UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING

DAY TWO

May 18-19, 2016

Conference Center - Lobby Level

2777 Crystal Drive

One Potomac Yard South

Arlington, VA 22202

P R O C E E D I N G S

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MR. HOUSENGER: Well, welcome back to part two. This morning we've got -- we only have until noon, so we're going to watch the clock. I don't want to cut into people's lunch time, and then we've got meetings the rest of the day.

We're going to talk a lot about workgroups, hearing first from the incidents workgroup, then resistance management that has been a topic that this committee has asked to hear about, as well as international activity. Then we'll talk about future workgroups and ideas that people have already submitted and what are in the minds of people today about what potential workgroups we might form.

So, Jackie Mosby is the Director of our Field and External Affairs Division, and she will lead this session from this table or the podium. So, Jackie, take it away.

MS. MOSBY: Thank you, Jack. Well, good morning. As Jack mentioned, I'm Jackie Mosby, the Director of the Field and External Affairs Division in

OPP, and I am the incident workgroup chair, the pesticide incident workgroup chair. Today, a team of us will report out on the PPDC incident workgroup activities. The workgroup members reporting will be Cheryl Cleveland, Julie Spagnoli, and Cynthia Palmer.

The purpose of this presentation is to give the PPDC an update on what the workgroup has been doing for the past six months. The workgroup was formed last year, and it consists of members from various groups, such as the NGOs, industry, university, states, and the regions.

This diverse workgroup was put together to provide advice to EPA on the long-term goal, which is developing an electronic pesticide incident data system that will be publicly available and useful to a broad stakeholder group.

I will go over a bit of background, the current state of the incident data, the ideal state of an incident data system, and what actions we've taken thus far, and challenges and concerns that have been raised, and the next steps in developing an electronic pesticide incident data.

First, I'll start off with a definition for

you, some background. What is a pesticide incident? Well, the definition of a pesticide incident is any exposure or effect from pesticide use that's not intended or expected. Pesticide incidents may involve humans, wildlife, plants, domestic animals, and bees.

The objective of the PPDC incident workgroup is to support development of a 21st century incident system, which includes providing input on data elements needed to make for a useful incident report to support risk management decisions and also benefit other stakeholders, support system development and testing of an incident system, support the identification of additional sources of incident data, and identify and provide advice on additional issues associated with developing a high-quality, publicly available, incident system, and other issues that the Agency wishes to bring to the workgroup's attention.

It is worth noting that as we move forward in this 21st century pesticide incident system, that this is a multi-year, multi-phase, multi-stage process. We've started one part, and I'll go over that today. So, for the last six months, we've been working on one charge.

The current state of the incident data system is why we are embarking on this effort to develop a pesticide incident data system. There are limitations of EPA's incident reporting system. We have primarily filed, so we don't have data in some cases. We have PDF files. Many of the data elements that have a PDF file, they aren't sortable. It makes it hard for us to do data analysis.

Also, the current system is limited in its functionality and usefulness. We have manual data entry. Inconsistent information and missing information. Incidents are reported to various parts of the organization, so we lack a central point of entry.

Incidents are submitted in various forms. We have received incidents on napkins, phone calls, various ways. So, we want to control that. Our current incident reporting system does not talk or communicate with others, with other systems.

So, EPA's long-term goal or preferred state is to develop an electronic pesticide incident data system that is publicly available and useful to a broad stakeholder group, a system that is easy to use with

standardized data elements. To do this, we want to build a sustainable framework, a framework that improves reporting to make reporting easier for both voluntary and required incident reports.

Also, to reduce the time on FOIA requests. That goes on both ends. If we have data that's publicly available, then we both can go and pull that information instead of doing a FOIA to get that information. It reduces the work that we have to do in the Agency in responding to those FOIAs.

The framework would enhance efficient use of incident data to obtain more and higher quality incidents for risk assessments and improve consistency in our reporting. EPA wants an incident data framework that supports quality science-based decisions and one that encourages data sharing between EPA agencies and others.

As we move forward in developing a 21st century incident system, and I like to call it our preferred state, we must address a number of issues. We look to the PPDC workgroup for advice on building a framework, including, but not limited to, advice on what data we should be collecting, determine data element definitions,

advice on how to collect the data, to enhance ease of submission, to ensure quality of verifiable data, advice on what safeguards are critical, quality assurance/quality control of data reported, which data are publicly available, make safeguards for personally identifiable information and sensitive business information, and what mechanisms or systems currently exist that can inform the development of the data system.

That takes us to the first charge of the workgroup. This is an action that we have done thus far to get us to our preferred state. The first charge was to get advice on our data elements. The goal of this charge is identify elements that would ideally be included in a quality incident report.

The process for identifying these elements was that OPP developed first an ideal data element for incidents involving general, human health, fish and wildlife, insect pollinators, and domestic animals, and plants.

The workgroup reviewed and discussed all the elements by these groupings. Some of the elements were added for consideration by the workgroup. The workgroup

then ranked the value of each element from essential to not needed. Most elements ranked high, although there were some that were ranked low. Those may be dropped as we move forward. The workgroup is generally supportive of the data elements that we have identified thus far.

No process goes without concerns or issues being raised. So, during our workgroup discussions about the data elements, a number of questions and concerns came up about 6(a)(2). Keep in mind, our goal is to have data elements that would be ideal in developing an incident database. The incident data system would house all voluntary and required incident reports.

Industry is concerned that any new data elements could have implications to future 6(a)(2) requirements. Industry also raised a concern that they might be expected to adopt these new non-required data elements.

The NGOs raised an issue that they would like to see the reduction or the elimination of the threshold in the current 6(a)(2) rule. The NGOs also wanted to see the elimination of aggregate reporting.

The workgroup members raised these concerns and

others. Cheryl Cleveland, I think, Julie Spagnoli, and Cynthia Palmer will discuss these concerns that EPA intends to address as we move forward. So, we hear the concerns. As I mentioned, we started with looking at the data elements. So, that's the first phase of this process.

In looking at the data elements, these concerns have come up. We will, as we move forward, work on these and look to address the concerns that have been raised. But I did want to make one point. Any changes to 6(a)(2) 40 CFR 159 would require a rule change. That is not a planned topic for this workgroup. Also, any 6(a)(2) changes would be a public process. That would be a separate track.

With that, I'm going to just turn it over to Julie to talk about the considerations. I don't know whether Cheryl or Cyndi will – ok.

MS. SPAGNOLI: First, from the industry viewpoint, we do appreciate the opportunity to allow the stakeholder input into having an opportunity to provide these inputs. We appreciate the fact that they're taking steps, but we look at the fact that each

step really has to be looked at in the context of the long-term goal and how these first steps will ultimately impact the long-term goal.

Since part of the long-term goal does impact required reporting, it obviously brought in concerns about 6(a)(2), since that is the required reporting. So, we understand that the rulemaking is not part of this process, but obviously, there's still some implications as we move forward on the process.

So, there's already reporting in place for 6(a)(2), and most registrants have systems by which they report this data. So, they've been doing this for many, many years now. So, there is generally a system in place. So, any changes that may come to these requirements does raise some concerns, because it's going to change how they're doing their business now.

The mechanism for data collection, I think going to a web-based portal, is not really one of the concerns. It's a consideration of how that system works. But the implications are for how data reporting is done now and how does it fit into the new system, and how does it fit in with others then that will also be reporting.

The number of data elements, if there's an expectation that these data elements are to be provided that are beyond what's required by 6(a)(2), it's what is the expectation. Is the expectation then even if it's not required under the rule, that it be required.

Another very important consideration is obviously the verification. Registrants have the opportunity when they have an incident to investigate. They can determine the validity of the incident if they choose to. So, there is some questions about if this system is open to reporting by essentially anybody, how the data quality is assured, the plausibility, the cause and effect.

Another issue that we put in as a data element was the definition of misuse. If an incident is going to be reported as misuse, again, who determines whether that was misuse or not misuse. So, that's just another consideration that have some concerns about.

Some additional considerations is the release of the database, how it will be released, which data will be made public. I think Jackie already touched on some of these. Then again, what resources are available to

maintain the database. A database is only as good as the information that's in it, keeping it updated and current, and the quality of the reports themselves.

Also distinguishing between complaints and incidents, there's a little bit of concern about the definition that's been proposed for a pesticide incident. We understand the reasoning behind it, but it is different than the current definition of an incident to be reported under 6(a)(2). Under 6(a)(2), an incident is reported if it results in an adverse effect.

So, just an incident of unintended or unexpected exposure that didn't result in an adverse effect does expand it and casts a pretty much wider net. So, there is some concerns with that. We know there's a lot of complaints of things like odor -- then become defined as an incident even if there was no adverse effect.

The number of data elements again is somewhat of a concern. The data elements that have come up by the workgroups about doubles the number of data elements currently required under 6(a)(2) reporting, even for the individual categories. So, for the human health

categories, it's going from like 32 to 60 data elements. Again, there's just a concern about the availability of all these data elements and then what is the expectation for registrants. It's filing a report if all these data elements are not maybe available.

So, we really have to look at even though we did a ranking, the importance of the data element may be relative to the incident itself. Where the weather might be very important in one case, it could be completely irrelevant in another case. So, each element really needs to be looked at a lot of times in the context of the incident itself.

So, I think the other considerations are really broader and really for the whole group and for the Agency with developing communication plans in a coordination with other agencies. Again, as we move forward, we can't keep disassociating this with 6(a)(2) reporting, because that is the major source of incident reporting at this point. As we work this into the system, it's ultimately going to involve 6(a)(2).

Again, with the public access to the data, there are some concerns as to how that data will be used

and who it will be used by. So again, we understand the desire for transparency and the desire to make information possible, but again, it really is dependent on how valid this data can be made and the quality of the data itself.

So, those are some of the concerns that we had. They're just considerations that we feel we need to be mindful of as we move forward on the project.

MS. MOSBY: Thank you, Julie. So, I will finish up with our next set, and then we'll open it up for questions.

Oh, I'm sorry, Cindy, did you want to come up? Go ahead.

MS. PALMER: It wasn't clear ahead of time whether we were presenting or not. So, I'd like to commend EPA on this effort. It was a really valuable exercise to work through the building blocks for an incident reporting system.

We all have many concerns, where this is going. We each have what we want out of it. But I thought EPA was very strategic in choosing to focus narrowly on the building blocks, what data is most useful for risk

managers and others when we're trying to learn from our mistakes and see how these pesticides are affecting non-targets.

From the NGO perspective, we, of course, have many concerns about protecting the identity of those who report, especially in the case of farmworkers. We want to make sure that the systems are in place so that no one gets in trouble or loses their job for raising issues.

Also, we wanted to urge that the beekeeping community is closely involved in the development of the data elements. I thought we had some very good discussions, and we could possibly use some more in terms of which elements are reported, which bees, what locations, and so on. It really matters what information you gather.

We do have broader concerns, as does industry, about the more extended incident reporting system. They were referenced earlier. Just to explain a little bit further, we're concerned about the aggregate reporting system and the high thresholds of dead animals needed to trigger requirements under FIFRA 6(a)(2). So, very few wildlife incidents are ever recorded.

For those who are not so familiar with the 6(a)(2) system, for hurting mammals, there are no specific reports required unless at least 50 mammals of a species are killed. For birds, the requirements kick in when 200 of a so-called flocking species, 50 song birds, or 5 rafters are killed.

For fish, there are no specific requirements unless 1,000 of a schooling species are killed. For bees, there are no specific requirements, no matter how many are found. For domestic animals or pets, there are no specific reporting requirements. So, we'd like to see that element, that aspect looked at a little bit more closely.

We'd also support public access to the data without time and resource intensive (inaudible) process, which can take many months. We have found and we know that there is a lot of data out there in the different federal and state agencies, and we'd like to see more coordination, if at all possible.

Behind all these efforts, of course, there will need to be some funding. We do have questions about how funding for laboratory testing and for state and federal

coordination can be found. I'm told it's too late for the current PRIA cycle. I'm wondering what other mechanisms are available. It doesn't take a ton of money, but we do need some upgrades in terms of the laboratory testing and so forth. So, where that money will come from is the question mark. Thanks.

MS. MOSBY: Thank you, Cindi. So, I'll just finish up with the next steps, and we can start answering some questions.

So, developing an improved publicly available incident database will be, as I mentioned, a long-term process. We appreciate the feedback already received by the PPDC workgroup. We will keep in consideration all of the issues and concerns that have been raised. We look forward to continued feedback and discussion. This has been very helpful in us developing and determining even the first building blocks the data elements are to be in and hearing the concerns that are being raised as we think about building, I would say, building like an enterprise or this ideal state data system.

Actually, the feedback is exactly what we wanted in terms of building this new data system. We

knew that doing this in isolation wouldn't provide what we got. So, this is exactly what we wanted. We wanted the feedback, even though the issues that are of concern, we will roll up our sleeves and think about how we can address those issues that have been raised.

At our next PPDC incident workgroup meeting, we will start discussing the second charge, or the second phase for the workgroup, and that is how do we think the specific data elements could be collected. This is the next step in developing an improved incident database, and this will require revisiting some of the data elements that we've already identified. Through this iterative process, some data elements may get changed. So, we started with the set, and that was a huge exercise. But as the process continues, we may see things shift.

Also, I would like to personally thank Rich Dumas and Melissa Panger for doing such a fantastic job in sorting through many of these technical issues. I wanted to thank the entire workgroup for our accomplishments thus far, identifying a set of data elements and raising the concerns and issues. That's all

part of what we need to move to the next step.

So, with that said, I will open it up for questions.

MR. HOUSENGER: We've got to go fast here. Bob.

BOB: So, can I ask a question and make a comment? So, what I remember used to be true, and I'm wondering if it still is true, is that the Agency can't receive advice directly from a workgroup, right? It has to be presented to PPDC and then PPDC has to -- is that still true?

MS. MOSBY: Mm-hmm.

BOB: So, this is just a working product, right?

MS. MOSBY: Mm-hmm.

BOB: And you're not accepting or asking -- well, that being the case, and I think it's already been said, but I'm really good at repeating stuff that other people said, which is that I think it was an extremely productive process, a good discussion, Jackie, Rich, Melissa. I think the discussion about data elements was really productive.

There's a lot of anxiety, though, about the

other stuff. Like, I remember years and years ago when it was customary to have notification registries for people who had multiple chemical sensitivity, and people would set up tables in shopping malls, and you filled out a postcard, and you got on a list with a state agency, and you had to get 72 hours advanced notice of a pesticide application. So, that image is in my mind.

It seems to me that it would be useful in this next set of activities to develop something like a white paper, a short white paper that talks about things like who must submit the data, whether it's voluntary or mandatory, who may submit the data, can any consumers go on the website and say my rosebush died and I think the guy next door sprayed some stuff that drifted over, who does it, how will it be used, how will it be validated, who will have access to it. I just think that would be a really useful step to ensure that everybody has a common understanding of what this data set looks like and how it's going to be used.

MS. MOSBY: Thank you. We'll look into doing that. I think that's a good idea.

MR. HOUSENGER: Cheryl.

CHERYL: So, kind of building on what Bob just said, I think slide 9 is the crux of what the angst is about. I was a member of the workgroup, and it was very difficult for me to rank data elements without context. I was told that it wasn't as difficult for other members. They could rank them without context, but I struggled with ranking outside of context.

Can you pull up slide 9, please? So, these are the really fundamental questions. When you're ranking a data element, are you ranking it to be mandatory or an open box if somebody has that information? I'd like to have more information if it's available, but I don't want to mandate it. So, the ranking exercise is really difficult.

I think the good part was all the discussion around the data elements. It's my understanding that you've maintained a spreadsheet that has all the comments in it. I think that was the value of this. But I do think that moving to the second step of trying to talk about how we're going to get the data is a little premature until we've answered some of these other things: what's mandatory, what's voluntary.

And one of the opening slides also said that you're concerned in some way that you're not getting all the data from other systems. Well, building this system down to the nth degree without looking at what are the barriers to getting data where you think it resides from other places, especially -- we really don't have anybody representing state agency, if we think that's a piece of this. We need to pull that in and figure that out before we go down and develop the next collection.

So, I know it takes a lot of time, and there has been progress, and we want to move forward in kind of a linear path, but I think this needs to be addressed before you move to the next step. Thanks.

MS. MOSBY: In the workgroup, one of the things we'd like to hear, if there are other systems and there's knowledge of other systems, we will start talking about that. Hopefully, the mix of folks that we have on the workgroup will be able to help us with that kind of identification.

I know it was a comment. I heard what you said, and we will do that.

MR. HOUSENGER: We're running horribly off

time, so I'm not taking any more people than the people that have their cards up already.

Robyn.

ROBYN: Just two quick comments. I'm also on the incident workgroup, so I applaud the report. Just to reiterate, from the health care and the research community, as much can be made publicly available. I understand about protecting public health information or private personal health information. Yes, I agree with all that, but if it can be de-identified as much as can be publicly available and standardized, it would really help the research community to be able to do health studies.

MS. MOSBY: Thank you.

MR. HOUSENGER: Marc.

MARC: Yes, and good morning, everyone. So, I have some concerns and then a basic question, which might go to a suggestion. My concern is that there seems to be something in effect to preclude rule change or rule making right from the start. I'm not quite sure that that's a way to start doing things, depending on what comes out of it. Enhanced monitoring is always a good thing. In

fact, I think something that Robyn was alluding to is this idea of surveillance and public health is very important. Sometimes we don't see patterns until we get enough data in to look at things. If we restrict the type of data that we get in, then how are we going to get those patterns and trends? So, I certainly would applaud an idea for enhanced monitoring, which, of course, I do think the workgroup is heading towards.

Then, of course, I realize that this is difficult in light of the fact that the Agency is supposed to be monitoring, but they have a decreased funding situation, and they're not able to do that. So, one of the things that I know is done in water is that there are 319H grants for the education of citizen scientists that will do more monitoring out there. They do that with lakes and streams with regard to water quality. Why can't something like this be done with regard to incident reporting so we can have more data from qualified people so that Bob doesn't get too upset about unqualified people, and have something like this being done?

In general, I think that there are ways of

enhancing monitoring. I do think that to preclude rule change is not a way to start out. At the same time, I'm not saying that you have to change the rules; I'm saying that we're not going to do this, even if we have data that says it should be done. Thank you.

MS. MOSBY: Thank you. I was just going to say it is our intent to have data elements for the voluntary collection. I don't think that we are precluding at this point any changes to 6(a)(2). There's work that always is going on in the Agency that will look at whether there is a need for changes to 6(a)(2). I think that there are separate venues for that. Our goal here is to look at developing this data system that will make the voluntary data better.

MR. HOUSENGER: Okay, Ray.

RAY: What is the source of the definition that was given on, I think, slide 2?

MS. MOSBY: EPA web site.

RAY: Where on the EPA web site?

MS. MOSBY: We can provide that for you.

RAY: It differs from the 6(a)(2) definition. Given its intended use, it must be subject to rulemaking.

It can't just be coughed up and changed at will by the Agency; it has to be subject to rulemaking, particularly in the sense that the first use proposed for this database is to support risk management decisions. That makes any incident reporting system a regulatory process.

Furthermore, any collection of data by the federal government, whether it's voluntary or mandatory, is subject to the Administrative Procedures Act, review and approval by the Office of Management and Budget. FIFRA regulates on the basis of no unreasonable adverse effects; it's not on the basis of counts of incidents or on the basis of any exposure or on the basis of any affecteds, no unreasonable adverse effects. These all need to be taken into account in the further work of the workgroup.

MR. HOUSENGER: Aimee.

AIMEE: Well, like many others, thank you so much for undertaking this process. I think incident reporting is so valuable. I'm glad that you're looking at how to make it more effective. Two quick stories that I've had dealing with 6(a)(2) and incident reporting.

The first one was Raptor Center (phonetic). I

called them up one time, actually not thinking that I was talking about pesticides but organizing a school trip. We found out that just chatting with the woman they think more than 50 percent of their raptor incidents are due to rodenticides (inaudible). That's how they manage and treat them. They know nothing about 6(a)(2). They're able to keep these birds alive, but they didn't know anything about those incidents, and they didn't know to report them.

So, we do need more information, and we need to be able to get this information out.

The other was myself trying to do a report. It was correlation; it wasn't a causal. But I was trying to figure out how to report a bee incident that had occurred. I called the registrant. I called the Department of Ag. I called the National Pesticide Information Center where I used to work. It was amazing how people didn't know what I needed to be able to report an incident. I figure I'm kind of on the inside, so that was concerning to me.

So, again, I really applaud this effort. It is so important. I think people have spoken to the value of

this monitoring and incident reporting already. Just to point out, it is used right now in risk assessment. We talked about yesterday how it's part of the weighted system; yet, we don't really know how much of the information we're collecting. That's really hard to meet, including it in a system when we don't really know how representative it is of the incidents that are out there.

So, again, thank you very much.

MS. MOSBY: Thank you.

MR. HOUSENGER: Steven.

STEVEN: Oh, man, I was nervous for a minute. I thought I was going to agree with Ray again, two days in a row. I'm close. My question was about the definition, who came up with the definition. You addressed that. It's in your consideration slides, so I hope you kind of figure this out, what Ray may not consider an adverse effect but I might consider an adverse effect. So, I think that's something important that you need to kind of flesh out pretty quick.

Then, another concern I had was state agencies. So, this current system which you're working, which I've

not been involved with, is going to be independent of reporting to a state agency? California has a lot of data; Mississippi has very little data on bee incidents. So, I think it's important to know -- that's my question. Are you integrating state information with this or is this independent of that?

MS. MOSBY: We will look at the data that's currently out there and figure out what makes sense.

STEVEN: See, that's part of the problem. As far as bee incidents, there's a lack of data.

MS. MOSBY: That makes sense. So, we would have to look at that and make that determination as we move forward.

STEVEN: If it's not there to see, then how do you see it? The incidents are happening, but it's not being reported. So, how can you look at it and say, oh, well, now I need to --

MS. MOSBY: So, what would be the alternative? What would you suggest we do? Where would we get the data? That's the sort of things we're looking to the workgroup for. Are there other places where we might find that data?

STEVEN: That's the million dollar question, because for the beekeepers, incident reporting ends up in a punitive action. So, beekeepers have no incentive to report, because it's punitive against the applicator or the grower or the beekeeper. So, I don't really know what the solution is, but I know that just because there's no data doesn't mean there's no incidents.

MS. MOSBY: We'll look into it and try to figure out a solution.

MR. HOUSENGER: Gabriele.

GABRIELE: I'm just reflecting on the conversation. One thing that I'm really hearing, and I'm picking up on the words of the difference between an incident which has a very particular legal meaning, at least to some in the audience, versus a complaint where it might or might not be an actual incident, which we don't know yet until we investigate it, or someone has taken a look at it.

This comes back to Cheryl's point, it's really hard to say what I should be talking about because there's a very different realm in this 6(a)(2) versus just trying to keep track of what everybody is seeing out

there or worrying about out there. Again, I'm not saying that they're not legitimate worries, but there's something going on.

My advice might be that you actually separate out the two processes. You talk about something that's voluntary reporting. You talk about something, and I don't know if complaint is the right word, but something that you take that word incident out of it, because it's clearly loaded. It has very specific loaded meanings.

So, then I think you'll be able to actually have the conversations about how do we figure out how to monitor and get information out from the public different from what's needed on the 6(a)(2). I'm not saying they're completely separate processes, one will inform the other, but I think you would get to a clearer result if you could differentiate the two, because as I listen to this conversation, it's clear that that's where the panic is. That would also make it easier to separate out and figure out ways to have concerns be raised without some of these other issues coming up about anonymity and so forth, because then you can start collecting that information without it having to meet

certain legal requirements.

So, I just really urge, as you go forward with this conversation, because it's clear that the membership of your group, including us, is hearing two things, and there's very different thinking, depending on which way you're going. Again, not that one shouldn't be influencing the other, but it would make life a lot easier and more clear cut, okay.

MS. MOSBY: Thank you.

MR. HOUSENGER: Tom.

TOM: Thanks, and I'll try and be quick. I'm on the committee also. Also, in a past life, I've filled out a lot of these forms under the old pesticide incident monitoring system as a state inspector. I think partly why that failed was because of how the data information was used.

So, I think before we go forward, we have to address a lot of these questions beforehand. Also, in the data, there's so much of it that's there, I think when people look at things to fill out, that I think if it's so voluminous, that people will just not fill it out because so much is there. So, I think we've got to look

at the amount there, too.

MR. HOUSENGER: Andy.

ANDY: I think Gabriele touched on what my question was. Are these reported as incidents prior to an investigation? Are we opening up the system for people to report incidents that aren't qualified to identify what an incident actually is?

MS. MOSBY: I'm going to let Melissa just answer that very quickly.

MELISSA: So, right now this wouldn't change the type of information in the sense of how it comes in. Right now, anybody can report an incident. There's voluntary reporting that's allowed. We get a range of data in right now. We get some incident data that have been fully investigated by the state. We have lab data. Then we've got other things that come in, like Jackie said, on a napkin. So, we get a wide range right now. That was one of the reasons of working with the workgroup, to try and standardize that a little bit on the voluntary side, primarily.

So, it ranges. We get data. We're dealing with all these issues currently with the data that we're

get in. These are not new specific issues. We get voluntary data all the time. We get registrant data all the time. We have to deal with a lot of these issues. So, the response to the question is we get a wide range of quality of the data right now.

ANDY: But are they reported as incidents rather than just complaints prior to an investigation?

MELISSA: The required ones come in under 6(a)(2) to our incident coordinator, a 6(a)(2) coordinator. Those come in under the 6(a)(2) requirements. The voluntary reports come in in a variety of formats. As I said, some come in and they're investigated; some come in not. We take them. Some might be complaints. Some might be incidents, however you define that. But we consider them incidents when they come in, and then we validate or look at the information before it's used.

That's true for all the information. When we use the incident information, before it's used in a risk assessment, they're all evaluated by the staff scientists before they're used. So, that's part of the process.

MR. HOUSENGER: Amy.

AMY: I want to say thank you to the workgroup and EPA for looking at this really important issue. I'm a little concerned about Bob's comments. PPDC is sort of echoing what the workgroup is coming up with, and I think that that's important to know.

One of the things I wanted to throw out there, as you move forward and as you look at the data, I know there's a lot of really good people on your workgroup that are thinking about this as well. There is a population that we know is overexposed. That happens to be the farmworkers. So, as we move forward with looking at incidents, making it so that these voluntary reports can be meaningful and used in a way to impact policy, I think that's really critical.

So, I commend you for looking at this. I want us to think about sort of the needs of special populations and a worker population that's the most overexposed population of pesticides.

MS. MOSBY: Thank you, and thank you, everyone. Are there any more questions?

UNIDENTIFIED FEMALE: I just wanted to say one more thing, because this kind of got flossed over in the

presentation. Anything we do will have a communication plan for the public, for the registrants, for the NGOs, so that we can make it as clear as possible and as transparent as possible.

MS. MOSBY: So, that's it. Thank you.

MR. HOUSENGER: That's the end of that one. We're 20 minutes over right now, so your break is going to be truncated.

Next up is resistance management. Bill Chism is leading that discussion.

MR. CHISM: Thank you very much. We've been working on resistance in the program for a number of years, and things seem to be coming together this year. So, I'm pretty pleased to be here today.

My name is Bill Chism. Nikhil Mallampalli and Jeannette Martinez will be talking about different sections today. We're going to talk a little bit about background on resistance, why we're interested in this, talk a little bit about a couple pesticide registration notices that are now active on our web site, and also discuss changes to the EPA's corn rootworm resistance management strategy. Then, hopefully, we will have time

for questions.

Pesticide resistance, what do we mean? Over time, agricultural pests become resistant to a pesticide. I think everybody in the room is aware of this. The process is greatly exaggerated or accelerated when pesticides with the same mode of action are repeatedly used on the same pests. We're going to hopefully address that with some of our PR notices.

The slide here talks about the number of resistant, case of unique resistance. So, if an insect is resistant to five different insecticides, that would be five cases. The black line is insecticide resistance, the red line is fungicide resistance, and the blue line is weed resistance.

So, as you can see, over the last few years, the number of cases has gone up dramatically. In the U.S., there's at least 155 weed species that are resistance to one or more mechanisms of action. Globally, there's at least 580 species of insects that are resistant to one or more insecticides.

Why manage pesticide resistance? Believe it or not, the Agency would like to extend the lifetime of

pesticides. They're very expensive. They take a lot of effort to get registered. We'd like to keep them effective as long as possible.

Some of the steps we'll talk about with the PR notices are to provide growers with information on how to slow the development or spread of resistant pests, help reduce the economic losses due to resistance, and potentially reduce pesticide usage and then unnecessary pesticide loading in the environment. When a pesticide is used and the pest doesn't die due to resistance, we'd rather avoid that situation.

Just some examples of herbicide resistance. In 2010, there is approximately 33 million acres infested with glyphosate-resistant weeds. Two years later in 2012, that number was approximately 61 million acres. The USDA reported in 2010 that corn and soybean growers with glyphosate-resistant weeds spent more money per acre for weed control. In the case of corn growers, they were spending an extra $67 an acre. In the case of soybean growers, they were spending an extra $23 per acre. So, it's having impacts at the grower level. In the case of Georgia, we have some information from them. In 2010 and

2011, they spent an aggregate of an extra $100 million for Palmer amaranth control in cotton.

So, we're beginning to see if there's some places we can interface with this problem. We're releasing two pesticide registration notices, one on guidance for pesticide registrants on resistance management labeling. This is an update to a 2001 PR notice that was already out. The second one is guidance for herbicide resistance management for labeling, education, training, and stewardship. This focuses on some overall strategies for herbicide resistance and would target the registration and re-registration.

I'll turn it over to Nikhil Mallampalli.

MR. MALLAMPALLI: Thank you. So, this slide just gives you a brief reminder of what pesticide registration notices are. They provide non-binding, voluntary guidance to pesticide registrants and EPA staff regarding pesticide registration activities and decisions. They should inform pesticide registrants and anyone else who is interested about the important policies, procedures, and information that should facilitate registration-related decisions. They support

EPA's commitment to be transparent in its decision making and should reduce the time, burden, and costs for registrants and EPA by providing guidance that makes it easier to comply with statutory requirements. So, it's just a very short overview of what these things are.

So, I'll just go over this slide and then turn it over to Bill for the second PRN. This slide briefly summarizes the general changes that an OPP workgroup has developed to the 2001 PR notice that addresses what registrants could put on their labels for conventional agricultural pesticides as far as resistance management guidance goes to the end user.

So, it's broadly three categories of updates in the new PR notice that supercedes the 2001 guidance. First it provides a bit more additional guidance on the details that registrants can put as far as resistance management information for the end user of the pesticides. It goes into more detail on the recommended format for things like the mode of action box that we hope all pesticide labels will carry eventually, which tells the end user what category of pesticides they're using.

Most of this information is pretty much the same as in 2001, but, for example, we have tried to add more examples of the IPM, integrated pest management, tactics an end user could use to help manage resistance. So, trying to go beyond just the mode of action box a little bit.

We have also included new references to external technical resources that registrants can use to find mode of action information, for example, referencing the web sites for the resistance action committees, that industry has reestablished the modes of action groupings for pesticides. And there's links to mention the relevant side of these societies, like the Entomology Society of America, for example.

Another big category of the changes to 2001 PR notice is how to submit changes to existing labels. Our new guidance explains that, for example, if resistance management language is the only change to an existing label, a PRIA fee will not be charged for that. It would consider it a fast-track amendment change. PRIA did not exist early in 2001. It wasn't really addressed in the original PR notice. It also goes into some detail about

how electronic submissions could be made, which also did not exist in 2001.

These updates were developed in collaboration with Canada's pest management regulatory authority, PMRI. They have had a very similar regulatory directive, which is what they call the same guidance, on their web site since 2013.

I'll also add, and it's not on the slide, we have also updated the label review manual, the chapter that addresses resistance management information that should go on the pesticide labels. This manual is a resource that EPA uses, mainly the registration division, to help improve the quality and consistency of labels. So, EPA staff do consult that. We expect registrants do also consult that when they are making changes to existing labels or developing new labels.

I'll be going into more detail in that chapter as to how to develop mode of action boxes for more complex mixtures of pesticides, such as make sure there's two or more active ingredients or a mixture of a fungicide or an insecticide. So, all of that is in the associated label review manual. We will be putting that

updated chapter along with this update to the PR notice out for public comment on regulations.gov.

With that, I'm going to turn it back to Bill. He's going to talk about the second PR notice, which is sort of affiliated with this one.

MR. CHISM: Thank you. The second PR notice should be released with the same FR notice that the first labeling one will go out. They're both due soon. They are on our web site. We will have that link at the end.

Why did we start with herbicides? There has not been a new mode of action introduced in the market in over 30 years. The most widely used type of pesticides are herbicides. The herbicide resistant weeds are increasing rapidly. We've had a number of groups come in and ask us specifically to do something about this. So, we thought it would be good to start with the herbicides and see how this works out.

What we've tried to do is provide a strategy to address resistance during registration and registration review. We've tried to introduce educational and training elements and try and see if we can provide a framework for educating the grower and the consultant and

providing information they might need.

It's a tiered approach based on the potential for resistance to develop. I'll show you that in a second. We're promoting use of 11 different elements adapted from the Weed Science Society to focus on label information and directions, some training and educational materials, locally developed resistance plans. We talked about early detection, investigation, and remediation.

I apologize this slide is kind of busy. This is the 11 elements. What we're proposing is that we have a low, moderate, and high category of concern. The herbicides with a mode of action that falls into the low concern -- there's, I believe, nine different modes of action that have no resistant weed species at all.

We would like them to put mode of action on the label. We consider that a critical element if growers and consultants are going to develop a resistance management plan. We would like the seasonal and annual maximum number of applications in pounds. You can't develop a resistance plan if you don't know how much you can use and properly plan for that.

We would like resistance management language

from the PRN. The Weed Science Society has best management practices. The Herbicide Resistance Action Committee has generic resistance language. All of that would be a wonderful thing and very helpful on the label.

We would like the labels to remind the users to scout before and after application, because if you don't scout before, you may not be correctly identifying the weed. If you don't go out afterwards, it may escape you and you didn't realize it until it's too late. These are recommendations on the label, not a requirement.

For the moderate category, there's about 12 modes of action that have somewhere between 1 and 9 resistance weed species. These are species in the U.S. only, not worldwide. We would like elements one through four plus define likely and confirmed resistance on the label.

We would like a statement reminding farmers to report lack of performance to the registrant or its agents. If they think that they might have a resistance problem occurring, we would like them to report that. List confirmed resistance species in a separate table on the label and list effective or recommended rates. If

those species can still be controlled in your state, they may be resistant somewhere else. But you can still control them in your state. We're hoping there would be a recommended rate for those weed species so you don't accidentally use a very low rate and select for resistant species.

Number 8, the registrant should report new cases of likely and confirmed resistance to the EPA and the users yearly. There's been cases of an HPPD resistant weed. It took five years before they could confirm resistance. We think early detection and getting that information out there is critical. If you can deal with it for the first four years, maybe it won't become resistant. So, we'd like early reporting to us, and we hope to make that available somehow on our web site so that growers and consultants can see those cases.

The areas of high concern, there's seven modes of action with high levels of resistant weeds. We'd also like any new mode of action. We haven't seen one in 30 years. We'd really like to protect it to have these resistance elements.

Also herbicide resistant crops, either

genetically modified or through traditional breeding we think fall into this category because herbicide resistant crops have been linked with herbicide resistance. Provide elements one through eight plus provide growers with a resistance management plan, a remedial action plan, which is what do you do if you suspect you have resistant weeds, and some educational materials on resistance management.

The resistance plans, remedial plans, should be locally adapted. They should be by the extension, the crop consultants, the grower groups such as the corn, soybean, cotton. They're very active in this area. I don't want to see them. I don't want to approve them. I don't want them on the label, because that would take way too long for them to adapt to local conditions. These things may have to change yearly.

For combination products with multiple modes of action, we would really like a table listing which mode of action is effective on which weed species. With some of these five-way combinations, I don't know how a consultant or grower can figure it out if he's got multiple effective modes of action for his weeds. This

could be something as a handout or on a separate web site, but it would be really important for the crop consultants to know if he's got multiple effective modes of action. It's really hard to tell with the combination products.

Then, finally, any additional specific requirements such as a crop rotation requirement, some unique agronomic aspects, time limited registrations, et cetera.

For Enlist Duo, the 2, 4-D, and glyphosate resistant corn and soybean, that was registered in 2014. The registrant incorporated herbicide resistance management plan into their registration. We did not have all 11 elements, so they didn't address it at that point. The most recent one undergoing review is Dicamba Xtend, which is the dicamba resistant cotton and soybean. They have gone through and addressed all 11 of our elements, so we think that through time, we'll get more groups cooperating with this.

So, the next steps, we hope to release the PRNs. They are up on our web page. Evaluate and consider comments. We hope to finalize both of them in

the fall of 2016.

I'd like to turn it over to Jeannette Martinez.

MS. MARTINEZ: Good morning, everybody. So, I'll be giving you a brief overview and background on the process behind the new framework for Bt corn and corn rootworm resistance management. Then I'll talk about the changes that were made as a result of this process.

My presentation will be more high level than the herbicide resistance presentation you've seen. But if you have questions afterwards, I'd be happy to answer them.

So, back in 2009 at a USDA organized meeting, we heard from corn rootworm entomologists that they observed (inaudible) failure, Bt corn failure in Iowa. In 2011, a publication went out confirming resistance to (inaudible) in corn rootworm. As a result of that, we here at EPA have had extensive and regular discussions with the corn rootworm experts. We then developed a white paper in 2013 discussing the scientific uncertainties for corn rootworm and the resistance management program that we have. We brought this before a scientific advisory panel in 2013 as well. The goal

was to develop new mechanisms in the EPA resistance management program that would result in more proactive detection of resistance in the field and more effective mitigation of resistance.

Here at the EPA we developed an initial proposal of the framework for Bt corn and corn rootworm in 2014, taking into consideration the SAP's recommendation. In fall of that year, we opened up the proposal for public comments. The comment period ended in spring of 2015, and the final framework was finalized in 2016. It addressed public comments and concerns and it incorporated SAP's recommendations. The goal of the framework as it is today is to extend the durability of these non-(inaudible) Bts that are aimed to control corn rootworm and its benefits.

We also developed this new program with an eye towards the future and the new biotech products that are in the corn rootworm control that reduce conventional pesticides in the environment and exposure to humans.

So, briefly, let me touch on five major categories of the framework where changes were made. I also included a docket number in the title section that

will lead you to the framework in the docket if you're interested to look at it more closely.

So, based on the SAP's recommendation, refuge alone was insufficient for non-high dose Bt corn (inaudible) and IPM was needed to extend the lifetime of these traits. That was the first major change. We also made changes to how registrants investigate and report unexpected damage and test for resistant populations.

The formerly relied upon (inaudible) acids were replaced with more fields representative on plant assays. Further changes were made to the mitigation of resistant populations that met EPA's resistance criteria, as well as annual reporting of IPM adoption and other activities surrounding grower education, et cetera.

The focus of the remaining slides will be on changes related to IPM for the first bullet, unexpected damage, and resistance confirmation, the second bullet, and mitigation of resistance of the framework which is the fourth bullet.

So, feel free to ask questions about anything else during the discussion section.

So, now I'm moving on to discuss the IPM

stewardship piece of the framework a little bit in more detail. So, biotech companies are required to develop and implement an educational outreach program for growers who plant Bt corn. Biotechnology companies must develop and help implement a multi-year management plan for growers using the Bt corn consistent with good IPM practices. These plans will allow a lot of grower flexibility and can be adjusted to a grower's specific situation.

IPM with Bt use is important, and it will delay resistance development. IPM tools include rotation to a non-corn rootworm host every few years, which is preferred and the most effective tool, planting of pyramided Bt corn and, of course, also non-Bt corn varieties with a soil-applied insecticide. This will be an especially effective tool right after the grower has crop rotated the fields and when we know that there are fewer (inaudible) in the field.

Now, let me discuss some of the changes that were made to the unexpected damage follow up and resistance confirmation section of the framework. Bt corn failure can be an early indicator for corn rootworm

having evolved resistance to Bt. So, therefore, proactive and robust actions are critical to lessen or, in some cases, to eliminate the impact of resistant populations in that area.

Therefore, when biotech companies investigate grower complaints, we have now standardized thresholds in place for single and pyramided Bt corn to determine if a field is truly an unexpected damaged field caused by corn rootworm feeding on those roots.

If the thresholds have triggered or exceeded, corn rootworm will need to be collected by the registrant and tested for resistance with these new on plant assays. Well, they’re not new, but they’re new to the program.

When unexpected damage has been confirmed, the biotechnology company must implement best management practices in the field and the surrounding areas based on good IPM. The preferred option is to rotate to a non-crop host in that field the following year. If that occurs, then we consider the area mitigated and no further actions or follow up by the biotechnology company is therefore needed. So, that’s a very powerful way to

reduce input by the registrants but also have effective proactive mitigation.

The second best option is to use pyramided Bt corn. Then, of course, we also have the option of planting different single Bt traits or non-Bt corn with a soil-applied insecticide. The last option is to use a soil-applied insecticide with Bt or a seed treatment or chemigation of adults if additional management tools beyond options one and two are absolutely necessary. The use of soil-applied insecticides with Bt is not a recommended option by EPA.

Now, I'm moving on to discuss some of the changes that occurred in the mitigation section of the framework, actually my favorite section in the whole document. We now have specific enhanced actions in place that are triggered if a resistance case is confirmed in a particular area. For example, the biotechnology company must notify the affected companies that also sell the compromised trait, the neighboring customers, extension specialists, and crop consultants where the corn rootworm are resistant.

Furthermore, a half mile radius will be drawn

around that resistant site which constitutes the mitigation action area. That distance was based on the lifetime dispersal within a generation of the corn rootworm.

Within this area, the sales of the compromised Bt trait will be discontinued, and planting will not be permitted until a resistance has shown to be mitigated. The biotech company must monitor resistant populations until mitigation is completed. Pyramids planted in a mitigation action area containing the compromised trait require now a 20 percent refuge. That's an increase from the 5 percent up to 20 percent because the pyramid is now compromised. It's not a true trait product anymore. That will be effective until mitigation is complete.

Of course, the most effective mitigation practice again is crop rotation. So, if this was to occur in the entire mitigation action area, we would consider this area mitigated until next year where the grower could continue to plant as he sees fit. Pyramids are the second best option to use. The biotechnology company needs to encourage the growers to use these tools.

Now, an important question that seems to concern a lot of people is, who does this new framework apply to. Well, it is a legally binding document for the biotechnology companies who sell the Bt seeds to growers. The biotech companies are also obligated under this agreement to annually assess the IPM adoption in the corn belt and to report this back to us so that we can check the adoption of IPM with Bt deployment increasing, decreasing, is it staying stable so that we can troubleshoot and see where the problem is and try and get this percentage up.

Grower education, of course, will be an ongoing process and is an important aspect to the success of the framework. The framework permits a lot of flexibility for growers, and it encourages an adoptive multi-year corn rootworm management plan. The burden on the growers should really be minimal.

Now, if you have any questions, we would be happy to take them.

MR. HOUSENGER: Bruce.

BRUCE: Clarifying question, and then maybe the first public comment on the proposed changes to the PR

notices.

Bill, I can't remember if you're the one who said it, but the update to the 2001 PRN, will it require -- I think fast track amendment was the term used. Will it actually require review and approval by the registration division, or BEAD, or can that still be done by notification?

MR. CHISM: If, for example, a company is putting the stated resistance management language from the PRN on there or if they're putting the mode of action on the label, then it would just be notification, as long as that's the only change.

BRUCE: My suggestion is, when you guys re-engineered that PR notice, have it end up in the same place -- I think it's the current one -- so that the utility of it is so straightforward, it can be done by notification. That will really bring consistency. I think it will help rationalize resources within the Agency and help really get this thing done in a consistent way. So, that's my suggestion.

MR. CHISM: That is a good point, and that is the intention of this.

MR. HOUSENGER: Gabriele.

GABRIELE: I just wanted to say that for a coop that's not GMO, we have the same problems. So, as EPA is thinking about these things, I would encourage you to think about it in a larger context. So, just to give you some examples, we have weed resistance because what we're -- I mean, the bottom line is it's an orchard crop. You can't rotate. So, you've got to think about that. You're in the same system for 15, 20, 25, 40, who knows how long in the case of pistachio years. So, that is not an option for us.

So, I just want to be clear that this is an issue certainly from us as a grower organization and funding research in an outreach, we keep harping on growers rotate, rotate, rotate your materials. One reason why we always want a multiple range of materials for growers to use. I just want to say it's really hard when something works well, and particularly if it's cheap, it's really hard to make those arguments.

I think the other thing to be careful of, and again it's coming back to rotations, in a previous life working with carrot growers, one of their concerns was

that over time, they had less crops they could rotate to because of economics. So, again, realize that economics is a big driver in crop rotation. I don't know how to manage that, but I think really thinking through -- I like that you're putting the mode of action on labels. I think that will be very helpful across the board. But again, give some thought.

I did have a question. I didn't understand this ranking of the mode of action for the herbicides in low, medium, high risk. It sounded like it was just based on whether resistance had already developed. To me, that's not a good idea, because if something is newer -- it sounds like with herbicides we don't have anything newer, but some of it is just a matter of time.

I mean, I would rather look at the mode of action as something that's going after multiple sites, is it more prone to resistance development or not. Just because it doesn't have it yet, doesn't mean it can't develop it without managing it carefully. So, I would revisit how you define low, medium, high in terms of weed management.

MR. CHISM: That's a good point. Just to that

last part, the low, moderate, and high, this is our proposal for trying to focus the attention on the cases where there's the most resistance. But there may be other ways, and we're hoping to get some good feedback, as you say, about rotations and whether that's a logical way to go forward.

MR. HOUSENGER: I don't think our attempt was to limit it to GMO. It's the start, and you have to start somewhere.

Cheryl.

CHERYL: So, my question was also about the low, medium, high slide. When you got over to the high, you had a whole lot of stuff. You said some very specific information. You said they're not going to be on the label. It wasn't clear what was going to be on the label, because when you started, it was thinking from the label.

My point is, it's a very fluid situation. Low, medium, and high is assigned for kind of ranking in part, bringing attention. But it's a fluid situation, especially as you have species coming on board that need to be verified, now you have an issue, and if it's moving

from state to state. Those kinds of things don't work well on a stamped accepted label or a package label.

So, please consider a URL where you can get to updated information that's going to make things much better than trying to force everything on the label. It sounds like you're partially there, but just reiterate that.

MR. CHISM: So, for example, the mode of action on the label, some sort of remind people to scout, remind people that resistance language. But a lot of this, you're right, would not be on the label because it's not quick enough to change. I don't want us getting in the way of being able to rapidly change with the existing conditions.

MR. HOUSENGER: Marc.

MARC: I'm gratified that the Agency is being as aggressive as they are on this. I can say that the original USDA programs for IPM in 1968 were generated because of resistance, particularly to the cotton boll worm with regard to the OPs and organochlorines. So, this goes back to the same thing all the time. IPM is a big part of it.

Speaking to that, I would say that when one is trying to get a community to adopt the IPM innovation, they need to go through a diffusion process. Simply injecting information is not going to work so well. But I know you know that. You can do what you can do on labels.

The main point here is that when it comes to the legal responsibility that the manufacturers have an IPM program and report adoption of IPM practices, that self reporting, in my experience, particularly with school IPM, is not effective. So, there needs to be something else, a third party system or something like that, if you want it to really work. So, you might consider that, although I know it's difficult.

MR. HOUSENGER: Annie.

ANNIE: We'd also like to thank the Agency for being proactive on this issue. One thing we'd really like to commend the Agency for was your 2014 decision not to approve the section 18 emergency application for the propazine and the Texas cotton fields.

We have really been predicting resistance from the beginning. I think it's clearly the nature of using

these chemicals that really creates that. So, I'm just wondering when we're going to start seeing the Agency assume this resistance at the start of the registration process and factor it in to how much the allowance of the chemicals that you're using. I think EPA and USDA have a lot of information on this, and we'd really like to see it be incorporated earlier when things are being registered.

MR. HOUSENGER: Sharon.

SHARON: Well, I see this as a really critical issue, not only for our agricultural system but also for the ecosystem, because any resistant species that may invade natural systems is of concern. The whole use of many of these pesticides in multiple systems is likely ultimately over time to result in some sort of resistance.

With that said, I look at this as a natural selection process. So, it's something that just goes back to basic biology. So, anything that the EPA can do to encourage non-chemical approaches in its resistance management plan I think is really critical, because it's just going to be a whole lot more effective. You're

going to have the pesticides available for a much longer period of time if the selection pressure against the pest due to these modes of action is just less overall.

With that said, I'm curious about the resistance management plans, the remedial action plans, the educational materials, and all of that. I'd really like to see some examples of that. I'm not as well educated on this as I'd like to be. So, I'm curious about what kinds of measures are included in that. Does it include mechanical, cultural, biological approaches?

I'm concerned on the moderate column about number seven about the confirmed resistant weeds, listing effective or recommended rates for those weeds with the table. It seems to me, I think, as Gabriele said, knowing that it may be just a matter of time, I'm not clear why EPA would even want to continue to encourage the use of a pesticide when we know that we've got resistance, even if it's in a different geographic area. It would seem that you would want to avoid use of that pesticide against that pest all together. So, that one concerns me.

I'm just very concerned about the continued

approval of GMO crops and pesticide combinations that we know are resulting in resistance. So, it just seems like we continue to approve things when we know we've got this resistance thing going this way. It's just a nonsustainable approach. So, I have a lot of concerns about that.

MR. HOUSENGER: Robyn.

ROBYN: Thank you. I applaud the Agency for everything that they've done. I echo Marc's encouraging of IPM and Sharon's concerns about GMO and pesticide resistance. I'm not familiar with USDA's study on slide 6. So, you say that corn growers and soybean growers spent extra money per acre. Was that because they were forced to use stronger pesticides or a combination of pesticides for both? Could you explain that a little bit more?

MR. CHISM: They're adding an additional herbicide to target those specific resistant weeds.

ROBYN: Okay, thank you.

MR. HOUSENGER: And Wayne.

WAYNE: Perhaps the answer to my question is in one of your web pages. I, too, was interested in knowing

more about the resistance management plans, remedial action, and educational materials. It was a little bit unclear. I know you mentioned things like connection to commodity groups and that sort of thing. Can you expound on that a little bit?

MR. CHISM: So, for example, in Georgia, for Palmer amaranth control, the extension service in Georgia, Stanley Culpepper, has a resistance management plan for that. It's one page front and back. It has recommendations for specific herbicides and specific timings. So, in that case, it's a pretty short document.

Remedial plan, in our herbicide resistance plan, we've adapted many of the elements that have been successful in the Bt. They talk about a remedial action plan. If you suspect you have resistance, not yet confirmed, what are you going to do. There are two reasons for developing those plans. I do not have an example of that.

There's two reasons for developing those plans and making them widely available. One so that everybody knows what maybe they could do if there's a problem. Two, if the retail system doesn't have those products or

that equipment on the shelf when you go to get it to use it, to buy it, whatever, if it isn't there, it's too late. They can't get it in time.

So, the remedial plan ideally would take care of the problem. It would be effective, take care of those weeds with whatever system is necessary, and we'd never have any reporting because they'd be controlled. So, it's just part of trying to think of the continuum. In some cases, the remedial plan is a rotation to a different crop, because the canopy will be competitive or there's some piece of the biology of that additional crop. So, the remedial plan may be the next season as well.

MR. HOUSENGER: Richard.

RICHARD: Thank you. In your resistant plans, how do you know what's the lifetime of the resistant plans before you get resistance to develop again?

MR. CHISM: We anticipate these plans will have to be changed quite often because of either a new resistant species or a selection within an existing species. That's why we'd like them to be developed at the local level. So, I think they're going to have to be

adapted quite often.

RICHARD: Thank you.

MR. HOUSENGER: Louis.

LOUIS: Thanks. I just want to add my voice to complimenting EPA for being proactive on this. Resistance is an issue that I confront each day I go to the field. It's probably more serious than many folks know, but I guess growers do know that quite well.

I'm happy to see that you're starting with weeds, because resistance to pesticides is really important. However, I hope that it wouldn't be long before you start looking at insect pests because that's an (inaudible). You have a picture of the diamondback moth. That's one that is really notorious. It's well known for that. There are others. So, the sooner you get on to that, the better for us.

I can't wait to see the revised chapter that you talked about. Put it on line so we can take a look at it. I just thought I'd add my voice to it, because it's an area of great need. Thank you for thinking it out.

MR. HOUSENGER: Ray.

RAY: I want to get a bumper sticker that says evolution happens. Pests can develop resistance or the potential is there to develop resistance to any control strategy. I've heard of insect pests developing resistance to crop rotation. So, it's not just a pesticide phenomenon, the resistance development.

One of the most important things that the Agency can do in terms of combating pesticide resistance development is to maintain the existing tools we have and approve new ones. I've seen recent concerns from the Agency about tank mixtures. Tank mixtures are one of the most beneficial means of approaching pest resistance by including multiple tools at the same time. So, I'd caution the Agency on moving very far in that direction to prohibit tank mixtures.

MR. HOUSENGER: No comment on that one. We're through our break. Do people need to get up for five minutes or want to just push on? Five minutes? All right, go.

(A brief recess was taken.)

MR. HOUSENGER: Okay, let's get started on international activities. Rick Keigwin is leading that

discussion.

MR. KEIGWIN: So, I'm probably the least equipped person to give this presentation, but with that said, there was a request to just get an overview from the office on the different international fora in which we are engaged and how we are engaging. I will just say this up front, I'm quite sure that there are a number of omissions from here. If there are omissions, it's my error. It's not to suggest that those activities aren't important. So, I suspect that some of those might come up, provided we have time for questions.

So, just real briefly, we've laid out for ourselves four essential areas of achieving OPP's goals of protecting public health and the environment when we engage in international work. One is the acknowledgment that increasingly it's an international marketplace, not only for pesticides and trade but the commodities that are treated with pesticides and trade.

There can be an impact on U.S. health in the environment as a result of our international work. When we register new active ingredients, new lower risk active ingredients, and those commodities, those chemicals,

those products are not similarly registered in other countries, it can create a trade barrier where U.S. growers can't adopt the lower risk technologies because they can't export to other countries.

Increasingly, there is a desire internationally for safer products to become available. Through a number of the trade agreements that are either in development now or are existing, provisions are being discussed for how we can promote the more global acceptance of safer products.

As a result, and we talked about this a little bit yesterday in the context of the pollinator discussion, that where we participate in international work, it gives us opportunities to increase collaboration and then rely upon some of the work that our international partners do.

So, yesterday we talked about how EPA was able to expedite the review of a varroa mite controll product because it had been registered in Canada. As a result of the harmonization efforts that we had undertaken, we could just pick up their reviews and move forward rapidly with a registration decision.

So, as a result, we set four goals for our international work. One is, as I was alluding to a few minutes ago, strengthening food safety, public health, and environmental protection. We can do that when we engage in international activities, both domestically and globally.

We can enhance the quality of our regulatory decisions through collaboration, improve scientist to scientist exchanges, help us make sure that we're looking at the data in the appropriate way that there's an adversity of opinion when we're considering those data so that we make the most informed decisions.

It also conserves resources where we can rely upon work that other countries have done where they have a high quality, scientifically-based/risk-based system for making pesticide registration decisions. It allows us to coordinate more effectively and allows us to be more efficient with our own resources moving forward.

As I said previously, when we can jointly register products or jointly review through our review evaluation program existing products, we can work towards minimizing trade barriers.

We are engaged in a multitude of fora across the international space. Maximum residue limits, or what we call tolerances, are one of our biggest areas of engagement, particularly through Codex. Dan Kunkel has always been part of our delegation to Codex, particularly the Codex Committee on Pesticide Residues. Increasingly, just within the past year, OPP has been getting more involved in the workings of the World Trade Organization's sanitary and phytosanitary standards committee.

So, we are routinely reviewing the various notifications that come from other countries, particularly where there's a difference in the proposed MRL in other countries, to better understand why they are setting their MRL at a different place and where we can't understand it, trying to seek from those countries the risk-based science rationale for why they're proposing the MRL where they are.

OECD is another area where we are engaged in a multitude of fora. We'll discuss those in a few minutes.

Then, third is the work that we've been doing for going on 20 years now with Canada through NAFTA,

increasingly with Mexico as well, and also as part of -- that's a typo. It's not the Regional Coordination Council; it's the Regulatory Coordination Council.

So, on the MRL front, our biggest area most recently has been in promoting harmonization internationally on the use of crop groups and the expanded use of crop groups. I believe at the most recent Codex meeting in China there was some significant additional movement in that direction, particularly with the pseudo-serials (phonetic) group.

Regulatory harmonization continues to be important. Many of you know this area better than I, but ensuring that we have similar scientific approaches for how we determine what the MRL is going to be, or should be, are quite needed. Recently, with the globalMRL.com database, we're effectively using that as a tool as part of our regulatory decisions.

The global zoning projects and comparison of residue levels across the world and trying to find where there are opportunities to reduce data sets and see where the diversity of, or even if there is a diversity of, residue levels as a result of different climatic and

geographical conditions continues to be important work for us.

In the interest of time, I think I'm going to skip through some of these and go to OECD. So, as many of you know, the OECD has a group called the Working Group on Pesticides, which is an effort for governments to cooperate across a large number of regulatory issues involving pesticides. The focus is not only agricultural products but increasingly there's been a lot of work both on biopesticides and the biocides as well.

This provides sort of an overview of the structure within the working group on pesticides. So, not only are there steering committees, but there are expert groups. The WGP has been looking at a whole host of issues ranging not only from the science issues but the information transfer opportunities and efficiencies to also looking at compliance-related issues.

Historically, within OECD, we've been looking at opportunities to facilitate streamlining joint reviews, not just for conventional pesticides but also for biopesticides. We've also developed a number of tools for increased work share and information sharing.

An important part of these efforts has been the work on the global harmonized submission transport system, which EPA is a co-chair of that effort with PMRA. As we move forward, continuing to facilitate minor use registration.

One of the important things going on within the working group on pesticides is sort of a retrospective of what has been occurring within the working group on pesticides, what areas all countries want to focus on moving forward, particularly as countries across the globe have seen reductions in resource availability.

We are going to continue to engage in this effort, but we want to find those areas where we can be most effectively engaged as part of this effort. I think over the course of the next year, there will be a number of opportunities for stakeholder engagement in helping to shape how the working group on pesticides functions moving forward.

Global joint reviews, as I mentioned, continues to be an important part of our work. There have been 27 joint reviews for new active ingredients completed since 2007. Right now, I believe there are about seven that are currently in review. They are primarily in U.S. and

Canada with some involvement from Australia. We are looking to see if we can bring some of our European colleagues back to the global joint review program. We do know that there are approximately 17 new submissions that we can anticipate over the next 3 to 4 years.

On the non-agricultural side, we have a significant investment in the OECD task force on biopesticides. Jennifer McLain, who is sitting behind me, actually chairs that group. They've been working on a number of initiatives to not only harmonize the regulatory approaches within the OECD, but look for opportunities for efficiency in the registration of biocides, both for the government and for industry. A lot of this work closely parallels the work that we've been doing on agricultural pesticides. But, as I said, it continues to be a very important area for us.

Some of the important priorities for the U.S. through this task force has not only been to promote increased work sharing but to look for opportunities for having harmonized guidance, for example, in how we waive or bridge in the acute toxicity realm, and also looking in the microbiology space for harmonized methods for

evaluating the effectiveness of different biocides.

On the biopesticides side, there is a group that focuses on those specific types of products. They, too, are working on guidance for the submission and evaluation of the data that come in. So again, very much parallels with the work that has been done in the other OECD fora.

They, too, have similar priorities from a U.S. perspective, developing harmonized guidance documents for how we're going to review data, updating guidance documents for risk assessments, and then looking for opportunities for joint collaboration on new reviews.

Then, I should mention as well the work that is being done through the OECD test guideline program. Wanda Hall in the Field and External Affairs Division devotes a significant amount of her time promoting this work and coordinating test guideline harmonization, not just for EPA but across the federal government, working with sister agencies, including FDA and USDA, so that there are harmonized approaches. When we can harmonize our approaches on these types of test guidelines, it promotes some of the joint review and work sharing that

we talked about earlier.

I believe this is the final area. So, NAFTA, as I said, we have been working with Canada for well over 20 years, actually pre-dating NAFTA in the Canada-U.S. trade agreement. So, we've recently released the 2016 to 2021 strategic plan that continues to focus on encouraging joint reviews. It is a trade agreement, so it's also intended to facilitate trade. As we do that, in our efforts to make joint reviews increasingly more efficient, we are continuing to look for opportunities to cooperate on both the science and regulatory issues.

Again, in the interest of time, we've talked about this, so I'm going to skip the next slide.

We also are working with Canada through the Regulatory Cooperation Council. We have a number of initiatives currently underway, particularly in the areas of joint reviews and harmonized approaches in electronic submission. We actually just met with stakeholders a couple of weeks ago to get their input on new initiatives for new areas that we should explore, as we wrap up the current projects that we have underway. Some of the areas that were raised to us were to think about

expanding some of our efforts to the RCC beyond the U.S. and Canada but looking into Latin America and South America. There was also a request that both the U.S. and Canada received at the recent RCC meeting to re-engage with our European colleagues.

I'm going to just end on this slide, again in the interest of time. Increasingly, we are being asked to participate in additional international fora. So, for example, the Asia-Pacific Economic Cooperation effort is an effort to promote harmonization of MRLs for imported foods in the Pacific Rim countries. So, we have been working as part of this effort to develop a guidance document for establishing import MRLs for imported foods where there is no domestic equivalent MRL in place.

We also are routinely working with our colleagues at FDA and USDA on a host of projects, including the review of grants that support data generation and research towards resolving MRL issues. It's always a challenge to participate in person in a lot of these fora, as I think in previous sessions Marty has talked about our resource base declining significantly. But we're trying to have a presence at these meetings or

making sure that we provide the appropriate knowledge base to people that can represent EPA in these fora.

Again, I know that was a quick overview, but in the interest of time, I wanted to just sort of plow through it and then see if there are any quick questions so we can get on to the workgroup discussion.

MR. HOUSENGER: Dan.

DAN: Thanks, Jack. I'm probably partially the guilty one to put this one on the agenda. Thank you, Rick, for going through in that much detail on all of the different activities. There are so many activities that the Agency participates in.

One of the other items I think I was looking for was who participates in each of these activities, so, if there's an org chart or something. With all the changes that are taking place both with the activities and the personnel, it would be really nice to know that, Mike, okay, he's doing the OECD work, David Miller went to the Codex meeting, and so on and so forth.

MR. KEIGWIN: Well, I think we can make that available. I mean, one of the things that we have done is I think now every single division is involved in some

way in international work. So, I think it could be helpful for you all to know who those appropriate points of contact are as different meetings are getting planned. We can do that moving forward.

MR. HOUSENGER: Virginia.

VIRGINIA: Thanks for that overview. So, I recognize that these are largely trade agreements and these meetings are happening in the context of trade. But I think it also presents an opportunity to share information leverage resources related to worker health and safety.

As you know, the agricultural labor force in this country is largely transnational, coming from many diverse regions of the world, including the Caribbean, Latin America, Asia, to name a few. So, I think it's important to work within this context to share information on training, education, even labeling language. I'd also like to hear about any sort of ongoing efforts related to worker protection.

MR. KEIGWIN: So, we do routinely receive requests to provide training to a number of countries on how we do risk assessment and how we do labeling. So,

when we participate in those events, it's not just focused on the MRL side of things; there are modules on labeling, worker protection, and all other aspects, even the ecological risk assessment side. So, in many of these fora to date, however, like I said, it has been MRL focused.

But even as part of some of the recent discussions we've been having on some of the trade agreements, the issues of how you do risk assessment on the worker side has been part of those discussions.

MR. HOUSENGER: Cynthia.

CYNTHIA: Thank you. That was very interesting and helpful. On page 7, there's a notation about special sessions to exchange information and identify areas for future harmonization. They list treated articles and dietary risk assessment, both of which are very important.

I'm just wondering about the transparency, if there's a public record from such meeting, if there are opportunities for public input, and a way to follow such discussions in the future since these are identifying areas for future harmonization.

MR. KEIGWIN: There are public reports after the meetings, I believe. For example, OECD has a web site where they will post those. At least at the OECD meetings that I've attended, the NAFTA meetings that we have, there is a public component to those meetings as well. So, public attendance is encouraged. There aren't oftentimes a lot of stakeholders that participate, but there is that opportunity.

MR. HOUSENGER: Cheryl.

CHERYL: So, thank you, thank you, thank you. Resources, resources, resources. I'm delighted to see that there is a set of OPP goals around international participation. I love to hear a stronger strategic coordination. I would hope that you would have your list of people engaged all talking and aligned because I think this is really important.

I think when we sit here in the U.S. and if you're only U.S. focused, you don't realize what an advantage we have of having a risked-based registration system relative to the rest of the world that does screenings and rudimentary things. The U.S. government has invested in so much data between the PDP and the CDC

and NHANES and the deep, deep tools that we have to look at refined exposure assessments and realistic exposure assessments that don't exist elsewhere.

This is really one of the barriers to being able then for growers to export, because you can't get those registrations. You can't get those MRLs. It's kind of difficult to understand, but there's also this lack of understanding of reduced risk. So, you have something that comes through the U.S. process, reduced risk, and it takes eight years to get through Europe. They're missing the boat. So, the more we can do to educate and at least stand up for the principles that we've adopted is very important.

I'd also like to really thank you for sending David to the CPPR. I thought he did a great job of managing some international expectations around the ISDI. But I would also encourage you to provide resources to continue to watch that. Thank you.

MR. HOUSENGER: I think probably every other day I get a request for someone to travel abroad to give a speech or give a training or whatever. It is a balance of how we spend our resources, not only travel. A lot of

these people are even willing to pay the travel. But just the FTE out of the office, you know. If you go across to Europe, it's probably a week or so. So, like Rick said, this is a piece of it, but we do so much more. We look to toxics and OSCP to help us out and try to shave it a little bit like that.

Louis.

LOUIS: Thanks, Jack. This is a very impressive outlay of the activities that EPA is involved in on the international front, an area which is very dear to me. I've been involved in international agriculture in some form for the past 30 years. So, I understand the importance of EPA's involvement in this.

I just want to go back to page 3, the bottom slide, where you talk about adoption of MRLs. Would you give us a little insight on how that is done, especially a visitor from another country? Is it on a reciprocal basis? They accept yours so you accept theirs? Hopefully not. But how do you handle that? Say, if you had one from some country in Europe, let's take Britain, for example, and it's against one from China, what's the basis of how do you treat those? Do they go through a

similar process of validation or what?

Another point I'd like to make is that having worked particularly in Africa and Asia, as well as in some South American countries, labels that come from the U.S. need to be understood by those who use them. Many countries, English is not their language. Or even if it were French or Spanish, the people who actually use them don't understand either of the above.

I know I did some work with Virginia Tech in the cotton producing countries in West Africa where they actually started the process of translating labels into local languages. That's very important. I don't know whether you have that in your books. It's something that you might want to encourage either financially or otherwise.

The other thing is the worker protection, which I have to tell you, based on what I have seen, it's almost nonexistent in some of those countries. At the end of the day, it's a U.S. product. Now, I don't know whether we should ask the chemical companies to be sure that they give that training, which I think we should, or have EPA weigh in on that. It's extra resources I know,

but it’s important, too.

MR. HOUSENGER: Gabriele.

GABRIELE: Again, thank you for trying to give an overview of the wide range of activities. I was just reflecting on two or three of the subjects we talked about yesterday involved international, trying to come up with the testing guidelines for bees and then Zika is all about trying to figure this out on an international level.

The crop, for those of you who don’t know, almonds are the top specialty crop in export value from the United States. I always like to say we help reduce the trade deficit. Ag is actually one of the few sectors that helps reduce the trade deficit in the United States. So, being engaged in some of these issues, it’s helpful for me to see all of this.

A couple thoughts. I echo Dan’s comment. It would be helpful to know who is doing what, because when we have different issues, to know whom to contact. I think the two other things I would note is it’s not just having a body there; it’s having someone with not only the right skill sets, some technical knowledge, but also

the right gravitas -- I don't know how else to describe it.

These are international meetings. There is sort of a diplomacy component to it. You have to have some willingness to think strategically, make alliances, and so forth. So, I just want to be clear that just having a body is not enough in my opinion.

Now, the other side, and I realize this is a real issue on the resources side, but there's two other things going on where these face-to-face elements are critical. So, there's an MRL conference held in San Francisco now. I think I came up with a 10th year or so of it.

The whole point of that is to have a place where growers, regulators from different groups, international people, and registrants can get together and just primarily focus on MRL issues. Not being there in person foils part of the purpose of that meeting. So, just FYI, that's the kind of thing.

The other thing that makes this so complicated, and this comes back to, Louis, your question, we would love it if MRLs were simple. It's just been getting more

complicated. There's two opportunities that I see there. I think this was touched on once. Several commentors have made it.

You have a number of countries -- I don't know what the technical term is now for what used to be second world or beyond developing. They're looking to implement their own risk assessment process, looking to develop their own regulatory process, especially around food safety, but it also relates to environmental and worker safety.

They are hungry. They are hungry to learn from those who have been struggling with these questions for many years. So, I know that at times EPA has sent technical staff, and there's also the ability at the technical level to have conversations that sort of at a political level there may be reasons for not doing it.

So again, I realize this is really hard, but there are multiple reasons for trying to be engaged. I'd really appreciate seeing the level of it, because again, I thought I had some clue, but I already knew I didn't have all the clue.

Coming back, I think Cheryl had a really good

point. I was really thinking about how can we be strategic in this, what are the reasons for doing it, and trying to figure out how can we help evaluate where to put those resources, because, as you say, there are so many requests in this regard.

MR. HOUSENGER: Nina.

NINA: Thanks, Rick, for that overview. I see Bob McNally hopped in there in the back, so you probably know what I'm going to say here. The biopesticide industry has been more and more active in responding to requests from OECD and member countries on exemption from tolerances and products and how EPA does their risk assessment. I also note here that on page 8, the last bullet on the OECD, the sensitization potential of microbials, we've also been asked to give a presentation in Paris in June regarding that particular topic. So, we are reaching out and having more and more discussions with our international partners. But I think we've had very little discussion between EPA and the U.S. biopesticide industry. So, I'd like to encourage that we keep up that discussion.

When you're talking about potential for

harmonization for MRLs, we might want to start thinking about how we talk about the exemption from tolerance products as well. The natural organic program of USDA is a very active trade agreement and reciprocality with different countries are going on and on.

As everybody knows, that is not a safety-based program at all; whereas, the U.S. has a very robust safety program when we look at biopesticides as well as conventional products. So, we'd like to have some attention raised there that there is a safety program for biopesticides, not just organic products.

MR. HOUSENGER: Annie.

ANNIE: Thank you. Just two quick things. You mentioned all the work that you're doing with Canada. So, I'm wondering, given PMRA's decision to do away with conditional registration, is that something EPA might consider?

MR. KEIGWIN: So, the statute lays out the conditions through which conditional registrations are authorized to occur. In fact, every me too registration that we issue, by law, it's a conditional registration.

So, I'm not sure that your comment is really about eliminating all conditional registrations, because if we were to do what you're saying, there would be no generic products that could come on the market, because those, by statute, are conditional registrations.

ANNIE: Okay, that's good to know and consider. We were just excited to see what they did there and were wondering if EPA might do something similar.

Then, I just also wanted to make sure that the record shows that there is a large body of peer reviewed scientific data supported by the international community that does directly link the use of pesticides to thinks like increased weed resistance, pollinator declines, and serious health conditions, including cancer. So, I wanted to make sure that was on the record. Thank you.

MR. HOUSENGER: Ray.

RAY: Rick, you expressed some hope for re-engaging Europe in joint reviews. I'd be interested if you had any special insight into that, because we would certainly like to see a greater engagement of Europe. They've been absent from that scene for a long time.

We appreciate very much the efforts of EPA in the joint reviews, the global joint reviews, the North American reviews. We think this is essential for promoting international trade and making the improved pest control products available worldwide. It's important we all avoid discouragement and work to overcome the obstacles that appear in the contest of individual compounds there.

With respect to Codex resources, I attended my first CCPR meeting a few weeks ago. One of the major points of controversy was prioritizing a workload which exceeds the capacity of the effort of the organization. I would like to encourage EPA and the U.S. government, more broadly, to find more creative ways to put additional resources and FTEs into that effort.

The JMPR which is responsible for the technical reviews of those compounds and applications has, if I remember right, just two EPA personnel involved in an effort that probably has a couple of dozen experts involved. Yet, it's my understanding that the U.S. is the origin of a much larger proportion of the applications going into the Codex process.

Beyond EPA, the USDA, the USTR, and perhaps other federal agencies, have a vital interest in the activities and success of Codex. I'd like to find a way to look for resources there, both in terms of expertise and FTEs, which might contribute to the JMPR effort.

I wanted to echo one thing that Cheryl brought up. We hope that EPA can maintain a strong and outspoken voice of leadership in OECD and other forums. Many other countries look to the U.S. for leadership on pesticide regulations. We would hope that EPA can vigorously defend and promote the risk-based and science-based approaches to pesticide regulation.

One final smaller point, and that deals with certificates of origin. The recent decision by the Agency to discontinue providing these certificates of origin kind of throws longstanding business practices into disarray. Many foreign governments still expect EPA involvement here. I know it's not something we can resolve at the moment, but we're looking at different approaches to come back to the Agency for some resolution here.

MR. HOUSENGER: And Pat.

PAT: Last but not least. So, I just want to echo a little bit of Ray speaking of EPA as a leader. This is, of course, in the area of toxicity testing and reducing the use of animals. So, global harmonization, or lack thereof, is still a huge barrier in adoption of some of these new tox 21 methods or just methods that don’t use animals.

I think a good example of this is in 2007, EPA eliminated the requirement for the one-year chronic dog test. They had done a retrospective analysis and showed that the data weren’t really valuable in risk assessments. Well, it took until 2013, I think, for EU to get rid of it. Canada just eliminated it this year. Brazil is doing the same this year.

However, Japan, Korea, some of these south eastern Asia countries are still requiring this. So, it makes it very difficult for companies that sell internationally to try to do the right thing as far as if they want to reduce testing of animals when other countries still require it.

I think EPA is in a position -- you know, you guys are taking a lead on many of these areas, coming out

with new guidance, particularly for the acute six pack, some of the work that's being done on that. I'd just like to say we commend your efforts, certainly to this point, and encourage you to keep going and continue with your leadership role in this area. Thanks.

MR. HOUSENGER: Okay, thank you. Our last session is mine. We want to talk a little bit about workgroups. In March, I sent out a letter, a note, to all the members of the PPDC as well as the workgroup members. At that time, the last time we met we had six workgroups functioning. Then we heard from the FACA police about what a workgroup actually was, and it wasn't supposed to be forever.

We took that to heart. We kind of looked at what these workgroups had done. I think there's a package that you got that outlines kind of the accomplishments of five of those workgroups that we have since sunset. The only workgroup currently in existence is the incident workgroup, and we had just established that the last time.

So, this session is designed to get people's thoughts about what new, if any, workgroups we would

create. I think our leadership here thinks that a workgroup on metrics to measure the success of pollinator protection plans is needed. We need help and advice on that. So, I think that's one that we'll see created.

I think our goal is to define an objective of whatever the workgroup is, give a time frame, and have it completed by then, not to have it go on for years and years.

So, Dea has received a couple requests through e-mail for creation of workgroups. Rather than me trying to describe what they are, Marc, you had one on the ever popular bringing back DDT for Zika. So, maybe you want to talk about that one.

MARC: I talked with Bob Rosenberg about it, and he's agreed to chair the workgroup. Actually, that was an e-mail I sent to you about something I wanted on the agenda to discuss, which I think we did okay with that yesterday. As long as there's now a task force for that, I think we're doing good.

I would like to say, as far as workgroups go, while I think -- and I believe I wrote you and said it was in agreement that the workgroup had accomplished its

charge with regard to school integrated pest management. You know how I feel about that. Good stuff. Of course, I think it's always ongoing, but that's not the point. I think that happened.

But I will say, and we've heard today, about this. Of the original charges on integrated pest management, the third one was provide advice on other issues relating to the promotion and use of IPM that the Agency brings to the workgroup. I see this as extremely important, and I also see this as kind of getting in the face of the workgroup police. I understand that, but -- aptly put, by the way. Whether it's resistance or Zika or other public health things, because we know there's going to be emerging public health problems coming along. But I was particularly impressed with what the resistance group is doing.

IPM is going to come along. As I look at regulatory agencies, and I know this is simplistic, but it's the way I teach it, is that they do permitting, or registration in this case, monitoring for compliance and enforcement, and then, lastly, and most cost effectively, technical assistance. That's where I think we come in as

far as IPM goes and can really assist the Agency.

So, I do think that we did a good job with the other charges. We did not complete the charge or, in some certain ways, address the charge of assisting the Agency on IPM matters. I would like to make the case that there's still a need for that. What the duration of that is I would leave up to you.

MR. HOUSENGER: Aimee, you had written about two items. One was synergy and one was cumulative risk assessment. I don't know --

AIMEE: I think that they could work together. I feel like there's a lot of uncertainty in risk assessment. There's a lot of qualitative information that isn't currently factored in. It would be really great. We talked about this yesterday with ecological risk assessment.

Is there a way for us as PPDC to provide input to EPA about how they respond to that uncertainty, to the fact that we're seeing interlinkings between disease and fungicides? How does that work into risk assessment? Is there input that we can provide on these areas? Synergy has different chemicals.

MR. HOUSENGER: Pat, I think you had written about alternative --

PAT: So, I was on the tox 21 workgroup that sunsetted. I talked to my colleagues. There was just thoughts that more work needs to be done in this area, obviously. Moving to tox 21 methods is a big area that's developing. EPA is certainly taking the lead. There's endocrine disruption and things like that.

But there's still a lot of sort of science and policy issues that we think may need to be addressed in the future with regards to regulation. Should these methods be required? Should they remain as voluntary? Do you want to use the non-animal methods or should you be required to?

It just seems to me there needs to be a continued dialogue to talk about some of these issues, obstacles to barriers that might exist, adopting them, both from industry's viewpoint and EPA dealing with them, how do they encourage more use of them. So, I guess that was just an area we'd like to see continue somehow under that sort of tox 21 heading or area of interest.

MR. HOUSENGER: So, I guess the question is, is there any support for any of those that we've discussed? Is there any ideas of other subgroups? Again, I think what we're looking for is specifics. What would that subgroup provide advice on and looking at a year or so time frame for doing so.

Robyn.

ROBYN: I'd like to second Marc's putting forward of the IPM working group or if it has to become a subcommittee, to make it longer lasting. I agree that we were not done our work at all. I think we still have a lot more to offer as it goes on.

I mean, I don't know how many times just over this past day and a half I heard IPM in a lot of the different discussions, Zika's conversation, the resistance conversation. It's just everywhere. I think it's an important thing to remember as we go forward that it needs to be incorporated.

MR. HOUSENGER: Bob.

BOB: So, actually, this is a little bit like what Aimee said. One of the things I think the Agency struggles with, always has, and it was evident again

yesterday, is as it becomes more and more sophisticated -- we heard that there's supercomputers upstairs that can calculate the impact of every known chemical on every known species and quantify it and rank order them. But it's always been a challenge how to characterize qualitative information and how that factors into risk assessments. There's like really hard numbers and then this other soft stuff out here.

Where I've always felt like it was a struggle was in how it takes into account benefits when it makes regulatory decisions. I wonder if it wouldn't be useful to have some sort of a framework for how the Agency articulates the way it accounts for qualitative and other non-quantitative stuff in the decisions that it makes. If a workgroup were able to work on that, whether that would be useful.

MR. HOUSENGER: Cynthia.

CYNTHIA: Thank you. Following up on a couple of the suggestions already on the table, starting with Marc's, given the importance of IPM and reducing chemical threats to consumers, farmworkers, and non-target wildlife, including birds, and in advancing resistance

management, and given the vast acreage of U.S. crop lands grown from pesticide coated seeds, we would like to suggest a workgroup that looks at the compatibility of IPM and seed treatments.

Secondly, on your suggestion on metrics and pollinator protection plans, I think that makes a lot of sense. I would just like to urge that it looks at all pollinators, including birds, bats, butterflies, beatles, and other pollinators.

As Aimee suggested, the importance of synergy and cumulative risk assessment cannot be overemphasized, and we would like to support that in any way possible, whether it's a workgroup or some other mechanism. Thanks.

MR. HOUSENGER: Marc.

MARC: So, of course I want to say that pollinator protection is something that always is in need of whatever, whether it's newer products, regulations, or IPM. So, that's part of some of our reasoning.

Really, what I want to do is divert from the idea of feathering our own IPM nest and ask the Agency, which I'm not quite sure if I'm allowed to, but really,

you know, I think IPM is something that's needed and probably we can provide assistance, which is a charge there. But what needs to come out is that --

Well, let's put it this way. I am mindful that when our workgroups or when this committee comes up with a need for a workgroup, that that is probably something additional on the plate of someone at EPA, or a branch at EPA. I am also mindful that's not their favorite thing to have happen.

So, I will say that while I strongly believe there is a need for IPM assistance, whether it's diffusion of IPM or being specific to certain problems that the office is working with, I wouldn't want to do it unless the folks in the Agency really wanted that assistance.

My experience in the last four years on the workgroups and different kinds of things is at times, because of the feeling and extra stuff on the plate, it was not good use of our time either. I want to be helpful to the Agency as opposed to something added to someone's plate. So, I just want to put that across. Thank you.

MR. HOUSENGER: I think it would be useful. IPM is such a broad topic. I think it would be useful to kind of refine what advice you think the Agency could use along something. I don't know if it's with Zika or whatever, if it's seed treatment, but just to say IPM and we want a workgroup on that, I think it gets us back into the same problem that we had before where we had this huge number of topics and say that looks good, that looks good. I think for the Agency to say this is going to be worth it to us, we'd like to see specifics surrounding that.

MARC: Well, I agree with that. If the folks that are working on resistance wanted some advice or help regarding how to ascertain that IPM is really happening, for instance, that would be something. There's been a suggestion. Dr. Gouge, who couldn't be here today, wanted to make sure perhaps resurrecting the public health group, and then IPM can be in there.

The fact is, even on any workgroup that you suggest, maybe just to try to make sure that there's an IPM person on there. That might be a way. I don't have the answers; I just have the willingness to help and so

do my colleagues.

MR. HOUSENGER: Steven.

STEVEN: I do think that a workgroup on the effectiveness of the MP3 programs is something that you need. EPA started that ball rolling, so now you need to see how effective it's going to be.

MR. HOUSENGER: Tom.

TOM: -- away down the road already. But the results of those are going to cause a lot less people to be certified because it affects the general use products. States are not going to have two different programs. So, there's going to be a lot of farmers, a lot of other applicators that will look at what the requirements are going to be and let their licenses lapse and their certification lapse. They're not going to be going to training anymore.

It affects the universities, it affects the state-lead agencies, it affects the manufacturers with the use of their products. I think it's going to have a devastating effect on pesticide use in the country with less people going for education and holding licenses and certifications.

MR. HOUSENGER: Ray.

RAY: I wanted to follow up on something that Bob Rosenberg mentioned with respect to benefits. FIFRA is a risk benefit balancing statute. You have ever more sophisticated and more complex means of assessing risks and managing risks. But the benefits picture is not quite as sophisticated. I think this is a good group to advise the Agency on assessing benefits in the pesticide regulation picture.

MR. HOUSENGER: Gabriele.

GABRIELE: I'm just going to ask a question. On the MP3s, I completely agree that the hardest part is this figuring out how much of a difference it makes. I guess my question is, I get the sense others are already working on this question.

So, I'm just trying to understand what the merits of having a workgroup from the PPDC work on it versus the efforts that are already ongoing. Again, I'm not saying it's not an important question. I think it's a really important question. I'm just trying to figure out from a workload perspective why PPDC versus the other groups.

MR. HOUSENGER: Well, I think the diversity of this body is useful to hear inputs from everybody rather than just specific groups, but I don't know.

GABRIELE: It just means more meetings for some of us.

MR. HOUSENGER: Yes, they could become part of the FACA group here.

Is there anyone on the phone from the PPDC that has any suggestions, thoughts, views?

(No response.)

MR. GRAGG: I want to know if our committee could consider how the EPA in its EJ plan 2020 and its guidance that it developed for its employees on EJ, how they're doing with pesticides, especially pesticides in these vulnerable populations as it relates to health disparities.

So, how is EPA, through the two entities or activities that I mentioned, in their other roles and responsibilities, how are they addressing that? How can we help them do it better if they are?

MR. HOUSENGER: Nina.

NINA: Going to your goals of international

acceptance of safer products, I was wondering whether it might be a short-term workgroup to talk about specific steps that the industry might use in helping achieve that goal?

MR. HOUSENGER: Sharon.

SHARON: This is just an agenda question, because I see we're running out of time. I think last time we had a short session at the very end about agenda topics for the next PPDC meeting. Are you planning to do that again today, or will that be via e-mail?

MR. HOUSENGER: It might be better to do it through e-mail. I think we got a lot of good suggestions last time through e-mail, so Dea can send out a reminder to people to put suggestions on, and we can choose from that. We don't need a workgroup for that, I don't think.

Anybody else?

(No response.)

MR. HOUSENGER: All right, we have public comments now. Julie Spagnoli.

JULIE: This is a suggestion under the workgroups. We did have a public health workgroup that I

was a member of. I'm thinking with Zika and some of the others, the public health workgroup when it started really was a lot of focus on bedbugs because that was the issue of the time. But we did have some unfinished projects, I think, from that workgroup on some outreach and some communication. Also, now with the Zika issue, it might be a good idea to continue that workgroup with maybe a focus more on that aspect.

MR. HOUSENGER: All right, any public comments on the phone?

(No response.)

MR. HOUSENGER: I guess there's no comments. Just a reminder that the next PPDC will be Wednesday and Thursday, November 2nd and 3rd so hold that spot.

I want to thank everybody for participating in this one. The last time I said goodbye to Bill, and Don sneaked out in the interim so I didn't get to say goodbye to him publicly. Marty and Susan will not be here the next time. Susan didn't make it in today. She's in the grand jury or something, some excuse.

So, I just wanted to acknowledge all the help that Marty has been to me since I've been in this position. I've been trying to convince her not

to go but it seems like the beach is winning out over me. I know that she has been a great resource for this program, especially in bringing PRIA home and she continues to work on that.

And we gave her Zika to try to entice her to stay. It may have driven her away, I'm not sure. But I'll miss her and wish her luck. Thank you. (applause).

So safe travels to everybody and see you next time.

(The meeting was adjourned.)

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