -- we've already run over time
20 -- I have a sense that what I've heard thus far is that
21 we need to do a little bit more work on the DfE logo
22 pilot, particularly around clarifying this issue of

1 antimicrobials versus other conventional type products
2 being included in a pilot or maybe a secondary pilot that
3 perhaps is not a comfort level that we would like to have
4 a recommendation to go forward immediately with that but
5 in very short order will get some clarity around that and
6 I'll follow up with Bob's suggestion that we have a
7 conference call to vet those kinds of issues that have
8 been raised.

9 I'm wondering if the remaining tenth -- and
10 what I'd like to do is hear from those that have not yet
11 had a chance to speak but also if you would like to
12 address the issue of factual statements. But before we
13 go there, I would like to turn it over to (inaudible).

14 MS. EDWARDS: So, here's my question. It seems
15 like there's an enormous amount of energy and interest in
16 this topic. We're going today until noon. So, there's a
17 couple options here. One is that we cut this off in
18 about five minutes, having already gone nearly 15 minutes
19 overtime. The other option is that we cut it off now,
20 come back and skip the ESA session and just continue with
21 this session the rest of the morning.

22 So, what is -- let's have a show of hands. Who

1 wants to hear the ESA session? I think that's the
2 important part. Okay, that's what we'll do then.

3 So, five more minutes and then we'll take a
4 break.

5 UNIDENTIFIED FEMALE: We'll hear from those
6 that have not had a chance to speak, so I'm going to
7 start with Scott.

8 SCOTT: Thank you. In reference to the
9 comments on the headline label, I do want to note that --
10 are not qualified to respond or (inaudible) the BASF
11 that's not at the table too. The degree of discussions
12 on that I think at least need to put on record that they
13 are not here to respond.

14 UNIDENTIFIED FEMALE: As a work group member, I
15 do want to point out that for the factual statements,
16 that there was not consensus that this be limited to
17 antimicrobial products. The scope of the principles that
18 we're looking at with regard to packaging claims or
19 corporate commitment claims are certainly not anything
20 that are unique to antimicrobial products.

21 On the one hand you're saying that other's
22 pilot is not going to be limited. I just disagree that

1 the factual statements should be limited to antimicrobial
2 products because obviously other types of products and
3 other companies have the same kinds of corporate
4 commitment and/or do the same types of things for
5 packaging and other nonpesticidal claims and issues.

6 UNIDENTIFIED MALE: Part of what I was trying
7 to reflect was the input that we did have from a work
8 group member, namely Ray McAllister (phonetic), who is
9 here in the room, who made it quite clear, at least on
10 behalf of CropLife, that their membership did not have an
11 interest in having this expanded to that sector. So, I
12 just want to reflect that.

13 Also, to just note that, as I said in my
14 presentation, it did seem to a number of members of the
15 subgroup that these principles apply very easily to, for
16 instance, something like lawn and garden products that
17 were consumer use type products.

18 UNIDENTIFIED FEMALE: I just wanted to
19 underscore that a lot of really hard work and very
20 thoughtful discussions went into developing certainly the
21 limited factual statements. I can't really speak
22 concerning the DfE pilot logo, although knowing the

1 people involved, I'm sure that's true of that effort as
2 well.

3 I do think it's very important in looking at
4 that pilot, logo pilot program, that you give -- that we
5 do exactly what you suggested, Marty, and that is that we
6 have more discussions about including pesticides and what
7 that would mean in terms of the criteria that would be
8 used to evaluate the pesticides because they are
9 conventional pesticides. They are very different from
10 the antimicrobials.

11 I would hate to see a pilot program that, as
12 far as we know, has been designed with testing
13 antimicrobials expanded without that same kind of
14 thoughtful deliberation. Then we end up with a bad
15 result, which would defeat the ultimate goal.

16 So, those are my comments.

17 UNIDENTIFIED MALE: I happen to, as I said
18 yesterday, think that there's a lot that can be done to
19 improve the trust in the agency. What I would not like
20 to see come out of this program would be a loss of trust
21 in the agency regarding pesticides that do not --
22 companies that do not choose to put their products

1 through a program like this.

2 Safety is a critical issue in the registration
3 of pesticides. So, I think we -- as we move into what
4 one referred to as conventional pesticides, we walk a
5 very fine line between the discrimination against
6 products that may not fall into this category while they
7 are still safe for humans and the environment because of
8 the rigorous program that they go through.

9 So, I agree with Beth entirely that we must
10 look at moving this program to cover more than
11 antimicrobials very very carefully and give it, in my
12 view, much greater rigor than we may be able to do with
13 antimicrobials.

14 I may have not heard well earlier in Michael's
15 presentation. How is the word safe and safer allowed or
16 not allowed to be used in the DfE program? Is the word
17 safe or safer allowed in any way in that program?

18 MICHAEL: If you go to the DfE web site --

19 UNIDENTIFIED MALE: Which I apologize, I have
20 not.

21 MICHAEL: I believe the language that's out
22 there does say safer. Clive would actually be better to

1 respond to this, but I do believe it says safer.

2 CLIVE: Yeah, it says -- in fact, the tag line
3 that's associated with the logo when the logo is used is
4 recognized for safer chemistry. But the group -- the
5 PPDC subgroup that's been discussing this issue has
6 voiced that that may not be the appropriate tag line for
7 pesticide products.

8 (Audio problems)

9 MS. EDWARDS: All right. For our final major
10 session during this PPDC meeting, we're going to give you
11 an update on our ESA consultation status. The session
12 chair for this is Don Brady. He'll give you a relatively
13 short presentation followed by time for some comment and
14 discussion.

15 Don.

16 UPDATE ON ESA CONSULTATION STATUS

17 MR. BRADY: Thank you, Debbie. I'm joined at
18 the table by Mark Diner (phonetic) from our General
19 Counsel's Office in case any technical legal questions
20 come up. I'm hoping they won't. If we hear a voice from
21 the speaker, it may be Arty Williams (phonetic), if she's
22 managed to call in.

1 This hour that's set aside I think reflects the
2 request at one of the earlier PPDC meetings that we leave
3 some substantial block of time to talk about ESA issues
4 as we in EPA move through with the things that we need to
5 do given the current state of the program, which I will
6 describe here for you today.

7 So, what I wanted to talk about today in the
8 presentation quickly is to describe the two final
9 biological opinions that we've received from NOAA on six
10 pesticides, give you a quick update on some of the recent
11 interaction we've had with the Fish and Wildlife Service,
12 spend about two minutes talking about Bulletins Live and
13 then give you some information on a work group that we've
14 formed in EFEED which involves both of the Services to
15 begin to address some of the science issues that have
16 been raised between the Services and us.

17 The biological opinions that we've now
18 received, the two finals, are from NMFS, are the result
19 of a settlement agreement between NMFS and the Northwest
20 Coalition for Alternative Pesticides. It requires
21 completion of consultation on 37 actions for which EPA
22 initiated consultations between 2001 and 2005. Opinions

1 have been issued for six pesticides. Those six opinions
2 are contained in the two biops that we've received.

3 There's remaining 31 actions or consultations
4 that will be addressed between now and February 2012 in 8
5 additional biological opinions. The next expected
6 biological opinion is in June 2010. I'll talk a little
7 bit about how we're hoping to use some of that time
8 internally to do some work on the (inaudible).

9 So, these opinions were issued in November 2008
10 for three OPs, chlorpyrifos, diazinon and malathion and
11 in April 2009 for three carbamates, carbaryl, carbofuran,
12 and methomyl.

13 What I've done in the next couple slides is
14 because there's some complexity -- these are large
15 documents. The first biop was 500 pages, the second biop
16 is 600 pages. So, these are substantial documents. I've
17 tried to put in table form first what the conclusions of
18 the biological opinions were and then the next couple
19 slides will describe what are called the reasonable and
20 prudent alternatives.

21 So, there are 28 ecologically significant
22 units, Pacific Salmona (phonetic) -- I can't say salmona.

1 That's bad for a guy with my job -- fish. I can say
2 anadromous, though. There's critical habitat designated
3 for 26 of those 28. So, as you look through the numbers,
4 they don't all necessarily add to those 28 ESUs.

5 But this table describes the findings. So, for
6 the three OPs, for all three of the pesticides included
7 in that opinion, in that biological opinion, jeopardy was
8 found in 27 of the 28 ESUs. There was adverse
9 modification to critical habitat in 25 of the 26
10 designated ESUs. There was no jeopardy or habitat
11 modification found in one ESU in the three pesticides --
12 the three OPs covered in the first biological opinion.

13 The second biological opinion, unlike the
14 first, treated carbaryl and carbofuran as one and
15 methomyl as a separate analysis. So, that's why they're
16 broken out separately on this table. I won't read each
17 one of these, but this hopefully gives you a snapshot of
18 what the findings in the biops were.

19 The thing to note is that when jeopardy is
20 found, the opinion provides an RPA, a reasonable and
21 prudent alternative, which when implemented will preclude
22 jeopardy. Then you're out of the realm of jeopardy if

1 you implement the RPA. But the action can still result
2 in individual -- take of individual members of the
3 species.

4 Therefore, included in the biological opinion
5 is an incidental take statement, and RPMs, reasonable and
6 prudent measures, are provided to reduce the impact of
7 take on the number of individuals in the population. So,
8 we'll talk about RPAs and RPMs. I just wanted to get
9 that concept out there.

10 So, on the next page we see the first four of
11 the biological -- of the RPAs provided; application
12 buffers, vegetative buffer strips, wind speed, and
13 moisture. Under each column there, it describes the
14 biological opinion provided by way of RPA for us. I also
15 included, if you look under --

16 In the first cell under application buffers for
17 the three OPs, you'll see one part per billion and 12
18 parts per billion. These were in stream concentration
19 that resulted when the models were run by NOAA based on
20 their buffer strips. I put that in there because these
21 in stream concentrations have gotten a lot of attention
22 and have been the focus of a fair amount of discussion,

1 certainly on the 12th floor in EFED.

2 But the thing to note is that the biop didn't
3 say meet the concentration and there will be no jeopardy;
4 the biop said apply the buffers and there will be no
5 jeopardy. So, it's a small nuance but it's important to
6 us as we in EPA decide how we are going to respond to
7 this.

8 The next page has the remaining two RPAs, one
9 for reporting and one for monitoring. So, for the
10 reporting example, fish mortality within four days of the
11 application and the vicinity of application was forwarded
12 to EPA. Those are the same for all of the opinions --
13 all of the consultations that we received.

14 If you read the biop, you'll know that the
15 monitoring plan is very specific, indicating the number
16 of sites, the number of days, the analytical methods that
17 need to be used. So, those six RPAs together are what
18 EPA now has to think about how we implement. So, that's
19 part of the choice that we're confronting here ourselves.

20 In the second biop there was an exception for
21 Willipa Bay and Greys Harbor. That was treated a little
22 differently because of some previous work there. It's a

1 detail just to show that there was some discernment in
2 that second biop that recognized some of the previous
3 regulatory actions that had been taken.

4 Then we go to the RPMs, the reasonable and
5 prudent measures, which we have to implement. So, even
6 with the RPA, the action will result in take. Therefore,
7 an incidental take statement was provided and we have to
8 implement the reasonable and prudent measures to minimize
9 the impact of take.

10 So, the RPM states that EPA must minimize the
11 amount and extent of incidental take from use of
12 pesticide products containing the active ingredient by
13 reducing the potential of chemicals reaching the water.
14 Monitor any incident take or surrogate measure of take
15 that occurs from the action. Report annually to NMFS
16 Office of Protected Resources on the monitoring results
17 from the previous season.

18 So, now you have two of the elements that EPA
19 is obligated to respond to, the set of six RPAs and the
20 reasonable and prudent measures that apply that are the
21 same for both.

22 Then there's a third set of terms and

1 conditions included in the biological opinion that EPA
2 must also respond to. So, I won't read everything on
3 this table. My hope was that these tables would help
4 guide people in their own reading and analysis of the
5 biological opinions.

6 But you now have the set of factors that we
7 need to consider in responding to the biological
8 opinions. We have to think about the RPAs, we have to
9 think about the RPMs, and we have to make sure that we
10 meet the terms and conditions in the biological opinion.

11 So, on the next slide it's just really a
12 summary of what I've tried to portray in the tables.
13 NMFS believes uses of the three OPs and three carbamates
14 will jeopardize the continued existence of the species
15 but jeopardy will not occur in the one year provided for
16 EPA to implement the biological opinion. I'll talk about
17 that in a minute. And EPA is considering how it might
18 implement the opinion and will inform NMFS of its
19 decisions.

20 One discussion point I thought there would
21 probably be a lot of discussion around is how EPA is
22 moving to implement. We'll get back to that as we go

1 through the rest of these slides just to set the stage.
2 The thing that's important for us is that we have until
3 November of 2009 to implement the first biological
4 opinion and we have until April 2010 to implement the
5 second biological opinion. That was part of what was
6 contained in the biops.

7 So, that's where we stand right now with NMFS.
8 We are moving in EFEED to provide recommendations to the
9 office director. The targeted date to provide those
10 recommendations on implementation is May 1st. So, it's
11 upon us and we're working very hard to do so in EFEED.

12 The next slide, 11, describes something that I
13 put in as informational because I thought people may have
14 heard about it. But on January 14th, we received a
15 letter where the Fish and Wildlife declined to engage in
16 formal consultation on a number of assessments that we
17 had sent them dating back to 2007 and 2008.

18 There were 45 determinations. These were
19 litigation driven. They encompassed effects,
20 determination from three different lawsuits. These
21 include all the red-legged frog assessments, several
22 assessments relative to the Barton Spring salamander, and

1 assessment of the effects of atrazine on a variety of
2 aquatic species in the east, the midwest, and the
3 southwest.

4 I've listed on this slide the points that Fish
5 and Wildlife made to us in terms of why they deemed that
6 the packages were not adequate to initiate consultation.
7 So, I just wanted to put that out there. This is another
8 thing on our plate in terms of our current ESA
9 implementation, is to decide what to do. Obviously, this
10 involves a lot of work and effort on our part to have
11 done these assessments originally. The next step is
12 something that we're still contemplating.

13 Rick may have a comment on that later. I don't
14 know.

15 So, the next thing I wanted to just bring folks
16 up to speed on, in the interest of getting to our
17 discussion time, is Bulletins Live. If you go to the
18 Bulletins Live page in the next few days, you will find
19 that it's down for testing. But we consider the system
20 at this point to be built and complete. We will be able
21 to use Bulletins Live as a way to implement mitigations
22 that we may ask to be put in place as a result of the

1 biological opinion.

2 So, the capacity in Bulletins Live is for a
3 mitigation on a county or a subcounty level. That
4 capacity is there for the whole country at this point in
5 terms of this system. So, we are looking to that as our
6 primary implementation mechanism.

7 The first bulletin that will go up is on for
8 Wisconsin and Michigan for methoxyfenozide. That is
9 going to go up very soon. I don't have an exact or a
10 specific date, but the work has been completed and it
11 should be up very soon.

12 These bulletins -- the bulletin that I just
13 mentioned, the first one to go into Bulletins Live does
14 implement a consultation that was completed with the Fish
15 and Wildlife on the use of this pesticide related to the
16 Karner blue butterfly and Hine's emerald green dragonfly.
17 So, this is a case where we've had a consultation and
18 we're implementing on the basis of that consultation.

19 We just wanted to clarify because we had some
20 questions about this system about what it means if
21 there's no limitations reported or no requirements
22 reported for a particular pesticide. All it really

1 means, it's pretty common sense, if we've assessed a
2 pesticide and there's nothing there, that would mean that
3 there's no additional requirements in place. If we have
4 not assessed the pesticide, you shouldn't view that as
5 saying that we don't think some mitigation will at some
6 point be necessary. So, we're looking to this Bulletins
7 Live as our primary implementation mechanism.

8 The next thing that I wanted to talk about is
9 on page 15. This goes to registration review. As you
10 undoubtedly know, our stated purpose in the pesticides
11 program is to complete our ESA consultations in the
12 context of registration review. We have done so with the
13 first two of the registration review risk assessments
14 that were posted on the web site yesterday.

15 These are for clomazone and fomesafen. They
16 took two slightly different analytical approaches to
17 meeting -- to describing the impacts on endangered
18 species. Clomazone was what we call biology driven. It
19 focused on the species biology that we were concerned
20 about. Fomesafen was location driven. It looked at the
21 location of the use with the species. So, that one
22 looked at on a spacial component.

1 So, these we consider pilots. We think that
2 this approach in the pesticides program will evolve a
3 little bit over time. But this is our primary mechanism
4 of meeting our endangered species consultation
5 requirements.

6 The draft risk assessments were posted on April
7 22nd. Letters initiating consultation with Fish and
8 Wildlife and NOAA were also posted. So, we have sent a
9 letter initiating consultation on these two packages to
10 NOAA and Fish and Wildlife. Our hope is to receive and
11 review public comments in the same 135-day time frame in
12 which consultation should occur. Then the proposed
13 regulatory action could then take into account public
14 input and information from Services' Biological Opinions.

15 This is the plan that has been developed in the
16 last few years in pesticide programs for getting
17 consultations completed as part of our registration
18 review process.

19 The next thing that I want to talk about is on
20 slide 17. I'm almost done and then we'll get to
21 discussion here. That is, we did talk last time we
22 addressed this group about the Endangered Species

1 Information Tracking System. We've even since then I
2 think come up with a fancy acronym, ESITS. I'd rather
3 get one maybe ERUNS but we couldn't come up with a more
4 active one.

5 We've had some discussions with the Services
6 since we started this to design this concept that are
7 clarifying that our work here and our hope to build in
8 consultation at first with governmental and then
9 ultimately with other partners, if that's possible.
10 We're not intending to duplicate existing databases.
11 We're really in the first case attempting to identify --
12 sort of take a census of databases that are available in
13 hopes that by spreading the availability, better use can
14 be made of the existing ones.

15 Then, the next step would be to go through a
16 joint design analysis to fill gaps and databases. So, we
17 continue to work with that and discuss that with our
18 federal partners. Hopefully, the next time we come back
19 to this group we'll have more details on what that will
20 exactly look like.

21 Then, the last thing that I wanted to share
22 with you is in EFEED what we're calling our registration

1 review workgroup -- the goal of this workgroup is to
2 develop a nationwide risk assessment process to evaluate
3 the impact of pesticides on listed species and critical
4 habitat in compliance with endangered species.

5 On the next slide, you'll see sort of our goals
6 for the process that this workgroup will follow: bases
7 decisions on best available scientific and commercial
8 data; produces assessments consistent with the overview
9 document, ESA and FIFRA; and is transparent
10 scientifically and legally. So, those are the sort of
11 principles that the group in EFEED is working on.

12 Now, it's not just an EFEED group. We are
13 having active discussions with the Services about
14 involving them in this workgroup. We've had extensive
15 discussions at this point with Fish and Wildlife Service.
16 They have agreed to work with us on this workgroup.
17 We've had the same commitment from NOAA but we haven't
18 had the level of discussions yet with NOAA folks to work
19 on that.

20 So, my hope here is that by working with the
21 Services, we can address some of these issues jointly.
22 If we can address some of these issues at the outset, the

1 consultation process should go somewhat easier than it
2 has historically.

3 I'd also note that the idea to work
4 collaboratively on some of these issues was an idea that
5 was proposed to us by the Fish and Wildlife Service and
6 we are working to implement that. So, we're trying to
7 get in a collaborative mode of working here.

8 We've asked them on slide 19 to develop a
9 process that considers mitigation as part of our
10 analysis, produce publicly available guidance, reference
11 documents and templates as appropriate, and consider
12 supplementing the overview document, if appropriate.

13 One of the things that is happening as we move
14 into registration review and as we start to have
15 mitigation considered as part of our assessments, and
16 then hopefully as part of decisions for registration
17 review chemicals, is that special registration and review
18 division will play a larger role in that process of
19 developing and hopefully working out mitigations with
20 registrants if mitigations are necessary. So, there will
21 be a little bit of focus shift here from what has up
22 until now been pretty much an EFED lead on ESA, but

1 special registration review division will start to play a
2 role.

3 Then, finally, I saved the best for last on
4 page 20. These are the substantive issues that we've
5 asked the group to look at: sublethal effects in
6 defining the action area and in quantitatively and
7 qualitatively evaluating risk; how to consider tank and
8 environmental mixtures; worst case versus high end
9 estimated concentrations; the information on species
10 habitat, biology, baseline status of listed species; and
11 data standards and open literature queries.

12 If you're familiar with the state of the
13 discussions between EPA and the Services, you'll
14 recognize that those are the topics that often come back
15 to EPA in communication from the Services. What I've
16 asked the workgroup to do is to look at these issues and
17 begin to see if we can make some adjustments in our
18 process to make some progress on addressing those issues.
19 I don't think we're going to come up with solutions
20 quickly and to every question definitively. But I do
21 hope that we can begin to take a step forward in
22 addressing some of those issues right now.

1 So, that's sort of a quick update of the
2 questions before us right now in OPP. It was a little
3 longer than the 15 but I'm sorry about that. I just love
4 this topic so much. I think we can go to questions.

5 MS. EDWARDS: Let me suggest that we go to
6 12:30 and end this discussion at 12:10 because we do have
7 a couple of public comments and I do want to close out
8 the meeting in an orderly fashion. So, at the most, 10
9 minutes after 12:00. So, we'll do the best we can during
10 that time.

11 It looks like there's not much interest. Just
12 Susan Kegley (phonetic) wants to speak. All right, we'll
13 start with Susan and then start back up here, since she
14 did get her card up first.

15 MS. KEGLEY: There will be more, I'm sure.

16 I guess the way a lot of the endangered species
17 work has been done in the past is to look at the
18 particular species, the particular area, and the
19 particular pesticides that are used in that area. I
20 wonder if EPA has a plan in place for dealing with
21 substitutions; for example, rodenticides and Bay area
22 endangered species.

1 There were some rodenticides that are -- or the
2 ones that are used in the Bay area counties, but there
3 are also the ones that have kind of relatively low use.
4 But if you take away or restrict in some way the ones
5 that are known to be used in that area, the other ones
6 will just come in to replace them. The same with
7 herbicides that might be more restricted in one area or
8 the other, another herbicide will just come in to replace
9 it.

10 How do you anticipate dealing with that
11 particular difficulty?

12 MR. BRADY: The way that we are doing the
13 consultations for registration review, first they're
14 national consultations which brings a degree of
15 complexity that we really haven't approached yet in the
16 litigation where we've dealt in more limited geographic
17 areas within the pesticides.

18 The consultations occur on the basis of the
19 current labeled uses. That's our approach. So, that
20 would be how the ESA analysis is done. It's on the basis
21 of that current use. So, substitutions, I think if
22 there's a labeled use, we have to deal with it. It's the

1 way these would be approached.

2 MS. EDWARDS: I'd just like to say a little bit
3 about that as well. Obviously, the challenge here for us
4 is again do all chemicals today. We have to do the ones
5 that we have litigation on first in the areas in which
6 we're required to do so by the court. So, that's what we
7 do. But we're trying to be somewhat -- quite a bit
8 actually -- strategic about the order in which you do
9 some of these chemicals in that you don't want outcomes
10 that are odd.

11 I think that's what you're getting at, where
12 you might have a reduced risk chemical where you did that
13 one first and had some restrictions on the use such that
14 you were driving people to a chemical that's less reduced
15 risk, or something like that. So, we're trying to take
16 those considerations into account as we move forward.

17 That was one among many reasons that we pulled
18 forward some of these chemicals like the
19 organophosphates, the carbamates, and even the
20 pyrethroids earlier in registration review. We would
21 handle those first. It's not going to be 100 percent
22 effective, but the goal is to not have unintended

1 outcomes as a result of this process.

2 JAY: So, first I would say, Don, you and your
3 team did a spectacular job in crunching together a lot of
4 very complex information, as you described it, into a
5 very clear presentation.

6 So, one question I would have is, could you go
7 back and explain the difference between an RPA and an
8 RPM? I ought to know that, but somehow I didn't catch
9 that as you went by that, just so we have a little better
10 understanding of what this means in terms of practical
11 implications as it stands now.

12 Secondly, I know Rich is here from Fish and
13 Wildlife. Is there anybody here from National Marine
14 Fisheries?

15 MR. BRADY: I think there is somebody here.
16 Arlene?

17 JAY: I'd just be curious to kind of get their
18 perspective on kind of how this is working now between
19 EPA and their shop.

20 Then, lastly, could you give us a little more
21 information about the Endangered Species Information
22 Tracking System, which I take is what you're now calling

1 what was referred to at the last PPDC meeting as a
2 megadatabase. I think those are one in the same. Can
3 you tell us a little bit more about the data that's gone
4 in there and what else might be cued up to be able to go
5 in there for future benefit?

6 Thanks.

7 MR. BRADY: Well, do you want to let Rick speak
8 to the RPA/RPM first?

9 UNIDENTIFIED MALE: I can try to handle that as
10 a legal matter and then Rick can correct me.

11 RPA is reasonable and prudent alternatives, are
12 the expert agencies, the Services' recommendations for
13 changes to the agency's actions to preclude jeopardy.
14 So, they're not, strictly speaking, requirements.
15 Agencies regain their discretion to adopt alternative
16 RPAs to address the jeopardy finding.

17 RPMs are mandatory in the sense that only the
18 Services can authorize take and the do so under specific
19 terms and conditions. So, take is only authorized by
20 users of the pesticide or the agency if it's done in
21 accordance with the RPMs. So, in that sense, they're
22 mandatory.

1 UNIDENTIFIED MALE: The second question, the
2 RFP and what's going on there? ESEEDs, right. Well,
3 this is, you know, truly I think a recognition of a
4 couple ideas. The first is there is data out there which
5 we all think we need access to in order to be successful
6 in doing assessments and completing consultations.

7 The first part of that RFP is truly a census
8 among the federal agency as to the kind of data that they
9 hold and then an analysis of what use we might make of it
10 as a federal action agency and what use all federal
11 action agencies potentially could make of that
12 information in their assessments.

13 The first step is what do you have out there?
14 What use are you using it for now? And then, what use
15 could we use it for in the future? The second part of
16 that first census element would be to some way facilitate
17 the connection between those data sources. So, if USDA
18 holds a certain data and information based on this
19 analysis that the agencies have gone through on species
20 characteristics or something of that nature, uses,
21 whatever that information might be, we would facilitate
22 the access of that by all the federal agencies.

1 So, that's the first idea. That's why it's
2 important to remember that in this first step, we're not
3 trying to reinvent or generate competing databases, if
4 you will. We're truly just trying to identify the
5 holdings that are out there and facilitate that
6 correction.

7 One of the examples of non-federal database
8 that's out there that we found very useful in the
9 fomesafen pilot was the (inaudible) database where we use
10 information there and we were able to get information on
11 uses and species location out of that database, which we
12 used in the assessment. So, that's the first part of
13 this.

14 The second part is on the basis of that
15 analysis to go to identify the gaps -- data that we would
16 like to have but that we don't have in a format that we
17 think we could use it to facilitate the whole process,
18 the assessment and the consultation process. So, again,
19 that's the principle behind it.

20 What we hope to do is complete the discussions
21 with other federal agencies to get that census. I'll
22 call it a census. I don't think that's the correct IT

1 term -- the list of data that is there now -- begin to
2 look at that in the context of the uses to be made of
3 that or that could potentially be made of that and then
4 just sort of work through that process in a deliberate
5 and thoughtful way. That's our hope.

6 UNIDENTIFIED MALE: So, first of all, this is
7 all going to be digitized so it has more utility among
8 the Services and EPA.

9 UNIDENTIFIED MALE: Well, we would hope. We
10 hope to make the best use we can as sort of the modern
11 approaches and the technologies. But I think one of the
12 things that I found in just our initial discussions is
13 not all of the agencies are on the same page nor have
14 quite the same capacities or capabilities. So, that's
15 something that will figure into how we do this work.

16 UNIDENTIFIED MALE: And will this be housed at
17 an independent site or EPA or --

18 UNIDENTIFIED MALE: For the first stage, it
19 will be housed in theory, right where it's housed now,
20 the existing data. We're talking about links. Again,
21 I'm not an IT expert but I know that they can make
22 anything talk to anything in this day and age. So,

1 there's no at this point building of some huge central
2 server that holds all this data and information. This is
3 more a facilitation (inaudible).

4 UNIDENTIFIED MALE: So, some of this data will
5 be CBI protected and some of it won't be. So, it raises
6 questions I'm sure from a legal standpoint as to
7 accessibility to the public, et cetera. Have you got an
8 idea around how that will be --

9 UNIDENTIFIED MALE: Well, we will have to
10 manage the CBI very carefully of course. The way that
11 we've managed CBI right now is we've made sure that
12 people in other agencies who are dealing with it have the
13 proper clearances. I don't know exactly how we'll end up
14 doing it in this case, but probably in some fashion.

15 The real issue, to be honest about it, is not
16 identifying -- I mean, there's substantial work in
17 identifying the data that's out there and making it speak
18 to each other, talk to each other. But the real issue
19 is, you know, the significance assigned to the data and
20 the level of peer review and things of that nature that
21 has gone into the data because that figures into the
22 certainty with which the analysis is done. I actually

1 think those are the thornier issues than just the IT
2 things.

3 UNIDENTIFIED MALE: Thank you.

4 UNIDENTIFIED MALE: Sure.

5 MS. EDWARDS: Don, I just want to add something
6 to that. The data that we're talking about here, just to
7 be clear, is location data and all of the biology data
8 that surrounds the species and its critical habitat. So,
9 right now for us to do these kinds of assessments, it's a
10 lot of back and forth, it's a lot of data mining, that
11 sort of thing. We don't necessarily even know if the
12 data that we're using will necessarily be viewed by
13 Services as the appropriate data.

14 So, with the huge challenge before us -- and I
15 think everyone here knows what it is if you're involved
16 at all in our goals around this is to get into complete
17 compliance with the Endangered Species Act through our
18 registration review program at some point and then have
19 follow-on registration be in complete compliance as well.

20 In order for this program to do that, we have
21 to have desktop searchable, state of the art IT systems
22 that our scientists can use every day at the same time.

1 So, we all have access to this information at the same
2 time. It has to be information that is bought into by
3 the people that evaluate our consultation packaging. So,
4 that's the challenge before us.

5 This is -- what we're talking about here is one
6 piece that we believe would help facilitate that in order
7 to handle the volume. You can do it the old fashioned
8 way, but I don't believe you can even come close to
9 handling the volume of work before us doing it that way.

10 UNIDENTIFIED MALE: If I recall correctly, the
11 Agency wrote a rather blistering commentary on the draft
12 report taking them to task for some significant
13 shortfalls and methodology, modeling assumptions, et
14 cetera. I'm wondering to what extent the final opinion
15 took into consideration those shortfalls, because we
16 share those considerations.

17 In looking at the RPAs, I notice there's a
18 1,000 foot buffer for malathion. That seems to me it
19 doesn't take into consideration that at a 300 foot above
20 ground level release point for mosquito control any
21 deposition even into the air column is going to be about
22 a mile down range. I think that's a little excessive, at

1 least for mosquito control.

2 So, what I'm asking is, first of all, did they
3 take into account your concerns? Secondly, how are you
4 going to work those concerns out if the final opinion
5 really doesn't give you a whole lot of room to maneuver?

6 UNIDENTIFIED MALE: Who is they?

7 UNIDENTIFIED MALE: They is the National Marine
8 Fisheries Services.

9 UNIDENTIFIED MALE: The second part of the
10 question I'll answer first. That is that in this period
11 of time between now and June of 2010, we hope to engage
12 with NOAA folks on some of the science issues that we did
13 raise in our comment letter.

14 Tomorrow, for example, there is a group of
15 about 20 EPA scientists going to NOAA to get briefed on
16 and discuss the population model that was used in the
17 first biological opinion to try to get a better
18 understanding of the assumptions and how that model
19 actually was applied. As you pointed out in our
20 comments, we were concerned about lack of transparency
21 and how the assumptions in the modeling was done that
22 resulted in the conclusions.

1 In the first biop, the way the timing worked,
2 we didn't get the final RPAs until the end. So, it's a
3 little difficult to answer your question on that one. On
4 the second biop that was just published in April, I think
5 that the biggest difference is there was no vegetative
6 buffer in the RPAs for that biop. I think that --

7 I would hope that that reflects our comments
8 that were made to them over the time about the
9 effectiveness of those vegetative buffers. But I have
10 not seen and I don't think the NOAA process provides a
11 point by point discussion of how our comments were dealt
12 with that I'm certainly familiar with from a rulemaking
13 context, you know, classic EPA rulemaking context where
14 issue one is identified and response.

15 I have not seen that. I don't want to
16 overspeak. I don't know if either Rick or Arlene wants
17 to provide further commentary on that point.

18 Our position, quite honestly, is we now find
19 ourselves with these RPAs. We're sort of working, I
20 think, on a couple of tracks here. One is we have to
21 respond to these two biological opinions and come up with
22 how EPA will implement them. At the same time, we're

1 hoping to use this period of time between now and June
2 2010 when the next biop is due and working through some
3 of these science issues with this case with NOAA.

4 UNIDENTIFIED MALE: It is not a rulemaking so
5 there's no expectation of a point by point response. But
6 the statutory requirement is that the opinion be based on
7 the best scientific and commercial data available. So,
8 to the extent that any comments are offered by the action
9 agency, I would expect to see some explanation of why
10 those comments may have been -- if disregarded, why we
11 thought they were misguided. It might be better to ask
12 Arlene because I don't know exactly what was done in that
13 particular opinion.

14 Do you want to come on up, Arlene?

15 ARLENE: In response to whether NMFS considers
16 the comments they receive from EPA and the applicants,
17 yes, we did. Rick is correct that this is not a federal
18 rulemaking process. However, when we look at our project
19 file, we do put into our record why we did and why we did
20 not consider comments. That's in our own project file
21 records.

22 So, again it's not something that we publicly

1 publish like as in responding to comments on a listing
2 package or in the recovery plans, but it definitely is
3 something that the entire pesticide team did consider.
4 We have it in our project file record. That question was
5 also raised previously too when we met with EPA on April
6 7th as to how do the federal agencies consider comments.

7 So, we recognize that people have taken the
8 time to do the review. We recognize that people have
9 concerns. We do weigh that. As Rick mentioned, we try
10 to use what we call is the best available science. We
11 are not limited to some kind of very quantitative
12 approach like some agencies have. So, we balance it
13 between a qualitative and quantitative analysis. Then we
14 discuss that in our project record.

15 MS. EDWARDS: All right. We have about 20
16 minutes left. So, I'm going to ask that the cards that
17 are up stay up and we'll get as far as we can moving
18 around the table. I think the next person, actually,
19 though, was Dennis.

20 DENNIS: I have a quick question on the work
21 flow that you have. Will these cases that you're talking
22 about, these litigated cases, will the work products

1 eventually be implemented through Bulletins Live?

2 UNIDENTIFIED MALE: Through Bulletins Live?

3 Yes.

4 DENNIS: Okay. And is there ongoing work with
5 other endangered species? We've got these two bulletins
6 coming up now, but are there other independent of
7 litigation? Are you expecting more of those or is
8 litigation going to be covering that, the mainstay at
9 this point?

10 UNIDENTIFIED MALE: We have litigation, you
11 know, which is what we're responding to in the biops. We
12 would expect the implementation to occur through
13 Bulletins Live. Then, in the registration review, since
14 our ultimate goal is to have the endangered species
15 requirements implemented in registration review, that may
16 be expressed -- that may be implemented through the
17 labels as part of the re-registration decisions. That
18 would be, if we meet our goal of working through
19 registration review, how that would come to pass.

20 DENNIS: I guess I was just trying to get an
21 idea of what will be coming out next? Is it most likely
22 these cases that you're talking about?

1 UNIDENTIFIED MALE: Yeah, the cases. What
2 you'll see from us next will be our implementation
3 decisions on the biological opinions. Those will be
4 implemented at this point through Bulletins Live.

5 MS. EDWARDS: Caroline, is that your card up?

6 CAROLINE: I just had a quick question. In
7 addition to posting that first bulletin, what will you do
8 to inform users of those chemicals about the existence of
9 the bulletin? How will you get the word out to them?

10 UNIDENTIFIED MALE: It'll be on the label and
11 then it'll be referenced as available in the bulletin.
12 So, that would be the way. At this point, it will be
13 reflected on the label.

14 CAROLINE: You don't have plans to do any work
15 with the farming community in the area or, you know --

16 UNIDENTIFIED MALE: At this point, I don't
17 think so. It might be something we want to think about.

18 MS. EDWARDS: Ultimately, it kind of ties in,
19 to be frank, with the web base labeling. Basically, the
20 label will have to say that in order to use this product,
21 you have to check through whatever mechanism and the web
22 will be the easiest way, I think, to find out whether or

1 not there are restrictions in your area.

2 I think there was another card down there that
3 got missed. Is that you, Carolyn?

4 CAROLYN: I wanted to quickly say that I think
5 it's really wonderful to see the agency coming in
6 compliance with the Endangered Species Act. It's been a
7 long time coming. I also think that just in terms of --
8 even if there wasn't a legal mandate in terms of EPA's
9 goal of protecting the environment, this is a really
10 important issue and I'm really glad to see it finally
11 being implemented.

12 I wanted to ask a question. When I talk to
13 people about Endangered Species Act issues, I often get
14 this response which is, you know, I'm really glad that
15 we're protecting famine or salamanders or whatever it is,
16 but I don't understand why there are buffers for baby
17 fish and there aren't buffers around my kids school. I
18 actually don't have a really good answer to that
19 question. I was hoping maybe one of you could give me a
20 better answer than what I use.

21 MS. EDWARDS: Well, a couple of things. One is
22 that if you've been following our fumigant decisions,

1 you'll know that we're looking at buffers for fumigants,
2 which are probably the most volatile pesticides that move
3 off site. We're also looking at what we need to do
4 potentially for semi-volatile chemicals. That's a little
5 more long term, but we're going to have an SAP meeting on
6 that later this year.

7 I don't know whether or not buffers would be
8 part of that, depending on what the chemical was and what
9 the risks turned out to be. But we're looking into both
10 of those areas. Then, I think if we felt that there was
11 a risk issue potentially from a spray drift issue, we
12 would put a buffer.

13 I don't know how frequently we've done that,
14 but obviously spray drift is going to be a big area as we
15 move forward in the coming year or so in determining
16 standard labeling statements and individual pesticide
17 statements as well. So, I'd recommend you stay tuned to
18 that. I think your issue is definitely on our radar
19 screen.

20 BETH: I'm just curious in looking at
21 fomesafens since we have to respond to that. It looks
22 like there's a 60-day comment period. I thought under

1 reg review, we were supposed to get 90.

2 UNIDENTIFIED MALE: Yeah, I don't -- does
3 anyone from SR --

4 MS. EDWARDS: It's 60 but sometimes people ask
5 for extensions. So, we have options.

6 BETH: Okay, thanks.

7 UNIDENTIFIED MALE: Thanks for being brief. I
8 go back to my favorite subject on the Bulletins Live
9 issue and the fact that you're going to put those first
10 bulletins up fairly close. What language are you going
11 to require on the intrepid level to guide people to know
12 that they've got that responsibility at this point? How
13 soon will that show up on those labels?

14 Is it going to say -- determine that there's
15 risks in endangered species in Wisconsin and Michigan, so
16 those are the growers that know they have to do it or is
17 it going to be a requirement that every grower who uses
18 intrepid has to look up to determine if in fact they are
19 in Wisconsin and Michigan and covered by the issue?

20 UNIDENTIFIED MALE: I think it's that there
21 will be a notice on the label and then you'll have to go
22 to the Bulletins Live and look up what the requirements

1 are. Now, I'm not sure that responds directly to the --
2 I may not be able to answer exactly, to be fair, but I
3 was hoping to get the question right.

4 UNIDENTIFIED MALE: Yeah. It's one of the
5 points that I raised a long time ago on the Bulletins
6 Live issue. The way I understood it it would be a simple
7 statement on the pesticide label that says this pesticide
8 has triggered endangered species concern or has jeopardy.
9 Then, every grower who has that label is then required to
10 go to the web site to see if their county of use is
11 recovered under those mitigation steps. That creates a
12 legal obligation to be able to prove that they've gone to
13 that web site from an enforcement statement.

14 It's been one of the questions I've had since
15 day one on how you're going to focus this to be sure that
16 it meets the needs of what the program needs to have done
17 and actually get to those people who are located wherever
18 the Karner blue butterfly and the Hine's emerald green
19 dragonfly are which is what this particular set of
20 mitigation steps are directed to.

21 UNIDENTIFIED MALE: I assume any enforcement
22 would be focused in the states where the butterfly is

1 present. But I think we do expect that when we find
2 endangered species concerns with the pesticides that we
3 want growers to be attuned to that concern and to be
4 checking Bulletins Live and to become familiar with it
5 because we think it's going to be something that's going
6 to be used relatively frequently in the future. So, it
7 should be something that grower familiarize themselves
8 with.

9 UNIDENTIFIED FEMALE: Follow up for Dan. I
10 think the question is, is the label specifically going to
11 mention the state for which that jeopardy is or is it
12 going to be a blanket statement? So, if it's only
13 Washington, Oregon and California and you don't have
14 salmon, is there just going to be a statement that says
15 there's jeopardy for endangered species, period, and you
16 need to go check the web site?

17 UNIDENTIFIED MALE: I think the latter is a
18 single statement that would say, you know, you must
19 comply with the endangered species bulletin for your
20 county. Check that on the label.

21 UNIDENTIFIED FEMALE: So, basically, any
22 applicator in the future that picks up a product that has

1 a statement that says there's an endangered species
2 jeopardy, they must go to a web site? We just discussed
3 this with web distributed labeling and the access to web
4 sites -- before they could even use that product. Even
5 though that jeopardy had no bearing in their state at
6 all, they would have to go to a web site before they know
7 they could legally use that product?

8 UNIDENTIFIED MALE: I do think that's
9 ultimately what the expectation would be because I think
10 this is -- now, your question is is there going to be an
11 enforcement issue surrounding that? I think, as I said,
12 I think our enforcement folks -- it's going to be on
13 where the endangered species is. But yes, I think we do
14 expect the growers would -- when there is that
15 restriction on a label, would familiarize themselves with
16 that provision, would check the web site.

17 UNIDENTIFIED FEMALE: There is a difference
18 between will familiarize themselves and they legally have
19 go to go that label to see if that species and that is
20 there. There's a big big difference. If every
21 application -- if that statement is on the label, every
22 applicator would have to find out if there was anything

1 in their area. So, that means every applicator has to
2 have access to the web site or every applicator has to
3 call a toll free number before they can even decide
4 whether they can use that product.

5 UNIDENTIFIED MALE: Well, I think they should
6 find out what -- if, in fact, there is that restriction
7 on a label, there is a possibility that that restriction
8 might be in their state. And they should find that out
9 first.

10 UNIDENTIFIED MALE: I strongly suggest that as
11 labels are revised, at least the state be listed on that
12 label so that the other 49 states -- if it isn't in their
13 state, those applicators aren't having to go and find out
14 whether it is. That makes web distributed labeling look
15 easy.

16 UNIDENTIFIED FEMALE: I don't know if I'll add
17 any clarity or not to the discussion, but some of the
18 concept in moving through into the decision making may
19 not be that every single time you use Bulletins Live as
20 the way to ensure that compliance of endangered species
21 has come in. (Inaudible) registration review and he's
22 doing national assessments. There may be some scenarios

1 where the label language will suffice in terms of use
2 rates and other things. You may not even have to go to a
3 visual display of the outcome of the label to be
4 compliant.

5 I don't know exactly how the Karner blue and
6 the Hine's emerald dragonfly will play out, but
7 (inaudible) scenario could be if those species only
8 reside in certain places of Wisconsin and Michigan, the
9 decision can say if you're in Wisconsin and Michigan
10 where these two species reside and for which we have to
11 do extra stuff, you need to click on www to see if you're
12 in those counties in Wisconsin or those subcounties in
13 Wisconsin.

14 We're going to try to work through, as Don and
15 Mark and them described in their conversation, this is a
16 multi-commentatorial hyperspace of species pesticides use
17 patterns. We're going to try to figure out the most
18 efficient way to get the right information to people
19 that's useful for the growers and enforceable as
20 appropriate.

21 UNIDENTIFIED FEMALE: I think it's critical.
22 Let's just say 10 years from now there's a particular

1 product that has 69 jeopardies. All 69 of those species
2 probably should be listed on the label so that that
3 person would know if there was even some merit that they
4 heard about.

5 MS. EDWARDS: Yeah, I think it's going to
6 require some education. It's going to be a challenge,
7 obviously. But our goal in having something that you
8 could get to that was very locally based was part of our
9 goal around endangered species, which is you have full
10 compliance with the Act but you keep the impacts on
11 agriculture as localized as possible that will allow you
12 to do that. So, we'll have to figure out how to do that
13 practically. That was the mechanism that we came up
14 with.

15 To the extent that the mitigations are, at the
16 moment -- see, what we don't know about with
17 methoxyfenozide is we've done the assessment for those
18 two species. We have not done it for anything else. So,
19 as you get more and more potential for other locations
20 and other species, your label could go back to being --
21 if you think you already have 50 page labels, you could
22 talk -- if you wanted to keep it very local mitigation,

1 you could end up with 1,000 page labels. So, that's why
2 we're trying to find a mechanism for people to move out.
3 In this particular case, I think we can make it pretty
4 specific and look at that.

5 Jay, I think you were next, and then Carolyn.
6 We may have to close off after that, actually.

7 JAY: So, we have something from the FQPA era
8 called smart meetings where registrants participated in
9 certain stages of evaluation. There were other
10 stakeholder access points. How is that -- is there any
11 parallel at the intersection of the Services in EPA as
12 progress is made in analyzing the issues on the table on
13 any individual compound, either leading up to the biops
14 or in the next stages now in progressing forward just to
15 allow real time interaction, particularly with the
16 registrants who presumably know the most about their
17 compounds, the label uses and practical applications on a
18 day to day basis?

19 UNIDENTIFIED MALE: This is one of the things
20 that we're actually working out as we go. In both of
21 these biological opinions that are now final, there were
22 meetings with the registrants and NOAA with EPA in the

1 room. Their regulations of the Services provide the
2 "applicants" with the ability to provide comments to the
3 Services on the draft. That did happen on the first two.
4 It happened in very compressed time frames because I
5 think we were all learning, us the registrants as well as
6 NOAA, on these first two.

7 But we have been going through a process with
8 them for the next biops that will be completed to
9 identify the registrants so the registrants can get a
10 little sooner notice that this is coming down the pike
11 and have a chance to participate in those conversations.

12 MS. EDWARDS: Carolyn, you get the last word.

13 CAROLYN: I just had a quick question. You did
14 a very good job of explaining what your experience and
15 track record is with NMFS. But other than the letter
16 that you received from Fish and Wildlife declining to
17 consult on 45 different cases, do you have any track
18 record yet of working that actively with Fish and
19 Wildlife?

20 UNIDENTIFIED MALE: I've been here about a year
21 in OPP. We have had in my time active discussion with
22 them on these issues. But in my time we haven't received

1 a biological opinion from them. There may have been
2 earlier ones. I don't think -- not in the recent history
3 I think is the way I would answer that, yes.

4 MS. EDWARDS: All right. Well, thank you again
5 for an excellent discussion around this topic. I
6 appreciate your insight.

7 At this time, I would like to move into -- we
8 have two public commentators. So, I think it might make
9 sense for them to just come up here to this chair to
10 speak. The first one is Cheryl Baldwin (phonetic) of
11 Green Seal.

12 MS. BALDWIN: Hello, and thank you for the
13 opportunity to provide comment. My name is Cheryl
14 Baldwin and I'm the vice president of Plants and
15 Standards at Green Seal. My comments are going to be
16 related to the work group on the comparative CP
17 statements and specifically on the aspects that relate to
18 the logo program that was discussed earlier today.

19 Just to begin with, Green Seal is an
20 independent, nonprofit environmental certification
21 program. We've been helping identify environmentally
22 preferable products for over 20 years. Our program has

1 been cited widely for purchasing organizations and
2 specifying reasons to help identify environmentally
3 preferable products. A quick example that relates to the
4 discussion today, that Green Seal is the most cited
5 program, actually, as it relates to cleaning products by
6 state and big government purchase programs.

7 So, we are very supportive of the progress that
8 has been made over the last year by the working group to
9 rethink the approach with environmental claims and
10 environmental certification programs. We're satisfied to
11 see that there's progress being made in that area.

12 But we do have a few concerns that I'll express
13 briefly today. I'll just begin with a statement that we
14 have submitted some process related concerns in
15 September. I don't want to go into detail today because
16 I do have a limited amount of time.

17 One component is that there has been
18 limitations on the stakeholder groups that have been
19 engaged in the work to date. There are some key
20 stakeholder groups that we feel are not represented at
21 all, if adequately represented. One of those the state
22 programs that are identifying environmentally preferable

1 products. They're not represented, nor are environmental
2 certification programs like Green Seal.

3 This comes to a point because -- I'll just
4 emphasize one of the comments made earlier that state and
5 government programs are looking to specify
6 environmentally preferable products to a great extent, so
7 their absence on the work group is a concern.

8 What we've heard from these particular
9 stakeholder groups is that they're looking to
10 environmental certification programs specifically in
11 their work because those programs fit their needs best.
12 There's a number of reasons why but I'll emphasize two
13 main points.

14 One is that these programs have standards that
15 were developed with a broad and open stakeholder group.
16 The compliance to those standards includes not just
17 looking at the product and its ingredients but also going
18 to the manufacturing facility and checking ongoing
19 compliance so there's a more comprehensive evaluation
20 that's included in that. So, it's a little concerning to
21 us to see that the selection of a program that is not a
22 certifying program is currently the recommendation of the

1 work group.

2 It seems a little arbitrary knowing that just
3 at the onset the majority of people looking for this
4 guidance are not going to have their needs met because
5 they are using third party environmental certification
6 programs for the way they specify environmentally
7 preferable products.

8 So, we would strongly recommend that as this
9 program moves forward from today forward, that
10 environmental certification programs like Green Seal be
11 included in the implementation of these types of logo
12 programs for registered products.

13 I'll just end with that. Thank you.

14 MS. EDWARDS: Thank you. Our next commentor is
15 Scott Jackson (phonetic) from the BASF Corporation.

16 MR. JACKSON: I'd like to thank the panel for
17 the opportunity to make a comment. I'm Dr. Scott Jackson
18 and I'm with the stewardship group at BASF. We're the
19 registrant of headline fungicide. We just want to make a
20 brief comment about the use of the term plant health.

21 Historically, what's happened with fungicides
22 is older compounds were curative in nature and newer

1 generation compounds are preventative. So, BASF started
2 calling really to help the user community understand how
3 these compounds are used. We started calling these
4 preventative compounds under the term of plant health.

5 As we started using this term in the grower
6 community, we received comments from state regulators
7 regarding this. Of course, probably many of you are
8 aware you cannot just revise a federal label to include a
9 term on it without going through the formal process. So,
10 that's, in fact, what we have done. So, that's resulted
11 in this term being added to our existing headline
12 fungicide label.

13 Really, the whole goal for this is just an
14 attempt to add clarity to the use of these products. I
15 would like to state that if you think about soy bean
16 rust, there is an active monitoring program that goes on
17 by the federal government and that's done for several
18 reasons, to help people identify when to properly use
19 these products so that they aren't just used -- to use a
20 term -- willy nilly; they're used where there's a reason
21 to use them. That's based on history. It's based on
22 expert opinion from crop advisors and the presence of

1 normally spores that are actually actively monitored for
2 them.

3 So, that was basically the extent of our
4 comment. Just the use of the term plant health is just
5 been used by us to try and help people using these
6 products to understand the difference between a curative
7 and a preventative fungicide.

8 MS. EDWARDS: Thank you. All right, that
9 pretty much closes us out for today except for we were
10 going to talk a little bit about planning for next
11 meeting. I don't know that we have time to do much of
12 that. What I was going to suggest, though, is that we do
13 some of this via e-mail.

14 I believe that it helps to have more time to
15 discuss specific topics. We attempted to move in that
16 direction in this session and to have more panel
17 presentations with just a couple of brief updates. I
18 still think it's a possibility that we tried to do too
19 much. So, I think there's a lot of interest and there's
20 a lot of issues, obviously. I don't expect that will
21 decrease in the future.

22 So, we have a couple of options. We could

1 consider extending the meeting a little bit into the
2 afternoon in the future. We could consider having -- I
3 have often thought it might make sense to have one key
4 topic the morning of the first day, one key topic the
5 afternoon of the first day, and one key topic the morning
6 of the second day so that you cover three major topics,
7 handle most of the rest of it through written materials.

8 But I think that's too much for us to get into
9 in great depth today. So, probably what I'll ask Margie
10 to do at some point is we'll pull together as the time
11 approaches some topics that we think are hot and get your
12 almost like multi-voting on them, bearing in mind that
13 the major purpose of this committee is to provide advice
14 to us. So, occasionally, we're going to decide what we
15 want to talk about or, more to the point, what we want to
16 hear from you about because we're seeking advice from
17 this multi-stakeholder FACA committee.

18 So, let's just begin to think about that now,
19 whether that makes sense or not. Then we'll just move
20 on.

21 The other thing I wanted to mention since
22 headline was broached again here, just so that you're not

1 left thinking the agency isn't engaged in this at all, we
2 have received a letter relatively recently, within the
3 last couple months, from a number of university plant
4 pathologists throughout the midwest concerned about these
5 claims. Their major concern that they expressed in that
6 letter was the possibility for overuse resulting in
7 resistance development which could then result in
8 actually less effectiveness of the product which could
9 cause it to be lost as a lower risk fungicide tool.

10 So, we are looking into that. What we will do
11 is -- looking into the whole issue, by the way, not just
12 that aspect. But that was the major concern expressed in
13 that letter. We will make that letter public along with
14 our response at some point in the next few months. I
15 just wanted to let you know that we are focused on that
16 and this is not the first time we've heard of those
17 concerns.

18 So, I guess with that, I'd like to ask Margie
19 to come up here. I want you to be able to see her. So,
20 first of all, I'd like to thank the entire committee. I
21 think you've been very very engaged this last day and a
22 half. We really appreciate all of your active

1 participation, a lot of enthusiasm, I think, in the room.
2 If anything, we had to cut you off as opposed to try to
3 get you to participate.

4 In addition, we really appreciate that we get
5 diversity in the views. I think all of our stakeholder
6 sectors stepped up to the plate and participated in this
7 meeting, and that's the whole objective here. So, we
8 really do appreciate that.

9 I'd like to particularly thank the work group
10 members. Work group members put in a lot of extra time.
11 I think we found in this committee that we get some of
12 our best work done that we can actually take and run with
13 through these work groups. So, we really appreciate
14 those of you who have volunteered and then not just
15 volunteered but showed up for the meetings and took the
16 time to commit your time to participating and providing
17 us input and recommendations to bring to this larger
18 panel through those work groups.

19 I'd like to thank the public for participating.
20 I think that's important as well. This is a public
21 meeting. It's part of the way our government functions.
22 We seek to be very transparent in this program, so we

1 like having these public FACA meetings. I hope we can do
2 more, as I mentioned in the opening remarks.

3 I'd like to definitely thank all of the OPP
4 staff and management that put so much hard work into
5 preparing for this meeting, chairing work groups,
6 preparing presentation materials and so on and so forth.

7 I think the person I want to thank the most is
8 the one I asked to come to the table. That's Margie
9 Fehrenbach. Margie does an enormous amount of work.
10 This is one of the biggest FACA meetings in the agency.
11 It's very complex to run. She sits over there and you
12 don't see that she's trying to make sure everything
13 works. I think she's very responsive to all of you.
14 None of the logistical problems we had at this meeting
15 had anything to do with her. So, please give her a round
16 of applause.

17 (Applause.)

18 We have a meeting with some of the NGOs this
19 afternoon. It was supposed to start at 12:30. I'm going
20 to suggest to you that you go find yourself some food.
21 Oh, Margie is getting you sandwiches. See what I mean?
22 Try to get up there by around 20 to 1:00 since she's

1 actually going to get the food in that case. So, we can
2 start that a little bit late.

3 Anyway, I appreciate all of you coming today.
4 What does Margie want me to tell you? Oh, tentative
5 dates for the next PPDC meeting are October 14th and 15.
6 So, please mark your calendar, October 14th and 15.

7 So, thank you very very much and have a great
8 afternoon.

9 (Whereupon, the meeting was concluded.)

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