U.S. ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING

Thursday, May 21, 2020

10:00 a.m.

DAY TWO

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I N D E X

Agenda Item:	Page:
OPP Risk Assessments	5
OPP Updates Part I	65
OPP Updates Part II	89
PPDC Workgroup Formation	114
Public Comment	137

P R O C E E D I N G S

DAY TWO - MAY 21, 2020

MR. KEIGWIN: -- Pesticide Program Dialogue Committee meeting. We're going to kick off today with a joint presentation on how OPP does risk assessments. So I'd like to introduce Dana Vogel, who is the Director of our Health Effects Division, and Marietta Echeverria, who is the Director of our Environmental Fate and Effects Division.

Dana, I'll hand things to you.

MS. VOGEL: Okay, great. Thanks, Rick. Good morning, everyone. As Rick indicated, Marietta Echeverria and myself will be chairing this session today on OPP risk assessments. We're going to be providing you with an overview of our risk assessment methodology that we use for both human health and ecological risk assessment. I'm going to keep my comments pretty short so that we have enough time to cover both presentations, as well as a good amount of time for questions.

We have two presenters today. The first will be on human health risk assessment, and that's going to be given by Mike Metzger; and the second is going to be given by Kris Garber from the Environmental Fate and Effects Division, and her presentation will be on

ecological risk assessments.

So if you can see the slides that are up, just briefly, to introduce the session and kick it off, I wanted to touch on the types of scientific expertise that we have in the Office of Pesticide Programs. So this is not an all-inclusive list, but it gives you a general sense of the different type of scientists that we have in the entire Office of Pesticide Programs across all of our scientific branches.

Okay, I'm going to try and advance to the next slide. Okay. So this slide is just a follow-on to the last. It's to give you an idea of kind of the numbers of scientists that we employ across the Office of Pesticide Programs. And, again, this is a snapshot in time. I would kind of emphasize that we have been, over the past several years, the entire Office of Pesticide Programs, has been focused on a pretty significant hiring effort, so these numbers are just a snapshot in time.

For example, our numbers in HED, and I assume that this -- I'm pretty sure this is the case for the entire Office of Pesticide Programs, but for instance, we are hiring -- we have, over the past two weeks, we just onboarded three or four more staff, and we

continue thinking that that trend will move forward and we will have the same kind of things going forward in the future, so we're hiring a lot of people across the Office of Pesticide Programs. So this is just a snapshot. You can see we have a good number of scientists across the Office to do the scientific analysis work, but just to kind of give you an overview and a feel.

So without further ado, I think I'll move on and hand the mic over to Mike Metzger, who is a Branch Chief in the Health Effects Division, so he can go over the human health risk assessment overview, and I'll let Mike take it away.

Mike, are you there?

MR. METZGER: Can you hear me now?

MS. VOGEL: Yes, we can hear you.

MR. METZGER: You can hear me?

MS. VOGEL: Yes.

MR. METZGER: Okay. I am trying to advance the slides, and they're not moving.

MS. VOGEL: So, Mike, I can do that for you, if you just tell me when you want. Okay, here we go.

MR. METZGER: Okay, just go to the next slide. There we go. So I'm going to be talking today about the overall human health risk assessment and how

we do them. Next slide, please.

Here's the roadmap of what I'm going to be talking about, first of all, the basis for our risk assessments, and, secondly, the mechanics about how we do them. Okay, I can move them now.

First of all, the legislative basis for our risk assessments. The work that we do generally in HED falls under two laws. First is FFDCA; second is FIFRA; and the third one is Insecticide, Fungicide, and Rodenticide Act. Under FFDCA, we do our aggregate risk assessments. The aggregate risk assessments are comprised of human health risk assessments for dietary exposure and for residential exposure.

And the FFDCA/FQPA assessments are done with a -- essentially, we assess the risk, and the risk standard is a risk-only standard, not a risk/benefit standard as is true for FIFRA. The risk standard is shown on the right, a "reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."

So, again, FFDCA/FQPA is a risk-only standard, whereas FIFRA -- under FIFRA, we do the occupational risk assessments, and we determine

whether or not a pesticide can be registered under FIFRA, looking at both risks and benefits.

Okay, how do we do our risk assessments? Well, the basic construct for how we do our risk assessments is shown here, and it's the standard construct that's been in place for nearly 30 years now, where we break the risk assessment process up into four components: hazard identification, where we look at the toxicity of the pesticide; dose response assessment, where we essentially quantify that toxicity; exposure assessment, which is self-evident; and risk characterization, where we combine the hazard and the exposure assessments in order to quantify the risks and describe what those risk numbers mean.

Within OPP, we express risks in three basic ways: for dietary risks for both acute and chronic we express them as a percentage of the population adjusted dose. And the PAD is equal to the point of departure, such as a NOAEL from a toxicity study, which we'll talk about again in a couple minutes, divided by what other -- whatever uncertainty factors are required for that particular assessment. And the risk is a percentage of that PAD, which is equal to the exposure divided by the PAD times 100.

For occupational/residential risk, we express

the risks as margins of exposures, or MOEs, where the MOEs are equal to the points of departure, such again as a NOAEL from a toxicity study, divided by the exposure. The target MOE is equal to the combined uncertainty factors. If the MOE is above those combined uncertainty factors, we assume there's no risk concern; if it's below, there is potential risk concern.

Finally, cancer risks are expressed as population-based estimates. For example, one times ten to the minus six, which is the same as one over ten to the sixth or one-in-a-million cancer risk.

On HED, we're comprised primarily of scientists, so we want to have scientific rigor obviously built into our assessments, so we have well established guidelines and GLP criteria, which are the basis for our methods. All of our key approaches have undergone extensive peer review, primarily by the FIFRA Science Advisory Panel.

Our risk assessments are generally vetted in public participation processes. And many -- I would say actually most of our methods are broadly accepted on an international level. And I truly believe we are the leaders in cutting-edge science policy development in the world.

Now some key definitions related to hazard characterization and dose response assessment. The endpoint is the adverse effect upon which the risk assessment is based, such as liver effects, kidney effects, whatever. It's the actual toxic effect.

In a toxicity study, the lab animals are dosed at a variety of different dose levels. The lowest level that you actually see an adverse toxic effect is called the low observed adverse effect level, or the LOAEL, and the dose right below that is called the no observed adverse effects level, or the NOAEL.

We want to regulate. We want to begin our quantification of risks at the equivalent of a NOAEL. The value that we use to quantify risk is called the point of departure, whether that be a NOAEL or a LOAEL. But if it's a LOAEL, we want to extrapolate down to where we think the NOAEL will fall in order to begin our quantification of risk so that we assure that our risk assessments are protective. And we'll talk about how we do that again in a couple of slides. And, finally, the control is the background response with the dose equal to zero.

Okay, how do we do our hazard identification or our toxicity assessment? Well, we get a battery of

toxicity studies. We're very data-rich in the Office of Pesticide Programs, we get a lot of studies. And all of that data covers a variety of potential adverse effects as shown here: neurotox, repro, developmental effects, cancer, immunotox, and many others as well.

The studies are conducted in different species as shown. The treatments range through a range of durations, going all the way from a single, acute dose up to the equivalent of a lifetime of dosing, which would be two years in a rat study.

We get non-guideline data as well, such as the comparative cholinesterase studies that we get for organophosphates and carbonates and comparative thyroid studies that we get for certain thyroid toxins, which we use to make sure that we're being protective for developing organisms.

The last bullet on this page is essentially talking about the HASPOC, the Hazard and Science Policy Committee, which is a committee within the Health Effects Division which examines the toxicity databases. One of its functions is to examine the toxicity database for a chemical and make sure of two things: make sure, first of all, that we're asking for all the toxicity data that we need so that we're regulating on the most sensitive potential endpoint

for that chemical.

The second purpose of the HASPOC is to make sure that we're not asking for data we don't need to make a regulatory decision. We only want to ask for the data that we need to make the regulatory decision so we're not asking for a bunch of extraneous data that's not necessary.

Okay, again, a little bit more information about the hazard identification. This slide shows that again we look at a variety of durations of exposure, going all the way from an acute, one-day dose all the way up to a lifetime of dosing, and we look at the three major routes of exposure: oral, dermal, and inhalation.

For the acute and chronic assessments, we focus on dietary only, but we also cover the residential assessments in the short- and intermediate-term assessments, which look at anywhere from essentially one day up to six months of exposure. In some cases, we also do a residential assessment for chronic exposure. An example of that would be a pet use because pet use would result in exposure over essentially a lifetime, potentially, of exposure. So there are some unusual situations where we would look at a chronic exposure duration for a residential use.

I mentioned uncertainty factors, and here are the uncertainty factors that we would typically incorporate into our assessments. First of all, the two standard factors: the interspecies, where we're taking into account extrapolation from animal data to humans; the intraspecies, where we're looking at the variability among humans, and then three factors which contribute to the total FQPA uncertainty factor: one for extrapolating from less-than-lifetime exposures to a lifetime exposure, for example, a situation where we have a lifetime exposure, for example, to residues in drinking water but we only have toxicity studies that are subchronic. In that case, we might apply a 10X factor to extrapolate from less-than-lifetime to lifetime exposure.

A uncertainty factor for going from a LOAEL to a NOAEL that I talked about previously. If you're seeing adverse toxic effects all the way down to the lowest dose of a toxicity study, we don't want to regulate based on that LOAEL. We want to estimate where that NOAEL is going to fall and regulate on that, where you're seeing no toxic effects. So we would apply a safety factor of a LOAEL to estimate where the NOAEL is going to fall and use that for regulation.

Finally, for an incomplete database, if we're missing a toxicity study primarily that we think could result in a point of departure which is lower than what we're currently using, we would add a safety factor for that as well. Each of these factors are generally 10X, unless we can show that a smaller factor would be protective, and that's very rarely the case. We're almost -- these days almost always using 10X factors, and we go to a maximum uncertainty factor, a safety factor of 3,000. The idea behind that is if you have to have a safety factor above 3,000, you probably don't have a sufficient toxicity database.

Okay, moving on to the third pillar of the risk assessment, the exposure. The three major exposure types that we consider are dietary exposure, looking at residues and exposure from food and drinking water; residential exposure, which for us is equivalent to any nonoccupational exposure, for example, exposure to pesticides that you use -- might use to treat your lawn or exposure to pesticides in a situation where you're playing golf on a golf course that's recently been treated with a pesticide; and, finally, occupational exposure, an exposure that a person might have applying a pesticide in an

agricultural setting or ChemLawn or whatever, something like that.

Here are some of the key factors that we would have to consider in exposure assessment: the use information, how is the pesticide used; what's the application rate; what's the type of application; what's the type of formulation; and what crops might it be applied to.

On the chemistry side, we would look at what the metabolism of the pesticide is, what the degradation rate is in foods. Human behaviors, how are people likely to be exposed: apply the pesticide to the lawn; a child goes out and plays in the lawn; puts their hands down on the grass; puts their hands in their mouth. So we have to look at human behaviors as well. And, finally, the fate and transport of the pesticide in the environment.

If we go on to dietary exposure, I'm going to start out on this slide looking at the lower right, where the acceptable level of dietary exposure is essentially equal to the aPAD or the cPAD, or the steady-state population adjusted dose. One hundred percent of those values is equal to the maximum acceptable exposure.

Moving to the left, the residue data that we

typically get is for tomatoes, for example, raw agricultural commodities, for wheat, something that's a raw commodity. We don't get residue data, for example, for pizza, but somehow we have to convert that residue data for the raw commodities into a residue data for pizza, which people eat. So we use a food recipe database, FCID, to convert those residues in the raw agricultural commodity into a residue in pizza or some food as eaten.

And the food consumption database that we use to determine how much of that pizza is eaten is what we eat in America. So that's essentially how the dietary assessments are done. There's a lot more information about this available online, or you can always, you know, send me an email if you have questions about any of this stuff.

An algorithm for how we do the dietary exposure, it's a very basic algorithm shown here, consumption times the residue equals the dietary exposure. Our assessments range from simple to complex, but they're based on the same general algorithm. And, again, we use data from the survey, "What We Eat in America," on the consumption side. We have the FCID information on the recipe side and residue data can come from a variety of sources,

ranging all the way from field trial data and tolerance levels all the way to monitoring data.

When we're doing these assessments, the assessments can either be done very quickly, or they can take a long time. What we try to do is to minimize the resources that we expend in doing assessments so we only refine an assessment to the point where we show an acceptable risk -- that way we're using our resources most efficiently -- if we can refine it to the point where we have an acceptable risk.

So we always start out -- we usually start out using a tolerance-level residue and 100 percent crop treated to run our dietary assessments. That takes many an hour to run, or even a half an hour. As you start incorporating all of these other factors into the assessment, it can take a week or a month to incorporate this information into your assessment so it's a lot of additional work. But it's necessary at times to attain a refined dietary exposure and dietary risk assessment which actually reflects real-world risks.

Some of the data that we would use would be percent crop treated; average field trial data; a variety of different types of monitoring data of

residues out in food in the real world; primarily the Pesticide Data Program data. We would incorporate processing studies, cooking factors, et cetera.

And the U.S. slide talking about the chemistry and the residue levels discusses tolerances and MRLs. Tolerances are essentially a label-compliance tool. They are not a health-based standard. They tend to reflect the maximum amount of pesticide that can legally remain in or on a food.

So when tolerances are calculated, it's based on results from field trials, which are designed to identify the highest concentrations in the crops using the maximum application rates, the maximum number of applications, the shortest application between -- shortest time between application and harvest. And generally the actual measured residues that we find in monitoring data in the real world are ten- to a hundredfold lower than the tolerance levels due to the degradation during distribution, storage, and washing of the commodities.

I'll talk briefly now about the drinking water assessment. Essentially, we evaluate potential exposures in drinking water, and most assessments are completed on a national scale, meaning one high-end estimate covers the entire country. Now, this doesn't

mean we really believe that you're going to have one high-end residue throughout the country, but this is, again, part of our tiering approach.

If we use one high-end residue estimate that's applicable to a certain location and the risks are acceptable using that high-end value, we can stop there. We don't have to do any more work because if using the high-end drinking water number shows acceptable risks, you're going to have acceptable risks everywhere else. However, if they don't, then we have to modify our risk assessments, we have to dig deeper into the data, and we can do regional and subregional scale assessments as well.

In our dietary assessments, we typically would use either a single pesticide concentration to do a deterministic assessment, or we could use a timed series of pesticide concentrations to do a distributional assessment.

This slide here kind of talks about what I've already mentioned, basically a tiered approach is used in order to make sure we're most efficiently using our resources. The lower tiers can be done quickly and easily. The higher tiers take a lot of work, so we only do those -- we only move on to those additional tiers if we need to refine an assessment because the

risks are unacceptable.

All right, moving away from dietary exposure, we're going to talk now a little bit about residential exposures. Again, residential exposures are not just around your home but they're any nonoccupational exposure, around your home, on a golf course, athletic field, any public area where a pesticide may be treated. Exposure scenarios are divided into two different types. The first is handlers -- people who mix, load, and apply the pesticide around your own home for example, and post-application exposures where -- an example I used previously, a child goes out and plays on a lawn that's been treated.

When we do these assessments, particularly for the post-application, we consider what we call an index lifestage. We recognize that anybody, for example, could be exposed to pesticide residues on turf after your lawn's been treated; however, one lifestage is going to be the lifestage that's likely to have the highest exposure. In the case of the lawn example, that would be children one to two. If we do an assessment for that index lifestage and it's acceptable, we know that we're being protective for all of the other lifestages. That's, again, a way to efficiently use our resources.

The routes of exposure that we consider for both dermal and inhalation, we consider both the application and post-application exposures. And for the oral route, we consider post-application exposures only to children, children who play on a lawn or indoor, get the residue on their hands then lick their hands, for example.

The key tool that we use is the Standard Operating Procedures for Residential Exposure Assessment. These are very complicated. They're very long, but they're available online, and they're pretty straightforward. If you go to the residential SOPs, you can walk your way through each of the many, many scenarios that are presented there to see exactly what data are used, what algorithms are used to calculate the exposures and risks for each of the scenarios that we look at.

Here's an example of one of those algorithms for residential handlers. Take the pounds of the chemical applied per area, which we get from the label, times the area treated per day, times the milligrams of chemical exposure per pound of chemical handled. That's called the unit exposure, and you're going to hear more about that when we talk about occupational handlers as well. And then you divide by

the kilograms body weight to get your exposure in milligram per kilogram body weight per day.

The unit exposure is a very useful tool that we use. Again, it's the amount of exposure that you would expect per pound of active ingredient handled. We always -- we tend to get a lot of comments on that, and there's a lot of misunderstanding of the unit exposure concept. Essentially, we assume that the more you handle on a given day the more exposure you're going to get. So if you handle 10 pounds per day, you're going to get a certain exposure; if you handle 100 pounds per day, you're going to get 10 times as much exposure. And that's not just an assumption; that is actually based on a lot of data that we've gotten through working with our partners, both in industry and in academia and others as well.

The other two pieces of information that we would use would be the dermal absorption and body weight.

Post-application residential exposure. These are very complicated. Some of these are very complicated. I would ask people if you're interested in understanding how these assessments are done, go to the residential SOPs and walk through some of the scenarios. The exposure source characterization is

important. For example, playing on the lawn, you're going to apply a pesticide to the lawn, you're going to get certain residue of pesticide on the lawn, and a certain portion of that residue called the turf-transferrable residue is going to rub off onto the skin of anyone who touches that lawn.

Several behavioral-based approaches are listed here that are also part of these assessments: the index lifestage, which I've talked about; the dermal contact levels; behavioral issues; the mouthing rates; the breathing rates; the frequency and duration of each of these activities; and the types of behavior that are done by each population subgroup and how we would address those. Again, this is discussed in great detail in the residential SOPs.

An example of algorithm for post-application residential exposure is shown here: the micrograms of chemical per centimeter squared -- that's the residue. It's how much chemical are you getting or seeing on a centimeter-squared of leaf surface or grass surface, for example. Multiply that by your transfer coefficient, which is in centimeter-squared-per-hour, and that's essentially a measure of contact with the residue. Then you multiply that by the hours of activity per day; again, divide by the kilogram body

weight to get your total exposure.

So I've already talked about the information that we need to implement this algorithm is the label/use directions; the transferrable residue data or the residue level; the activity component, which is the transfer coefficient; the exposure time, which is the hours of activity per day; and finally again the dermal absorption and body weight.

So I want to point out that these are not my slides. I'm just presenting these slides. These were prepared by someone else, and my assumption, therefore, is that these are beer steins in this slide here. So what this slide is meant to represent is the risk cup concept. The risk cup is how much exposure essentially you can have before you reach the maximum exposure that would be considered safe.

So when we're doing our aggregate exposure assessments, just off to the left here, you can see we have food only, which might comprise 20 percent of the risk cup. When you add in drinking water, that might add another 20 percent. It might bring you up to 40 percent of the risk cup. When you add in residential exposure or nonoccupational exposure, it results in a higher percentage of the risk cup being taken up. But the idea is just even understanding of what we mean

when we talk about the concept of a risk cup.

As we already mentioned, the aggregate exposure is what we're shooting for when we're doing our FQPA assessments, and we have to make sure that the aggregate exposure is safe. Again, "safe" means "there is a reasonable certainty that no harm will result from the aggregate exposure to the pesticide chemical residue including all anticipated dietary exposure and all other exposure for which there is reliable information."

Essentially, we're combining routes of exposure and exposure scenarios. We're combining the dietary -- food and drinking water -- plus the residential, generally for a single compound, generally across routes, if you're seeing the same toxic effect by the different routes of exposure, assuming we have reliable estimates of the exposure for each route and we avoid overestimating.

We want our estimates of the aggregate exposure to be realistic, high-end or upper-bound estimates, but we don't want them to be unreasonable estimates. So we avoid compounding overestimations when we're adding together various sources of exposure from different scenarios. Aggregate exposures are only done for residential uses. They do not include

occupational exposures.

Aggregate scenarios are shown here. They're the same ones that I talked about earlier, basically acute, short-term, intermediate-term, and chronic, and we also do cancer assessments. And I won't go over those because of time constraints.

Occupational exposure. Again, we look at handlers, those who mix, load, and apply the pesticide; post-application workers, those who enter previously treated areas where a pesticide's been applied. And here are some pictures of some mixers, loaders, and handlers.

Here's the typical algorithm used to calculate the exposures for occupational handlers, where, again, you're looking at the application rate times the area treated times the unit exposure. And we've already talked about these concepts, so I will just move on to the next slide. Again, if there are any questions, you can always ask me afterwards or send me an email.

For occupational post-application exposures, these are exposures that occur from contact with treated areas and crops. It varies by the type of crop and activity being performed because you're likely, for example, to get a higher post-application

exposure walking through an almost-mature sugarcane field with all the leaves slapping you versus walking through a field where you have spinach which is an inch tall. We have over 7,000 crop/activity combinations identified and in common use in our assessments.

The algorithm -- an example of the algorithm used for occupational post-application exposure is shown here, with the key inputs being the dislodgeable residue; again, the amount of residue that can transfer to your skin from the foliage times the transfer coefficient, again, a measure of contact with the foliage in centimeter-squared-per hour; and a time estimate, how much time were you spending doing these activities on a day.

An important part of the occupational post-application assessment is the concept of the reentry interval. As you go from the time of application to some time further down the road, your dislodgeable foliar residue or your turf transferable residue is going to decrease. Therefore, as you move through time, your total exposure is going to go down.

When your total exposure goes down to the level where it’s safe, that’s typically where we would set the reentry interval, and that number of days

after application it's safe to go back into the field.

Okay, we've talked about all the components of the risk assessment except for the risk characterization, the final component. When we're doing a risk -- when I'm typically giving this talk, I give it using a different set of slides, and the title of it is Risk Assessment 101. A risk assessment is not a number because a risk -- if you just give someone a risk number, in my opinion, it's meaningless, unless you tell them exactly what the inputs are so that they know what that risk number means.

And that's what risk characterization is. It tells people what that number means. So we routinely consider a lot of factors in characterizing the risk: data quality, distribution of the data, interdependency between variables, the co-occurrence of exposure, and many other factors. In the other presentation I'll usually give, I'd have maybe 35 or 40 different components that should be part of a typical risk characterization.

And that's all I have, so I'm going to pass the baton now to Marietta.

MS. ECHEVERRIA: Great. Good morning. Can folks hear me okay?

UNIDENTIFIED FEMALE: I can hear you.

MS. ECHEVERRIA: Great. Thanks. Thanks, Mike, for the great presentation. And for folks who don't know me or for our newer members of the PPDC, my name is Marietta Echeverria, and I am the Director of the Environmental Fate and Effects Division. So we are really similar to the Health Effects Division except that we are focused on the ecological risk assessments.

So we are the group within OPP tasked with conducting the ecological risk assessment in support of both the registration and the registration review program for conventional pesticides. So I do want to point out that ecological risk assessments are also -- and human health risk assessments, of course -- are also conducted by the Antimicrobials Division and the Biopesticide and Pollution Prevention Division for antimicrobial and biopesticide products respectively.

And as Dana said in the beginning of this session, in EFED, we are an interdisciplinary science division. We have approximately 75 scientists, both staff-level and senior-level positions, which brings us to a total of approximately 85 folks, including our managers, across the division. And our experts include many of the disciplines that Dana's first

slide showed. You know, we have biologists, chemists, ecologists, ecotaxicologists, environmental engineers, soil scientists, GIS specialists, hydrologists, wildlife biologists, just to name a few.

So the way that we operate, these experts in these various disciplines, they work together in teams, various registration and registration review cases every year. And just to give folks a sense of the volume, the number of risk assessments that we conduct just for conventionals alone -- and I imagine these numbers are very similar for Dana's group as well -- so for ecological risk assessments for the conventional program, we're conducting approximately 50 ecological risk assessments every year to support the registration review program. We conduct up to 10 new chemical assessments to support the registration program, and then anywhere from 50 to 100 new uses every year. So you can get a sense of the volume of risk assessments that are conducted to support the Office of Pesticide Programs.

So without further ado, I am going to introduce Kris Garber. Kris is our Senior Advisor in the Environmental Fate and Effects Division, and Kris' goal today is to present an overview of the ecological risk assessment process. I will point out, in

addition to the eco risk assessment, we do also support Dana's group by conducting the drinking water assessment that Mike touched on briefly for the human health risk assessment, and we also do our endangered species assessments. But for this presentation, Kris is focused on the eco risk assessment.

All right, Kris, over to you.

MS. GARBER: All right, thanks, Marietta. Can you hear me okay? Great.

All right. So I'll go through our general ecological risk assessments that are done for conventional pesticides. You saw kind of a matrix at the very beginning that Dana went through, other divisions. So there's also antimicrobial pesticides, enviro-pesticides, and so those would fit into a different category, and they certainly do risk assessments but I'm really focused on the eco risk assessments that the Environmental Fate and Effects Division does for conventionals here.

All right. So when -- let me adjust the slides here. Thank you for your patience with the technology.

All right. So here are some parallels to what Mike went through for the human health. Now, for our eco risk assessments, we also -- we also follow

the Federal Insecticide Fungicide and Rodenticide Act, where really the goal is to not cause unreasonable adverse effects on the environment. So as Mike said, that's a risk/benefits statute where the risk managers consider both the risk to human health and the environment, as well as the benefits of the use of the pesticide, so those two kinds of sides of the coin are considered in making decisions.

We also do risk assessments with consideration of the Endangered Species Act, and that is a risk-only statute, where the concern is that the action of the agency, which in our case is the registration of pesticide rules, is not likely to jeopardize the existence of a species or impact its critical habitat.

So our ecological risk assessments are intended to evaluate the impacts of conventional pesticides on non-target organisms, and what we mean by non-target organisms is aquatic and terrestrial animals and plants, either on the field, like birds and mammals, that might be on the treated area, or is adjacent to the field. When we do a risk assessment, you know, very similar to what Mike went through for human health, really it's kind of boiled down to what is the exposure and how does that relate to levels

where we might see effects. And for non-target organisms, we're really focused on survival, growth, and reproduction to animals and plants.

When we do a risk assessment, we're integrating a lot of different information, and that involves, of course, toxicity and exposure information, an understanding of risk or like the characterization that Mike had of how, you know, risk isn't just a number, you have to explain what that means. So a lot of what we do is laying out lines of evidence in the risk analysis, and, of course, understanding the regulatory context, the purpose of the risk assessment itself.

So our risk assessments are tiered. As you heard from Marietta, we do a lot of risk assessments every year, and so we start out conservative, and with approaches that are meant to be efficient so that we can really screen out quickly and efficiently those cases or those taxa where there's a low-risk scenario so that we can spend more time and effort on the cases where there is a risk concern and there might be some, you know, mitigations that need to be considered, for example, so a more complex analysis might be needed.

Typically, our ecological risk assessments are at a field scaled, where we're looking at an

application to an orchard or a cornfield, for example, and we're concerned about effects to animals that might be on that field or adjacent to it, exposed to spray drift or in a pond nearby. Not all risk assessments are like that. Often, we'll do larger scales. For example, when we're doing endangered species assessments, the scale might be in the range of that species, which certainly would be larger than just a field.

Our risk assessments are based on peer-reviewed methods and simulation models, and we integrate the best available data that we have at the time. You know, registration review is a process that happens every 15 years, and part of that is, you know, methods change, evolve, new data become available, and so at the time when an assessment -- when a chemical is scheduled for registration review, we would basically bring that chemical's risk assessment up to date with the current methods, models, and data needs at the time that assessment is done.

But certainly we do a number of different other assessments in EFED. In the Environmental Fate and Effects Division, we assess the ecological risks associated with new active ingredients or new chemicals that are proposed by registrants for

registration, and then we'll also do assessments for changes to existing labels or additions of labels that might change the use of an existing chemical.

So this is -- all of our risk assessments are conducted according to the ecological risk assessment framework. It starts with a problem formulation, and then we move on to characterize the exposure and ecological effects and integrate those information into a risk characterization. I'll go into more detail into each of these four phases in the following slides.

The risk assessment isn't necessarily static, though, so, you know, once we do our risk assessment, we might stop and kind of check in with the risk managers and see if, you know, maybe we need additional data to really complete the risk assessment, or there might be additional analyses that are needed to address some of the uncertainties that are identified in the assessment. So it's certainly an iterative process where, you know, the environmental fate and effects scientists in EFED would work with the risk managers to make sure that that assessment meets the needs of the registration action that's being considered.

One thing you might see in registration

review is that we actually start out with a problem formulation by itself where we'll go through a process and identify data needs, and then call in data that are reviewed by EFED and then later on do the risk assessment once the data are available. And so then -- so as part of registration review, a problem formulation might be -- it is generally released and then followed a couple of years later by the full ecological risk assessment.

So what's a problem formulation? It's essentially the kind of roadmap for the risk assessment. It describes what the federal action is, which means essentially what are the labels, what are the uses that are registered. It lays out the purpose of the risk assessment, including a conceptual model and which risk hypotheses might be tested, and it also defines what the stressor is, so are we just concerned about the parent molecule, or are there degradates that are of toxicological concern as well.

Really, one of the key aspects of the problem formulation is the analysis plan that looks at previous risk conclusions, describes the scope and the complexity of the assessment, so for example, are we doing a general, national-level risk assessment, or is this a more refined pollinator-only risk assessment,

or is it an endangered species risk assessment? So those are some examples of kind of the scope that might be defined in the problem formulation.

We look at available data and data gaps and identify what models will be used in the risk assessment based on use patterns and the fate and transport of the chemical, and then identify what uncertainties are key to that particular chemical, given data gaps or other properties that might exist for that particular chemical.

So once we go through the problem formulation, then we go into the exposure and effects characterizations. When we are looking at the exposure characterization, really there are two main objections: one, we're trying to characterize the fate and transport of the pesticide in the environment, essentially where is it going to go and how does that impact -- how is that relevant to non-target organisms.

And then our objective is to quantify exposure of that pesticide and any degradates that might be of concern to non-target organisms. So when we basically start out our exposure characterization, we look at the physical, chemical fate and transport data that are available for a chemical, and then

determine what routes of exposure are most relevant based on those properties. So typically we would be concerned about a direct application onto the field and organisms that are present there, like birds that are present at the time a chemical might be sprayed, for example. And then spray drift would also -- spray drift is also a typical -- sorry about that. Somebody was trying to hurry me up.

Okay, so spray drift is also a typical route of exposure, as well as runoff. If the chemical might have some -- based on properties of volatilization it might be a semi-volatile chemical, for example, or it might bioaccumulate, and so in some cases, we might also consider those transport routes.

We do receive a suite of degradation studies that are either abiotic, meaning they're -- sorry. I'm not sure who's moving the slides, but would you mind leaving the slides in the current position, please?

Okay, so for biotic degradation, those are microbial-mediated degradations that -- degradation processes. All right.

Okay, so when we -- one of the key parts of the exposure characterization is developing this conceptual model, and essentially what we do is we

look at the applications of the pesticide based on the labels, what we know of the state and transport of a chemical, and then consider different environmental conditions that might be relevant. And then for a given chemical, some of the arrows that are kind of on a figure like this may or may not be relevant.

So as part of our exposure analysis, we would look through the available fate data, the laboratory studies from the biotic and abiotic different mechanisms and look at what kinds of residues might be present, degradates, and basically determine whether some of those degradates might be of concern. Really, when we're estimating exposure, we rely very heavily on computer simulations, which we call models, to basically estimate exposure for aquatic and terrestrial organisms. If monitoring data are available for a chemical, that will actually be considered part of the weight of evidence for characterizing exposure.

We'll have to consider the kind of nature of the monitoring data that are available. A lot of the data that we have are from programs like USGS's NAWQA program or CDPR. They also have data that are fairly ambient monitoring data. One of the kind of gaps in information for those data is that we don't

necessarily know when an application of a pesticide and where relative to the sample site the pesticide may have occurred, and so that's an uncertainty that we generally understand.

With ambient monitoring data or some cases where there's targeted studies, where a pesticide sampling site is known to occur kind of downstream of a location where a known pesticide application had occurred, so we can actually tie, you know, those samples with detections of the pesticide to known application sites.

So as I mentioned, we use a suite of exposure models to conduct our ecological risk assessments. For terrestrial models, we use the T-REX model. Not a dinosaur, T-REX stands for terrestrial exposure. And essentially what that model does is estimate exposure on different dietary items on the treated field, and then we can use that to calculate risk quotients for birds and mammals.

We can also couple those exposures with our spray drift models, typically the aggregate to determine different residue concentrations off of the field and how far from the edge of the field the risk to a given taxa might occur.

We use the BeeREX model to estimate dietary

and contact-based exposures to bees. And those honeybees are used as a surrogate for other bee species.

Our TerrPlant model is used to estimate exposure to terrestrial and wetland plants that are adjacent to a treated area.

And then for aquatic exposures, we use the Pesticide in Water Calculator to estimate exposures to fish and inverts and plants that are located in a simulated pond that's near a field. This model is the current kind of evolution of our previous models called PRZM and EXAMS that you may have heard of. If there's a rice and a cranberry use, we also -- we have a different model called PFAM that estimates exposures in those -- in those paddies or bogs and then in the release water.

So moving on to effects, so the effects characterization that's done in the risk assessment is really intended to quantify the effect that the pesticide might have on the survival, growth, and reproduction of animals and plants. And we typically refer to these as taxa, so we'll use toxicity data for surrogate test species like rainbow trout is a very common test species, and we'll use that as a representation of the effects to fish.

So our endpoints that we use in our risk assessment are meant to kind of represent an effect that is biologically relevant and is something that would be of concern. So we wouldn't -- we're concerned about potential mortality to fish or reproductive impacts to birds, for example, so these are ecologically relevant and something that are relevant to our management goals in terms of, you know, they're of concern, they're something we would want to avoid.

So we have -- under FIFRA, there are a suite of standard toxicity data that are required. There are also a suite of standard gate studies that I went through as well, but these are all intended to support the registration of a pesticide, and so in order to have consistency among chemicals and for risk assessment purposes and standardization with our endpoints of concern, all of the tox studies that are required follow standard test guidelines. And the goal of those studies is to generate kind of endpoints that we can use to quantify those effects to the taxa that are included in the assessment.

For acute exposures, our endpoints are 50 percent lethality level from a dose, and LD is 50 percent dose level or 50 percent lethal dose or 50

percent lethal concentration. For invertebrates, it can affect concentration, and that represents immobility.

For chronic exposures, you heard the terms already from Mike, we use a no-effect level, which is the level where there's no adverse effect relative to controls, and then we also would obtain a low-effect level from those that are low toxicity studies as well.

For plants, the standard endpoints are an inhibition concentration of 25 percent for terrestrial species or inhibition of 50 percent growth in aquatic species. Generally, the tests for plants represent declines in biomass, either a length or height or dry weight, or it might be a growth rate.

One of the more important steps of evidence that we will incorporate into our risk assessment is incident reports. An incident is basically an exposure or an effect that's not intended. These -- there are a whole suite of categories of incident reports, and for ecological risk, we really focus on fish and wildlife effects, insect pollinators and plants.

When we receive an incident report, then we evaluate that for -- to determine the certainty that

that particular incident was associated with, a chemical that's identified. And we'll consider different factors like were there residues of the chemical measured in the birds that were found dead on the field. Or there might be other considerations like other pesticides that may have also been applied. And if those other pesticides were more toxic, maybe that might lead to less certainty that the chemical that we're assessing was associated with that incident. Those are some of the things that are considered.

We also consider the legality of the application of the pesticide. So, for example, if the incident is associated with a registered use that's currently registered, then we would have, you know, more confidence that that incident is representative of current registrations.

The risk assessment and the risk characterization will lay out the incidents that are reported for a given taxa, and its use as a line of evidence in addition to the other analyses that are done.

So when we get to the risk characterization, this is essentially where we integrate the exposure characterization and the effect characterization. And

we'll start out with risk quotients. We basically divide exposure by the tox endpoint to derive a risk quotient. And then we'll look at whether or not that risk quotient exceeds all our standard levels of concern, and this helps us to essentially answer a yes/no question.

So if your risk quotient is above your level of concern, then you can say, yes, we have potential concerns; we should, you know, proceed to some additional characterization. If your risk quotient is below your level of concern, then we can conclude that we have low risk and essentially can stop the analysis there. You know, as Marietta went through earlier, there's -- you know, we do a lot of risk assessments, and we have limited staff, so, you know, this is a tiered process where, you know, we can kind of focus our effort on those taxa where there are potential concerns with our screening level process and spend more time on the characterization so that our risk managers can have a greater understanding of what those potential concerns might be.

A lot of our refinements, well, they're really specific to the chemical that's being assessed, what data might be available, and what taxa is -- has potential concerns, but we'll -- generally, we'll look

at what conservative assumptions might be made in the risk assessment. We might do some additional analysis to look at the distributional effects if there's field-level data available or incidents -- those are other characterizations that will come into play.

So, you know, this is really -- what I'm describing is the process of a screening-level risk assessment where, you know, it's intended to be reasonably conservative and kind of save our effort for those taxa where there might be concerns. And, really, this approach is intended to help us to avoid cases where we say that there's a low-risk scenario when, in fact, there is risk. So it is intended to be conservative to avoid those what we call Type II errors.

So I've gone over the risk characterization. You know, this is where we include our risk quotients and then evaluate other lines of the evidence and discuss the assumptions and uncertainties that are present in the risk assessment. There might be cases where we evaluate alternative assumptions related to the use of a pesticide that might help inform mitigations that the risk manager might be considering. For example, aerial applications have a much wider drift footprint, as opposed to ground

application, and that can have implications for the risk picture.

So as I said earlier, we use a lot of data in our ecological risk assessments. There are -- there's a large suite of studies that are required under FIFRA for the fate, to describe the fate and ecological effects of a chemical, and, you know, those are required -- it's required that the registrant admit those data in order to support the registration that they're requesting. All those studies follow standardized test guidelines.

We also search the open literature for available data, particularly for toxicity information. We use the ECOTOX database that the Office of Research and Development in Duluth maintains to identify open literature that might be relevant to a given chemical.

Once data are available to us, either through registrant submissions or the open literature, we review, we conduct independent reviews of those studies. We review them to make sure that they're scientifically valid and consistent with the standard test guidelines. And then we also conduct an independent analysis of the raw data to determine the appropriate endpoint.

All of our reviews that we do are recorded in

data evaluation records, and those basically describe the studies and our opinion on the results and utility of those studies. For open literature, we do something very similar. We have these open lit reviews of published articles.

And, so, there's a lot of quality assurance and quality control that goes into our ecological risk assessments, starting with the models and tools that we use. We base them on the best-available science and data, and then those models, once they're developed, go through a peer-review process, first internal by senior scientists in the division.

And then a lot of our models go through the FIFRA Science Advisory Panel to pull in external scientific expertise and recommendations. Each of our risk assessments also go through a QA/QC process once they're written by EFED scientists. They'll be reviewed by other scientists within their own branch, and then the risk assessments will also be reviewed by a group of scientists, including other senior scientists as part of a review panel.

So I went through that very quickly. It usually takes several months for new scientists to learn how to do a risk assessment, so I provided here for your reading pleasure a few additional resources

that might be helpful. Some of them go through the ecological risk assessment process, as well as some specific guidance, like on pollinators. There's also an endangered species reference for our current website. Some of these standard test guidelines are available here, and some of our peer-reviewed documentation.

And so with that, I can turn it over to Dana and Marietta.

MS. VOGEL: Okay, can everyone hear me?

MR. KEIGWIN: Yes, Dana, go ahead.

MS. VOGEL: Okay. So I think in this part of the session we wanted to open it up for your questions. I think kind of like you've done in past sessions, it's probably easiest to put it in the chat, although we can accept your questions other ways if that works for you. But if you can, if you could put it into the chat, that would be probably the easiest way for us to respond, and I'll read your questions, and we'll assign whoever will reply to it.

So I see one. I think I see one so far. How rare or common is it for a pesticide to receive an exemption from tolerances? Okay, I'm trying to figure how best to answer your question. I think -- I mean, it's a process to go through to determine whether or

not a (inaudible) something qualifies for an exemption for tolerance. So I wouldn't -- I don't -- I wouldn't say it's common. I mean, there is a practice. There is an evaluation that happens to determine whether it meets the criteria.

Mike, do you have anything to add to that?

MR. METZGER: Yeah, I would add that it's fairly uncommon for a conventional pesticide. It's often more common for a biochemical pesticide where they tend to be less -- you know, significantly less toxic, of less concern, so an exemption makes sense from the hazard perspective. In terms of the rate, you know, what percentage of the chemicals get tolerances versus exemptions, I really can't answer that.

MS. VOGEL: Okay, moving on to the next question that I see in the chat from Carol Black. Mike, how often does HED use more than 100X safety factor?

Mike, do you want to start? I think it really depends on the chemical. I don't know if it's -- it really depends. All the uncertainty factors have to do with how much confidence we have in the database that we have. How often is it more than 100? I don't have the numbers off the top of my head.

MR. METZGER: Yeah, I don't either. Like you said, it kind of depends on the class and which data we have and which data we're missing. For a lot of the thyroid toxicants where we don't necessarily have all the data in yet, so many of those may have greater than 100X. There are some other classes that have greater than 100X, but just in terms of actually calculating the numbers, I really don't know.

MS. VOGEL: Okay, I'm going to move on to the next question that I see. Mike, thank you for the presentation. How do your human health toxicity studies handle the common situation that post-application workers are often exposed to multiple pesticides? So, Mike, I'll start, and then you can add in if you want.

So we do -- as Mike said, we're going to do an individual assessment of each pesticide. So that would cover the individual exposures to those pesticides, and we do make assumptions of maximum application rate and other assumptions that provide us with protective and operant assessment of exposure and risk for workers, whether it be handlers or post-application exposure that you would get after application.

Mike, do you have anything to add to that?

MR. METZGER: Yeah. I would add that typically -- I'm not sure how often a person would apply more than one pesticide in a given day, but when we do our assessments, we typically assume that a pesticide -- a person's going to be exposed to that pesticide for a significant period of time. Our endpoints are typically selected to reflect 30 days of continuous exposure, so you have that conservatism built in on your tox side.

So we don't assess directly post-application risks from combinations of pesticides, but I think because of the way we do our assessments, the endpoints that we pick and the duration of exposure that we assume, I think we're still being protective.

MS. ECHEVERRIA: So, Dana, the next one --

MS. VOGEL: Yes, go ahead.

MS. ECHEVERRIA: -- sorry, this is Marietta. So the next one from Gary looks like one for eco risk. So the question is under incident categories, where do soil health microorganisms fall? So, Gary, generally, the incidents that are reported to the agency are things that you can observe, so we're usually getting reports on fish kills, a bee kill, or an incident involving birds. I am not aware of us receiving any adverse effects reporting on soil health

microorganisms.

Kris, would you have anything to add to that?

MS. GARBER: No, I'm not aware of any microorganism effect either, incidents. One other category we very often get is plant incidents, where there's some kind of damage to crops typically. So that's another effect that's pretty common that's a sudden lethal effect.

MS. ECHEVERRIA: That's back to you, Dana.

MS. VOGEL: Okay. So the next one is what about long-term effects with low-risk pesticides? Can you explain this? So Mike went through in his presentation a little bit about the different kinds of studies we get, the comprehensive toxicology studies that we get to assess a given pesticide. And we look at all of those studies. We look at all the different effects that we see, and we determine our -- where we're going to select points of departure for use in our risk assessments based on what we're seeing in those studies. So we try to cover all the different effects and the appropriate duration for those effects that could occur.

I think what you're getting at here -- and you can correct me if I'm wrong -- is that you're concerned with pesticides, being exposed to lower

levels of pesticides over a longer term exposure or a chronic exposure. And to answer that question is we feel that the assessments we do are protective of -- the endpoints that we're regulating on are protective of those as well.

Mike, do you have anything you want to add to that?

MR. METZGER: The only thing I can think of adding to that is typically for a worker, for example, who's going to be exposed to a pesticide over a long period of time, we do assessments which are for intermediate term. So we would look at an endpoint that goes up to roughly three to six months of continuous exposure at a high level. And, so, we're picking a point of departure that corresponds to that fairly long duration of exposure. And usually you don't see PODs that are significantly lower, but the longer duration than that six-month exposure, for example in a rat or a dog study.

So from that perspective, I think we're being protective for any long-duration exposures at significantly lower levels, simply because of the endpoints we pick for those intermediate-term assessments and the relatively high exposures we assume for those intermediate-term assessments.

MS. VOGEL: Okay, so there's a lot of comments coming in, and I am having difficulty -- okay, so there they are. They're back up. So I want to make sure that I don't skip any.

So the next question is what about residential exposures to pesticides normally annualized for occupational exposures, for example, from workers who live in onsite housing?

So is this -- I'm assuming that this question has to do with -- does this question have to do with potential for spray drift? That's how I'm going to interpret it. And we do do assessments that assess potential for spray drift and bystander exposure for those type of exposures. And those are part of our assessment. So that would be agricultural applications and potential for spray drift.

The next question -- Mike, sorry, did you have anything you wanted to add to that?

MR. METZGER: Nope.

MS. VOGEL: Okay.

MR. METZGER: Nope, I don't.

MS. VOGEL: Okay. So the next question is -- sorry, I'm trying to keep up here. Okay, I think I may have missed one, but I'm going to try and catch it. I asked my question, epi-studies frequently show

evidence of multiple agricultural pesticides in workers' urine samples, suggesting exposure by whatever route among farmworkers. What is known about potential interactive effects of diverse pesticides encountered through different routes?

So we do -- I think you're referring to -- and I think because I saw it as part of a comment maybe in an earlier comment that you had, are you -- I think you're referring to possibly the agricultural health study. And if you, that is something that we look at as part of our risk assessment process. We have a branch that does evaluations of incidents and epidemiological data, and the ag health study is something that they will look at for chemicals that are included in the agricultural health study. So we do look at it and analyze it for its use.

Mike, do you have anything to add? I'm not exactly sure how to answer that. I mean, we've used it for different chemicals, and our assessments are available where we've looked at the agricultural health study for a given chemical.

MR. METZGER: Again, nothing to add for me.

MS. VOGEL: So I think I'm to the end. I'm not sure there are any other questions here. Again, we do look at all different kinds of data that's

available for a given chemical. We're looking at the data, the hazard data that's submitted. Our assessments have a lot of basis in actual exposure data on our exposure assessment side. We look at the agricultural health study. We look at different incidents data. We look at epidemiological data, as I'm sure you're aware, that becomes available.

And we look at the overall body of evidence no matter where it comes from to make sure that we feel that our assessments are being protective based on the available scientific defensible data that is available. So I just wanted to kind of end with that.

Marietta, did you have anything you wanted to add?

MS. ECHEVERRIA: Well, it does look like, Dana, just viewing the chat that I think Damon wanted to make a comment and do a question verbally, so I think we would welcome him to take himself off mute and make his comment. And then there is a question from Tim Tucker about percent adjusted dose. I'm not sure if you see that, Dana, but -- yes, that is correct.

MS. VOGEL: Yeah, I think I missed some because they're scrolling by so quickly, so I apologize for that.

MR. REABE: Yes, I can jump in here. My first comment is there was a comment made about the aerial application and spray drift, and I just wanted to clarify that that's particularly apparent during Tier I analysis of using the ag drift model, and we want to commend the agency for working closely with our industry during those processes and going in and using Tier III inputs. We'd like to continue that dialogue because there are dramatic changes in the drift characteristics of these aircraft as we go into Tier III and use more current technology in that risk assessment.

And then to follow on to that comment, that is the very reason why this Committee has heard me repeatedly expressing concerns over the need for spray drift risk assessments to be done for all aerial platforms through the ag drift model because the very nature of releasing pesticide droplets from the air, from a craft that's supported aerodynamically, does, in fact, create additional considerations that have to be analyzed in order to ensure safe application.

And then my question is has the EPA considered -- so these are excellent presentations. I very much appreciate them, and I'll just use a couple of examples. For instance, the dislodgeable foliar

residues as one example of an input when we're doing farmworker exposure, it's my experience that type of input is always considered in a worst-case scenario. The expected environmental concentration is worst-case scenario. When we make inputs into the ag drift model, it's worst-case scenario.

Has the EPA considered quantifying in a scientific way when we compound worst-case scenarios on top of worst-case scenarios what type of -- does this automatically turn into a very significant safety factor or uncertainty factor in and of itself?

MS. VOGEL: This is Dana again. I mean, I think I understand your comment, and I just wanted to kind of reply by saying I think we try really hard to make our assessments. Obviously, we want them to be protective and high-end. I understand your point about compounding conservativisms. When we have data to refine, we try to use it as best we can and in the most appropriate way but still trying to have an upper-end assessment that we still have confidence in is protecting at a high level.

So, yes, I know a lot of our assessments, a lot -- there is an opinion that a lot of our assessments are higher -- can be screening level, and that is often the case to -- when we don't have data

to possibly refine to a more refined assessment. We are -- you may have -- you may be aware, I know that the spray drift assessment may be on the higher end of that.

We are using -- we do use as your example on the dislodgeable foliar residue dose, in our individual chemical assessments, we do, when that is available, use it. We start as we explained in this presentation at a higher level screening level. And then we do use it and we look at that data and the patterns that it shows and the data that we can rely upon from that study to refine our assessments to when it becomes necessary to make it closer to what is actually a real-world exposure but still making sure that our assessments are protective and conservative.

MR. REABE: Thank you. And my question, I guess, is more has the EPA done an analysis of is there a change in magnitudes potentially from all of the compounding worst-case scenarios.

MS. VOGEL: So I think -- I mean, we put a -- go ahead.

MS. ECHEVERRIA: Sorry, this is Marietta. I was just going to just make a couple of comments. First, Damon, we do appreciate the work that we've been doing on the spray draft and the interaction that

we've been having. I'm not aware of an analysis that gets to exactly what you're saying, but on the eco side that EFED works on, we do have various sensitivity analyses for our different tools that can give us a sense of the impact of various assumptions on the overall assessment.

But I'm not aware of exactly what you're asking for, Damon, what's the impact of using all conservative assumptions all the time, what's sort of the magnitude of that effect exactly, but we do have other analyses that can get at I think what you're looking for.

MR. REABE: All right. Thank you.

MR. KEIGWIN: This is Rick Keigwin. I think in the interest of time, it looks like we have about two questions and then one more comment in the chat. So we'll take those three and then close out this session.

The first one is from Tim Tucker, which I think it's just a clarification about what is a PAD.

Dana and Mike?

MR. METZGER: Okay, the PAD is actually the population adjusted dose.

MR. KEIGWIN: Thanks, Mike.

And then Jim Fredericks had a comment.

MR. FREDERICKS: Thanks, Rick. And in the interest of time, knowing that lunch is -- knowing that lunch is on the horizon, I'll make it quick, but I wanted to thank the presenters for these presentations. I always find it really reassuring to have that risk assessment process laid out like that.

The comprehensive work that you all are doing is really what makes EPA the global leader in this field, and, you know, in my work, it really gives me confidence to be able to communicate to applicators in the structural pest control industry, as well as consumers, that when used according to label instructions, these products, you know, cause no unreasonable adverse effect to human health and the environment.

So -- and along those same lines, as I hear these complicated procedures that are gone through for each of these products, I would also encourage the agency to continue to engage stakeholders like specialty applicator groups such as structural pest control so that you can better understand the way that we use these products that may be different from agriculture in the future. And I know that has been an ongoing process, and we appreciate that and encourage that process to continue.

MR. KEIGWIN: Thanks, Jim.

And then the final question -- it looks like it's from Andy.

MS. VOGEL: So this is Dana. I will take a shot at this one. So for our assessments and what we like to say in all of the pesticide programs is the label is the law. So if there is on a label protective equipment listed and different REIs, so we will do our -- we do our assessments based on that. And you will see our assessments sometimes with baseline, which means no PPE, and then an additional level that demonstrates what it is with the different levels if PPE.

So we look at everything that's available, and -- but I think the most important here, and to answer your question, is yes, if there is a label, the label is the law, so if the label indicates a certain level of PPE or a certain REI, then that's what our assessments are going to, at a bare minimum, demonstrate in the risk assessment, as well as other possible scenarios that you would see with other levels of PPE, if it's warranted.

MR. KEIGWIN: All right. With much thanks to Dana and Marietta and Mike and Kris, we are going to close out this session. We thought it was important

to provide this detailed overview of our risk assessment approaches to the PPDC. Many of you are new to the PPDC and may not have -- and/or may have not have had recent experience with our risk assessment approaches.

And, you know, over the course of the next year and a half as we're bringing topics to you all for input and advice, we wanted you to have that framework that we use that will help to inform how we will integrate the feedback that we receive to you and to our risk assessment and risk management decision-making. So my thanks again to our colleagues in HED and EFED for their presentations.

In this last session before lunch, as part of the meeting materials, we provided the PPDC members with a series of updates on a number of topics, some of which are either the issues in development or we have recently or are about to start a public comment period, or there was just a general interest in where we were.

So our plan for the next 30 minutes was just to see if based upon those issue papers if members had any questions. And so for this morning, we're going to focus on six of those issue papers or update papers. And so in the chat box, let us know if you

have any comments or questions about -- I think they're listed in the agenda, or they're not. So the six that we'll talk about this morning are the following: the PRIA update, the Worker Protection Standard update, the certification and training rule update, the chlorpyrifos update, the glyphosate update, and the pollinator protection activities update. So if anyone has any comments or questions about those six update papers, you could just raise your hand in the presenter chat box.

I want to just confirm that there are no...

I see multiple people are typing, so we'll give folks a moment.

So, Joe, why don't you go first. And, Joe, while you're asking your question, let me just say, the six that we'll talk about this morning are PRIA, worker protection, certification and training, chlorpyrifos, glyphosate, and pollinator protection.

So, Joe, it looks like you had a question.

MR. GRZYWACZ: Yeah, I'm sorry about that, but my question was actually about the neonicotinoids, so I'll hold off for that discussion.

MR. KEIGWIN: Okay, yeah, we'll do that one after, in the afternoon session.

Mily, I think you have some questions about

worker protection, and certification and training. Okay, Mily, you can type the question in the chat. We cannot hear you, Mily. If you hit pound-six, it should unmute you from your phone.

Pound-six.

I'm sorry, Mily, we still can't hear you, so you may want to type your question in the chat box.

Jim Fredericks.

MR. FREDERICKS: Thanks, Rick. My question was actually on certification and training, and in the Next Steps section of that document, the very end, I know we briefly touched on it yesterday, there was a statement that EPA is developing a statement of flexibilities for states. And I recognize that it has not been developed yet, if you are currently developing it, but can you talk a little bit about what that might be, and is that in regard to existing state plans or is that with regard to the proposed state plans? Just any kind of additional detail would be helpful there.

MR. KEIGWIN: Let me see if Carolyn Schroeder can field that question.

MS. SCHROEDER: Hi, Rick. This is Carolyn. Can you all hear me?

MR. KEIGWIN: Yes.

MS. SCHROEDER: Excellent. Hi, this is Carolyn Schroeder. I'm in the Certification and Worker Protection Branch in the Office of Pesticide Programs, and I think I can answer that question. We do have a draft document that we're working through. We've had multiple -- just a couple calls with all of the state lead agencies and some tribes and also federal agencies regarding their certification plans in this COVID-19 public health emergency. We've also had a lot of interaction with individual states, you know, contacting the regional staff and such.

So there's been a lot of really great conversation about it, and the general message was we wanted to be able to give the states some flexibility in order to respond but also making sure that they're not diminishing the competency of their applicators and also not putting their plans, their future -- their certification programs in jeopardy, such as the good example is if you're going to do examinations online, then you wouldn't want to compromise your program by making those questions getting out there, the integrity and security of those exams.

So that -- just with that introduction, what we've been looking at for our statement is something that it's directed at the EPA-approved plans that are

already existing, already in place. We're not looking at the revisions of the ones that were just submitted in March. So the ones that are actually (inaudible) right now are still the existing plans that were previously approved.

With that said, the certification -- the certification rule, that rule was revised in 2017, and it is the only rule that is out there. So you have to keep that in mind if someone's going to be making a major change to their current program, and you wouldn't want to take a step backwards. Really, the regulation that is in place that is effective is that 2017 rule. We have to be reviewing that one as making big changes.

So what we are proposing trying to look at anyway is how we can modify -- and modify a plan and yet not -- what flexibilities can we provide with the current policy and current regulations. And some of the things -- a lot of what we're hearing are things that would already -- would be in compliance with what the regulation says. And a good example, one that we're hearing commonly that we think is okay but we want to put it in a statement and let people know what types of changes would be acceptable on that higher level, and that would be something like the

recertification period.

So for -- we know that the testing centers and training programs are -- some are halted, some are trying to get up and running in different ways, do something remotely or try to get -- use other state programs, that sort of thing. So in some cases, there's a delay. So for three certification periods, you're able to extend those certification periods beyond what a state might have. And a lot of states are more stringent than what we have as that bar in the federal regulation. We have five years as the maximum period in the 2017 revisions, and so the state has three years. They can make modifications. That would be something we would allow under the rule; however, you normally would submit that, we'd review it, those sorts of things. So we're trying to -- what we're really trying to allow is some of those changes being done on a temporary period and allow those flexibilities with a lot of -- not a lot of burden and delay to get those accomplished.

And, so, we hope to come back to you very soon on what that looks like, and as of we know now, a lot of the states have already been moving forward with some of those changes like expanding their recertification period.

Did I answer your question barely?

MR. FREDERICKS: Yeah, that's very helpful. And then one other just quick question, a note. It's noted in the document that 56 plans were submitted by states and territories. Is that -- so I guess my question is did all the states and territories successfully submit their plans on time? I don't know how many --

(Audio interference.)

MS. SCHROEDER: Yes

MR. FREDERICKS: Great. Congratulations.

MS. SCHROEDER: All plans -- all (inaudible) really. It was a really heavy lift, and I know the teams and EPA regional staff were really working hard as well to have a lot of contact in advance. And the states and the territories didn't have such a heavy lift to get those in on time. And, yes, absolutely, we also received some from a few tribes. We have a proposed EPA plan for those tribes, which are most of the tribes, actually, that fit underneath the EPA-administered plan. But they do rely heavily on what the states have in place in order to get those initial certifications and recertifications, and then we issue those federal certifications. So we have that one as well, that's been released for public comment. And we also received -- I believe it was five federal agency

plans, like the Department of Defense, USDA, BLM. So

we have a lot in-house that we're under review.

MR. KEIGWIN: Carolyn, while we've got you, there are a couple of questions regarding the Worker Protection Standard. And I don't know if you can see the chat or not.

MS. SCHROEDER: Let me pull up and see if I can.

MR. KEIGWIN: One had to do, I think, with the status of the rule and what's currently in effect now versus what we proposed.

MS. SCHROEDER: Oh, okay. I can answer that. I don't -- I can't see the chat --

MR. KEIGWIN: And then I think (inaudible) okay, so that -- so if you can clarify maybe for everybody what rules are currently in effect as relate to the Worker Protection Standard, what we proposed, and the status of the proposal, and then their second set has to do with the status of the designated representative and maybe talk a little bit about some of the work that the General Accountability Office was doing on that.

MS. SCHROEDER: Sure, I can. Give me one second, if that's okay.

I can talk off the cuff, but I wanted to see if I could get the dates pulled up in front of me. I

can start with saying that all of the -- the WPS was revised in 2015. And all of -- the entire rule now is in effect. So that part's easy, but if it helps to know, and I was going to pull up that, there was a standard implementation of that. There were a few provisions that were in effect a year later, and then things related to the training components, we knew that there needed to be time to revise and have training materials available. That was the way -- and I was going to just pull up to see if I can get those dates real fast.

And if I can't, that's okay. I think I have it here. So all of the training materials, once we did have some developed, with that said, a six-month -- we put out an FRN, and then that triggered a six-month delay to allow those materials to get adopted and incorporated into the Worker Protection -- anybody who needed to provide those pesticide safety trainings. And so I think that was by 2018. And then I was just letting this pop up.

MR. KEIGWIN: I believe that's correct.

MS. SCHROEDER: Yeah, thank you. So in June 2018, we had a Federal Register notice for that. And, so, all of -- so all of the new training materials with the expanded content was required by December 19,

2018, and that may be more specific than you need, but I like details, so I like to provide those.

And then also part of that delay was the responsibility for handlers related to the application exclusion zone, and that -- all of that from was -- that was a two-year period, so that one actually the compliance was required for the new content, and the application exclusion zone was delayed from the initial -- the compliance. That was for every other provision. But all of those are now in place as of December 19th, 2018.

And as far as the designated representative, I can -- I think I can answer that question for you as well. That one was also in place, and that one as far as what the PRIA is for, when that came into place last May, there was some new language in there that, one, prohibited us from making any changes to anything besides the application exclusion zone provision. So we did put out a proposed rule for the application exclusion zone back in November of 2019. That comment period closed in January -- at the end of January of this year.

And we are working towards developing a final rule for that, but any other provisions that were being looked at, like something like the minimum age

as well as the designated rep, those we're not developing anything on, and we are prohibited through the PRIA 4 language to make any types of changes to that rule or even look at making revisions to the rule until October of 2021.

With that said, there also was -- there is some language in the PRIA 4 that has GAO looking at the designated representative as -- and needs to report to Congress, have a written report by that date -- same date in October of 2021 to report the effectiveness of that provision. And so we have been contacted. It started last November. They're kind of in -- I think they said to us that the first year would be reaching out to a number of entities, and they have reached out to federal agencies, we know, like NIOSH and ourself. We met with them a couple times.

I know they're reaching out to regional staff at EPA and reaching out to the states that had such similar provisions prior to the start of the rule. They likely are also going to reach out to states now because now that has been in effect, they might start having some experiences or information to be able to share.

They've had a lot of contact with our Office

of Enforcement and Compliance, interested in the inspections, and there is a new WPS inspector pilot that was initiated back in December that some states are participating in. So there is some information and questions going around but it's an investigation kind of stage right now, and then I think they're planning on making sure that the second year would be more compiling and writing and they'll issue that report by the deadline.

I think that might cover it. Yes.

MR. KEIGWIN: Thank you. So I'll just -- there may be some more as we get deeper, but two other things that I know. One, Joe had a question about has EPA provided any guidance on how to conduct the WPS training in a manner given that we're under COVID-19 conditions, and so we are currently working on some guidance. We've had a number of discussions with our state co-regulatory partners, and we hope to have some guidance there shortly.

There was also a question about maybe some members didn't receive the WPS or the PRIA update one pagers in their packets. If you happen -- I'm sorry, if you go to that PPDC website, both of those papers are available on the PPDC webpage.

MS. SCHROEDER: Section 5 and 6 and the very

first one for that session is the certification, and if you're sort of in a hurry for it, the very last one is the WPS one.

MR. KEIGWIN: Right. And then the PRIA one's about three above the WPS one.

Lori Ann had a question on glyphosate, so Elissa and Marietta, that has to do -- there's a question about the glyphosate decision and our efforts to protect monarch butterflies. I don't know if you can see that one in the chat.

MS. ECHEVERRIA: So this is Marietta. I see the question specific to what is EPA doing to protect milkweed from glyphosate. So I do think if Elissa is on or if someone from the glyphosate team who's aware of our stewardship activities that we've been doing and the recent webinar would want to comment.

Elissa, I do think PRD's) probably the most appropriate in terms of answering with respect to the decision and the stewardship activities.

MS. REAVES: Yeah, so can you hear me?

MR. KEIGWIN: Yes.

MS. REAVES: Can you hear me? Okay.

MR. KEIGWIN: We can hear you, Elissa, yeah.

MS. REAVES: So as you know, EPA is committed to protecting pollinators, including the monarch

butterfly, from pesticide exposure. As with all herbicides, we're requiring registrants to update the label language for these pesticides to raise awareness for their potential effects of pollinator habitat and direct users to insertions to minimize spray drift. And so our strategies to protect the butterfly and other pollinators include collaborating with federal, state, and other stakeholders on conservation efforts and promoting best management and integrated pest management practices to reduce spray drift and help preserver pollinator habitats, and this would include the milkweed, which I think is part of one of the questions.

We also have some webinars that we are planning on doing. I don't think we've published a schedule for this, but some of the webinar series were including -- involved including habitat, treating habitat in schools and communities. That was back in March. Advancing the science of assessing risk to bees from pesticides is another one. Engaging stakeholders is another webinar series, as well as another one for mitigating risk. So those are some of the webinars that we're planning on holding throughout the year.

Rick or Marietta, or I don't know if anyone

from RD would have anything to add to that.

MR. KEIGWIN: I think maybe, you know, a related set of questions within the chat is some of the additional work that we're doing on pollinator protection. Tim has a question about the webinar series and anything specific in regards to our plan for assessment and engaging with stakeholders.

Marietta, do you want to talk about some of the work that we've been doing with the USDA?

MS. ECHEVERRIA: Sure. So, Tim -- are you guys hearing an echo?

Okay. In response to -- Alex mentioned yesterday Administrator Wheeler is very interested in pursuing some goals around pollinators, and specific to this, we are working in collaboration with the USDA to build a science workshop in the fall. So that's going to be virtual only at this point just because of the COVID situation, but the idea is to have a state of the science and translating scientist actions, a seminar that -- or rather workshop that is being hosted by EPA and the USDA.

And between now and then, we're doing the webinar series, specific to assessing risk to pollinators, that webinar session is still under development, so we're in the process now of

identifying speakers and actually kind of planning for it. So I don't have a specific date at this time, but we will get back to, you know, the PPDC as soon as we do have firmer dates.

And then additionally, like Elissa was mentioning, one on engaging stakeholders and best management practices. So those are some of the activities around pollinator protection. And like I said, once we have our schedule more firm, we'll be sure to circulate that to the PPDC.

MR. KEIGWIN: Thanks, Marietta.

Dana, I think this one might be you. Joe has a question about the Lang and Borenstein papers.

MS. VOGEL: I'm sorry --

MR. KEIGWIN: And that might be --

MS. VOGEL: -- I'm not sure I can see it.

MR. KEIGWIN: This may be one that we have to get back to Joe offline. It talks about statistical techniques used in the recommended analysis that was done or reviewed for some of our work.

MS. VOGEL: (Inaudible).

MR. KEIGWIN: Maybe we can get -- it doesn't mention a specific chemical. Maybe this is one that we can have Carla and Shannon pull out of the chat and we'll get back to Joe separately.

MS. VOGEL: Okay, sounds good.

MR. KEIGWIN: Lori Ann also had a question about pollinators and some of the decisions that we've made about neonics and sulfoxaflor. In terms of the neonics, is there anything, Elissa, that you would want to say at this point in terms of what our objectives are in working towards a risk assessment decision?

MS. REAVES: So for the neonics, I don't know if everybody knows, but we recently extended the comment period for the neonics, so we're planning on going out in 2021 with a risk assessment strategy, so that's the timeline for it.

Was there anything more specific in the comment that I can address?

MR. KEIGWIN: Lori Ann is typing.

MS. REAVES: Sorry, I can't see the question.

MR. KEIGWIN: And, Joe, we'll have to get back to you, while Lori Ann is typing.

So Lori Ann's question is why don't any of the strategies for pollinators include pesticide reduction.

MS. REAVES: So our strategy has been to reduce exposure to the pesticides, and we can do that through spray drift reduction so that it's not getting

and impacting the pollinators, kind of the strategy we've tried to take there, just in general.

MR. KEIGWIN: Right.

So, Joe, we will get back to you with more specifics about the meta analysis question that you had regarding glyphosate.

Charlotte had a question about PRIA and the current high renegotiation rate and if we had a plan to minimize or reduce our renegotiation rate. I'm not sure that Mike or, of course, Steve Schaible could address that question.

MR.SCHAIBLE: Yeah, I don't see Mike on...

Can folks hear me? This is Steve Schaible.

MR. KEIGWIN: Yes.

MR. SCHAIBLE: I don't see Mike on the line or anyone from RD, so I'll go ahead and take a stab at it. Mike did present an update on this at the PRIA quarterly stakeholder meeting back in April. He indicated at the time that the numbers are high. They're somewhat high across the board for all the divisions, AD being the exception. And this would have been through mid-year FY20, so end of March.

And he did say that generally speaking, and I

note from our monthly tracking this is true. Our renegotiation rate for the RD actions, PRIA actions peaked around December, and they have been slowly going down since then. They did an analysis within their division, and some of the impacts from the shutdown are finally diminishing in terms of being able to get actions scheduled in the different science committees because there was an impact from the shutdown for that. And they're starting to see a downward trend in their renegotiations.

I think we're also more long term looking at some of our IT improvement activities, hopefully being able to provide efficiencies in how we're able to do our actions. I think with regard to working remotely, I think that really a benefit to that experience has been, I think, the whole program is getting more facile with working in an electronic environment.

MR. GOODIS: Steve, sorry, this is Mike Goodis with the Registration Division.

(Echoing audio.)

MR. GOODIS: Thank you, Steve, for responding. I would just add, too, that, you know, we are taking renegotiation rates very seriously. We realize it's very high, unprecedented. We've been having to deal with a number of setbacks, which -- to

that increase. And as Steve mentioned, we pretty much hit our peak late last year, and we're starting renegotiating --

(Echoing audio.)

MR. GOODIS: -- on a slow decline, and we're hoping to implement them. I can tell you we're very busy during this current remote working situation right now, and been progressing through redoing a lot of these actions. We're also actively --

(Echoing audio.)

MR. GOODIS: -- that folks know that even though we're working at home remotely recruiting where we've been able to bring people on board during this period as well. So it's an interesting experience where their first day on the job is working at home for this organization, but now the challenge in front of (inaudible) long time is balancing a lot of the PRIA actions along with a lot of the non-PRIA actions.

You know, there was -- there's a significant need from industry in reviewing those activities as well, and so that's been, like I said, the challenge we've been trying to balance for these -- for the last year, year and a half at least. And, you know, we're doing everything we can to share resources within the

division. Our acute toxicity and product chemistry reviews, I think we've been able to try to stabilize the resources there as well so that that information can be reviewed timely because it really is an underpinning for a lot of other actions, also.

So it's -- yeah, the best I can say is we're trying to manage and balance things the best we can, and bringing on more people to try to bring things down. That's -- a lot of efforts, too, has been talking with companies to try to help perhaps combine actions so we're only looking at them one time, and also withdrawing any actions that they no longer need and just trying to be more efficient in that area as well.

MR. KEIGWIN: Thanks, Mike.

Lori Ann had added to her earlier question. This is back on pollinators, when referring to use reduction about why that wasn't articulated in the three goals listed at the top of the pollinator protection activities update. What I would say is that pesticide use reduction is part of management that we can consider on a case-by-case basis when we are undertaking our evaluations of pesticides.

So as Kris Garber noted earlier, for ecological risk, it's a risk/benefit-based approach,

and so a number of our reevaluation decisions focus on a variety of ways to reduce the exposure, which include at times if appropriate either use rate reductions or reductions in the number of applications, which in the end do result in reductions in the overall pesticide use.

I'm mindful of the time. Elissa, while I'm scrolling through, I wanted to see if there was anything you would want to add.

MS. REAVES: Yeah, and if we go back to for the neonics, we didn't put those kind of specifics in that updated paper, but we -- just so everyone knows, we did have some reduced rates, and we did have some crop stage restrictions as part of our mitigation strategy, so I just wanted to add a little bit to that, too.

MR. KEIGWIN: Okay, and then there's -- Amy's got one last question if Carolyn is still on board, and I think it has to do with a revision to the AED.

MS. SCHROEDER: I'm here.

MR. KEIGWIN: I think I might try to handle this one for you, Carolyn, actually. So the comment period did recently close on a proposed revision to the AED. We are in the rulemaking process. And I can't recall. You may have the number more readily

there, but under the comments we received, I know it was a very large number of comments --

MS. SCHROEDER: Yeah, I think we had over 18,000. It was a lot. It was a lot.

MR. KEIGWIN: It was a lot --

(Speakers talking over one another.)

MS. SCHROEDER: It was about -- I can't remember if it was 150 or 160, I would say, like, we would call unique comments, like how many comments if you look in the docket of how many comments were actually received and then under three of those comments what we would call a unique comment are campaign mail letters or a collection of submitted letters. So it shows up as -- so then they count each individual comment as comments as well, of course, and that's where you get the 18,000.

MR. KEIGWIN: So we are in the midst of reviewing and developing responses to those comments, so I don't want to prejudge the outcome of our response to comments, but we do take your question and the comments that were submitted by all stakeholders seriously as we decide how to move forward in that initiative.

I think with that it is East Coast time just before 12:15, and I want to give folks a little bit of

time to stretch and grab something to eat.

I believe, Shannon, we'll restart at 1:00. Is that correct this time? Yes, we will rejoin at -- or we will begin again at 1:00 East Coast time. And if you could try to log in a few minutes early so that we can start right on time, we'll appreciate it. And thanks for all the questions. See you in a little bit.

(Luncheon recess.)

AFTERNOON SESSION

MR. KEIGWIN: -- Mike Goodis, if he could respond to Amy's question.

MR. GOODIS: Thanks, Rick. Yeah, this is Mike Goodis, Director of the Registration Division. So we are in the process of evaluating information that's been provided, studies that have been provided to the -- by the registrants and other information collected by registrants and also information that we expect also to receive from the states and also academia and other sources as well.

The registration -- the current over-the-top registrations are due to expire in December of 2020, unless the agency takes some other action on that. We are, again, evaluating the information. We intend on making a regulatory decision. We want to try and do that in a way that helps inform growers for the 2021 season, but as far as details of what that decision will be, if and how long and what conditions still is yet to be determined. And, so, I can't really directly answer your question regarding how much longer, if any.

MR. KEIGWIN: Thanks, Mike.

Our next set of questions relate to alternatives to animal testing paper. Two questions

from Mano. What impact, if any, do you anticipate the upcoming SAB review will have on the activities of EPA and implementation of alternative approaches, and how is EPA advocating for best scientific practice and acceptance of NAMs for animal testing within OECD and other fora? So I would see if Anna Lowit is available to respond to those two questions.

Anna, you may have to hit pound-six.

MS. LOWIT: Hello, can you hear me now?

MR. KEIGWIN: Yes.

MS. LOWIT: Yeah, okay, sorry, I didn't know I had to unmute myself. So, yeah, so I heard two questions. So we do have an upcoming meeting of the Scientific Advisory Board. It's a collaborative effort we're doing with a number of stakeholders, including People for Ethical Treatment of Animals, for some industry colleagues, NIEHS, and the National Toxicology Program, in addition to some colleagues from the Office of Research and Development, so on -- specifically on a variety of activities we're doing related to carcinogenicity testing and corona testing in rodents.

There are five -- the documents will be available publicly probably about a week to 10 days. The evaluation is -- the consultation for the SAB is

on five projects that are really ongoing, sort of midstream, or in some cases just getting off the ground for some external peer review to see -- just to get some initial or midstream feedback.

The five pieces include, one, it's called the RECAP project, which is a waiver evaluation framework that we're developing with a number of stakeholders, including Australia and Canada. We have three projects looking at various ways to use new technologies, particularly Omex technologies. And the fifth project has to do with kinetically derived maximum doses.

And I think the quickest return from those activities that we'll see, I believe the first one or the fifth one, which is the waiver project and also the KMD project. We're actually already seeing submissions of kinetically-derived maximum doses, and so the hope is that we can get a more consensus consistent submissions for those.

The second part had to do with our engagement at OECD. We're actively engaged in a number of activities at OECD, ranging from ecotoxicology and endocrine disruption and skin sensitization, in addition to some other dosing activities.

The OECD and the international work is really

important as we think about harmonization to really realize the reduction in animal use. Our colleagues around the world need to have similar data requirements and similar animal use policies that we're moving towards. But the OECD process is quite slow. It just takes time, but it is an important part of what we're doing.

MR. KEIGWIN: Thanks, Anna. And stand by. Gina Hilton has a comment about this work as well.

Gina?

MS. HILTON: Hi, can you guys hear me?

MR. KEIGWIN: Yes.

MS. HILTON: Can you guys hear me? Okay, great. So thank you for the opportunity to comment. I'll be quite -- because I know we have a lot to discuss, but I wanted to echo the sentiment from Alex Dunn as she stated yesterday that this is truly an exciting time to see numerous cross-sector collaborations that are focused on modernizing regulatory approaches to chemical risk assessment through new approach methods, also known as NAMs.

And as we just heard from Anna Lowit, the EPA is collaborating with several international regulatory agencies, including Health Canada and Australia's APDMA, where they are pioneering a path forward to

develop and implement these NAMs or new approaches, and this is truly a critical step towards international harmonization, as well as engagement at the level of the OECD.

I also want to acknowledge the agency's actions to review data for regulatory decision-making in retrospective review such as we saw with the avian dietary and also with EPA's repeat dose study waiver program. These are all critical to identify and remove duplicate tests that do not add value to risk management. And ultimately these actions free up resources that can be used towards the continued development and validation of more relevant testing for both human health and environmental protection.

So I just want to encourage the EPA towards a paradigm shift in the way that the agency approaches risk assessment in order to provide rapid feedback to those workers and consumers, as well as greater protection to the environment.

For example, there were questions yesterday about mixture exposures for field workers during the COVID pandemic. There's also ongoing concerns for cancer risk. And ultimately, we simply cannot generate rapid and relevant information needed to inform chemical risk in these types of scenarios with

animal studies. So these animal methods were developed half of a century ago and they simply can't keep pace.

So just to wrap up with a few suggestions to keep pace with emerging technologies and new approaches, I think it would be helpful to see the agency provide more timely document review for projects related to NAMs, as well as more resources allocated to cross-sector collaborations, method development and validation, as well as regulator training.

I also encourage the agency to continue efforts to develop metrics tracking for animal use, which will be critical to meeting the goals set by the Administrator to eliminate mammalian tests by 2035.

So overall, I'm encouraged to see EPA's engagement and efforts to reduce testing on animals, and I'd like to thank the EPA for their hard work and commitment to protecting human health and the environment and also for allowing all of the stakeholders this opportunity to provide feedback.

MR. KEIGWIN: Thanks, Gina.

I know there were some other comments that came in, but since there's one other on the alternatives to animal testing, I thought we'd handle

that one here, and then we'll go back up to the other question.

Mano had a question: Anna, are there any concerns with regard to the implementation of the Administrator's directive on decreasing animal use in agency research and decisions in future administrations?

MS. LOWIT: I'm not 100 percent sure what you're asking. If the real question is do we -- are there concerns with the directive itself or that possible future administrations can maybe change the directive, so I'll just sort of cover both, I think.

So, you know, the Administrator's directive, you know, is going to free up some funding, provides, you know, direction to staff and managers on separate priorities, but it's important to remember that OPP has actually been working on these efforts long before the current administration. In fact, we started a lot of this effort back in the late 2000s, not long after the NAS report was put out. We had our first retrospective on the dog in 2007, actually.

So a lot of the activities that we're doing with regard to moving away from some of the animal studies and moving towards more human-relevant, taxa-relevant, we're going to keep doing, irrespective of

the administration because we believe it's the right science, we believe it's the right public policy.

So in that regard, I think the Administrator's directive just really reaffirms the direction that we're headed, and hopefully will provide some additional funding, at least in the short term. So I think that's all there is to say about that.

MR. KEIGWIN: Thanks, Anna.

There were a couple additional questions about dicamba. Mike, I don't know if you saw them in the chat box, but I'll try to -- I'm going to scroll up just so I can recapture them.

I think one had to do with -- from Dan Kunkel -- about the process for people to provide information to inform our upcoming decision, and then a second comment from Amy Asmus regarding the role of 24(c) labels and potential for regional labels in the future.

So, Mike, do you want to address those two?

MR. GOODIS: Yeah, this is Mike Goodis again. I do have Dan Kenny and Meg Hathaway on the line from our Herbicide Branch, directly managing dicamba. I don't know -- I think I'll see if they can chime in on this and we can kind of tag-team this a bit.

MS. HATHAWAY: Hi, this is Meg Hathaway. Can you guys hear me?

MR. GOODIS: Yes, we can.

MS. HATHAWAY: Great. I guess I will take a stab at the question regarding the agency's collection of information in support of the upcoming decision and how to submit that information. We've had an ongoing conversation with a number of stakeholders throughout this process, so we've been in touch with partners such as AAPCO, various registrants, certain crop commodity organizations that would be affected by any changes in dicamba registration. So there are a number of ongoing conversations.

If there's concerns or information that the group feels today has not been brought to the agency's attention yet, what I would recommend is you can contact myself. My name is Margaret Hathaway, and if -- my email address is based on that, but if people would -- it's on the website for contacts within the Registration Division for the Office of Pesticide Programs.

I would note, however, that as you know there's a certain time sensitivity to the decision-making process. We already have a large amount of information new to us this year in-house that we're in

the process of reviewing. So if there is something that you'd like us to take a look at, sooner is always better than later. I can't, in full disclosure, guarantee that everything will be reviewed fully in time for a 2020 decision if it's something like a full scientific study, but we're doing our best to cope with the large volume of data that we're working with.

MR. GOODIS: Okay, and this is Mike Goodis again. Just looking at the comment from Amy, you know, I think right now we're looking at all options are on the table regarding what type of -- you know, what kind of decision may come out later this year and how best to address potential risk issues from the use of the product. I mean, I see that you're asking, like, how -- is there an option to consider more regional labels as opposed to relying on each state implementing some kind of 24(c) special, local-need registration.

Also, we've been having some of that conversation. Again, we're not really clear yet exactly what the outcome will be yet, but, you know, I think that's an intriguing question that, again, we're actually considering, also. And at this point, you know, we'll see how things turn out later this year.

I think that's all we had for dicamba.

MR. KEIGWIN: Thanks, Mike.

So there were two -- I saw at least two questions regarding neonicotinoids. So, Elissa, one had to do -- and I'm not sure if Dana Vogel is still online, but the role that SENSOR has played in the incident analysis within neonicotinoids; and then the second has to do with the benefits assessment in the neonicotinoids relative to seed treatment and why we came to the conclusion that we did about the role of the neonicotinoid seed treatments in the IPM program.

MS. REAVES: Hi, Rick. It's Elissa Reaves from PRE. So for the first one, I think regarding SENSOR, I think it's important to keep in mind that that was just one set of data that we considered among many lines of evidence and that SENSOR wasn't the only thing that we relied on for our decision. I don't know if Dana Vogel from HED would add anything else to that specifically regarding SENSOR.

(No response.)

MS. REAVES: Okay. And then, Rick, what was the second one? Was it about treated seeds?

MR. KEIGWIN: Sorry, I was on mute. It was about treated seeds and specifically could we elaborate on why we considered neonics to be important in IPM programs, and which IPM protocols call for the

use of this kind of use.

MS. REAVES: I mean, for part of that, I would have to go back and check, but I seem to remember that treated seeds was not heavily looked at or considered specifically as an insect use. And I'm not sure if Dee would have anything to add on for that, as well, as far as IPM.

MR. KEIGWIN: I'm not sure if Kimberly was able to join us this afternoon.

MS. NESCI: Am I there?

MR. KEIGWIN: You are.

MS. NESCI?: Okay. Yes, I'm here. Could you repeat the question?

MR. KEIGWIN: Sure, yes. Can you elaborate on why EPA considers neonics to be important to IPM programs and which IPM protocols call for the use of this kind of use?

MS. NESCI: So I think neonics are important to IPM protocols partly because they provide a mechanism of control for a number of different species. A pest which can help to address any sort of resistance development to types -- groups of active ingredients sharing the same mechanism of action. In terms of the specific systems, we would need to get back with you on that, but -- so that's a very general

answer, but we can certainly -- certainly do that. I believe that some of that will be described -- or is described in the documents available.

MR. KEIGWIN: Okay, thanks, Kimberly.

MS. REAVES: This is Elissa Reaves.

MS. NESCI: And, also --

MS. REAVES: Go ahead, Kimberly.

MS. NESCI: One other thing, seed treatment itself can serve as an overall insect management program that includes -- also includes a soil and early season test, so that's another -- another way in which it fits into the system.

MR. KEIGWIN: So the earlier part of the question that I missed, and my apologies, is regarding how on a per-acre basis, and this is from Lori Ann, the vast majority of neonicotinoid usage is as a prophylactic seed treatment, and she expresses concerns that prophylactic use of an insecticide that is highly toxic to non-target beneficial organisms is not part of an IPM protocol.

KIMBERLY: Okay, thanks, Rick.

MR. KEIGWIN: And to what extent we address that in our benefits analysis.

KIMBERLY: So I don't think we address prophylactic use generally to either say it's a good

thing or a bad thing necessarily. I think in our benefits analyses we mostly talk about the tools that are available and alternatives that are available to control the pests that the active is targeting. So if there are some -- there are no alternatives, then we know how important the use is and also related to the -- you know, the total usage in terms of percent crop treated. The assumption is that that amount of percent crop treated is being treated that there's a reason that the growers are actually purchasing that product and using it. So prophylactic use is not specifically addressed in the benefits assessment.

MR. KEIGWIN: Thanks, Kimberly.

Many questions coming in, so if I miss any, my apologies.

Amy Asmus asked, dicamba precedent that's related to -- bases its final rule on the movement of certain genetically engineered organisms that was published on Monday called the Secure Rule. Will EPA speed up its registration process for the herbicides to be used on crops and systems like dicamba, especially where older formulations exist for the APHIS-approved herbicide-tolerant crop that could be applied illegally.

MR. GOODIS: This is Mike Goodis again. I'll

respond to that one. I think it's actually an excellent question. So you're right. You know, I think the situation regarding the deregulation of the dicamba-tolerant seed by USDA back in 2015, if I have my years right, did create a situation where dicamba products that are not registered for the over-the-top use were used illegally because there was not a EPA registration of an appropriate product for the overtop use. In fact, at that time, when the seed was deregulated, I believe we didn't have a complete application in-house from the registrants.

So, you know, this is a scenario, too, that we've been keeping a close eye on. I don't think it's realistic to expect that the agency can quickly turn around registration applications and decisions in all of these cases. I think the conversation really needs to be with the pesticide industry and the companies for appropriate product stewardship to make sure that the timing of the deregulation of the seed aligns with the expected registration for the appropriate pesticide product. I think that's the appropriate approach we should be expecting and taking with this type of scenario.

MR. KEIGWIN: Thanks, Mike.

Mano had an ESA-related comment. Mano?

Mano, remember to hit pound-six if you want to make your comment.

MR. BASU: Yep. Can you hear me now?

MR. KEIGWIN: Yeah.

MR. BASU: Hello? Okay. Thanks, Rick. Thanks, Rick. We appreciate the work the agency has done to improve the risk assessment and consultation process on ESA. We agree that significant progress has been made on the BE methods, but there are still some improvements, unfortunately, that we would like to share through our public comments on the carbaryl BEs.

We would also like the agency and other members of the IWG to convene public forums for stakeholder engagement for the effective implementation of revised interim measures, among other topics. These frequent stakeholder engagements assessing pesticides for ESA consultation we think would help EPA solve the ESA and pesticide consultation problem with meaningful stakeholder input.

And, again, thank you very much for all your effort. We appreciate the work that has gone in. Thanks.

MR. KEIGWIN: Thanks, Mano.

The next question was from Charlotte Sanson. As NAMs are accepted for use in regulatory decision-making, what is anticipated with regard to application of the database uncertainty factor?

Anna?

MS. LOWIT: So I guess it's important to remember that the concept of new approach methods, which is what NAMs stands for, fit all kinds of different purposes, everything from screening prioritization to hazard identification to quantifying points of departure, to actually using for different extrapolation approaches, like for example, a number of months ago we released our final evaluation of the pyrethroid and used a combination of physiologically based pharmocokinetic models with a series of in vitro studies that allowed us to reduce the FQPA safety factor for the pyrethroids down to one. And it's heavily based on a lot of the in vitro information in young children and adults.

So I think the question -- you know, you really have to look at the context of what the method is used for in relation to what the science question is. So there may be cases where the NAM is actually just used to look for the presence of absence of some sort of hazard. Or in other cases, you may use that

NAM to quantify a point of departure, like for example, you know, a number -- you know, about a week or so ago, we released draft risk assessments for some biocide preservatives actually proposing to use those in vitro studies to extrapolate the risk using point of departure.

And we're actually asking for public comment on how to handle the uncertainty factors in that case. So it depends on the situation. So we do have an upcoming FIFRA Scientific Advisory Panel meeting in September on some issues related to organophosphates and using different in vitro data to look at different -- the interspecies and intraspecies extrapolation factor, and also some ongoing research work that we're doing with the Office of Research and Development to use new methods for looking at potential for developmental neurotoxicity data. And so, you know, we'd encourage public participation in that meeting.

MR. KEIGWIN: Thanks, Anna.

The next question, Marietta, I think, is for you, from Lori Ann, and it's regarding ESA. In the endangered species update, EPA says we also continue to compare potential hazards of new pesticides to the registered alternatives to allow stakeholders to compare the relevant risks of the proposed

registration to available alternatives, which often have the potential to pose greater risk to ESA-listed species than the newer generally lower pesticides being introduced into the marketplace.

Setting aside that those introduced into the marketplace today -- sorry. Setting aside that this does not comply with the plain mandates of the ESA, does this mean EPA is taking steps to phase out the higher-risk pesticides such as chlorpyrifos, atrazine? Given the robust science recognized and their unacceptable impacts to endangered species, what is the basis of EPA's conclusion that newer pesticides are generally lower risk to endangered species, given that they have not gone through formal ESA consultation or even have the benefit of multiple years of study by independent scientists like the older pesticides have?

Marietta, how would you respond to...

MS. ECHEVERRIA: Thanks, Lori Ann, for the question. So when we're talking about the hazard comparison, what we're referring to specifically is our work to support the decision on the registration action. So what you will see when a new active ingredient is registered as part of the docket and part of the record is a comparison of the hazards

based on a taxonomic approach, so, for example, the hazard to birds for the active ingredient under consideration compared to the market leaders for that use and what the alternatives are.

This is not to say that we are phasing out older chemicals, per se, based on that hazard comparison. The hazard comparison is done, like I said, in support of the decision of the new registration. The consideration for phasing out older chemistries, as you know, is done as part of the registration review process, and as you know, for chlorpyrifos, we are actively in consultation currently, specifically, and we do have a biological evaluation scheduled for atrazine coming up. But those are two separate processes that we would -- we would be going through.

MR. KEIGWIN: Thanks, Marietta.

So in the interest of time, I'll just take the last couple of questions that we have here so that we can move to our next session.

And so a question from Amy Asmus that may require some additional context. Amy asked who would facilitate that timing. And I'm not clear from the chat, Amy, what that question was referring to. So if you can hit pound-six and maybe add a little bit more

so we can try to answer your question.

MS. ASMUS: Hello. This is Amy. I just wanted to follow up. I just wanted to follow up on the answer about, you know, the coordination and working together of APHIS, USDA, EPA, the registrants on the whole timing of approving system.

MR. GOODIS: Yeah, right. Yeah, this is Mike Goodis again. Yeah, I mean, I think that's -- we've been in contact and discussions with USDA and APHIS. I mean, I think they're aware of the situation as well, and I think that's an important part, also, is to know when applications are coming in for, you know, some type of tolerance seed evaluation and also the timing for the pesticide registration.

Again, I don't think we really have, like, a specific point of contact that would manage all this information. I think this would be ideally a conversation we would like to have with the company prior to the submission or application for their pesticide registration to make sure that, you know, things are lined up appropriately, that the timing will work out well, that, if appropriate, the tolerance seed and the pesticide product would be available simultaneously for use during whichever upcoming season.

MS. ASMUS: Yeah, I just think we need to somehow have a precedence on this. We're going through this with the Enlist systems and now with the isoxaflutol system. It would just be nice to have somebody that could facilitate the registration of all of it in a timely fashion.

Thank you.

MR. KEIGWIN: Thank you.

Christina had a question. In light of the highly limited public comment on sulfoxaflor and isoxaflutol, what is the likelihood of future pesticides being registered or re-registered without posting to the Federal Register?

Mike, I think that's in part a question about our participation process for registration actions, and Elissa might want to clarify the process relative to registration review.

MR. GOODIS: All right. I'll start off with the registration public process. So some years back or so, a little bit before my time, I think it's at least 10-plus years ago -- the EPA Office of Pesticide Programs took on a policy of being more transparent with providing public comment opportunities for the registration of new active ingredients and also additional scenarios, such as if a product was to have

a first food use. So it was a non-food registration, and it was amended to include a food use or a first residential use and some other types of scenarios.

There is no statutory requirement, nor is there any regulatory requirement or a public comment period for new registrations, unlike for registration review and the reevaluation program, and Elissa can speak with that. So this is a policy that the agency took on sometime back and, you know, and I think we've been operating under the policy, again, for some number of years now.

The process was to provide all the supporting information in the docket and to make available on our website the availability of that registration action for comment. And, again, for a long time, it was working -- again, you know, working reasonably well.

The recent actions, I think, the program has identified that further outreach may be appropriate for these type of actions, and so just recently, I think it was even just this week, there was a new active ingredient that we're proposing to register, and we took the extra step to issue an OPP update, which is a communication tool that goes out to thousands of organizations or individuals that signed up to receive that information.

So we just wanted to make sure that, you know, again, there was more awareness, that that type of -- or that regulatory action is being proposed, and that the comment period was being opened. And so I think that's how we intend on doing further outreach going forward for these types of regulatory actions.

MS. REAVES: Thanks, Mike. This is Elissa Reaves --

MR. KEIGWIN: Yeah, go ahead, Elissa.

MS. REAVES: -- of the Pesticide Re-evaluation Division. For registration review, so we do post on our website upcoming schedules for reg review. So when this one comes up on our reg review schedule, we'll have proposed dates, starting with our preliminary work plan. And that does involve public comment period.

And as you know, another significant public comment period is the draft risk assessment phase, as well as the proposed interim decision phase. So there are multiple stages during our reg review process for input, and we consider sometimes thousands of public comments. So that's kind of an overview for our reg review process.

MR. KEIGWIN: Okay. There was a comment in the chat box about the neonicotinoid benefits

assessment that prophylactic use is part of IPM in situations where site history indicates prior issues. Some of the criticism over use of seed treatment is sometimes valid, but because of the difficulty in getting soil test, seed treatments have massive benefit. We could provide further reasons if folks are interested. And that was from Sheryl Kunickis at U.S. Department of Agriculture.

I think we'll make this one the last one. Joe had a follow-up question regarding the SENSOR information used in the neonicotinoid proposed interim decision. The SENSOR program is active in 13 states. Both SENSOR and the Incident Data System both rest upon reported incidents only, yet substantial public health research indicates that the vast majority of exposures are unreported, either because they produce mild to moderate symptoms or because healthcare providers are poorly equipped to identify pesticide exposure.

So he asks, given the known flaws in the system, how can risk be reasonably evaluated. And then he clarified this to say that the documents conclude based upon the continued low frequency of dimethoxane and then closely added in incidents reported to both IDS and SENSOR, there does not appear

to be a concern at this time.

So, Elissa or Dana, do you have any further follow-up?

MS. REAVES: Yeah this is Elissa. So I would really refer to HED on that one regarding the human health and SENSOR, or if David Miller's on the line? I mean again, SENSOR's only one piece of our way of evidence.

MR. KEIGWIN: Thanks Elissa. So I think we're gonna close out this session and switch to our last session of the day which is really focused on how do we as a committee want to organize ourselves for the next year and a half.

You have heard today, or if you've participated or attended previous PPDC meetings that we have over the years had a number of workgroups to help inform this committee's work and recommendations that have come forward.

You heard yesterday, for example, some work out of previous workgroups on public health that helped to inform EPA's emergency response plan. We have had other workgroups in the past that have worked on 21st Century toxicology issues, which have helped to inform our work on alternatives to animal testing. And we've had other workgroups that have helped to inform any number of label improvement initiatives.

So we thought we would spend some time this afternoon at this first meeting of the new committee to -- in light of what you've heard or given your interests and volunteering yourselves to be considered

for this Committee, what types of issues you would like to engage on with the agency. And what Shannon has done is she will kind of take notes for all of us on this whiteboard, and we'll kind of see what ideas are out there for potential workgroups.

I will -- and then once we have some ideas up there, we'll try to work through a process this afternoon to begin to prioritize this list and give you our next steps from there.

So, Shannon, does that kind of work for you?

I don't know if Shannon can hear me.

MS. JEWELL: Sorry, I was double-muted. Can you hear me?

MR. KEIGWIN: Yes.

MS. JEWELL: Yes, that absolutely works.

MR. KEIGWIN: Okay. So the first suggestion comes from Dan Kunkel regarding emerging technology. He's wondering if a workgroup could be helpful to provide expertise and help make progress. We certainly would not want to slow down any progress or processes but to possibly add broader expertise. It's a broad topic. It may be best to have an overarching group on technology and then a focus on UAVs.

It sounds like one suggestion that's come forward is an emerging technology workgroup, if we want to put that on the whiteboard.

And Amy Asmus has a comment, working on consistent labels, where information is in the same section so easy to follow and find and point out to growers. So I think we could call this one label.

And, Amy, if you want to unmute yourself, I want to make sure we capture this right on the whiteboard. Is this about consistent formatting of labels? How would you characterize this group if we were to name it?

MS. ASMUS: Yes, I would say label formatting.

MR. KEIGWIN: Okay.

MS. ASMUS: It's just difficult, the different manufacturers have different sections for different information. This time of year, especially when guys are out working in the field, we get calls on label questions all the time. It would be nice if we knew Section 1 was all one kind or to know to go to Section 3 to answer a certain question, or Section 5, because right now, it's difficult, and without e-labels, there's not really a good search lookup function.

MR. KEIGWIN: Thanks. I just wanted to make sure we're capturing it in a pithy way so that when we went back over these we knew what.

MS. ASMUS: You can always call, Rick. Thank you.

MR. KEIGWIN: I know, I know. Okay.

Our next one is from Komal. Appreciate the work and application of the emergency preparedness and action plan that was informed by the current public health workgroup; however, this workgroup, as she understands it, was primarily focused upon the insect sector and response to Zika. On behalf of certain

members of the workgroup, as well as the CDC, they ask that a separate workgroup be formed to address emerging pathogens and human transmission. I envision that members of the group would include federal representatives like EPA and CDC, FDA as well.

So perhaps we could call this idea emerging pathogens workgroup. So let's add that one.

And then as Shannon adds that one, David agrees strongly with Dan Kunkel's recommendations on workgroup on emerging technologies and another specifically on UAS.

Lauren agrees with the consistent labeling workgroup. At Farm Bureau, they get the same questions from growers.

Damon says I agree strongly with the standardizing labels workgroup.

So, so far, we have emerging technology, consistent labeling, and emerging pathogens. Carol has a suggestion that as part of the format consistency workgroup that we include a focus on basic PPE layout and wording, consider international work on gloves and permeability. So that could be part of that group's mission as well.

Damon has a question on a potential emerging technology workgroup and specifically a UAF focus.

So, Damon, if you want to take yourself off of mute by hitting pound-six, we can hear your question and move from there.

MR. REABE: Thank you, Rick. There is a workgroup that EPA's involved in. It's a UAS drift mitigation workgroup that involves diverse stakeholders, and they're going to be holding their first meeting, I believe it will be June 1st. I'm wondering if we were to develop a UAS focused workgroup if that wouldn't be duplicative of what this other workgroup is doing that the EPA's involved with.

Did you get that, Rick?

MR. KEIGWIN: I did. Thanks. I just wondered if Ed wanted to add any clarity.

MR. REABE: Oh, sure.

MR. MESSINA: Hey this is Ed. Can you hear me?

MR. KEIGWIN: Yes.

MR. MESSINA: Yeah, Rick, can you hear me?

MR. REABE: Yes

MR. KEIGWIN: Ed, go ahead.

MR. MESSINA: Yeah, certainly I think that there would be overlap. I think that group is specifically focused on drift, and there's probably broader areas that, you know, UAV science needs to work through, but, yeah, I think that's a fair point.

MR. REABE: Yeah, maybe if the group decides

on a workgroup like this, we could know that that work is being handled by experts in the field so that the

focus of the workgroup can deal with the other issues that have been presented.

MR. MESSINA: Yeah, I mean, from my perspective, having some sort of level of coordination, because this is an issue that affects, you know, industry and environmental groups and workers, and it's a technology group as well, which is different from the registrant community and other agencies, it is sort of an area that lots of coordination and recommendations about how EPA should address this new technology and others, I personally think would be helpful.

So I think drift is an example of that, but I think there's other examples as well. But it's really, you know, up to you guys, I would say, to think about, you know, what you've heard from these meetings and decide on what would be good.

MR. REABE: Thank you.

MR. KEIGWIN: Okay, Amy has another aspect of the emerging technology workgroup that we could consider, which is to have a group that's focused on equipment but instead other emerging technology such as biostimulants or pest management systems.

So maybe we could add-- maybe just an emerging pest management approaches or something like

that as a separate workgroup.

Gary says I agree with all three based upon experience as a producer, industry agronomist, and experiences across various commodity groups.

Other thoughts, comments, suggestions?

Okay, others online, multiple people are typing, so just give us a moment.

Okay, Liza says given there are existing workgroups on both emerging technologies and labeling, we suggest that any newly formed workgroups work to have a liaison with existing workgroups as part of the membership. Okay, thanks, Liza.

Gary asked could we lump resistance management to emerging pathogens and (inaudible).

MR. MESSINA: Hey, Rick? Can you hear me?

MR. KEIGWIN: Yes, go ahead, Ed.

MR. WAKEM: I was wondering if Liza might give some background on the labeling workgroup that's out there already, which I'm a part of, and for the group.

MR. KEIGWIN: And just to clarify for everybody, before she does that, it's not a PPDC workgroup. That is a SFIREG/AAPCO workgroup.

Liza, if you want to unmute and just talk to people about the effort that SFIREG has underway.

MS. TROSSBACH: Sure, happy to do so. Just to confirm that I can be heard?

MR. KEIGWIN: Yes.

MS. TROSSBACH: Okay, great, thank you. So, again, this is Liza Fleeson Trossbach, the AAPCO representative. And SFIREG, which is a permanent committee of AAPCO, and SFIREG stands for the State FIFRA Issues Research and Evaluation Group, they have put together a workgroup at the direction of the AAPCO board that is envisioned as a long-term project looking at label improvement. And this effort is in its infancy still. We did start earlier this year, and with COVID-19 there have been some delays in moving forward. But what this project is intended to do is to look at pesticide labels holistically and identify those areas where improvement is needed.

Some of the things that were mentioned, for example, formatting is one of those things that has been at least initially identified as a priority area. The project is divided into stated (inaudible) at, like, a project management. There is a project manager. There is a project chair. And there are core group members that have been initially convened to identify these areas.

Now, because of the workgroup, it is a state

workgroup, or I should say made up of state and territory regulatory officials. We do have EPA participating as well in this preliminary stage, so to kind of put this project together. As it moves through various stages, this core project management team will be laying out the long-term plan, and then they will be in the next phase, execution teams to kind of work on some of these priority areas. And as we move forward, we'll be bringing in other stakeholder groups, so for example, pesticide safety educators, members of the regulated industry, you know, user groups as appropriate and, you know, as determined by this core project management team.

And, so, what we'll, you know, ideally be able to do is if, for example, PPDC decides to have a workgroup that focuses on consistent label formatting or any other kind of, you know label-related items that someone from this label improvement project liaison with the group and work with the group as well, just to make sure that we're all moving forward. I think it would be a great way to, you know, share information, you know, not to duplicate efforts, but to certainly be able to address, you know, any issues or questions or items that come up

You know, the same would be with the emerging

technologies. As mentioned yesterday, AAPCO has a workgroup that's focusing on that. Right now, we're looking at UAVs, and we would certainly want to have somebody, you know, participate as part of the PPDC workgroup as well.

MR. MESSINA: Yeah, and this is Ed. The last thing I would add is so it might be good to provide a presentation on the latest efforts for our OPPEL or smart label work, which has a component of trying to create the label consistency within that. So at some point, if there is a workgroup formed, you know, having some liaison work and maybe getting some -- getting the workgroup members educated on agency efforts, along with state efforts. It might be a good first step.

MS. TROSSBACH: And, Ed and Rick, I would certainly offer to provide additional information, you know, in the future about AAPCO's and SFIREG's label improvement project if that would be of benefit to the group.

MR. KEIGWIN: Thanks, Liza. I think that was important context as we think about what workgroups we'd want to have.

Okay. I'll put out kind of a last call on any additional workgroup ideas.

Okay, generally how PPDC workgroups function is this is that they are an opportunity to broaden participation beyond PPDC members to ensure that we're bringing additional expertise into the discussion, so workgroups, now each should have some members of the PPDC, in fact, need to have some members of the PPDC on them. We can bring in non-PPDC members to be part of the discussion.

The workgroups themselves, the work does not represent formal recommendations back to the agency, but what they do -- how they do function is they develop work products that would then be brought to those PPDC meetings for discussion, and they might even have some recommendations for the PPDC to consider. The PPDC would then after hearing the presentation from the workgroup have a discussion, and then the agency would ask the PPDC if there is consensus on the workgroup's product or as modified by the PPDC. And then that would then be considered to be the advice that was received through the PPDC.

So I know that sounded a little bureaucratic, but I just wanted to give people a flavor for kind of the functions and how it works. We've had some great success with workgroups, and like I said, it's a way to bring additional knowledge and expertise and

membership into the workings of this body.

So in terms of next steps, it sounds like we have potentially three or four workgroup ideas that have come forward. We may want to split, for example, the emerging technology piece into one that's more equipment-focused and one that's more focused on pest management systems, but -- so potentially the list is -- if we were to split the emerging technology group in the way that I was offering potentially we could put resistance management there. It might fit better there than emerging pathogens, although there could be a resistance management aspect to emerging pathogens.

Let me see if there are any other ideas that come forward. I see a couple more people typing in the chat box.

So a question from Charlotte was can you remind us of the timeline for a workgroup. So workgroups are meant to be short-term in nature. So what we would do is give -- is the PPDC would give the workgroup a specific charge or direction on a specific topic that we would like them to further develop, at which time they would come back to us with a work product for our consideration.

So in the past I know we've had workgroups that have gone for quite a bit of time. We've

received some advice from the Federal Advisory Committee expert that there are -- are not the best practice for a workgroup, but that doesn't mean we can't have subsequent workgroups that are also -- and I'll use the emerging pathogens one as kind of a public health workgroup example. We could have multiple iterations of a public health workgroup, but they would have a specific charge.

If we decided that we wanted to have a group, like, kind of permanently focused on a given topic, that would be considered to be a subcommittee of the PPDC, and we would essentially have to go through the same type of chartering and membership drive and everything that we went through to recharter and constitute this current version of the PPDC.

It's my understanding that this is where I may need help from Shannon as our designated federal official to confirm or correct what I said. Shannon?

MS. JEWELL: I'm sorry, Rick. Could you repeat the question.

MR. KEIGWIN: Yeah, the question had to do with, you know, if we were to have a workgroup that was longstanding, I think the advice we've received is that would probably need to be a subcommittee, and we'd -- if it were a subcommittee, I believe we'd have

to go through the chartering and membership process, similar to what we went through to constitute this PPDC. Is that correct?

MS. JEWELL: That's exactly correct, yes. Workgroups are supposed to be -- have a narrow focus for a limited time. And the subcommittees, it's very formal, and they also have to be appointed by the Administrator.

MR. KEIGWIN: Okay. Again, not a reason to do it. I just -- for purposes of edification for the group, I wanted you to just be aware of that process.

A couple of people, David and Komal, have suggested that the resistance management piece maybe be brought -- maybe should be broken out into a standalone workgroup.

So for purposes of the whiteboard, Shannon, maybe let's move resistance management into one of -- into a standalone workgroup, separate from the emerging technology work.

Okay, we've got one more comment coming in.

Damon writes, Given that emerging technology is ongoing, should it be a subcommittee? We realize it's a difficult piece in forming them, but it may be needed.

Okay. You know, one option for us to

consider is that a group could start as a workgroup and then -- so it doesn't have to be either/or. Something could start as a workgroup and then over time, if we decided to make it more permanent would be appropriate to make it more permanent, we could consider pursuing making it a subcommittee.

Joe asked, Many of the titles we've heard about during the meeting and the proposed group seem to be topical. Is there a need for cross-cutting issues group? NIOSH implemented some of these cross-cutting groups as part of the national occupational research agenda. Possible topics might be health inequity.

So we could put that down as a potential additional workgroup, Shannon, maybe just call it cross-cutting issues workgroup.

And then Mily asks, Are we all going to have groups related to PRIA, WPS, certification and training, or it's just for some topics?

So, Mily, let's put your suggestion for WPS and certification and training group on here as a potential option.

So I think if we include cross-cutting issues we're now at one, two, three, four, five, or six potential workgroups. Any other suggestions before

the last part of the input that we want to get from the PPDC this afternoon relative to workgroup formation is how many workgroups do we think we can effectively have and make meaningful progress, because we will need active participation from both members as well as bringing in external folks.

So while people are thinking about that, Mano asks, Who leads the federal emerging technologies group, how can we join, what groups? I think those are two separate questions.

Ed, do you want to speak to who leads the federal emerging technologies group?

MR. MESSINA: Sure. It would be -- yeah, it would be Walt. Are you looking for me to step up? I'm happy to do that. Are we looking --

MR. KEIGWIN: Well, I think -- and, Mano, if you want to come off of mute to clarify your question, I think he's asking who leads -- he says who leads the federal emergency technologies group. So there's been some discussion already about a preexisting group outside of PPDC, and I think he's asking who leads that effort.

MR. MESSINA: Sure.

MR. BASU: That is correct. Yeah, thank you.

MR. MESSINA: Okay, great. (Inaudible). Yeah,

so I'm sort of the de facto lead on the EPA workgroup, but there are others -- Dan Rosenblatt in RD; there's Jeff Dawson, who's our senior scientist within OPP; Amy Blankenship has been taking a lead role, and the meeting was referenced coming up in June. So I'm both sort of, you know, in my main portfolio, and I've been a liaison that's been working with the AAPCO/SFIREG group on the technologies workgroup, so we've attended a number of those meetings with Robby Personette and again, Jeff Dawson and Dan Rosenblatt and I have sort of been tag-teaming that policy group, if you will.

Anything else I should mention --

MR. KEIGWIN: Thanks, Ed. No, I think that's good.

And, then, Mano, I think your separate question about how can people join a workgroup --

MR. BASU: Yeah, this was the PPDC workgroup, Rick.

MR. KEIGWIN: Thank you. Yeah, I thought that's what you were referring to there. Once we've decided which workgroups we would want to have, we would send out first a note to PPDC members to see who would be interested in joining, and then we would have sort of a call with members who had raised their hand for those particular workgroups, at which time we'd have kind of an organizational discussion within that

workgroup on what other individuals or perspectives or expertise that we think we needed to bring into the workgroup for the workgroup's efforts to be successful. I hope that helps.

Carol comments that she thinks that the applicator certification workgroup may be premature until EPA has completed the first round of reviews. And then Liza says prior to determining how many workgroups or which workgroups PPDC should have I think the purpose or issues to be addressed need to be discussed. And thanks, Liza. I think that's a good suggestion.

All right, and let's have that. I will put out, there are some limitations on how many workgroups I think we can have, just from a bandwidth standpoint. Your point is a good one. Now that we have these ideas, maybe have our discussion about what each of those workgroups could be, or a suggestion from the PPDC could be for you to ask the agency to go flesh out what these ideas would be, and then we would come back to the PPDC.

Komal asks if there are existing workgroups that should be sunset. I would have to ask Shannon. I know the public health workgroup is still in existence. I think we did sunset a number of the

other preexisting workgroups, but I would have to go back and check the status of that, right, Shannon?

MS. JEWELL: Yes. Can you hear me?

MR. KEIGWIN: Yes.

MS. JEWELL: The public health working group is the only one that is technically still in operation. That said, they really aren't working anymore, and so the question was asked last year as to whether it should be continued with a new topic, but they finished up the current -- or the previous topic, which was an emergency preparedness plan. So unless they pick up adding something like situations with pandemics to that plan, I don't know that they'll actually be operational anymore at all.

That said, we were thinking maybe three-ish groups would probably be the maximum that would really be feasible workload-wise. So does that answer your question?

MR. KEIGWIN: Yeah, that helps, Shannon. Thank you.

A couple more typing in the chat box.

So Carol suggests that we ask PPDC members to provide Shannon with more detail for suggested workgroups, and then EPA could flesh out an overall scope and some issues to get things rolling, then

folks could volunteer. And Damon is concurring on that concept. He says given the venue, which is great by the way, I think the agency forwarding purpose and issues to us would be helpful. These could then be discussed and decided upon at that time.

And then Sheryl asks, I thought workgroups ended. Wasn't the charter renewed this year? I may be incorrect, but that was my understanding.

So you're right, Sheryl, the charter was renewed. Workgroups are somewhat informal, whereas subcommittees would be a little bit different. But as Shannon, as our GFO has just chimed in, a continuation of the public health workgroup technically, the ending group, so thank you for that clarification.

Any other thoughts? If not, I like Carol's suggestion that perhaps outside the meeting people could send to Shannon some additional details for each of these suggested workgroups. We would then, at EPA, kind of flesh those out a little bit more, develop an overall scope, and then come back to you all, and then when you see what these groups might look like, we could then prioritize these a little bit more.

As Shannon was indicating, I do think three is probably the maximum, at this time, given other priorities that are before us that we could probably

effectively engage in, and I suspect many of you with more heavy workloads could have some likely time limitations as well.

So let me see if, one, there are any further suggestions for workgroups, and then if people are okay with that proposed path forward, and rather than everyone chiming in yes or no, maybe let's just see if there's anyone that has a proposed different course of action. You could type that in the chat box.

I mean, I thought I saw somebody typing but then it stopped, so I just want to give them just a minute.

Charlotte suggests assigning an owner to each one to draft the proposal. So in that vein, might I suggest that first person who put forward each of these concepts send us a sentence or two on -- to Shannon -- what each of these might be, and then EPA could take that next step. If that works -- I'm scrolling back to the top where we got -- where we began the discussion. I don't want to penalize people necessarily for raising their hands first, but several people weighed in on emerging technology, but -- so we'll get some suggestion there.

Might I ask Amy to kind of flesh out the label consistency concept? And then perhaps Komal to

flesh out a little bit more the emerging pathogen concept? Let's see. Maybe Gary -- somebody else who suggested resistance management be its own workgroup, so one -- maybe, Gary, could you flesh out the resistance management one a little bit more?

Or, sorry, David, I think is the one who suggested it be a standalone, so perhaps David for that one.

Maybe, Joe, if you wanted to flesh out what a cross-cutting issues workgroup might look like.

And, then, Mily, if we could ask you to flesh out what the WPS and certification workgroup might look like.

Which one did I miss? I think we kind of moved the emerging pest management approaches into its own group. Does anyone want to raise their hand to flesh out what that one might look like?

And then I think we do need somebody to flesh out the -- kind of the emerging technology, kind of more the equipment-focused one.

(Inaudible) people more time.

Dan, did you have a comment?

MR. KUNKEL: Can you hear me all right?

MR. KEIGWIN: Yes, go ahead.

MR. KUNKEL: Good? Okay. Yeah, I kind of

started the emerging technology note, and I mean, I have to say I'm not an expert by any means. I just supported this working group because I felt like there's a lot of emerging technologies, and it's moving a lot faster than what we're seeing label language. It seems like we've been discussing this for several meetings, and I haven't seen much, obviously not on labels.

So I guess with that said, at the same time, I thought there would be a groundswell of specialty crop growers looking for making applications of pesticides with some of these emerging technologies, like the UAVs, but I haven't heard that from my perspective. I mean, they use them for scouting and whatnot, so -- but at any rate, I'm not an expert, so I don't think it would be appropriate for me to chair the committee. I wouldn't mind participating in it.

And possibly another alternative could be something like to have some of the PPDC members to liaison with some of these other working groups that we've mentioned with the federal agencies and state agencies working together. So I just wanted to put a couple of those comments out. Thank you.

MR. KEIGWIN: All right, thanks, Dan. And just to clarify, we weren't asking for chairs of the

workgroups at this point, but it looks like Mano may have raised his hand to help flesh out developing a description on the emerging technology group.

MR. BASU: Yeah, Rick, we are happy to help with developing a description for the emerging technology.

MR. KEIGWIN: So hopefully between Shannon and Carla we captured who was going to kind of develop those statements. Once we have those and EPA has kind of fleshed those out a little bit more, we will recirculate those to everybody, and then we'll find a way to convene to kind of prioritize the list. It will be important once we identify which workgroups we're going to form that we have representation and participation from all perspectives.

We want to make sure that when advice ultimately does come forward to the workgroup that the workgroups' work products have been informed by the multiple perspectives that are represented on its group. So even if you weren't able to raise your hand now, you still have an opportunity to not only inform how the group might be directed but also to participate.

Okay, if there are no other comments relative to workgroups, perhaps we can transition into the

public comment period. And so with that, I believe we have two public commenters today, and they happen to be the same two public commenters from yesterday. So we'll go in reverse order from yesterday. The first person would be Ray McAllister. Ray?

If we can unmute Ray's line.

MR. MCALLISTER: Can you hear me now?

MR. KEIGWIN: Yes, Ray. Thank you.

MR. MCALLISTER: Okay. It takes multiple unmutings to make this work right, I guess. I just had a few follow-up questions regarding the workgroup process. Can people who are not members of the PPDC participate or volunteer or be nominated to participate on those groups? And how soon would you make decisions regarding the workgroups? Must it wait for the next PPDC meeting, or can they get underway before then?

MR. KEIGWIN: Thanks, Ray. So the first one is easier for me to answer than the second one. The second one I may need some help from Shannon. But relative to the first one, yes, non-PPDC members can participate on workgroups. We just need to have some of the membership be PPDC members. In terms of getting the workgroup started, I'd like to work with Shannon to get some further input from the PPDC

intercessionally so that the workgroups could get going before the next meeting.

And, Shannon, maybe a question for you, if that's feasible or if we have to wait for a formal meeting of the PPDC to get the workgroups going.

MS. JEWELL: I don't believe that we do, no. We can start working through that and getting staff assigned and start forming them.

MR. KEIGWIN: Okay, great.

MR. MCALLISTER: (Inaudible).

MR. KEIGWIN: Thanks, Ray.

And, then, I believe Dave Tamayo also had a comment, so, Dave, if you are available, we can unmute your line and make your comment.

Just a reminder, pound-six.

MR. TAMAYO: How about now, can you hear me?

MR. KEIGWIN: We can hear you, Dave. Thank you.

MR. TAMAYO: Oh, okay. Yeah, thank you very much. Yeah, I'm with the County of Sacramento Stormwater Program, and I'm also the Chair of the California Stormwater Quality Association pesticide subcommittee, and we have a long history of communication with EPA on pesticide issues that impact urban receiving waters.

I wanted to comment on the risk assessments. Thank you very much for a very informative presentation this morning. I did want to just repeat some things that -- some I think deficiencies that we've noted over the years, and sometimes they're dealt with satisfactorily, and other times, and I realize that OPP's a fairly large organization and sometimes things that appear to be etched in your process don't translate over to the next registration action.

So I'll just go through a list of these. We've submitted letters that have more detail on these. So one of our first concerns is that frequently -- or, no, I'll take back frequently, but on occasion the toxicity data that's used in the risk assessment doesn't really include the sufficient range of test organisms that are looked at to adequately assess the ecological risk. And in particular sometimes there's things that are clearly more sensitive and more relevant in -- given a certain active ingredient or mode of action. And, so, we'd like EPA to take a look at how they can use a more robust data set to look at in the risk assessment. And it's -- we've found that it's generally not -- hasn't been consistent with the test organisms that

are used in the Clean Water Act world where we're held -- as regulated entities, we're held to certain types of test organisms that are intended to reveal lower -- a higher sensitive organisms that are better representative of ecological risk in our receiving waters.

And I've also found that it's fairly often that the assessments -- the risk assessments don't accurately reflect an accurate knowledge of common use patterns. And I'd like to suggest that your staff have -- gain a better awareness of the types of data sources that they can use to get a handle on how things are actually used in the real world. And just as an example, we've found that there have been statements that have been made of how things are used that are contrary to some very robust data in the California Department of Pesticide Regulation, pesticide use reports. They're very easy to find. It's publicly available data. And it's somewhat puzzling when that kind of information is not used to look at, well, what are the use patterns that are actually occurring around the country.

And then another shortcoming we found is that the model parameters that are used, they don't really reflect the types of urban applications that we know

occur, at least in urban areas that are similar to the urban areas of California. And we provided information on how the Department of Pesticide Regulation has adapted different parameters but within the same models that are used by EPA. In fact, they're an EPA model.

So I would suggest that you continue to look at how to fine-tune those models, the use of those models to better reflect conditions in California, so -- or in California areas.

That being said, I wanted to switch to a few comments on neonicotinoids, and just to reiterate some points that we made in the recent letter that we turned in, I believe it was back in March, as your -- since your risk assessment for the neonicotinoids, in particular, imidacloprid (inaudible) know they predicted that -- or identified that there's a significant aquatic risk associated with these, even in urban areas. And we're wanting to reiterate that even with that finding the risk assessment underestimated the risk because it ignored some pretty obvious pathways and use patterns that would contribute to impacts on urban receiving waters.

And in our letter, we did suggest a number of additional mitigation measures that we would like EPA

to consider because the proposed mitigation measures did not seem to accurately reflect a need to address the risk that had been identified in your own risk assessment. And a number of those are based on further restrictions on uses on impervious surfaces that are a clear pathway to urban receiving waters, and then also further restrictions on impregnating materials, or at least labeling of impregnating materials so that the end-users know that there are neonicotinoids in this and if they don't want to use it in a place where these things can discharge the active ingredients to our surface waters that consumers would have better information on that. And as I said, there's additional detail in the letters that we've submitted recently.

And thank you very much and hello to everybody that I've worked with over the years. Thank you.

MR. KEIGWIN: Thanks, Dave.

I just want to confirm with Shannon that we don't have any additional public commenters.

MS. JEWELL: You know, actually we do have a late-breaking comment, and so I'd like to invite Kelly Moran actually to make a comment.

MR. KEIGWIN: Great. Thank you.

Kelly?

MS. JEWELL: Kelly, you have to press --

MS. MORAN: Thank you. Hi, can you hear me? Can you hear me?

MR. KEIGWIN: Yes, we can hear you, Kelly. We can hear you, Kelly.

MS. MORAN: Sorry about that. My name is Kelly Moran. I'm a scientist, and I work with municipal wastewater treatment plants in the San Francisco Bay Area on pesticides, water pollution. And I do want to thank the scientists from the EPA staff for their review of EPA's risk assessment methods and for the decades of hard work that have gone into developing predictive methods for pesticides, which is no small challenge, and the hard work that they do.

The purpose of my comments is to let the PPDC members know some of the same things that Mr. Tamayo was just saying, that those methods have been focused on agriculture and are really robust in some areas, but are less robust in other areas, in particular, half of all pesticide use puts a lot of antimicrobials, in particular, are used in urban areas in our nation and we don't really think about that.

But our predictive modeling methods that EPA

has available to it right now are not robust and often underestimate or completely omit exposure pathways that have proven through scientific research to be quite important environmentally. The two big gaps are municipal wastewater treatment plants and discharges through those which occur, for example, the COVID-19 antimicrobials are probably generating a lot of discharge right now, as well as pet flea spot-on treatments for which there is a robust set of scientific studies showing a strong weight of evidence that those are connected to effluent concentrations of some of the pet flea spot-on treatments that exceed toxicity thresholds.

EPA has not addressed any of this in any of its risk assessments and, in fact, rather horrifyingly so omitted the pathway completely from both its neonicotinoid risk assessments and the recent fipronil one that was just released. So that's something that we understand that the science needs to be built to do that modeling. We've been providing information and support for that for almost two decades now and are hoping that EPA can find scientific resources to address that. We recognize these resources are limited but the cost of POTWs associated with the effluent toxicity and Clean Water Act noncompliance

and Endangered Species Act compliance issues quickly run into the millions of dollars.

There is also a gap, as Mr. Tamayo mentioned, regarding urban runoff, and I will note that EPA has robust and numerous scenarios for modeling for various crops and locations around the country but practically none for urban. They've got a couple of averaged scenarios nationwide that certainly don't match conditions in New York City or San Mateo, California, or Phoenix or Seattle or other places where there's a lot of impervious surface and used for various reasons.

So these are things that the PPDC -- I wanted to make you aware that there are these gaps and they have resulted in water pollution that the kind of lagging indicator is the number of 303(d) listings under the Clean Water Act for impairment of waters, which are extensive. I think in California alone there are hundreds of them, and we're expecting hundreds more as the data catch up with through the regulatory process, which can take a decade or longer.

There's a recently published paper in Environmental Toxicology and Chemistry that tells the story of this and importantly tells the story of how improved good quality and thoughtful modeling and use

of monitoring data to improve that modeling can inform risk management measures that allow and provide for robust pest control measures and continued use of pesticides, but really by understanding those exposure pathways and honing in on what the sources are, which are usually only a tiny fraction of all of the uses, it's very, very possible to develop mitigation programs that continue use of most pesticides.

So the goal here is not to eliminate pesticide use but rather to have more robust management programs so that we can avoid the externalized costs, which I will also point out are not being addressed right now in EPA's assessment, so when a proposed decision comes out, it does not describe that when a pesticide is allowed to occur in urban runoff at concentrations exceeding toxicity threshold that could trigger Clean Water Act compliance costs that total billions per large watershed areas. So, I mean, we're not talking small amounts of money.

And the same on the POTW side, that the costs nationwide can be simply unbelievable. So there is a very significant public need to do this, and it's a really, really important step for EPA to take. So I am hoping on behalf of the agencies that I represent

that the PPDC will keep this in mind as it's giving advice to EPA about prioritizing its efforts so that these issues can be addressed and addressed in a way that's productive for everyone.

Thank you. I really appreciate the time, and I really appreciate your listening. Thank you.

MR. KEIGWIN: All right, thanks, Kelly.

Okay, with that, Shannon, is there anything that we need to do to conclude the meeting?

MS. JEWELL: I don't believe so, Rick. Sometimes at the end of meetings we do discuss the next dates for the meeting. Right now, we are so in flux, both with the pandemic and our impending move to DC that I think we'll need to reach out to the members going forward and probably do a Doodle poll based on the dates that we can get as well as the venue that we'll be able to obtain for the next meeting, so please stay tuned for that, members. And otherwise, that's all I know of, Rick.

MR. KEIGWIN: All right, thanks, Shannon.

And let me just thank publicly again Shannon and Carla and Troy and Clive, and I'm sure that there were others in the background who helped us move what has been a quarter-century of meetings in-person in relatively short order to trying to do this through

virtual means. So thank you all for that. For our first go at it, I think it actually went rather well. We would invite the members to give us, you know, offline some feedback while we would all, I'm sure, hope that we're not in a pandemic situation this fall. If we find ourselves there or maybe even for other purposes, I'd invite the members to give us some feedback on the use of this as a potential platform for our future work.

I think with that, I'll just say thank you to everybody for your participation over the last couple of days, and juggling your schedules to participate over the last two days. We really appreciate it. And we hope that you and your families stay safe during this very difficult time.

Thank you all for participating, and have a good rest of your day.

(Multiple simultaneous sign-offs.)

(Meeting adjourned.)