U.S. ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING

Wednesday, June 5, 2024

11:00 a.m.

DAY 1

PESTICIDE PROGRAM DIALOGUE COMMITTEE ROSTER

June 2024

NAME	AFFILIATION
User/Grower Groups/ Farmer Representatives	
Andrew Architect	National Pest Management Association
Bob Mann	National Association of Landscape Professionals
Claudia Arrieta	Cargill
Gary Prescher	National Corn Growers Association
George Parker	National Agricultural Aviation Association
Grant Morris	National Potato Council
Jill Schroeder	Weed Science Society of American
John Wise	IR-4 Project
Kim Brown	University of Tennessee
Patrick Johnson, Jr.	National Cotton Council
Robert Nielsen	Gold Course Superintendents Associations of America
Environmental/ Public Interest/ Animal Welfare Groups	
Alexis Temkin	Environmental Working Group

NAME	AFFILIATION
Anna van der Zalm	People for the Ethical Treatment of Animals
David Shaw	Mississippi State University
Ed Hardy Kern	American Bird Conservancy
Kelly Bills	Pollinator Partnership
Nathan Donley	Center for Biological Diversity
Rosemary Malfi	The Xerces Society for Invertebrate Conservation
Farmworker Representatives	
Alexis Guild	Farmworker Justice
Becca Berkey	Northeastern University
Emma Torres	Campesinos Sin Fronteras
Mily Treviño-Sauceda	Alianza Nacional de Campesinas, Inc.
Public Health Representatives	
Alanna Bares	California Environmental Protection Agency
Daniel Markowski	American Mosquito Control Association
Joseph Grzywacz	San Jose State University
Marc Lame	Indiana University

NAME	AFFILIATION
Chemical and Biopesticides Industry/Trade Associations	
Anastasia Swearingen	American Chemistry Council
Daren Coppock	Agricultural Retailers Association
Keith Jones	Biological Products Industry Alliance
Ligia Duarte	Household & Commercials Products Association
Lisa Dreilinger	Arxada
Manojit Basu	CropLife America
Terry Kippley	Council of Producers and Distributors of Agrotechnology
State/Local/Tribal Government	
Brian Verhougstraete	Association of American Pesticide Control Officials
David Heimer	Washington Department of Fish and Wildlife
Eric Gjevre	Tribal Pesticide Program Council
Wendy Sue Wheeler	Washington State University

NAME	AFFILIATION
Federal Agencies	
Ed Messina (Chair)	Office of Pesticide Programs Environmental Protection Agency
Gina Shultz	Ecological Service US Fish and Wildlife Service
Kimberly Nesci	Office of Pest Management Policy US Department of Agriculture
Walter Alarcon	National Institute for Occupational Safety and Health Centers for Disease Control and Prevention

I N D E X

P R O C E E D I N G S

DAY ONE - JUNE 5, 2024

MEETING LOGISTICS

JEFFREY CHANG: I'm going to start now. Good morning. Warm welcome to members of the public, Federal Advisory Committee members, workgroup members, EPA and other agency staff who have joined virtually. This is Day 1 of June 2024 Pesticide Program Dialogue Committee meeting.

My name is Jeffrey Chang, the designated Federal Official for the PPDC and moderator for the next two days.

If technical issues arise, please bear with us. If you have any technical questions, please email Kevin Annas as Annas.Kevin@EPA.gov. That's A-N-N-A-S.K-E-V-I-N@epa.gov.

Accommodations, ASL, CART, and translation services are available.

In just a moment, I'll pass it over to Deputy Assistant Administrator for Pesticide Programs Jake Li to officially open the meeting. But before I do, I want to go over some quick housekeeping items as we get started today.

I want to draw your attention to the interpretation button on the bottom panel of your

Zoom window, to the right of your screen. In just a moment, I will enable interpretation. Regardless of your preferred language, you will need to click on that button and select either English or Spanish and mute original audio to be able to fully participate in the meeting. This will place you in either the English or Spanish channel, and as we anticipate a bilingual meeting today, it is important that you choose one of these channels.

For our Spanish-speaking colleagues, I will now turn it over to Jacqueline, who will provide these instructions in Spanish in the main channel.

(Instructions in Spanish.)

JEFFREY CHANG: Thank you, Jackie.

Give me a second. Is interpretation enabled? I'm sharing the screen, so I can't -- give me a second.

Okay. Let's move forward. Elton or Faraz, is interpretation on?

MALE: Yes, interpretation is on.

JEFFREY CHANG: Okay. Perfect.

THE INTERPRETER: I am sorry to interrupt. I am not in my channel.

MALE: You're not in your channel?

MALE: Jeffrey, you can just make me a host. I can set that up.

JEFFREY CHANG: Okay. Sorry, guys. Give me a second.

Nope. You know what, I can do it. I believe you are added now, Jackie.

THE INTERPRETER: I am not.

JEFFREY CHANG: Nope?

Kevin, you're a host now.

KEVIN: She's in there now.

JEFFREY CHANG: Great.

Closed captioning and live transcription is available to those who use the service by checking the closed captioning button in the bottom panel of your Zoom screen. We also have an ASL interpreter today and CART provider. These services can also be accessed through the interpretation button used to select Spanish translation.

If you're a member of the public, unless you indicated interest in providing oral comments when you registered, you will be in listening mode for the duration of the event. If you did not preregister for comment, you may email me at Chang.Jeffrey@epa.gov or use the "raise hand" function once we come to the public comment period

at the end of the day and we will do our best to recognize you during the public comment session on each day of the meeting after we recognize those who signed up to make public comments in advance.

PPDC and workgroup co-chairs are designated as panelists in Zoom, meaning that they can request to be recognized during the discussion sessions by using the "raised hand" function and can unmute themselves and activate their webcams after being call upon. It is very important that you remain muted with your webcam off unless you are recognized to speak.

Today's meeting is being recorded for the purpose of having meeting transcripts produced. We ask that all presenters speak slowly and clearly to ensure that everyone can understand and participate fully in the meeting. Conversations should take place orally. The chat function should only be used to contact the meeting host.

Finally, as I recognize members of the PPDC and public for comments, I'll do my best to correctly pronounce your names, but I apologize ahead of time if I mispronounce your name and ask that you please correct me in the case that I do.

I will now hand it over to Jake Li, Deputy

Assistant Administrator for Pesticide Programs, to give a welcome message.

Welcome, Jake.

MEETING WELCOME

JAKE LI: Great. Thanks very much, Jeffrey. And good morning, everyone. Welcome to the PPDC.

This is a new cycle of membership. So we wanted to give our new and returning members a really warm welcome. We actually got a lot of interest in membership over this past cycle and we really appreciate our new members for their time and the perspectives that they're going to provide.

We have members from various organizations, including industry, nonprofits, universities, and collectively they represent a really wide range of stakeholders that I know care a lot about our work. We really appreciate that you're here to learn about our work and to actually help us do a better job.

As Jeffrey has noted, we have a really full agenda today and tomorrow. I'm going to talk a bit about the PPDC and its charter and what we're here to do today.

So first up, let me refresh everyone on

what the PPDC is charted to do. It's a Federal Advisory Committee formed in 1995 under the FACA, which stands for the Federal Advisory Committee Act. And the point here is to create an orderly process for federal agencies to seek collective advice from customers, partners, and stakeholders.

FACA establishes the procedures for how federal agencies need to manage these Federal Advisory Committees to ensure transparent decision-making by the committees and to ensure balanced representation.

So PPDC supports EPA in work under FIFRA, under the Food, Drug and Cosmetic Act, under the Food Quality Protection Act, and under the Pesticide Regulatory Improvement Act. Our Office of Pesticide Programs is entrusted with ensuring that Americans aren't exposed to unsafe levels of pesticides in foods, protecting Americans from unreasonable risk, of educating pesticide applicators and others who may be exposed to pesticides and protecting the environment, special ecosystems, and wildlife from pesticide risk.

The PPDC is a policy-oriented committee that provides policy advice, information, and recommendations to EPA. The PPDC provides a public

forum to collaboratively discuss these pesticide issues, including regulatory development and reform and how EPA implements its pesticide program. These evolving policy issues may include OPP's work on environmental justice, climate change, pollinators, and endangered species protection.

Now, with this background from the charter in mind, I want to give you a bit of background on the workgroup updates that you're going to hear about today and tomorrow. This is really just a refresher for those who are familiar with the workgroup and an introduction for those who aren't familiar. So workgroups are sometimes formed to help the PPDC with research, information gathering, and documenting and drafting support documents for the full committee to consider.

Now, as described in the PPDC charter, workgroups and subcommittees are formed either by EPA or with EPA's approval for any purpose that's consistent with the charter. These subcommittees or workgroups may not work independently of the charter committees and they must report their recommendations and advice to the PPDC for full deliberation and discussion.

Subcommittees our workgroups have no

authority to make decisions on behalf of the committee, nor can they report directly to EPA. There are four PPDC workgroups that were formed in 2020. These workgroups explored charge questions on emerging and viral pathogens, emerging agricultural technologies, farmworker and clinician training, and pesticide resistance management.

These are all really pressing issues for OPP and we continue to develop practical and protective approaches based on some of the recommendations that came out from these subcommittees and that went through the full committee.

The reports and the presentations are on our website, including the full transcripts of everything that was discussed during the meeting. This is also true of the past PPDC meetings.

In 2022, the PPDC voted to have the Label Reform Workgroup and the Resistance Management Workgroup Number 2 to handle three charge questions that came out of the original Resistance Management Workgroup. And, finally, at the most recent and this last PPDC meeting, the PPDC voted to reform the Farmworker Workgroup. This means that the Committee currently has four active workgroups, the Label

Reform Workgroup, the second Resistance Management Workgroup, the Emerging Pathogens Implementation Committee, and then the Farmworker Workgroup.

The Label Reform Workgroup will update the PPDC on their progress after lunch today and the Emerging Pathogens Group will talk, and we'll conclude with Resistance Management. Tomorrow, we'll hear from the Farmworker Workgroup. Each session will be followed by a discussion about the whole PPDC, and we welcome active member engagement. This is a discussion facilitated by Ed Messina, but really this is your discussion.

In addition to the workgroup updates, we have interesting sessions over the next two days based on input from the PPDC members. We're going to start off from a discussion from Ed Messina on OPP's work over the past year on science and technology and on the various deliverables that we had last year and what's happening over the next year. And then we'll have another group discussion on anything that OPP has done this past year. And you can offer advice on that work.

We're also going to share updates on endangered species activities and PRIA 5 implementation and we'll have a session on improving

how we spread information about risk reduction programs for pesticides.

The PPDC has a history over these many years of engaging in open dialogues and respectfully sharing different opinions on these issues with the goal of working together as a committee and providing advice to EPA. We're confident that the meeting today and tomorrow will result in really helpful feedback for EPA.

And, now, in concluding my remarks, I want to turn to the member introductions. I'll hand this over to Jeffrey, but before I end, I want to say to our returning members, thank you for your many years of service, and to our new members, welcome and we look forward to working with you over the coming years. Thanks again.

JEFFREY CHANG: Thank you, Jake.

Let's take a minute to walk through the agenda. In just a moment, I will roll call members of the PPDC. After that, Ed Messina, the Director of the Office of Pesticide Programs and PPDC Chair will give an update from the Office of Pesticide Programs. Then, we will break for lunch starting at 1:00, reconvening at 1:45 for an update from the Pesticide Label Reform Workgroup, followed by a

discussion.

At 2:45 p.m., we will receive an update on the Emerging Pathogen Implementation Committee with an opportunity for a discussion. After, we will hear an update from the Pesticide Resistance Management Workgroup Number 2. At around 4:30 is the public's opportunity for comment. This is the only time when we will hear from the public. As mentioned before, we will open the meeting up to those who signed up to provide comment and we'll get to as many of those who have contacted us during the meeting as time will allow before we adjourn at 5:00 p.m.

PPDC MEMBER INTRODUCTIONS

JEFFREY CHANG: Now, I will roll call members of the PPDC. I will call these in alphabetical order by first name. The list of members will be shown on the screen. Those who have an asterisk next to their name are brand new members. We thank you for your service.

When I call your name, please unmute your microphone and tell us your name, role, the organization or group you represent and their mission. And as a reminder, please mute your microphone when you are finished.

Starting first, we have Alanna Bares.

ALANNA BARES: Hi, my name is Alanna Bares. I am a Public Health Medical Officer with the Office of Environmental Health Hazard Assessment, which is part of the California Environmental Protection Agency, and my role is to train clinicians on pesticide illness and pesticide exposure.

JEFFREY CHANG: Thank you.

ALANNA BARES: Thank you.

JEFFREY CHANG: Alexis Guild.

ALEXIS GUILD: Hello. My name is Alexis Guild. I am the Vice President of Strategy and Programs at Farmworker Justice. We are a national organization whose aim is to empower farmworkers to improve their living and working conditions, and I work on our policy and programmatic work.

Thank you.

JEFFREY CHANG: Thank you. Alexis Temkin.

ALEXIS TEMKIN: Yeah, good morning. I'm Alexis Temkin. I'm a senior toxicologist at the environmental working group, which is a nonprofit research organization focused on environmental health and communicating exposures and health risks on chemicals in the environment, especially

pesticides, but also industrial chemicals and consumer product chemicals to the general public.

Thank you.

JEFFREY CHANG: Anastasia Swearingen.

ANASTASIA SWEARINGEN: Hi, I'm Anastasia Swearingen. I'm the Executive Director of the Center for Biocide Chemistries. We represent antimicrobial registrants and a range of industrial residential and consumer applications.

JEFFREY CHANG: Andrew Architect.

ANDREW ARCHITECT: Hey, good morning. Andy Architect. I'm the Chief Operating Officer with the National Pest Management Association. We're a nonprofit trade association that represents pest control operators that protect people, food, and property from pests and the diseases that they transmit.

So thanks for having me.

JEFFREY CHANG: Anna van der Zalm.

ANNA VAN DER ZALM: I'm Anna van der Zalm. I'm here representing People for the Ethical Treatment of Animals. My background is in chemistry and biophysics. I trained at the University of Oxford in the U.K., and for the past six years, I've been advisor to the PETA Science Consortium

International. And as an organization, we're made up of 25 scientists collaborating with government, industry, method developers, academics, and other NGOs to advance reliable and relevant non-animal toxicity testing approaches with the aim to protect human health and the environment.

So thank you so much for having me. I'm looking forward to the meeting.

JEFFREY CHANG: Becca Berkey. She might not be here.

Bob Mann.

BOB MANN: Good morning, everyone. I'm Bob Mann, Senior director of Technical and Regulatory Affairs from the National Association of Landscape Professionals. Good to be with you this morning.

JEFFREY CHANG: Brian.

BRIAN VERHOUGSTRAETE: Hi, there, Brian Verhougstraete. I'm with the Michigan Department of Agriculture and Rural Development. I am the Pesticide Section Manager for the State of Michigan. My program is the state lead agency for pesticide regulation in the State of Michigan. I am also on the APPCO Board of Directors.

Thank you for having us.

JEFFREY CHANG: Caleb Ragland.

CALEB RAGLAND: Here. I represent the American Soybean Association. I'm a farmer in Kentucky.

JEFFREY CHANG: Claudia Arrieta.

(No response.)

JEFFREY CHANG: Daniel Markowski.

CLAUDIA ARRIETA: Sorry.

JEFFREY CHANG: Oh, sorry, Claudia.

CLAUDIA ARRIETA: Yes, my name is Claudia Arrieta. I work for Cargill in Research and Development and I am the lead for integrated pest management in our facility working with different crops on IPMs.

JEFFREY CHANG: Daniel Markowski.

DANIEL MARKOWSKI: Hello, good morning. Dan Markowski. I'm with the American Mosquito Control Association, technical advisor representing a group of publicly-funded mosquito control professionals, researchers, academicians, industry suppressing mosquito populations and mosquito-borne diseases.

JEFFREY CHANG: Daren Coppock.

DAREN COPPOCK: Good morning, everyone, Daren Coppock. I'm the president and CEO of the

Agricultural Retailers Association. Originally, a farm kid myself, our association represents the companies that are trusted advisors to America's farmers, providing the products and services they need.

JEFFREY CHANG: David Heimer.

DAVID HEIMER: Hello, I'm David Heimer. I work for Washington Department of Fish and Wildlife as a noxious weed coordinator. And the Department of Fish and Wildlife's goal is to preserve, protect, perpetuate fish and wildlife while providing sustained fish and wildlife recreational and commercial opportunities.

JEFFREY CHANG: David Shaw.

DAVID SHAW: Good morning, everyone. David Shaw. I'm a weed scientist at Mississippi State University representing the Weed Science Society of America. The society is a nonprofit professional society that is -- whose mission is to promote research, education, outreach, and awareness of weeds and manage the natural ecosystems.

JEFFREY CHANG: Ed Hardy Kern.

ED HARD KERN: Good morning, everyone. My name is Hardy Kern. I am Director of Government Relations for American Bird Conservancy. I

apologize if anyone is having trouble hearing me. I had like an internet blip on my end, so everyone is frozen. But we focus on regulatory and policy solutions to accidental toxic threats and toxic threats to birds and other wildlife across the Americas.

JEFFREY CHANG: Emma Torres.

EMMA TORRES: Good morning. My name is Emma Torres and I am the CEO and founder of Campesinas Sin Fronteras, 501(c)(3) community-based organization located in Yuma County, Arizona. We work with the agricultural industry, particularly with the farmworkers families, providing pesticide [connection issue] environmental health and social services here in our community. Thank you.

JEFFREY CHANG: Eric Gjevre will be joining us later, I believe.

Gary Prescher.

GARY PRESCHER: Yes, good morning, everyone. I'm from Minnesota and I'm a director on the Minnesota Corn Research and Promotion Council. Through that, I represent the National Corn Growers Association and the interests of the 40,000 dues-paying members across the country. The mission

of the NCGA is to help protect and advance corn grower's interests.

JEFFREY CHANG: George Parker.

GEORGE PARKER: Good morning. My name is George Parker. I'm a second generation aerial applicator originally from New York. I operate in Crop Jet Aviation in Southern Idaho, and we make applications on regular farm crops, field crops, species, we make applications for invasive species, weed pest management for government agencies, and we also spray spongy moth forestry applications for government agencies through the Northwest.

I am here representing the National Agricultural Aviation Association, and our goal is to share perspective on aerial pesticide applicators and maintain aerial labels on the products that are so critical to our feeding the world.

JEFFREY CHANG: Gina Shultz.

(No response.)

JEFFREY CHANG: Grant Morris.

GRANT MORRIS: Hi, my name is Grant Morris. I'm a potato grower from Washington State, and I am here representing the National Potato Council.

JEFFREY CHANG: Thank you. Jill

Schroeder.

JILL SCHROEDER: Good morning. My name is Jill Schroeder and I am an Emeritus Professor at New Mexico State University. I am here representing the Weed Science Society of America and, as you know, we are a nonprofit organization with emphasis on research extension and outreach and education in all areas related to weed science and invasive species management. Thank you.

JEFFREY CHANG: Joe Grzywacz.

JOE GRZYWACZ: Hi, my name is Joe Grzywacz. I am at San Jose University where I'm the Associate Dean for Research. I am on this committee representing both public health-related research and farmworker protection and advocacy. It's great to be here. Thanks for your time.

JEFFREY CHANG: John Wise.

JOHN WISE: Good morning, everybody. I'm John Wise. I'm an entomologist by training and I'm representing IR-4, which is NIFA-funded program that develops data requirements for registry pesticides and biopesticides for specialty crops. Thank you.

JEFFREY CHANG: Karen Reardon.

KAREN REARDON: Good morning. I'm Karen

Reardon. I am Vice President of Public Affairs with the trade association, RISE, Responsible Industry for a Sound Environment, and we represent the companies that manufacture, formulate, and distribute the pesticides that would be used by consumers and professional applicators to protect people and places. Thanks.

JEFFREY CHANG: Keith Jones.

KEITH JONES: Good morning. Keith Jones. I'm the Executive Director of BPIA. BPIA is the association representing the biopesticide industry.

JEFFREY CHANG: Kelly Bills.

(No response.)

JEFFREY CHANG: Kim Brown.

KIM BROWN: Hi, my name is Kim Brown with the University of Tennessee, and I have spent a career doing pesticide safety education and working with growers and pesticide applicators on how to use pesticides safely and correctly.

JEFFREY CHANG: Kimberly Nesci.

KIMBERLY NESCI: I'm Kimberly Nesci. I am Director of the Office of Pest Management Policy in the U.S. Department of Agriculture. I represent USDA. So I'm one of the federal members on the committee. And my office, the Office of Pest

Management Policy, is the lead office for pesticide, regulatory, and policy issues for the Department of Ag. And we were established by Congress to serve as voice of growers in conversations with EPA on pesticide regulatory issues. Thank you.

JEFFREY CHANG: Ligia Duarte.

LIGIA DUARTE: Hi, everyone. I'm Ligia Duarte, Senior Director of Regulatory Affairs at the Household and Consumer Product Association. HCPA is a trade association representing companies that make and sell products used for cleaning, protecting, maintaining, and disinfecting in homes and commercial environments, and our mission is to protect, promote, and enhance the household and commercial products industry and the consumers and workers who use our members' products. Pleased to be here and I look forward to this meeting.

JEFFREY CHANG: Lisa Dreilinger.

LISA DREILINGER: Hi, good morning. Lisa Dreilinger, Global VP of Regulatory at Arxada. We are the global leaders in sustainable preservation and microbial control solutions.

JEFFREY CHANG: Manojit Basu.

MANOJIT BASU: Good morning, everyone. Manojit Basu. I am the Vice President - Science

Policy at CropLife America. CropLife America represents the developers, manufacturers, formulators, and distributors of pesticides and planned science solutions for agriculture and pest management in the United States. CLA's members produce, sell, and distribute virtually all pesticides and biotechnology products used by American farmers. Thank you.

JEFFREY CHANG: Mark Lame.

MARK LAME: [Connection issue] represent public health. I am an Emeritus Professor at Indiana University's School of Public and Environmental Affairs where I teach environmental management. And as a clinical professor, my work was in -- as an entomologist, was in integrated pest management. I implemented integrated pest management programs in agriculture, and in the built environment more recently, for the last 35 years. Now, I try to teach young folks how to become environmental managers.

This is a great committee. You'll learn a lot being on it. So welcome and thanks for having me around.

JEFFREY CHANG: Mily will be joining us later.

Nathan Donley.

NATHAN DONLEY: Hey there. Nathan Donley. I am the Environmental Health Science Director at the Center for Biological Diversity, and we work to protect people and wildlife from pesticide harm. I'm happy to be here.

JEFFREY CHANG: Patrick Johnson.

(No response.)

JEFFREY CHANG: Robert Nielson.

ROBERT NIELSON: Hi, my name is Bob Nielsen. I'm a golf course superintendent in Bedford, New York. And I'm representing the Golf Course Superintendents Association of America, which is comprised of 20,000 men and women maintaining approximately 2 million acres of turf grass.

JEFFREY CHANG: Rosemary Malfi.

ROSEMARY MALFI: Happy to be here with you all. I'm Rosemary Malfi. I'm here to represent The Xerces Society, a donor-funded, nonprofit that is dedicated to conserving invertebrate species and their habitats. This includes, but is certainly not limited to, pollinator insect species.

I work in the Pesticide Reduction Program as a policy lead, but I will actually soon be transitioning to a new role as the Director of

Conservation Policy for the organization.

Very happy to be here and to learn from you all. Thanks for having me.

JEFFREY CHANG: Terry Kippley.

TERRY KIPPLEY: Hello, I'm Terry Kippley. I'm the President and CEO of the Council of Producers and Distributors of Agrotechnology. Our members distributed approximately 85 to 90 percent of about the $16 billion pesticide market in the U.S. Our members also are inert manufacturers, in-tank adjuvants. I grew up on a dairy farm outside of Madison, Wisconsin. When I was able to convince my dad that, hey, I wasn't going to milk cows, I was an intern as a crop scout, walked potato fields in Wisconsin.

I then started my career walking soybean and cornfields as a technical agronomist for Monsanto, then went into the commercial side of the business where I was a president of a post-patent company that relied heavily upon EPA for registrations, and now I'm happy to support the industry, and the focus of our group has really helped farmers with agrotechnology. And happy to be here.

JEFFREY CHANG: Walter will join later.

Wendy Sue Wheeler.

WALTER ALARCON: I am here.

JEFFREY CHANG: Oh, sorry, Walter.

WALTER ALARCON: Good morning. My name is Walter Alarcon. I am a research epidemiologist with NIOSH CDC. My role is (inaudible) officer for the SENSOR-Pesticides Program. The SENSOR-Pesticides Program attracts acute pesticide poisonings among workers. The program is with the National Institute for Occupational Safety and Health with the Centers for Disease Control and Prevention, and we're located in Cincinnati, Ohio. Thank you.

JEFFREY CHANG: Wendy Sue Wheeler.

WENDY SUE WHEELER: My name is Wendy Sue Wheeler. I am the Director of Washington State University Pesticide Resources and Education Program. The organization that I represent is AAPSE, the American Association of Pesticide Safety Educators. AAPSE's mission is to enhance public health and the environment through involvement in education, outreach and research which directly benefits pest managers, policymakers, and the public for nearly two million people across the United States. This includes farm laborers, backyard gardeners to inner city and remote rural communities

with education and outreach each year. It's great to be here.

JEFFREY CHANG: Thank you members of the PPDC for being here today and for your service to the EPA.

Now, I will hand it over to Ed Messina, Director of the Office of Pesticide Programs and Chair of the PPDC, to give an OPP update. Thank you.

OPP UPDATES: RECENT ACTIVITIES, ACCOMPLISHMENTS, AND WORKLOAD METRICS

ED MESSINA: Thanks, Jeffrey. Thanks, Jake, for opening remarks. And thank you, everyone, for attending this meeting. As folks who have attended this in the past, you know that this is one of my favorite meetings. It really brings together stakeholders from across the spectrum that are focused on protecting human health and the environment and delivering food to the table of the American citizens and the world. So it's an amazing experience, I do agree.

Hopefully, you will learn a lot and, hopefully, your experience in your own right, will provide great feedback for the agency here on various topics that are built by the PPDC members

and suggestions. At the very end of this, we'll take a survey back of how we did in terms of delivering information and see what we can do better at the next meeting and we'll take that forward to the next PPDC meeting that we will have in the fall.

I would have much rather have been with you in person. Those discussions are always fun and it's really great to have some of the side discussions and meet the people face-to-face. Apologies. Unfortunately, our budget for '24 did not allow us to have the adequate funding to have this in person, so we did go remotely. I've got a couple of slides that are of interest to many of the members and members of the public who are attending in terms of our resources and our metrics. So with that, I will start sharing my screen and walk through the various topics that PPDC members were interested in hearing about.

So let me share my screen. So hopefully, folks can see my screen. Can I get a thumbs up? And it's in slide view, so you see the big view. Thanks, Dan.

All right. So some changes to OPP in terms of folks' positions. Mike Goodis, who had been -- had a basically a 30-year career in the

Federal Government, his last day was last week. We had a number of send-offs for him. He was really instrumental in helping the Office of Pesticide Programs be the best it could be. The former director of the Registration Division, among many positions that he held and, ultimately was the Deputy Director for Programs, so that position is now vacant. We've done announcements and we are doing interviews to select somebody for that role.

Leo Gueriguian was -- who had been acting as the Deputy Director for Management has now been made permanent, so some good news there, since the last time we spoke to this group.

Liz Donovan was also made permanent as the Associate Director in the Antimicrobials Division.

And then Anne Overstreet, who was the Director of the Biological and Economical Analysis Division, and before that, the Deputy in the Biopesticides and Pollution Prevention Division, and before that, Field and External Affairs, when that was in OPP, so she's had positions in multiple divisions within OPP, she is now the permanent Director for the Pesticide Re-evaluation Division where a lot of our registration review work gets completed.

And then Neil Anderson has stepped into acting role while we do a search for a new director for the Biological and Economic Analysis Division.

In terms of folks also on this list, Monique Perron, who you will hear later from today to talk about systematic review and NAMs, which was a topic that was of interest to PPDC members and what EPA is doing there; Catherine Aubee, who is a senior advisor, who has been implementing many of the programs and the Endocrine Disruptor Screening Program, that came over in the reorg from a number of years ago into OPP, and we've got a slide on some of recent activities there; Dana Vogel, Health Effects Division Director; Jan Matuszko, Director of Environmental Fate and Effects Division, where a lot of our ESA work is coming out, we have a section on that later on in the agenda; Anita Pease, Director of Antimicrobials Division; Madison Le, Director of Biopesticides and Pollution Prevention Division; and Billy Smith, the Registration Division Director.

So with that, I will go to the next slide on budget. The PRIA 5 passed a couple years ago now, and we've been doing a lot of implementation. In fact, there's a session on that as well and related to the farmworker grants that were in PRIA

5. So we're pretty proud about that work.

The new PRIA 5 set the minimum appropriation levels for OPP at $166 million. We have not reached that level. We did have an increase in our budget for '23, which was $138 million. The '24 budget, which is, you know, partly why we've had to make cuts, was $6 million less than the '23 budget. The President's '25 budget calls for $175 million dollars for OPP and appropriations. And as folks know, we get money from fees, we get the PRIA fees and the FIFRA fees, and that represents about a third of our total budget with the appropriations representing the other two-thirds.

So with that slide on -- you know, in terms of how we have been appropriated over the years. The red line describes the PRIA minimum appropriations trigger level set by the PRIA Coalition and as ratified through Congress. As you can see over the many years, there's been a shortfall from that appropriations number, and now with the increase in that appropriations number from the $120 million up to the $166 million, the gap is a little wider in terms of the minimum appropriations trigger for PRIA 5.

Congress provides a waiver for themselves from that trigger, which is why there's a decent-sized gap between the trigger number and what OPP receives. And you can see the dip from ‘23, where there was the bump-up finally, getting closer to the PRIA minimum, but then in ‘24, a reduction from about $6 million.

We've also experienced a bit of a shortfall from the PRIA fees in that there have been recently less submissions. I have slides on some performance metrics around how we're doing to meet our deadlines and -- so there's about a $6 million difference from what we had anticipated for receiving in ‘24 from what we've actually collected. So it's actually close to a $12 million shortfall for OPP that we're trying to absorb for ‘24.

So folks have seen this chart before, but just to give a sense of the FTE numbers for OPP, we have been hovering around the 570 mark. ‘23, we ended with 552 for 2024. We are going to hold -- and the next chart will show in order to hold the FTE constant, the significant cut in contract spending and travel and other items and pushing some digital transformation work off and a little bit further out to spread that out.

So if we were to hold contract spending constant with the cuts from absorbing the '24 budget, and if we assumed that '25 was the same budget, OPP FTE would need to only be able to be supported at about 470 level, which is probably the lowest OPP's been over the many years. You can see, you know, our highest being out in the 2004, 2005 range, where we were close to 900 folks. That was pre-reorg where we had an additional 95 folks that were in various parts of OPP, including the IT and the communication's folks.

This chart has been normalized to have the 95 deducted from the program level funding. So it's normalized to show if the 95 folks were not in office in OPP in 2005, this is what this chart would look like so that it's normalized. But, generally, OPP has recently been hovering around the 570 mark.

This chart shows in order to maintain the FTE levels within OPP, which is our plan, to maintain at about the 565 level for 2024, it requires about a $34 million cut to contracts, taking that $6 million cut, the $6 million reduction for PRIA, and then also supporting the same level of FTE rather than reducing FTE, in part because we've hired -- you know, our greatest resource in OPP is

the scientists that we have here that do that cutting-edge science. We want to train folks; we want to keep them.

And so, you know, since we've hired them, we want to maintain having those folks in the office because it takes longer to retrain folks on how to do risk assessments and human health risk assessments and eco risk assessments and ESA and all of the on-the-job training that you get in OPP. So in order to preserve our greatest resource, which is the people in OPP, we're looking at $34 million cut to contracts.

Those contracts are used to support the registration and reregistration work. So a lot of the front-end contract work is, you know, looking at studies, categorizing studies, really helping the OPP staff have a package that's ready for them to review rather than sort of assembling that package and, you know, making calls on different studies and having the staff really do that federal work, which is -- only federal employees can do, which is doing that risk assessment. So the contracts really are integral to making that process more efficient and so there will be a delay in registration decisions as a result of some of the contract cuts.

Some of the immediate impacts to the budget, going virtual PPDC. So here we are, you know, sorry again, apologies. I do prefer the in-person meeting with this group and getting to see everyone, but we were not able to support the travel that we provide to the members. We had to make some tough calls.

Also, you know, we've had a number of scientific advisory panels and so those are going virtual in the future -- foreseeable future.

We've cutback on crop tours. I've got a slide on the valuable nature of having those tours, having staff go out to meet with growers and understand their needs and how their pest pressures are impacting them and the products that they use. So we've had to scale that back.

As I mentioned some of IT development, sort of slowing down some of the timing on things that we want to get done. Portal development is one of those things. We're still progressing with that, but some of our timelines have been pushed back and really trying to replace the infrastructure for where we have about a ten-year technical debt that we have to bring up to speed so we can do some of the fun things that we want to do, like electronic

labeling and labels that a smart tractor can read or really providing that information in the field to somebody who needs to know geographically where they're located and what products are available and how they might better comply with their Endangered Species Act obligations through the label language. So some important IT tools that we want to make sure that we're continuing to move forward.

We're going to basically hold constant. There probably will be a hiring freeze at OPP. We'll try to backfill, but it will be really at a limited basis to keep at the levels that we can support. As I mentioned, the significant cuts to contracts, delays to registration actions and then delays to the PRIA and non-PRIA actions.

I do have some metrics later on where we've actually, through process improvements and some of the IT work, we've actually been completing more actions. But you'll also see that the level of actions and the backlog still exits and the lateness of the actions is still pretty high.

So these are our priorities. They are consistent the last couple of years. My slide deck sort of follows the various priorities here. So we'll start with PRIA 5 implementation. We'll talk

about registration and registration review. We'll talk about Endangered Species Act deficiencies and meeting our obligations. Again, there's a whole separate session on that. I'll then talk about some of the science and other policies, like environmental justice, climate change.

Monique will help with state-of-the-art science topics, where we'll talk about the systematic review and new approach methods. I'll talk a little bit about some of the rulemaking guidance and then I'll end with our digital transformation work and show some of the new dashboards that exist internally for OPP to understand where our work is in flight and to be able to visually represent that and then make decisions about how to engage lean process improvements to review bottlenecks, which there's been a number of examples that have occurred recently.

Just to give you a sense of the overall submissions and highlights for this year, incomplete obviously for Fiscal Year 24, so far we've received about 7,000 submissions via our portal. We have completed about 1,000 PRIA actions -- sorry, we've received 1,000 PRIA actions. We've only completed

700. Only. I should say, that's a pretty big number. But as you can see, at least up until now for FY '24, we've received more than we'd be able to complete.

For the non-PRIA actions, notification fast track amendments, we've received about 1,800, and for the first time, we've actually completed more than we've received, and that is a testament to the work in Billy's group and the Registration Division, who gets the substantial workload on that. They've done a number of process improvements and focused tiger teams to reduce the non-PRIA backlog. That was a request that was in PRIA 5 for us to focus efforts there. And so we've got some positive success to share on that score. So you'll see some charts at the end of this presentation when I go through the digital transformation slides.

In terms of PRIA 5 implementation and our success, again, we have a separate session on this later on, so I won't spend too much time on this. But we're pretty proud about the fact that we issued our PRIA annual report. It is on the web. You can find it on our PRIA 5 implementation website, which once these slides are provided -- and they have been provided to the PPDC members -- we'll send out the

final delivered and then we'll post these on the web. You'll be able to click into our PRIA 5 website that is tracking all of the deliverables, for which there were many in PRIA 5.

We're working on the training set-asides to train OPP staff using an existing contract and then changing that over to a grant announcement to develop training curriculum and curricula for OPP.

There's also a requirement for OPP to do a workforce and process assessment using a contractor. We're using an existing Office of -- EPA Office Of Mission Support contract for a contractor that specializes in process improvement, so at some point, once we're able to put money on that contract, we will fund it to have that person and contractor do an assessment of OPP's processes to determine if there are some process efficiencies that we can gain and then implement those process efficiencies once the report is delivered and the pay increase or the fee increase associated -- there's two different options within PRIA 5 for OPP to -- ability to seek a 5 percent increase in fees.

And the trigger for that is that we've implemented elements of this process improvement. The first trigger was reached when we were able to

move the Registration Division through the digital transformation process and have them be in the system for which we completed fairly recently.

We are looking at non-PRIA backlog. There's lots of great work that you'll hear about later on the farmworker and the health clinician cooperative agreements and providing technical assistance to those grantees about how to seek grants from EPA, and that's in the works.

Bilingual labeling, of course, all of the outreach that's been done there; frequently asked questions which have been updated and will be placed on the web; the DER process implementation, we've got some activities associated with that; IT modernizations; and, of course, website that we launched.

Since November of the last PPDC meeting, we've made a lot of progress in a number of areas for PRIA 5 implementation, including the significant amount of outreach to multiple stakeholders on bilingual labeling; again, the backlog for reducing non-PRIA actions and the metrics there; and then the IT system we couldn't be happier with the level of agile development, sprints, improvements to the system that are occurring, and there is plenty to do

to really improve our IT systems.

We also established the Vector Expedited Review Voucher Program, so we're examining whether and to what extent new submissions that provide for the control and spread of vector-borne diseases might be able to obtain and sell a voucher. We've developed the process, as I mentioned, for sharing EPA data evaluation records with applicants at the time of the regulatory decision, rather than having to wait, which had been the practice in the past.

Supporting farmworker training, as I mentioned, the Pesticide Safety Education Program cooperative agreement, and announcing of funding opportunity for partnership grants, which we'll talk a little bit more in the later session. And then we requested, as outlined in PRIA 5, stakeholder input on program design for health care provider training under the cooperative agreements.

So now into the -- really the one area that folks were interested in in terms of the registration decisions, registration actions, before we move into registration review for which there's a number of chemicals that folks were interested in.

If you've been following the Dicamba litigation, you're aware that in February, the U.S.

District Court for Arizona vacated our 2020 decision that allowed over-the-top applications of Dicamba, particularly on soy and cotton. We issued, after that decision, an existing stocks order, which allowed product that was already in the possession of growers that were in the channels of trade that were outside the control of the pesticide companies to continue to be used for the '24 season.

It allowed for limited sale and distribution that was already in the possession of the growers and those existing stock provisions followed the labels which provided for the cutoff dates for which Dicamba would be allowed to be used up until those dates that are on the label or that were modified by individual states as part of their programs to allow the application of Dicamba over-the-top on soy and cotton based on previously approved labels only for 2024 and only to the extent that those labels allowed the over-the-top application for the dates specified on the label or as modified by the states.

We recently, I think yesterday, announced an application that we received from BASF. We have previously announced the application we had received from Bayer. The proposed products include use of

Dicamba on Dicamba-tolerant soybeans and cotton, and we provided a 30-day public comment for both of those products and we will be considering that public comment.

There is also -- will be other activities in terms of providing additional information as we head towards an understanding of the desire for soy and cotton growers to have those products in the 2025 growing season. We've made no decisions on that yet and we are working with registrants on their submissions and the process continues.

There's a lot of steps along the way, including an Endangered Species Act review and including, you know, public notice of these things and doing an entirely new risk assessment. We are looking at, you know, how we can consider the need for the 2025 growing season with all of the processes that need to occur. It's a pretty short runway. So we'll provide updates as we get closer to the '25 growing season.

Okay. Pesticide registration review, so we're going pretty well on meeting our deadline. There's about 789 cases that are due by 2026. We've done about 91 percent of the draft risk assessments; 71 remain, and we've done about 80 percent of the

interim decisions and about 173 cases remain.

At various steps along the way, as folks that are familiar with this process, we provide public notice about the preliminary work plan, we provide all of the science that we've done as part of draft risk assessment and then we, yet again for public comment, put out the proposed interim decisions so folks can comment on the mitigations for the various chemicals that are going through these steps.

It represents a lot of work from a lot of incredible staff. You know, getting a draft risk assessment done and out the door and all the review and the science that it takes and then putting that up for public commitment is no easy lift, but OPP has been pretty incredible in getting a lot of the draft risk assessments done to meet the 2026 deadline.

Some information on specific cases that folks were interested in hearing about, chlorpyrifos, in December of 2023, the Court of Appeals for the 8th Circuit vacated EPA's August 2021 rule which revoked all tolerances, which was in response to the 9th Circuit case, which told EPA to make a decision within the time frame delivered by

the Court. At the time, in 2021, we indicated that we could not make a safety finding for all of the uses that were on the labels, and so we issued the final order in 2021. However, the 8th Circuit struck down that decision and, at this time, all chlorpyrifos tolerances have been reinstated.

We also have been taking steps working with the registrants to conform the labels to the Proposed Interim Decision that had previously which indicated that although all uses of chlorpyrifos would not pass the human health risk assessment, there were a subset of uses that would pass, about 11, and so we've been working with the registrants to conform the current labels with the 11 food uses that we can make a safety finding under the 2020 Proposed Interim Decision.

So in June, you will see coming out as part of an OPP update, some existing stock's provisions and some reduction and some cancellations of products for certain products that are conforming to the 11 uses in certain geographic areas and we will continue to update the frequently asked questions around chlorpyrifos and do OPP updates where we are amending labels, again, to reduce the amount of chlorpyrifos to meet the 2020 Proposed

Interim Decision.

In addition, the National Marines Fishery Services Biological Opinion was issued and so we're heading towards meeting the mitigation measures that were proposed in the Biological Opinion in the 2024 season probably by the end of the summer. So that's the chlorpyrifos update.

Acephate, which is another organophosphate, in April, we released the proposed interim decision for that product to cancel all but one use of that pesticide. We retained the tree injection uses because they did not contribute to the drinking water concerns and water exposure that we were finding with Acephate and there were no risks to workers with those proposed label changes for tree injection.

The revised Human Health Draft Risk Assessment and Drinking Water Assessment were released in August of ‘23, and the PID was released in April and is available for public comment in July of 2024. Having worked with a number of growers on this product, we understand it's pretty important for cotton, so we're going to be looking at taking comment and considering all the comments that are associated with Acephate to make sure that any new

labels or, you know, conforming to the tree injection are consistent with Human Health Draft Risk Assessment for Acephate. So more to come on that once we receive public comment.

So the other organophosphates, which I know are of interest for many stakeholders, there's 18 organophosphates in Registration Review. Their decisions are generally scheduled to be completed by 2026, which is the deadline.

We have some upcoming actions. As I mentioned, you recently saw Acephate, but in June and very soon, you'll see Dicrotophos' Proposed Interim Decision for the mitigations proposed there; Dimelthoate's Proposed Interim Decision coming in June; Malathion Proposed Interim Decision for July, and then TCVP Interim Decision for June of ‘24. So stay tuned for a number of organophosphate chemical updates and, obviously, I will continue with that class of chemicals, and when we do the next FR notice for the new sort of quarter for all the Proposed Interim Decisions and Interim Decisions that OPP is conducting, we will update the schedule that's on the web that folks can look at to see when the expected delivery date is for the various Draft Risk Assessments, Proposed Interim Decisions, and

IDs in the coming couple of years..

DCPA was another product going through registration review, and in April, based on the risks that we had been finding with this chemical, we warned folks in issuing the Draft Risk Assessment that was associated with DCPA and announced sort of steps that we were taking, working with AMVAC, who's the company -- the sole manufacturer of DCPA to reduce the risks associated with this chemical and we're working with the registrant and we're also looking at pursuing other action, as appropriate, to reduce exposures to this chemical.

You know, we took the rare step, given some of the risks that we saw to pregnant individuals, including developing babies exposed to DCPA, as part of an OPP update, to warn the farmworker community about the concerns that we were finding. This is sort of an example of where, you know, EPA has been doing endocrine work. So some of the, you know, impacts are related to thyroid issues associated with DCPA.

So looking at those studies, we were compelled to provide an update and information about what we were finding and we'll continue, again, to pursue further action to quickly remedy some of the

risks that we're finding for this chemical.

Rodenticides Proposed Interim Decision was published in November of '22 and then the draft Biological Evaluation was published in November of '23. We received 20,000 comments on the PIDs. A lot of themes contained below in comments, basically concerns of this class of chemicals on nontarget wildlife species and exposures, misuse issues and identification of potential misuses of rodenticides, also the benefits. Obviously, you know, rodents are a vectoring pest. We want to make sure we're keeping those pests and the diseases they transmit from our food supply.

So they represent a class of chemicals that are of real importance to the grower community, both on the ag side and on the structural side, obviously. So there are certainly high benefits for the rodenticides. And then also some comments on the mitigations that we put this place, in particular, the feasibility of carcass searches and concerns related to restricted use pesticide designations and PPE.

So lots of comments that we are going to be considering and we are going to first complete the BE part of this. This is one of those areas

where our Endangered Species Act review and our Registration Review decisions get to line up a little bit, which is great, which is how we want the process to be in the future. And so we're going to issue the final BE in November, and then after issuing the final BE, the amended PID will be released around 2025.

We want to make sure, you know, we're consulting with the services as well and providing sort of an update for mitigations that are aligned both with the FIFRA Eco Assessment and with the ESA opinions that will come back from the services for the rodenticides. So some work yet to be done on rodenticides, but we're progressing and doing a lot of work and considering all the comments that came in.

Atrazine, an example of where -- if there are novel issues of science that require additional, I would say, information and feedback from external scientists, we will convene a Scientific Advisory Panel. We did that in the case of Atrazine, related to agency's look at what's called the CE-LOC. So the SAP opined on the studies that we used to develop the CE-LOC and issues related to maps or actually -- mostly the SAP was related to the

science part. And they released their document in November.

We responded to the SAP recommendations in March, and as a result, as part of the review and taking into account the Scientific Advisory Panel's recommendations, we're going to release or revise CE-LOC with updated mitigation maps, along with our next steps and a timeline related to proposed mitigations to ensure that we're protecting the aquatic plant communities. So we're hoping to do that in '24. And then revising by the end of 2024, the mitigations, the new CE-LOC watershed regression and pesticide modeling and then some -- incorporating some new available Atrazine monitoring data and then looking at public comments on the mitigations. So that's the Atrazine update.

Paraquat, so the last PPDC, I provided -- and it's in the transcript -- I would say, you know, five or six slides. We took a little deeper dive on Paraquat in the last PPDC on some of the science concerns related to this chemical. We have a petition from stakeholders regarding our 2021 Interim Decision on Paraquat. We've agreed to hold that case in abeyance while we continued to look at new data that has been provided in terms of the

science. We released an initial draft of our reconsiderations in February of ‘24. We opened, again, the docket in April, closing in April.

Then we're looking at issuing a final document describing our next steps and timelines by January of 2025 based on our agreement with the petitioners. And that document will consider additional information, as I mentioned, and then consideration of public comments that were received on the draft document. Again, one of the many chemicals we're committed to transparency and continuing to monitor the best available science to inform adverse health outcomes, including any potential links to Parkinson's disease, which we have not seen thus far, but we are looking at new studies and we'll provide an update in the coming months.

Glyphosate, as part of registration review, the ID was published in 2020. The 9th Circuit vacated this ID for the human health portion, asking us to provide additional information on how we arrived at our decisions there. The Court granted EPA's request for voluntary remand on the ecological portion, but they indicated we had to complete that by 2022. Obviously, that was a pretty

tight deadline. So we withdrew the ID because we were unable to meet the 2022 deadline. But we are continuing the Glyphosate registration review, looking at the scientific findings regarding Glyphosate, including, you know, looking at our decision as to whether Glyphosate is not likely to be carcinogenic and we continue to look at that science.

And that conclusion, up and to this point, has remained the same, but we are looking to better describe that in the future as part of proposed final decision, which will revisit and better explain the carcinogenic potential of Glyphosate, revisit the risk analysis related to the in-field effects on the monarch butterfly and other ecological risks and then complete the ESA consultation and respond to the petition related to Glyphosate. So Glyphosate continues work by the team with some upcoming deadlines and deliverables.

So ESA, an area we're really proud about and, you know, incorporating Endangered Species Act science reviews into pesticides kind of for the first time in the many years that both of those statutes have existed in 40-year span. We have an agenda item on this to take a deeper dive as well.

But, you know, generally, at the high level, we are continuing to make progress on the various strategy documents, including as we're working on the strategy documents, increasing the efficiencies for which we're able to provide biological evaluations for individual pesticides and the number of ones that you've recently seen and some new ones that are coming out in the future.

Obviously, committed to transparency and obviously committed to stakeholder input. Just yesterday, we met with the States on mitigation approaches. SPIREG was in town and there was a session covering that as well. We're looking to refine the maps to make sure that those species are protected and they are protected where their habitats and their ranges are important, and ensuring that growers are undertaking mitigations where those are needed, but also understanding and narrowing the geographic restrictions really to those areas where protections are needed for endangered species, working with multiple stakeholders who are helping us look at how to refine those -- what are called PULAs -- for where pesticide use limitation areas are needed for pesticides.

And I'll move on and say there's, again, quite a full dance card, much like for registration review, but quite a full dance card for ESA activities, you know, recently putting out the draft herbicide strategy and then looking at doing the Hawaii workshop, the mitigation workshops, outreach on refining PULAs, and then what we hope to do in mid-2024 is finalize the herbicide strategy, begin to inform our registration review decisions as we finalize that decision, releasing a draft insecticide strategy, releasing information on an online mitigation menu, which there's a webinar up and coming, which I've got some information on how to sign up for that.

And then, beyond that, obviously, continuing to work on strategies for insecticides and fungicides and, you know, beyond also getting a lot of biological evaluations done and finalizing the draft Hawaii strategy. So lots of activity under ESA.

As I mentioned, there's an upcoming ESA Mitigation Menu Webinar. We're going to hold a public webinar on June 18th from 1:00 to 2:00 p.m., to provide an overview of Mitigation Menu website that will describe mitigations and options for

reducing pesticide exposure to nontarget species and a walk-through of what the draft website will look like. So there's information for how to sign up for that in the recent OPP update and there will be a further discussion on that in the next session on the agenda for PPDC.

So in addition to this FACA group, which we love, there are other FACA groups that intersect with the work that the Office of Pesticide Programs is doing. One of the other FACA workgroups is the National Environmental Justice Advisory Council or the NEJAC, and they provided recommendations on farmworkers and pesticides. Again, there's some additional information that we're going to talk about this on the agenda as part of farmworker workgroup.

But the NEJAC provided, at our request, information and recommendations for how we could do certain activities under Spanish labeling, develop new methods to provide access to information on bilingual pesticides for farmworkers, one of the requirements in PRIA 5 that we're seeking to implement, and looking for measures, understanding exposure, and then training for inspectors who conduct worker protection inspections.

So those were the recommendations we received. These are the specific ones that they provided in April, providing information to EPA on the various topics, bilingual recommendations, worker protection recommendations. So the workgroup within OPP -- there are two workgroups that have been formed to address the recommendations associated with the charge questions. And then the fourth one, being a recommendation both to OECA and OPP related to enforcement, we've been binning those recommendations into various categories, things we're sort of already doing, things we think we can implement, and things that maybe we can't implement, you know, various categories and then providing information back to the NEJAC as requested at their next meeting and then subsequent meetings.

The other workgroup that's not mentioned here, the other FACA is called the CHPAC, Children's Health Advisory Committee, and there's a number of cross-sections with providing information on our risk assessments and feedback that we've had from the CHPAC that we're tracking as well.

The other workgroup is the RRAC, which is the Rural Ranch Advisory Committee, which is managed out of Rod Snyder's shop. So we've been having a

number of engagements with that group and providing briefings for them as well. So lots of FACA activity in addition to PPDC, and we wanted to surface that as requested by the PPDC members related to the recent NEJAC work. And, again, we have a specific session on this.

Continuing with some of the emerging science issues and science priorities for climate change continues to be one of our priorities within OPP. Understanding the climate adaptation part of climate change, so really focused on ensuring that we are attune with any impacts on climate change on our risk assessments.

Year one was developing plans for approaching sort of priority actions. Year two is developing case studies to identify and refine these priority actions, and then year three will be focused on broader implementation and refinements to processes, criteria, and data surety related to making sure that our risk assessments understand and include and assess how climate change could be impacting pesticide applications, including, you know, you can see connections related to, you know, potential increased vectoring of habitat ranges or increased weed species pressures because of climate

drought, wet areas, you know, the impact on how we need to change our risk assessments to understand and adapt to the climate changing.

Endocrine Disruptor Screening Program update, again, lots of activity and lots of proud moments for OPP, similar to Endangered Species Act work, making sure that science around pesticide risk assessments is sound related to endocrine disrupting potential chemicals. So we published the availability of new approach methods in EDSP in January of ‘23. We published a near-term strategies document in October, for which we received about 2,000 comments. We're working on responding to the NAMS and response to comments.

And as part of the strategy where we've been, various chemicals, needing additional data, we'll be issuing DCIs coming out this summer. That's one of the technological fixes we need to do in the digital transformation that's in flight. We need to make sure that we can issue and track that and it's no short order. Multiple registrants with multiple chemicals tracking multiple studies isn't something that you can easily do in Excel. So our systems’ upgrades, where we had kind of lost that capacity to really issue DCIs because the aging

infrastructure, we're actually doing some sprints and deliverables to be able to, this summer, begin issuing endocrine disruptor DCIs where they're needed, where there's data needed, and then the responses would be due 90 days after DCI receipt for the registrants.

I'm now going to turn it over to Monique Perron, who is OPP's Science Advisor, and she's going to talk a little bit about our efforts related to systematic review and new approach methods, and then I'll pick up the mic and get us back -- we're doing pretty good on time, so we're rounding out the end here for the presentation. But with that, I'll pass it over to Monique.

MONIQUE PERRON: Thank you, Ed. Yeah, I'm going to jump in here for a few slides and give Ed a break. If whoever is in control of the slides could just advance them forward for me. As I move along, I'll let you know when.

So good afternoon or good morning, I guess, to those of you on the West Coast or in between. As Ed mentioned, I'm Monique Perron, I'm the Science Advisor for OPP. I just wanted to give a little bit of information first on our systematic review processes.

So when we're talking about systematic review, we're talking about approaches to utilize standard methods for collecting, evaluating, and integrating scientific data to support our decisions. So in OPP, we take a fit-for-purpose approach, so that we are working towards answering a particular question, so that's why the problem formulation stage is important for us. You know, whether we're trying to answer a very particular question like we did for Glyphosate on carcinogenic potential versus are we trying to look for any and all hazard data that could inform a risk assessment are two very different questions.

So inherent in all of that is the fact that one size does not fit all. So not all of our systematic reviews technically look exactly the same, but the underlying principles of collecting and evaluating those data in a transparent manner is still -- you know, holds true. And those systematic review approaches are used for our open literature reviews that are routinely performed. These include for supporting our incident and epidemiology assessments, as well as our human health and ecological risk assessments for registration review.

And so one question -- if you can move to

the next slide -- is why do we focus our systematic review evaluations during registration review? You know, at that point, we're looking to potentially fill or inform some of the data gaps or uncertainties, so we get a more holistic view while we're looking at the whole package that's available for an active ingredient. It also allows time for space to be conducted and published. So for a new active ingredient often, you know, they're very novel or low profile, so they just don't have a large literature presence. So it gives some time for the chemicals who have been used and studied by additional scientists.

So it really is our best opportunity to really do a large search of the available information and incorporate it all at once, along with the updates that we're making regarding also exposures and models and other things that are utilized in our risk assessments. However, this doesn't mean that stakeholders can't bring published data to us to our attention at any time that they think would be impactful.

We often get studies sent to us, you know, whether there's no actions going on and new uses happening. So outside of registration review, we're

still looking at information that comes to our attention. So I don't want to give the impression that we don't look at stuff -- we only look at it at registration review. Registration review is when we have a designated time that we will look at all of the available information that's out there.

And if you could move to the next slide.

The other topic that I'm going to briefly talk about is new approach methods. For EPA, we use a pretty broad definition when we're talking about NAMs. And I've written in the really long kind of word version of it, but basically we're referring to what a lot of people used to call alternatives. So it can be in vitro models, like in silico, in chemico, but also a combination of those. So there's things called defined approaches, as well as integrated approaches to testing and assessment or IATAs.

So all of these, we use a very large umbrella term when talking about NAMs in the agency and that's pretty consistent with other federal agencies that are part of ICCVAM, which is the Interagency Coordinating Committee on Alternative Methods -- for the Validation of Alternative Methods, excuse me.

And I think actually, just real quick, to mention the use of "new" in this term can be a bit misleading. I'm sure many of you are very familiar with the use of in vitro assays for evaluating genotoxicity. We've been using different alternative methods in nonguideline studies to inform mechanistic and mode of action for decades. So sometimes that term -- that part of the term gets a little bit misleading, but this isn't actually a new thing. And as I mentioned, a lot of times it used to be considered -- called the term "alternative." So I'm waiting for the next term that we'll be using to refer to these types of assays and different approaches.

But EPA, at our program, as well as other parts of EPA, are working with multiple national and international organizations and stakeholders to develop and implement NAM approaches. Several of these are highlighted on OPP webpage that we update annually, and that's in middle of the slide. It's not all-inclusive; it's not a comprehensive, everything that we're doing. We just have our hands in lots of different pots, but it does provide a good, I think, summary of the projects that are further along and where we have actually moved

forward with either a guidance document to try to reduce our reliance on animal testing or other examples of where we were able to use new approach methods to inform our risk assessments.

And, lastly, I just wanted to mention the EPA NAM workplan. So a few years ago provided a directive from the EPA Administrator for the Office of Research and Development and the Office of Chemical Safety and Pollution Prevention, so OPP and OPPT, to develop a workplan in conjunction with the other programs as well, to lay out objectives and strategies to move forward with the new approach methods, and building confidence, a lot of the objectives and strategies are around building confidence, training. You know, I think it's a really good resource if you want to go here to just see the different objectives and strategies.

We originally put it out in 2020 and then did an update in 2021, but those objectives and strategies remain largely unchanged, but we did extend it from just mammalian to all vertebrate species.

And I think that might be the end of the break for Ed. I think he gets to come back in on next slide. So thank you.

ED MESSINA: I do get to come in. I had to find my mute button, so apologies.

And I get to continue to talk about some Of the other science that OPP is undertaking. So you may have heard or seen the OPP update related to the antifungal and antibacterial resistance work that we're doing with HHS and USDA to make sure that our assessments are complete, related to antifungal and antibacterial pesticides that could potentially cause resistance to humans and create the ineffectiveness for medical drugs.

So it's an interesting concept that brings together two important components of, I would say, you know, pest protection. You know, one is related to the ag part and the other is related to how we protect humans from fungal diseases, which that is a pretty big area. There are many folks that succumb to fungal diseases around the world. In some cases, they develop resistance in part. We're pretty familiar with the antibacterial resistance that can develop and the multiple antibiotics that are out there, depending on the type of strain you have. So it's a pretty important issue related to -- on the human side that we've been working with our federal partners on.

So recently, we put out a concept note last December, asking for specific charge questions to help resolve some of the uncertainties and data gaps that may exist in this area. We received about 5,000 comments to that paper, and there were a number of comments that provided more specific details around this intersection.

So the next step for us is we're going to be issuing a framework coming out in June. The framework is going to lay out our intentions for how we will collaborate across the Federal Government related to EPA's assessment for any potential resistance related to pathogenic bacteria or fungi that could have an impact on the resistance to medical drugs. So I would say stay tuned for that framework.

Also, the framework will talk a little bit about some of the science that needs to be completed in this area. Is there a big intersection? How much resistance are we seeing from agricultural products? How big of an issue is it? And then, certainly, taking into account and coordinating with our other federal partners around products that are in the pipeline that have sort of that dual-use purpose and making sure that there's awareness

amongst the various federal partners. So stay tuned for that.

We also received a petition for rule-making to require the efficacy data for systemic insecticides. Petitioners asked EPA to amend FIFRA to require that all applicants of registrants of the neonicotinoid class and other systemic insecticides, particularly for seed treatments, provide performance data to the agency. We published the notice of receipt for that and sought comments. We received about 2,000 comments on that approach and the team is currently reviewing the comments, and we will proceed with updates as we're able to move forward with responding to that petition.

Some other good news, in terms of our commitment to sort of bilingual and Spanish translations, as part of the earlier Pesticide Program Dialogue Committee Recommendations in the spring of 2021, from the Emerging Viral Pathogens sub-workgroup, there was a recommendation that EPA translate some documents related to the emerging biopathogens work, so the emerging viral pathogens guidance and status of antimicrobial pesticides website and the disinfectants for emerging viral

pathogens, or EVPs List Q website and instructions.

So in May, recently, these translations are up on the website and live and available for the public related to Spanish translations for emerging viral pathogen documents as suggested by prior PPDC workgroups. So some examples of where EPA is committed to that and also responding to the recommendations from this workgroup.

International work continues, you know, the travel budget issues in our budget has caused us to have to scale back a lot of engagements, but we're continuing to work with our partners, OECD, the U.S., Mexico, and Canada Trade Agreement, our USMCA, various bilateral and multilateral meetings with other international partners. The big priorities in the international work is clearly MRL harmonization. We've been focusing on illegal online trade as well. Unmanned aerial systems is a topic that's being talked about amongst the various international problems. Biopesticides is starting to come into forefront and then harmonization of data requirements and some joint reviews that we're conducting with Canada have been topics that have recently been discussed.

The USMCA next meeting is scheduled to be

in Mexico. They are the current chairs of that group, and there's talk of having a meeting in Mexico in October related to USMCA work.

All right. Last couple of slides. I wanted to give you a sense kind of how the digital transformation is working. There was some interest in some of our metrics, too. So the DCI -- these are the various things that are in flight. You can see the DCI overhaul is one of those on the left. The migration for cases going for, you know, the RD cases, we've got about 70 to 80 percent of the workflow that OPP does in the new system, but there's about 30 percent that still needs to get in there.

And then we sort of needed to migrate some of the legacy data that was recently done and that's why we're able to kind of have a bit of a look-back for what our metrics look like, finally giving us a window into the kind of work that's in flight and how long it's taking.

There's a lot of infrastructure that needs to be updated. When I talk about this, I talk about our little server that's in North Carolina that's very old, that's running, you know, a pretty old version of the software and it's not just, you know,

going out to a computer store and buying a new computer and having all new software on it. You've got to update the software. You've got to make sure that all the connections are working to find the data, you know, for your data integrity and to migrate the date, so that ultimately the end goal being we can, you know, migrate that information into a secure cloud environment where there's, you know, multiple redundancy for backup.

We saw, you know, where the front-end processing system, a couple of months ago was crashing. That was the server going down. That was data not making it from one communication portal to the other. It's no redundancy. You know, there was one person who kind of knew how to do that work, and if they went out on vacation, you know, it was hard to get things moving through the system.

So a lot of folks on the front end are working really hard to make sure that the data is coming in and is disseminated within the organization, and we want to try to automate some of the stuff and make their lives easier. So that's part of that infrastructure in that middle column that needs to be done in order for us to have the foundation to do some of the exciting stuff that we

want to do.

Portal development, this is, again, a PRIA 5 deliverable. Having more resolution for registrants that are submitting information to the agency, having greater stakeholder information for what products have gone through ESA, what products can I use on this particular crop, you know, really having better accessibility to the data for all stakeholders, including our registrants, where they're entering the portal. We provided recently some information and some data metrics as a step towards providing realtime information for where things are in flight.

And then lots of things for continuous improvement, we are doing this through agile development, which means that we do a session with folks and say, hey, what would you like to see in this. All of the folks that are in the system can provide feedback to say, hey, it would be great if, you know, we had a button that did this or, you know, it would be great if the system did this, and then we put it on what's called a backlog. We design a sprint. We deliver that sprint and we continue to improve the system on a monthly basis.

So we have about six or seven sprints

planned for the future that are going to increase the functionality for staff. One of the neat things that's coming out in June is the ability for the system to provide a draft letter if items are missing in a particular package or if scientific studies need work.

It's basically drag-and-drop and it uses information from the system to say, hey, would you like me to respond to this company, here's the address, here's the letter, I've used the language that are in templates. You know, would you like me to send this letter? Click yes to send.

So really just making it easy for the staff to focus on the science work and having them not have to spend time on the administrative parts of doing their job.

So we've launched a couple of dashboards, provided this, you know, externally. It's contained in these slides. And it really -- this is virtually a live view of kind of where we are in our performance metrics right now. On the left-hand side, I'll just, you know, without going into a deeper dive, given the time that we have here, but what this document is saying is that for all the open PRIA actions that we have, if you look at that

top left in the right circle, RD is the one that's that circle to the right.

RD has about 2,000 actions and already those actions are late and 70 percent of those actions are late. So these are things that we have in-house, these are things that we haven't even approved yet. So this is what we call a lead measure. A lag measure would be for all the things that we have approved, how late are they?

So for RD, we know that for everything we have in-house, already 70 percent of those actions are past the PRIA deadline and then we know how late they are. So RD, on the right-hand side, is the middle column, you see to the left of that the yellow bar is the total number, which is close to -- the late case is about 1.4 cases -- 1.4 thousand cases, 1.4k.

Then all of those actions are 100 percent late, which means they're basically twice the deadline. So for 1,000 actions that RD has already, those 1,000 actions are twice the lateness from the PRIA deadline. So you can see those metrics are pretty bad, but as you can see from the beginning, we're getting a lot done, even though we're getting more than we can actually get done.

This is more detailed information based on new products, new uses, new AIs and inerts. So you can see on the left-hand side for new products, the total number of cases we have, you know, in the 2,000 range and then the median days to complete them. So for AD, which is in blue, 193 days; for BPD, which is in purple, about 282 days; and then for RD, which is in green, about 364 days, or let's just call it a year for new products, so some information we're providing as part of our PRIA quarterly updates.

The good news chart -- you know, first let's start with the bad news and all those late things. The good news is so you could see this -- the orange line is how much work we received and the green line is how much we've gotten done. You can see that from 2020 all the way to about 2023, we received more than we got done on a consistent basis. The backlog represents that area under the orange line and above the green line. So that backlog was pretty significant and is still pretty significant as you see from the prior charts.

But for the first time in many, many quarters, the green line is a little bit above the orange line for work completed for PRIA actions.

Now, this is actually not just total actions, but it's workload. So what the system enables us to do is look at how many months something is required to do for the timeline and then how many months it actually takes. And so this is looking at not just total number of actions but workload. So you see that our workload over many, many years was well above what we could get done and got done through this chart.

But recently for PRIA actions, finally -- and you can see the PRIA actions going down, the total number of submissions going down, and also our completions going down, but then slightly going up for the '23 third quarter.

And then for non-PRIA actions, again, something that the PRIA 5 statute requires -- we need to focus on these -- for the first time in any recent history, we have completed -- and these are just number of actions, not workload -- we have completed more non-PRIAs than we've received. So we're chipping away at that backlog, which still exists, but you can see that the efforts by the Registration Division to focus on non-PRIA is coming to fruition.

Closing out, crop tours, we focus on

these. These are important. Just some recent ones since we've last met, we had a Farmer Association meeting down in Florida in March of '24, we had a local rodenticide tour sponsored by National Pest Management Association in D.C. in April. There was a rodenticide tour hosted by Colorado and Wisconsin, a Department of Ag in February, and then my most recent crop tour was locally in Maryland and also went to North Carolina -- I just popped in for the Maryland part of trip -- was in May where Rod Snyder, the Ag Commissioner, attended, and we talked about the needs for potato growers within the Maryland Eastern Shore area.

We do have some upcoming crop tours still to come. Thank you for those who are interested in hosting OPP. We have an IR-4 tour that's coming out in Pennsylvania. I'll be attending that one. And we have lots of other cotton, landscape professional tours, especially crops where we're going to be sending staff out. We sent about 197 folks out or about 200 folks last year. It's probably going to be less and there's probably going to be less crop tours because of the travel budgets, but we still think it's important to get out there.

In terms of OPP updates, last year was

almost a record year in the number of OPP updates we've put out. Year-to-date, we've had about 50, so we're in line with sort of our average, but in the interest of transparency making sure that all stakeholders are informed of important topics and things that we're doing in OPP. We've issued about 53. If you're interested in signing up for updates, here's the QR code and you can click on the link in the slide deck when you receive it.

And then also for your reading pleasure are all of the OPP updates since the last PPDC meeting with some bullet points and links to the various updates that have gone out. I'll just click through them and close this out.

And we will open it up for discussion. I'll kick it over to Jeffrey. So thanks for listening. Hopefully, that was good information to set up the meeting for PPDC members and to think about topics that you'd like to hear about at the next PPDC meeting and also topics that you think warrant further discussion with PPDC members. So thank you for your time.

JEFFREY CHANG: Thank you, Ed. Now, the PPDC members will have time to discuss amongst themselves what was presented. Please use the raise

hand function and I will call you in order that your hand was raised. We're supposed to go to lunch at 1:00, but if you guys want to push it, you know, a little over, it's okay.

So who would like to start? Okay, I am seeing Mark Lame.

MARC LAME: Hi. Good presentation, guys. So my basic question for this is -- I recognize and have, as a guy who has been on the PPDC for a number of different administrations, I know that budgets are tough, but this is -- so we had one year of remote meetings and then, you know, probably more than that, but since my newest term, and then we had one in-person meeting and now we have remote meetings again.

Is that for the foreseeable future or do we expect to get together in November as a group in-person? That's a question.

ED MESSINA: Yeah, we're -- this is for you guys to talk amongst yourself, Marc, but I'll answer the question. It really depends on budget. I like the in-person meeting, but, you know, but it really depends on budget.

MARC LAME: Well, then to follow up as a discussion amongst ourselves, you know, we can --

you know, we can do certain things remotely, but I feel, as a group of advisors, that it's difficult to develop the relationships and the communication that is needed to provide the best advice unless we are meeting together. I think it's a matter of priorities and I wish that our FACA had a higher priority. I'm not quite sure how my fellow committee members feel.

ED MESSINA: Thanks, Marc.

JEFFREY CHANG: Nathan Donley.

NATHAN DONLEY: Great. Well, thanks, Ed and Monique. I appreciate your overview. It's nice to see all the work that OPP is doing because it's actually pretty impressive. So thanks for that.

There's just a few things I want to bring up. You all have two applications on your desk right now. One is to approve Dicamba, the new use that federal courts have twice vacated, and the other is to expand use of one of the most disgusting pesticides ever to be used, which is Aldicarb, on Florida citrus. I can really think of no better examples where the agency just flat out needs to say, no, this won't work. It's something so simple, yet something this agency struggles with, just saying no.

I can't tell you how many FOIA productions I've gotten and gone through where EPA goes to meet with registrants preparing to tell them that they can't get this pesticide to pass and then registrants come back with their consultants and say, no, no, every looks fine, go back to the drawing board, and it goes back and forth like this for months and even years sometimes until the political pressure gets so hot that EPA makes regrettable approvals.

So there just seems to be a problem here with saying the word "no," and nothing would make me happier than for me to look like an idiot because EPA actually did something I said they probably wouldn't do. So please make me look stupid and tell the registrants that these harebrained schemes just don't meet the standards we have in place here in the U.S. and no amount of horse-trading or negotiations are going to get those products to meet our standards.

And then in regards to NAMs, while we're supportive of EPA's decision to cancel most uses of Acephate, we're strongly opposed to the way in which EPA has used NAMs to eliminate the FQPA child protective factor, both for Acephate and Malathion

and probably more organophosphates to come. And, you know, I want to stress we're not opposed in general to the use of NAMs in regulatory assessments. They provide data and data is always useful.

But it's important to understand what the data are capable of telling you and what they can't. And I just think there's a disconnect between how EPA believes these tests can be used and how the broader scientific community believes they can be used based on their notable limitations, notably EPA's Health Advisory Committee, the Children's Health Advisory Committee and OECD being among those organizations.

So right now, DNT or development on neurotoxicity, NAMs are good at telling you whether a hazard is absent, but they're not really great at telling you whether a hazard is absent. Type 2 errors are still quite common. Type 2 errors are false negatives. So our worry is that these tests are being used to preclude the presence of a hazard, a neurotoxicity hazard, to get rid of vital protections for very young children. So I just want to, you know, urge the EPA to take a protective approach here, one that aligns with environmental

justice principles and retain the FQPA child protective factor for the organophosphates and many more pesticides beyond that. Thanks. That's all for me.

JEFFREY CHANG: Mano Basu.

MANOJIT BASU: Thank you, Jeff. Ed, thank you very much for that overall view of where we are with the OPP and the registration process. Again, we all pride ourselves on the robust scientific risk assessment process that EPA follows and that takes time.

SAPs are required in many instances and science evolves and improves and, you know, we appreciate that conversation, these meetings, and the back-and-forth with the registrants and the willingness to engage with the scientific community. It takes time and it's a slow process. At the end of it, we always hope that the right decision based on proper science is made.

So I also understand, you know, the challenges you have with the fees and resources. What would be helpful going forward as -- you know, again, as you said, part of the OPP budget is from fees. I didn't see a graph of how you are tracking fees, the PRIA fees that you collect, and that's

kind of an incomplete picture of where we are from a resource. So that would be helpful for overall PPDC, if we can track how much fees you are collecting year on year.

Also, thinking about yes, staff, the number in itself is important, however, the average tenure could also have a significant impact because as you are bringing in new staff, they still need a lot of time to come up to speed, while those that have been with the agency for several years, again, you know, know the ins-and-outs. So that kind of information would be helpful as well to balance things.

You mentioned about the contract cuts and we understand, from a budget point of view, you have to make those decisions to manage within the budget that is available. Thirty-four million is a huge number, but what would be helpful is kind of getting a breakdown of what those -- and getting a little bit more insight on what are those contract cuts are whether it's BRD, RD, what are those contractors doing with the up-front work you mentioned. Having a little bit more breakdown would certainly be helpful.

The reason I bring this on, you know, I

certainly have complained in the past in my current organization or previous organizations -- thankfully, my CEO is not here -- but budget cut is a real challenge and it is a real challenge for our industry, for academia, for government. And, you know, we all have the amount of work that we need to do in the budget we have and, unfortunately, the project hasn't, in my case, grown over the years. We just kind of always find a newer way, more efficient ways.

And as we think about it from even an EPA perspective, okay, the 34 million and you said there are contractors who come in and help prepare the package so that staff is not spending too much time to develop that package and they can get into the review process, is there an opportunity for industry or for someone to take that work on, putting the package in a way that staff can start working on? You know, what are those process efficiencies? Is there a possibility for a few of us, whether it's a PPDC workgroup or however we want to consider this, to look into ways of bringing more efficiency in?

Because I understand the budgets are less, but we cannot expect to do the work the same way and

get an output within the timeline if budgets are being cut with the same resources. We have to find newer ways to get the same amount or a higher amount of work done with fewer resources.

So those were just some of my comments. I really appreciate with the push on progressing the science, whether it's on NAMs -- I think, as science evolves, it is important to consider new technologies that are coming in, to inform the regulatory decisions at the level that is feasible, possible.

I appreciate the work that is going on in AFR/AMR world. I know there is a session later today on the resistance and that resistance is mostly focusing on the herbicide, insecticide, and fungicide. However, you know, is there an opportunity to look into a broader scope of AMR and AFR.

I know there are several other hands and I'm just eating into their time, but, again, thank you for your overview. There are a few things that we should consider for more data and efficiency improvements. Thank you.

ED MESSINA: Thanks.

JEFFREY CHANG: Grant Morris.

GRANT MORRIS: Yeah, hi, just real quick, obviously, budgets are what they are having reduced everywhere, but these crop tours, I believe, are really beneficial, both for the stakeholder and for those involved in the rulemaking process, so if there's anything that -- I don't know the possibilities, I don't know the rules around it, but if there's any way to help facilitate that as stakeholder going forward, or I would at least encourage you guys to maybe find a way to get that information -- if you can't do it in person, if there's other ways digitally, to acquire that knowledge because I think that's a really important part of what you guys are doing. Thanks.

ED MESSINA: Thanks, Grant.

JEFFREY CHANG: Kim Nesci.

KIMBERLY NESCI: Hi, this is Kimberly Nesci. I have a couple of questions and I'll just put them in here and others can respond as they wish.

So the first one is considering the cuts and budgets being what they are, do you, Ed, anticipate needing additional time to complete registration -- this round of registration review or do you anticipate meeting that 2026 deadline? So

that's question number one.

And the second question is about Dicamba, and the question is whether the applications that you have in hand contain enough new information that would allow you to make a safety finding. I know you don't know that yet, I'm sure. But I personally can't envision how that would happen. So I would encourage you to let growers know as soon as possible if you're in a place where you determine that you can't make that safety finding, so that growers can adjust for 2024 season -- ah, the 2025 season. Time goes by quickly. Thanks.

ED MESSINA: Thanks, Kimberly.

JEFFREY CHANG: Anastasia.

ANASTASIA SWEARINGEN: So thank you so much, Ed, for the presentation. It's really great to see that there have been improvements, particularly around the approval of noncoded PRIA actions. We really appreciate the efforts that have been made by RD to improve those and really encourage the sharing of what RD has learned and improving the approval of those registering decisions.

I want to share Mano's comments about improving efficiencies. We'd love to see more of

that and we are looking forward to getting the audit and those findings underway, too. So thank you so much for the work that you're doing with the budget that you have, and it would be great to see you all in person in November and I hope the budget allows for that to happen.

ED MESSINA: Thank you.

JEFFREY CHANG: George Parker.

GEORGE PARKER: Yes, good morning. Good afternoon for you guys over there, I guess. Thank you, again, for that presentation.

As you know, I'm new to the PPDC, but I know my predecessor, Damon Reabe, was involved with the PPDC Emerging Technologies Ad Hoc Committee. And as I understand it, the committee recommended -- and it's also the EPA's intention -- to model pesticide drift and efficacy from drone applications and to develop label language accordingly.

I also know that that work is underway by the consortium of pesticide manufacturers under the unmanned aerial pesticide applications system task force to better understand the movement of applied pesticides from drones and that the National Agricultural Aviation Association is working with the stakeholders to recode the ag drift atmospheric

model that basically all of us are pattern-tested and models pesticide applied movement to better facilitate incorporating drone applications into the model. I believe the EPA is being informed about both of these efforts currently.

My question is if there's a timeline the agency has established to begin modeling the pesticide application movement from drones in the reregistration and labeling of pesticides separate from existing single crop and single rotor large-crewed, manned aircraft. I believe currently other governments, such as Canada, require drone-specific atmospheric testing be conducted and evaluated before they label pesticide applications for uncrewed aircraft. And, currently, as the wave takes us on, the current drone operators are sort of operating in a gray area with no specific language.

Thank you.

ED MESSINA: Thanks, George.

And if you want to throw your question in the chat, it seems like others are doing the same. We can, you know, take some of this back and make sure that we're addressing these, and then also, particularly for some of the other sessions, there will be plenty of time to talk about emerging

pathogens, ESA work, farmworker work. So just look at the other agenda sessions and think about some questions and conversations there for those panel members as well. Thank you.

JEFFREY CHANG: Anna van der Zalm.

ANNA VAN DER ZALM: Hi, I hope you can all hear me. Thank you so much, Ed and Monique, for those updates. And I know that we're probably wanting to get to lunch, so I'll try and be really quick.

But I just wanted to jump in on this issue of NAMs as well, and, in particular, I suppose, the issues or so-called issues with the DNT assays, I've been following the OCD process for those assays very closely, was involved in some of the assessment of the methods and in the development of that guidance document, and I just wanted to confirm for the group that in terms of sensitivity, the DNT assays are sensitive and in terms of picking up certain mechanisms associated with human DNT.

But I think maybe some of the issues may come about with interpretation, but I think that's a problem that we have with current in vivo studies as well. And those in vivo studies have significant problems of their own. They lack reproducibility,

relevance to human outcomes in certain -- in certain situations.

And I just would like us all to think about the problems with the current set of tests that we have and how we can improve on them and I know that many of us echo this as well. But, yeah, it's about improving the technology that we use in toxicology. We're not using the same technology for our phones and our cars that we were 10 years ago, 20 years ago, and most of the methods that we're relying on are, you know, up to 40 to 80 years old at this point.

So we're trying to move the science forward as Ed and Monique said, and I'm very pleased with how the EPA are working through that workplan. So thank you so much for the updates.

ED MESSINA: Thank you.

JEFFREY CHANG: Anyone else?

(No response.)

JEFFREY CHANG: Okay. Ed, if you would like -- we can go to lunch now, if people would like, and please return at 1:45 p.m. Maybe a few minutes beforehand is great. Please do not leave the meeting. Just put yourself on mute, so you can easily come back into the meeting. Does that make

sense?

ED MESSINA: Yes, thanks, Jeffrey. See everyone in about a half an hour.

JEFFREY CHANG: Yep, thank you.

(Lunch break.)

JEFFREY CHANG: Welcome back, everyone. We hope you had a good lunch and are feeling refreshed for our first workgroup update from the Pesticide Label Reform Workgroup. Leading the session will be workgroup co-chairs, Lisa Dreilinger from Arxada, Sarah Hovinga with Bayer, and Michelle Arling with the Office of Pesticide Programs. Welcome.

PESTICIDE LABEL REFORM WORKGROUP UPDATE

MICHELLE ARLING: Thanks, Jeffrey. I'm just going to take a second to pull up the presentation.

LISA DREILINGER: And lower our hands.

MICHELLE ARLING: Perfect.

LISA DREILINGER: While Michele is doing that, I will take the opportunity to thank all of the workgroup members that are on here today or are not listening, but may see the recording, that it has been an amazing year of a very dedicated group. So we just wanted to -- just as a very heartfelt

thank you to the workgroup members, which Michele is going to put up the names, but I just want to say thank you before we begin because we could not have had this update without them.

MICHELLE ARLING: Thanks, Lisa. So I'm going to start us off and then pass it to Lisa and Sarah to further describe the work of this Label Reform Workergroup over the past year or so.

So as Lisa mentioned, we do have a lot of dedicated workgroup members. They're all up on this slide. It includes a bunch of people from a variety of industries or sectors. On this slide, you can see where the workgroup members come from and it is a range of interests that are represented, and I will say they have all been actively engaged, and the conversations are really respectful and enlightening for everyone in the group. So we're really grateful that we have such a diverse set of members.

So for this workgroup, it was formed after the Spring 2023 PPDC meeting. And following that kind of charge to form from the PPDC, the workgroup developed some charge questions and goals. The goals were around the efficiency of the review and approval process, the consistency of that same

process, and then the adoptability of whatever's developed by both industry and consumers.

So we made charge questions in two areas. One is around the label submission and approval and technology, and the other is around content and accessibility of labeling.

And under the first charge question, we quickly realized we had to break it into short-term and long-term goals. So short-term, we're looking at tools that we could use to improve or maximize efficiency, and then long-term, looking more about what the optimal electronic labeling or structured digital labeling process would look like to improve things on the agency side, industry side, state approval side, and then finally down to the users.

And then the second charge questions around content and accessibility are kind of like what we could do to make labeling more accessible, thinking about what labeling currently looks like and what needs are not being met and then also looking at what changes would be good to make to the Label Review Manual.

This is a lot for any group to take on, so we put some things in the parking lot. So we, right now, have in our parking lot display issues, so

issues around the what the final printed label would look like, as well as the end user experience, and that's mostly because we're beginning at the beginning of the process, so looking more at the approval side, and then that will funnel down towards the end user experience. So not off the table just later in the process.

And then the other thing that we found out early we had to put in parking lot is directions for use. We are able to look at a lot of different parts of the label that were easier to segment and talk about. Directions for use, as most of you know is a real behemoth and varies a lot across products, and so in order to keep our forward momentum we put directions for use in parking lot temporarily.

So next up is our timeline and how we've been working together. So as I mentioned, we formed the PPDC workgroup last spring or last summer, and then from the middle of the summer on, this group has been meeting weekly on Thursdays from 2:00 to 3:00, through a Teams meeting, and it has been a lot of dedicated work and a lot of progress is being made because of the dedication and really consistent meeting of this group.

We share documents on a Teams site. We

also have a lot of conversations during the meeting and then over email.

So our original target was to have our recommendations completed and submitted to you all in Spring 2024, and we're going to get to some of those recommendations later in the presentation.

LISA DREILINGER: Thanks, Michelle. We're going to get to some of those recommendations, but then we're going to highlight what we weren't able to finish in the time period that we have and what we're hoping to continue to be able to work on in the short term.

I just want to special shout-out to Michelle who runs the Teams and runs the calendar invites, as you can see, there is a large number of people that are on this meeting and it is not easy. So a special thank you to Michelle, who is the owner of the Teams and calendar invites. So thank you, Michelle.

So we presented in November that a core structured digital labeling is necessary for label reform. And we obviously are standing by that. We have not changed fundamentally anything that we had presented in November. So some of this you might have seen in November, but we have built on it, so

we wanted to share it again.

In the short term, we really believe that creating a voluntary label structure is important. I think, in November, we used the word "template." The word "structured" is starred on the slide because we are still in discussion about what the nomenclature needs to be and the terminology needs to be. And what we learned is that a lot of the group members are saying the same things, but they are using different language. So we are trying to take a step back and level-set on the words that we're using to make sure we are all agreed and that we all understand that we are speaking the same language, so to speak.

So our overall goal was to share information with the USEPA in a consistent order, using recommended similar words, stock language, or controlled vocabulary. But I have to highlight that this is voluntary, that there would be no requirements to use this structure. We are hoping to be able to incentivize registrants to use the structure in a way that it would build efficiencies, and that will come later, I believe, in our recommendations.

So our overall goal is to have all

pesticide products, so products that would fall under the Registration Division, Antimicrobial Division, and the Biopesticides Division would all use the same structure. So maybe the data elements that we have identified would not all be required for each of the different types of pesticides, but that we could use the same overall structure for all the different types of pesticides.

We do have an example of an antimicrobial label, which we will share in a couple of slides, I believe, or maybe even in the next slide, and it's just to give an idea of what one example of a structured label will look like. It is still a work in progress, I want to highlight, that we are not quite there yet. But we did want to share what we were thinking.

So we did identify all the data elements that are necessary. We are going to highlight the source of the information. We're hoping that this would provide an education for some users that do not know where to find the information on what goes on a pesticide label.

We have also worked on a pick list, so that standardization of language, the stock language. We have not planned right now for that

pick list to go in the label structure. As of right now, it's a standalone separate document and it has not been integrated because it was so cumbersome and so large that we actually did not know how to integrate it into this system manually. So we are open to suggestions, and our recommendation is that we provide the pick list for those that would like to use the structured labeling.

So we have some data elements that we think could be representative in a way that would build efficiencies and maybe maximize on the EPA's resources. And we know -- we heard Ed this morning -- that there is obviously some stress on EPA resources, and I'm being kind and gentle, but obviously there is a $12 million gap and we're all virtual so we understand we've made some sacrifices and we have tried to highlight some places that we think could be just as effective by being a representative placeholder.

So some examples of that are QR codes and websites, and telephone numbers, as we think they're important to be representatively on the label, but because they are so dynamic in their nature that it may not be beneficial to have them reviewed at the time of registration.

So we recommend that, obviously, for further efficiencies that EPA use compare doc technology and we have kept that in mind as we have made recommendations for the structure of this label.

And I think we can go to the next slide and maybe it will be easier to explain. Oh, okay, I'll wait until the next slide, the Table of Contents slide, and we can go back to the label compare.

But basically, we put all the marketing claims at the back of the label because that is what generally changes the most when you are looking for a shortened antimicrobial label. So our thinking was that if you put the marketing claims at the end, then when you compare tool a doc, only the end document -- the end pages would have changed and then, therefore, those are the ones that would have to be reviewed.

The overall goal is just to stop de novo reviews from happening when some of these submissions are going in two times a year or even every other year. Not a lot is changing and maybe only what's new needs to be reviewed as a way to keep things moving.

Now, we can go to the next slide. Sorry.

So that is what structured labeling looks like, and then, of course, structured label is going to lead into digital labeling. So right now, our data that we use is actually leading towards our master label and what we can put on the master label. And one of the ideas is to actually create digital data that would potentially autopopulate the structured labeling, in which case the data would be driving the label automatically instead of it being manual.

So, of course, we want to think about digital data in the same way that we sort of think about emails. So you can use any email system and you can talk between people. Like I could use Gmail and Michelle could use her EPA.gov account. But we can talk, it doesn't really matter, as long as the email is in a necessary form. And what we're trying to capture and understand is different people might use different digital data, but we want to make sure that no matter what platform we are using that the data is robust.

So, of course, we don't know what system EPA is going to choose. I know there has been some progress in this area, but because we don't know

what system, we have put the system itself in a parking lot and really talked about the digital data, itself. I just wanted to give a background that we -- and it resonated with me that when you think about it in terms of an email system that really sort of the labels go on, that you really want it to be fluid and not just bound to one system, but that the data itself would be digital and shared.

So obviously, the chemistry data that we are submitting goes on an ECSF. The tox data that we are submitting directly drives the precautionary language. The use directions are related to how the efficacy studies have been run, and the storage and disposal is also related to, of course, the chemistry. So when you take all of the data that goes into a package and then gets reflected on a label, it would be awesome to have that label digitally available and potentially autopopulate parts of label in an ideal world. If nothing else, it would be digitally available. That allow for speed of looking up certain aspects of the label when the agency is reviewing them.

I mean, digital labeling and digital data would significantly speed up the process of label

generation and data review in general in terms of registration approval. So we're looking to not only change in the short term, but looking overall in the long term, the best way that we could really have a master label substantiated with data and used for risk assessments and all the other parts that go into -- all the other considerations that go into an approval from a regulatory point of view.

And it's really, in general, a movement of -- instead of a document-centric -- so everything is related to the master label right now, it actually would all go back to the data and that your registration would be data-centric instead of label-centric.

So then, of course, we want to include automated information for the end user as much as possible. So we're not really sure how that would tie into, you know, programming traffics or end user specifics. We think there's a lot of opportunity once the data is digital to really -- that second charge question that Michelle was talking about, you know, about the diversity and inclusion and accessibility of some of this data and this information to the people who are actually using these pesticides could be priceless. And we want to

make sure that we consider that as we develop our recommendations.

Next slide.

So this is a voluntary approach, as we've said. These are short-term proposals for the electronic structured labeling. Just some things to keep in mind as these are agreements we made, as I'm about to show you what our short-term structured label actually looked like for antimicrobial product. So not every data element is mandatory on every label. So just to keep in mind that, in some cases, it might be okay to have an empty space next to data element.

The pick list or standardized language that we were talking about has been compiled except for the use directions, which Michelle noted was in the parking lot because they were just too different and we would not have made as much progress if we stopped. And we hope that that list will be available at the time that the structured labeling is also piloted.

There will always be an option to add free text. This came back again and again and again, almost as many times as the voluntary question came up, the “will we be able to add free text.” The

answer is yes. Our recommendation is that you would always be able to add free text. There are always exceptions to rules and we don't want to create an environment in which a registrant cannot add what's appropriate for their registration.

All data and information would fit into one of the data elements. We did not create a miscellaneous data element and we did that because we want to really drive the need to fit into one of the data elements. If there's information that needs to go on a label that does not fit into one of the data elements, then we fundamentally missed a data element and we need to go back and reassess.

And, of course, the information should be understandable by all audiences so that any education level can understand the pesticide label.

And, of course, we want to be prepared for when technology advances that we can reduce the review time and use the compare tool as much as possible, and we want to create efficiencies to make sure that the agency is able to drive innovation and protect public health all at the same time.

So the electronic labeling data of elements is -- this is a table of contents. So these are the data elements that have been

identified for antimicrobial product that are necessary. So every data element -- and some have been lumped together as you can see. Number 1 includes product name, active ingredient, net content, signal word, the “keep out of the reach of children” statement and the restricted use pesticide statement, and then, of course, that's all on front of the pack, and then the general information for Number 2 is on the front or the back of pack.

So not only are we trying to educate about the data elements that are required for the label, but we're also trying to educate where those data elements are required to go.

Again, we're hoping that this is going to help those that are less educated in terms of putting a master label together to really understanding what's needed and where it belongs, and then, towards the end, you'll see we also put in where more information on each of these data elements can be found.

So next slide, please.

So this is just an example. The 1, 2, 3 and 4 would be the size of entire page. You would put the information, your product name, active ingredient, net contents, et cetera, into that white

space that is there. And, again, the pick list would be in a separate document that you could pull from. We could not figure out how to create this Word document, which kind of is similar to a safety data sheet in terms of the sections that we are creating in hopes that it would create -- you would always know where to look for -- net contents would always be in Section 1, for example, or first aid would always be in Section 3 and precautionary statements always in Section 4.

The hope is that you would -- knowing where to look for the information, you would be able to, in the future, also when you are updating the legal or looking for information or needing the digital data that drove the label language, you would know where to look for it.

So on the next page, I think you can find the references and then whether or not they're required on the front of pack or back of pack. Again, this was just in the hopes to create some sort of education as part of the structured labeling for those who are really interested in knowing either more information or where they can find information on each of the data elements.

I know that this is somewhat specific to

the antimicrobial example. It is definitely broad enough. It is missing some data elements for conventional, but the structured labeling theory should apply to all of the pesticide types. So I believe this is my last slide and I'm going to send it to Sarah.

SARAH HOVINGA: Thanks so much, Lisa and Michelle. And for my part, it's been also a great privilege to participate with this very passionate and active and engaged group, as well as co-chair together with Lisa and Michelle. So thanks for everybody's work.

I wanted to highlight that in addition to the work on the charge questions that Michelle went over and Lisa and also the master label structure exercises, for example, the antimicrobial example that Lisa just showed, we did the same sort of thing for agricultural products and want to continue work on that.

Another thing that really helped the group jointly learn about many of the fundamental concepts that need to be worked on prior to a submission tool, so all of the fundamental kind of IT needs, the, you know, controlled vocabularies, rules, et cetera, that Lisa went over in a little bit more

detail, we have this opportunity to exchange with many groups on their perspectives and expertise around digital infrastructure, standards, digital labeling possibilities, so what could the future look like, current pilots that are underway in different countries, so we can learn about specifically what Canada is doing, and then also some of the academic approaches that are being thought about in the same context of the structured approach and overall label reform.

So in a big meaty topic like label reform and digital labeling, you know, it's really important to not only get the perspective of, you know, scientists and people that are capable in the pesticide labeling and registration and review side of things, but then also there's this [connection issue] of IT concepts and digital transformation concepts that the group definitely has learned along the way. So that contributed to a lot of what you saw in terms of our recommendations.

One entity I realized that wasn't listed here was we actually went to them, was AAPCO [connection issue] the states and definitely as you saw on the first slide of the stakeholders, we have states involved and so definitely a key stakeholder

of this group and the overall needs of label reform, once we get to that more end user piece after the more upstream piece of submission and review like we've been talking about.

And to mention, you know, the very diverse group of stakeholders, not only that we've engaged with on this slide, but also on the group, are extremely important to this topic. You know, pesticide labels touch different groups of stakeholders along their life cycle, and so really ensuring, you know, we're mapping out the different stakeholders and their touch points to the label along the way in some sort of a roadmap, you know, to make sure that at that point in the life cycle it's working for the benefit of that stakeholder, would be the ideal scenario at the end of the day.

I think we can go to the next slide here. So summarizing, we have a couple slides left and you've heard already some of the work on the charge questions and also some of the short-term recommendations that Lisa went over. You know, again, really we're meeting every week and so that is time out of people's schedule. People show up, turn on camera, are having great conversations, have side conversations in email, and so it's obvious

that we have a lot of expertise and contribution on this team which is greatly, greatly appreciated and has been one of the reasons why we've been able to make so much progress on such as a complex topic.

It should be noted that even though the group is working towards the final vision of digital data and electronic labeling and really the full digital transformation is really going to be necessary for us to realize full benefits, there are possible baby steps. So I think that's been a big focus of this group as well, you know. What are those baby steps?

Also, you'll see in the next slide -- I don't want to go to the next slide yet, but you'll see in that reflected, too, just the need to clearly define some of the expected outcomes of some of those baby steps so that we can continue to show incremental progress, especially with a project that will take some time like digital labeling.

In the meantime, we also had the opportunity to look at the EPA white paper that came out last November, which is a great read from the perspective of EPA in terms of how they're thinking about digital labeling, as well as some proposals for steps, you know. That comment period has since

closed. But as a PPDC group, we had the chance to look at that and we're encouraged that many of the areas that we were working on and some of the things that we were thinking also overlapped with the perspectives. So that was encouraging that our work is supporting, you know, what's happening at EPA, so hopefully this continues to support.

As Lisa identified, you know, we went through the data elements and identified those where there's the potential for pick lists or not in the case of, you know, the need for free text. We identified possibilities for automation, like with signal words, for example. There's stock language that can be used. Also identified, you know, potential databases that could be referenced, possibilities for controlled vocabulary. So I think there's a lot of work that can still be thought of for this.

And as Lisa mentioned pick lists were created, very good progress on the master label structure format. Again, we're still needing to align on that terminology and vocabulary just to make sure that we're speaking the same language. And even though we're not yet at the place where we would recommend a tool, because all of these

fundamental concepts that we've gone over first need to be worked on before that tool would provide what you need. You need to define the needs first and then the tool delivers on those needs.

We did want to make sure that we were collecting some of the kind of Eureka moments that came out of some of these exercises. So document repair technology, like we've mentioned, some sort of way to update. Let's say -- I don't know -- a new mode of action or a new terminology that hadn't been thought of before, so a way to update some of those standard language options, pick list options, for example.

In the case where maybe like a phone number, you know, there's areas for self-certification. Prompting of mandatory text. If it's already legally required to say something, for example, why not just have that be a prompt and users can kind of easily accept it without having to create it de novo.

Out of population, functionality, you know, if then some of the data elements are contingent upon each other, so why not make that link a little bit more clear. And then there's other systems that users, for example, you know,

BulletinsLive, there's databases like PPIS that perhaps can be linked to increased efficiency. You know, version control so there's this trust factor, you know, what's been done to the document, for example, and publishing topics. So ideally, we're looking for the single source of truth to really improve the overall efficiency on both sides of registration of dossiers.

So I think the next slide has some of what we see as possibilities in the future for this group. So I hope you see that with the diversity of expertise and the amount of network, let's say, that all of these stakeholders from their different approaches have in the PPDC community. The group and members of the group can really be considered a source for testing, you know, if a concept is needing a sounding board, for example; education on some of these fundamental concepts that we've really been discovering along the way; and then, of course, you know, discussing and kind of understanding different approaches that different stakeholders have.

You know, EPA is thinking about this a lot, you know, as evidenced by projects, for example, the white paper. So the PPDC group and

members of the group can really be considered as experts in case there's digital platforms, you know, controlled vocabularies, phrases, metrics that need to be thought about and so really consider this group as a source for that consultation, if needed.

I know there are parking lot issues and topics that Michelle had brought up in beginning of the presentation more on the end user piece. It would be our hope to kind of understand that big picture and map out where the different stakeholders are and where their needs are because if we can show the fundamental concepts that need to be in place and then at what time point we need input from different stakeholder groups, I think that just helps everybody plan appropriately and also know that their needs are being heard.

So we also wanted to put that out there specifically with the states and we've had great engagement and some suggestions there, so we're looking forward to working more than that. And then like was mentioned, maybe more tangible themes working on this, you know, common set of vocab that we're using to describe digital labeling and structured labeling, et cetera, and then also ideally come out with a proposed structured master

label, so we have a similar order in which these data elements are appearing, no matter what the pesticide, and that could be a very short baby step in the short-term that could be achieved.

So all-in-all, this is our last slide and, yeah, again, it's been quite a journey. But if we reflect to even a year ago, a year and a half ago, it's really amazing the amount of progress that's been made. The discussions in my opinion are at a very high level talking about data systems and IT requirements and so really, really impressed at the -- all of the different perspectives brought from all of the members and what we've been able to achieve so far. So thank you.

JEFFREY CHANG: Thank you, Sarah. Before we get into open discussion period, I wanted to remind our members that if you could speak slowly for our captioners and our translators and to keep all comments verbally in our meeting.

With that, I will open it up for discussion and please raise your hand and we will go down the list.

Robert Nielsen? Oh, you're muted.

LISA DREILINGER: Robert's hand has been up since you asked us to raise our hands in the

beginning. So I'm not sure if he has additional comment. It might be --

JEFFREY CHANG: Oh, you're saying it might be a legacy hand.

MICHELLE ARLING: Yes.

JEFFREY CHANG: Okay.

LISA DREILINGER: Yes.

JEFFREY CHANG: Joseph Grzywacz.

JOSEPH GRZYWACZ: Thank you. In academia, we refer to that as students who show up for class and then leave. So I'm not sure if that's Robert's situation.

But, first of all, thanks to my excellent colleagues who presented on behalf of our committee. I really appreciate your fabulous work in summarizing, let's just call it, the herding of cats that you guys have been engaged in for the last year.

I also want to apologize because, in part, I have been traveling and so I haven't been able to attend the last few. But I just want to complement and add a couple of extra items if I can to the great summary points that have been made.

I mean, the first one that I wonder about that I would really like to hear from the PPDC more

broadly would be is there any value in being able to think about, you know, kind of generating sort of a minimal viable unit, if we will, because we've been in these abstract conversations, and as academics, I know we can easily get lost in abstract conversation without -- you know, without gaining traction on the ground.

So I would propose, you know, it would be great if this workgroup could actually get some money to be able to kind of create a minimal viable unit that maybe takes, you know, a couple of the registrants and maybe does work with Caliper or one of the other ones to just simply start to see if this actually works in terms of using the templates that are there. Because, otherwise, I fear that we just get so lost in the abstraction that we can lose sight of the fact that we have to make it work, too, and so that means we have to be able to bring those things together.

So I would really advocate for being able to say, golly, is there any way of facilitating some kind of a pilot project that gives us a minimal viable unit so that we can actually start to see does the translation actually work if we want it to be bilingual, right, or do we start running into

snafus then when we try taking those data elements and then turn them into Spanish or Brazilian or whatever the translation would be. So that's the first thing that I'd like to throw out there as far as, you know, sort of a point of discussion.

The second point of discussion -- and I know you voted on it at the last meeting, but we still had a boat load of work in front of us and I can't help but wonder whether or not we need to see to it that we still have some life in front of us. Not that I want to meet forever, but my Thursdays without Lisa and the rest of the gang just wouldn't be the same. So I don't know if we need more time in front of us. I just wanted to throw out those two elements at least as far as discussion.

JEFFREY CHANG: Nathan? Oops, sorry if you were going to respond, Lisa.

LISA DREILINGER: No, I was going say that -- thank you, I think those are fair comments and I think one of the topics for discussion that we threw out in the beginning was the need for more time on this group.

SARAH HOVINGA: Yeah, and I would just add I completely agree, Joe, that it's -- you know, it's a journey and digital labeling is not going to

happen like this (snapping fingers) overnight, and I think that's why it's incumbent upon us, as a PPDC group, also the PPDC group in general, to think of very tangible things that can be achieved in a relatively short amount of time, and I think that's reflected in our recommendations about the structure. And, you know, if we can align on the structure and some of the building blocks, let's say, for what we know will be helpful for the future in this Label Reform Working Group, I think that's already a good step forward, even knowing that we have a lot more work down the way.

And I think that just helps us refine for -- I'm not saying this is a formal recommendation now, but maybe we revisit it, you know, for example, at our next meeting, but if there was a need for a specific PPDC group, for example, to look at user requirements or form groups around very specific outcomes that we know are the building blocks for what is needed here, that could be a way to think about it. And I think the work that our group has done is sort of mind-mapping all of these different things out and we need to see kind of where they fall and in what order and stakeholder group it affects and I think that informs, you know, what

type of expertise would be needed for that specific PPDC charge question, for example.

JOSEPH GRZYWACZ: Yeah, I totally hear that. I would just counter back, though, just that whole idea of, you know -- at least academics, right, we can think things to death and then we take it to implementation and it doesn't work. So, you know, in the spirit of the sprints that Ed was talking about on the front end, you know, thinking about can we get a sprint or two in here that kind of says, hey, can get a basic minimal viable unit in some way, shape, or form to test out some of the valuable items, I just think that that's needed sooner rather than later.

LISA DREILINGER: I was going to say yes to both of you because I think there are things that you're both saying that are sort of the same and complementary, where we take what Sarah is saying and actually apply it to a pilot program, which is what we are sort of talking about, right? Like does a structured label work in practice and it maybe doesn't need to be perfect and what's missing and what data elements have we -- we have everything identified, I think, but if we don't for whatever reason, right, let's add them.

I think it's always going to be a dynamic document. I don't envision that Word document that we are talking about short-term structured labeling ever being a static document. I just don't think it's possible to live in this world and be static. So I'll say thank you both and throw it back to --

SARAH HOVINGA: Yeah, I definitely agree. I don't think the two are mutually exclusive, so I agree.

JEFFREY CHANG: Nathan?

NATHAN DONLEY: Yeah, thanks for your comments, Joe. And I think this discussion really underscores the importance of this subject matter. First off, I really want to thank everyone involved in this workgroup for the work you've put in so far and will continue to do, I imagine. So, yeah, you know, great work here.

There are a few comments I want to make. One is that I'm a little worried about the voluntary nature of what you're proposing. I think initially a voluntary electronic reporting system makes sense to kind of work out the kinks and figure things out and get things really streamlined, but I don't see the point in all this unless this pretty quickly becomes mandatory.

You know, it would basically keep in place a hybrid system at EPA and it would juggle between paper submissions and electronic submissions and that really seems completely inefficient and even detrimental to what you're trying to achieve here. So this strikes me as catering to the wants of the regulated industry rather than in the interest of gaining efficiencies and setting EPA up for success in its endeavors.

And I know that came off kind of harsh, and that was not my intent, but -- I certainly don't mean that in a mean way, but what I'm trying to get at is I think it can be easy to say, well, this company has five employees, we don't want to burden them, but ultimately this increases efficiencies for everyone, including those companies. And, you know, to be quite honest, if your company is not set up to operate in 21st Century, then you've got bigger problems than being forced to submit your CFFs or CSFs online.

So, you know, phase it in, do what you got to do to help everyone out, but I really don't see the point in this unless this becomes mandatory in a reasonable amount of time.

And then the last thing I want to say is

this -- and I know you know this is an issue because you alluded to it multiple times in your presentation, but there seems to be a lot of focus here on the submission process and very little so far on actual kind of label usability. And I'd love to see that prioritized moving forward. I know we only have so much time in a day and you guys have already put in so much work into this and I acknowledge that for sure, but submitting electronic labels helps EPA and it helps registrants, but it doesn't really do much for the person who has to read a 70-page label and make sense of it.

So, you know, a lot of labels are not requiring users to consult Websites, like BulletinsLiveTwo, and even, you know, checking tank mix requirements and stuff like that. So for better or worse, labels are becoming more web-based and there's a lot of challenges with that, particularly with broadband issues in the rural environment and, you know, with farmworkers' lack of access to electronic devices to, for instance, read QR codes and log in to the Internet. But with those challenges, there's also lots of opportunities, I think, with web-based labeling and things that could be explored by this workgroup that would not only

help out registrants and EPA, but also those who are struggling with labels that are, quite frankly, getting a whole lot more complicated to follow.

So, yeah, that's all for me. Thank you all.

JEFFREY CHANG: Ed?

ED MESSINA: Thanks. Yeah, just to tie some of these concepts together in terms of what's going on in my head. I'm not saying this is all right answers, but so I'm thinking what we're doing here as sort of like the requirements gathering, right, or the human-centered design, for a lot of where we want to go in terms of the digital transformation and the vision that many folks on this call are talking about, and I'd separate it out into four areas.

There's the intake piece of the information; there's the how we use it internally and review it; there's the how we publish it to the digital label; and then there's how do we access or how can somebody access sort of data amongst those various parts. So for example, how many of these labels are allowed on strawberries, right? So kind of having that via a data flow that people can access throughout the entire process, including kind

of those four steps.

So in terms of a minimum viable product, to address Joe's point, the first part of this probably will be taken up with the portal piece, which is kind of that intake part, which is a lot of what's happened here, which is great, which is what information do we want to collect, how should it be digitized, what format indexing should it be in, so that when it comes in, it can help support those other three elements, you know, review, publishing, and then sort of data requests.

And then the other part that's happening, to Nathan's point, is that sort of digital label, BulletinsLive, Spanish labeling, right, QR codes, being part of that solution, and that's kind of in that third or fourth category of sort of how do we publish it in a way that's digitally available. And the whole workflow piece, the migration, the digital transformation, has been largely focused right now on that middle part of how EPA is going to be doing its reviews in a digital environment.

We don't do a lot of paper anymore. I think most folks are submitting digitally. I think that's by way of just, you know, the culture. So there may not be a need to require it. Maybe at

some point we can, you know, make it mandatory, but a lot of the information that we're getting is in a digital format. The review times are probably easier when it's in the digital format. So there's incentive for companies to not submit things in paper so that they have to spend time banging around the front end and getting scanned and putting it into formats. So I think the registrants sort of understand that that's a benefit.

So I'm ecstatic, I would say, with the level of effort this group has undertaken. They're laying the groundwork for how we can do this the right way when we have the time, money, and resources to apply towards the digitization and we are doing some of that right now, and I think, you know, in '25, assuming we have the budget to do it, there will be some additional functionality where minimum viable products will be presented to industry and others for consideration as we do sprints to say what about this, right?

So those are just my thoughts. Others can share different perspectives and I'm definitely open to hearing perspectives on the team or on the PPDC workgroup.

JEFFREY CHANG: Mano?

MANOJIT BASU: Thanks, Jeff. And a big thank you to Michelle, Lisa, and Sarah for leading all this work. I've seen them. I've attended a few of these meetings. There's a lot of work, a lot of progress, so thank you very much for all this work.

And I also appreciate that you are including the outreach to the states. That is great and needs to happen because, again, a lot of this information is something that the states will need to process as well. So thank you for including the states.

Ed, looking at this morning, you know, from a budget perspective, the budgetary challenges are those challenges, but, again, this is an area where it will bring efficiency gains, it will hopefully speed up some of the challenges that exist with the paper-based system and a nondigitized system at EPA. Though there are budget shortages, how is this work or how could this work be prioritized and sped up to ultimately have more efficiency gains and, you know, help EPA with the resource challenge it has? Because clearly there are benefits of this work.

ED MESSINA: Yeah. So I have that slide on everything that's in flight right now. The

portal is one of those priority areas. As I mentioned, I think that's where some of this will start to be shown, and then, again, on the Spanish labeling, I think there's where there will be pressure to do things.

We have a pretty full dance card for ‘24, even ‘25, particularly with the legacy systems upgrades, so we can kind of go to a cloud environment, which we can't run this on a little server in RTP, right? So we've got to fix that infrastructure. And that's correcting ten years of technical debt.

When we're done with that, I don't know, I think probably it's a year, given the speed at which we're at and that's -- so I would say within 12, 18 months, and I want to talk to Michelle and Dan Schoeff about when we think we might be able to start doing, you know, real digital label approvals and, you know, it's sort of like what is your question about what will be completed because we're going to -- this is going to be an iterative process, it's going to be an agile process, and so new functionality is going to start to be added as soon as December for some of that portal experience that we're shooting for this calendar year as well.

I don't know if Michelle has any input.

MICHELLE ARLING: I think you got it, Ed.

MANOJIT BASU: Thank you.

JEFFREY CHANG: Any other comments? We have six minutes. Don't be shy.

ED MESSINA: And my understanding is there were no sort of questions to table for the PPDC members. This was sort of an update. We're going to continue with this subworkgroup. You guys are going to continue having discussions to add. I just want to confirm for the PPDC group, you know, are there any asks, and if they are, what are they and what were you hoping to gain other than information sharing from this session, which is great.

LISA DREILINGER: I don't think there were any questions. I think it was more an information and here's what we plan to do, we plan to take a second year. This could not all get done in one year, not that I think anyone here thought that that was possible. What we're hoping to do in the next year is continue on the journey of defining the structured labeling.

I'm with Joe. Personally, I think we should trial the structured label content and see if it helps, and if it doesn't, where it helps; if it

doesn't help, why doesn't it help and how can we fix it. Again, it's a dynamic document, so trial and error is going to get us to the best place and I think we're approaching the time which it's the right time to do that, at least on a very short scale.

The hope is that nobody objected to this group going ahead and continuing their conversations, continuing their data gathering, and really helping to define, again, the terminology and potentially being a resource for both Dan and Michelle and the rest of the team that as you get your front end and the systems up and running, how could we help, what discussions and where can we add value.

In the meantime, we're going to continue talking to our resources, trying to figure out where the structure of the label really lines up between the different pesticides. And to Nathan's point, it's not the first time or the last time that we've had -- I'm sure it won't be the last time, I should say, that somebody is asking about the end user and how the work we're doing is really going to impact the end user. And while I think we all feel really passionate about that, I think the information that

the end user gets is a direct reflection of what is submitted and the label that is approved by Federal EPA.

So I know it might seem like it's far away and that we're really slow, but what we've actually done is approached this in a very methodical way so that we could first deal with the information as it flows through to the consumer. So while I understand it's somewhat painful and slow and I respect that and I understand the feedback we have been given, I stand by the order in which we've approached this and why we've done it the way we have in an effort to get the most efficient information to the Federal EPA, how we use the data, how we apply it, and then how -- basically, how is it enforced and then how is it used by end users. It is the natural flow of the information.

So nobody is saying that the information that goes to the end user is not critical or important; it's just for where we are in the process, it's a little bit harder to see, but it will get there.

ED MESSINA: Great. Thanks. I would suggest this workgroup, as they continue, Michelle, think about what specific asks for the contractor

working with Dan Schoeff in terms of building some pilot workflows that we want to add to what's called the backlog -- it's a bad term, but in IT, it's like things you want to get done, you put on backlog -- so that we can fold it into a sprint and then we can, maybe at the next PPDC, talk about maybe we have some ideas for what sprints are and when we're going to add them to the release cycle.

JEFFREY CHANG: We have another comment from Gary Prescher.

(Pause)

GARY PRESCHER: Yes, thanks. Here again, thanks to the workgroup for the effort. As I've listened to all of your comments regarding NCGA's view on what you're working on, you seem to be checking all the boxes that we're talking about internally, you know, as corn producers. So I just wanted to say keep up the good work and continue to reach out to all your stakeholders as you work through all the challenges here. So from the NCGA's perspective, good work so far.

ED MESSINA: Thanks. And thank you, team. The other thing I'll mention, too, is much like this group has approached, you know, sort of the needs on their end, I would say, particularly for those

customers with the data, like our NGOs, farmworkers, you know, what data do you want access to and how and when, you know, what's important. Be thinking about those things so that when we are ready to talk about that stage, folks have already, you know, thought about it. And maybe as this group continues, as it starts focusing on other parts of this digital process, maybe the PPDC members would be interested in a workgroup that would tackle that issue, right. So just keep that in mind as well.

JEFFREY CHANG: Great. If that's it for comments, we can move on to the next section, which is the Emerging Pathogen Implementation Committee Update. We will hear from Tajah Blackburn, Senior Scientists from the Antimicrobial Division in OPP; Anastasia Swearingen, Senior Director of the American Chemistry Council, and Rhonda Jones, CEO of Scientific and Regulatory Consultants, Incorporated.

Welcome, all.

EMERGING PATHOGEN IMPLEMENTATION COMMITTEE UPDATE

TAJAH BLACKBURN: Good afternoon. Let me get my slides. Is everything visible?

JEFFREY CHANG: Yes.

TAJAH BLACKBURN: Excellent.

Thanks again for the opportunity to

provide an update of the amazing work that the Emerging Pathogen Implementation Workgroup has completed since we met about six months ago.

My name is Tajah Blackburn, and I'm Senior Scientist in the Antimicrobials Division's Efficacy Branch at the EPA. Additionally, I serve as one of the three chairs of the Emerging Pathogen Implementation Committee, EPIC, as we like to call it, because of the work we do, we are so passionately driven towards.

Along with Rhonda Jones and Anastasia Swearingen, we will provide our spring report.

There we go. Through the next couple of slides, I will navigate the conversation through a brief background, timeline of events, then briefly share the genesis of the current workgroup committee. Then, along with the two other chairs, we will provide small workgroup updates and accomplishments, with the remaining time for PPDC questions.

The initial workgroup was conceptualized and proposed to PPDC by the Center for Biocide Chemistries in the Fall of 2020. The original proposal envisioned a group charged with conducting a retrospective analysis of EPA's antimicrobial

response to the COVID-19 pandemic.

From proposal to reality, the formation of the initial group, the Emerging Pathogen Workgroup, was pulled together in December of 2020, with the first workgroup occurring in early 2021. The initial group consisted of 20 persons from regulated industry, academia, trade associations, regulatory technical consultants, transportation industry, and the Centers for Disease Control and Prevention, CDC. These 20 members worked diligently and were dedicated to addressing four charge questions through biweekly meetings spanning over a period of two years.

At the workgroup's sunset, greater than 85 recommendations were given to EPA's Antimicrobial Division to consider, prioritize and, if adequately developed, implement. Within the Antimicrobials Division, we did just that. We worked through 85 recommendations. We prioritized the recommendations and the results of that exercise were presented in the Spring 2022 PPDC meeting.

During that same meeting, PPDC voted to, number one, form a new group to refine, develop, and provide a pathway for implementing the recommendations, and then, secondly, to expand the

focus of the EVP to other types of antimicrobial pathogens. The current workgroup, EPIC, was formed and operationalized in July of 2022. This group is scheduled to sunset in November of 2024, after requesting a year extension during the last fall's meetings.

The implementation group has managed several of the big-ticket items from the previous workgroup's 85 recommendations. The other recommendations are siloed through three small workgroups within the larger group. The Technical Small Workgroup has focused on the EVP guidance and the PPDC's request to expand the EVP to other antimicrobial pathogens.

The Communications/Education Small Workgroup has gathered and identified community communication and educational gaps from sectors that use antimicrobial pesticides. We've prioritized those gaps and we've began to develop and consider tools to address the identified gaps.

While the final small workgroup, the Policy Workgroup, has identified policy change revisions to better enhance, better clarify policies centric to the EVP guidance while considering other possibility for EVP label communication strategies,

the small workgroup meetings are typically booked in by the larger EPIC meeting to bring all members up to date following the discussions of the smaller workgroups.

I've covered most of the information in detail on this slide, but what I really, really want to highlight here are those remaining PPDC requests from the Spring May '22 meeting. In addition to creating a new workgroup, PPDC requested an expanded EVP focus on additional antimicrobial pathogens. This request was tackled from two different angles by the Technical Small Workgroup.

The first angle was expansion of antimicrobial pesticide options, coupled with the expansion of qualifying pathogens for EVP claims. That is an expanded revised EVP guidance.

The second angle tackled expansion of the EVP template and framework for other microbial outbreak scenarios where antimicrobial products are used.

The second request angle is currently underway by the Technical Small Workgroup led by Rhonda Jones, and she'll provide those updates shortly. While the first request was delivered by the Technical Small Workgroup to PPDC and the

Antimicrobial Division in May of 2023.

In the Antimicrobial Division, again, similar to what we did before with those 85 recommendations, we completed a line-by-line review of each proposed change, alongside an implementation posting plan for this revised expanded EVP guidance. And all of these efforts were completed around the Fall of 2023.

After that period of time, the Antimicrobials Division management was briefed in early 2024, and we decided that, at that time, that the EVP revisions would be implemented once the sanitizer-virucidal guidance document is posted, possibly by the end of 2024.

So why are these two documents closely linked and associated together and why, in essence, is one holding up the other? Well, several of the revisions to the expanded EVP guidance are linked to a novel EPA sanitizer-virucidal guidance that's in the final stages of development. This new guidance will represent the first time an EPA-registered sanitizer will be allowed to support virucidal claims in the presence of acceptable efficacy data using existing EPA virucidal standards and methods.

So since the revised expanded EVP is

anchored to this new novel sanitizer-virucidal guidance and to avoid the nightmare of multiple revisions and iteration of this expanded EVP guidance, the Antimicrobials Division has determined that the completion of the sanitizer-virucidal guidance should occur prior to implementing the expanded revised EVP for optimal clarity and, of course, this recurrent theme, prudent use of stretched resources. So, to sum this up, the revised expanded EVP document is in a holding pattern for a very short period of time.

So these are our core members of the EPIC Workgroup. This group has been working diligently in small workgroups and large workgroups to get a lot of these recommendations developed and subsequently implemented. And as you can see, the membership is very diverse across many stakeholder groups, including industry, federal agency, trade associations, and consultants.

We have also recruited additional subject matter experts to assist with some of the small workgroup efforts. These relationships have proven to be amazing, resulting in some fantastically exciting scientific discussions, nerd-out events, what I like to call them, and some exciting

deliverables as well.

So right now, I will transition to the Communications/Education Small Workgroup update. Again, this membership is very diverse, a lot of brilliant minds come together to better understand how we take these identified educational communication gaps and develop tools and resources to bridge that divide.

This slide, I like to say, is an oldie, but a goodie, because it's been a slide that I've referenced several times in the past, but I think it provides excellent context to what we're working on and why it's important. The original charge question proposed and addressed by the initial Emerging Pathogen Workgroup was a deep dive to determine what education is needed during a pandemic or other emergency for the public, end users, and other regulating authorities.

The retrospective analysis revealed that there was ineffective messaging across several sectors due to information and educational gaps. To address this gap, this small workgroup, the Comms and Education Small Workgroup, has served to develop, identify targeted resources and references for general and specialized messaging for key

sectors at different stages of a pandemic emergency gathered through planned outreach tools and lessons learned.

To better understand those gaps, we gather specific information from a broad range of sectors. We successfully completed this information gathering phase in August of 2023. This slide kind of condenses all of that information and gets to the crux of what those gaps were, and they highlight it here.

During this operational period, the workgroup prioritized which efforts to work on, continue working on, to address the previously identified gaps. So those two circle portions in the middle of this graph -- or the middle of this slide, rather, detailed what we focus on as far as prioritization of informational tools, infographics to develop, as it relates to many different sectors because these were recurring themes that typically showed up during those discussions and the information gathering sessions.

That second circled section highlights language barriers, dialect issues, and overall literacy challenges that were exposed during those discussions with different sectors. And I know Ed

highlighted this earlier, but we are excited about that translated section of key resources for the EVP guidance and we're working on additional topics and areas to improve that gap as well.

So when we're thinking about the different tools that are needed to address these gaps, we wanted to consider not developing something that was new and novel, but things that are already done, have been used, that potentially may just be in a different place and not readily accessible. And so the first goal was to see, since infographics was kind of the focus for addressing a lot of these gaps, what infographics exist, where are these infographics located, and how can EPA use these infographics maybe through cobranding or other ways to get these infographics visible, present, to bridge a lot of those gaps that were identified.

So the Comms and Education Small Workgroup has been working diligently to determine what that universe of resources looks like, right? We have nailed down a couple of the issues for infographics, working with a couple of stakeholders. The next big step is to work with EPA's Office of General Counsel to determine how to successfully utilize these tools and how to eventually post these tools on EPA's

website so they're readily available. Hopefully, in the fall, fingers crossed, we can provide favorable news regarding this effort.

And then, lastly, I want to highlight -- I know Ed mentioned this previously, but I just want to stress it again. This is a labor of love from this particular group, but back in the Spring of 2021, PPDC requested at least an initial translation of EVP resources into Spanish. The Spanish translations were targeted for two major resources within the EVP framework, and that's the EVP Guidance website and the instructions for List Q. These translations were completed in December of 2023. And as recently as last week, the translated sections were -- these translated sections were live on EPA's website.

We will have future opportunities to translate and revise other portions of the EVP as that document becomes revised and is expanded, and we're also considering other resources that can be translated for future postings.

I will now pass the virtual mic to Anastasia for the Policy Small Workgroup Update.

Anastasia?

ANASTASIA SWEARINGEN: Thanks, Tajah.

So like Tajah said, we've had a really engaged small group within the Policy Workgroup of the EPIC overall. Our members are listed on the screen.

You can move to the next slide.

So one of the charge questions that we had is how to consider how to make it easier for a user to understand when a product is effective against an emerging pathogen. As Tajah shared from the Communications Group, there's a lot of work that's been done to provide accessibility of the website for the emerging viral pathogens into Spanish, but we also considered how can we make it easier at point of sale for a user to understand whether or not a product is effective against an emerging pathogen.

And one of the proposals that we've come up with within the EPIC is the creation of a QR code that could be triggered when a product is eligible to show the emerging viral -- that it's effective against an emerging viral pathogen. And so we showed at a previous update of this group to the PPDC what that QR code might look like, how it might work, and show a menu of options, including the ability to show bilingual labeling in accordance

with the PRIA 5 requirements for Spanish labeling.

But right now, all of this work on the QR code is on hold as we wait for EPA to develop policy around the use of QR codes, particularly within the context of bilingual labeling. We really see the QR code as a valuable tool, so that you don't have to necessarily create anything new on package, which is obviously difficult to do when you're triggering in the emerging viral pathogen policy, which only allows for that website labeling. But this would allow users to have quick and accessible information up to date once the emerging viral pathogen policy is triggered for those applicable products.

So the next slide.

So the other aspect that we looked at over the last few months within the policy subgroup is how do we improve the Section 18 process for a public health emergency. And what we saw during the COVID-19 pandemic was that ther was a huge influx of Section 18 applications for products that could be efficacious against COVID, but weren't registered products. So we know that most of the Section 18 training -- and there's a tremendous amount of Section 18 resources that have been developed including a checklist -- but it's really

focused more on those regional outbreaks that are more in the agricultural pest space.

So we wanted to figure out how can we improve this process and make it easier for applicants for Section 18 applications for a public health emergency to understand what type of information is most useful for EPA. So we've had some discussions, including with the folks in EPA who were responsible for reviewing those Section 18 applications during the pandemic, and got some good ideas for what information could be most helpful to include for those public health products.

We think it would be a really great addition to the existing Section 18 trainings to have modules that are specific to a public health pandemic. But we recognize that that is going to take significant resources from EPA to develop those modules and that those were done through a grant to an outside organization previously. So it continues to be a recommendation from this group, but we recognize that it's on hold pending more EPA resources.

And I think that is the end of my part of the slides. So I'm going to turn it over to Rhonda Jones to continue with the Technical Workgroup.

RHONDA JONES: All right. Thanks, Anastasia.

Go ahead, Tajah, and advance one more.

Similar to what Tajah said, this team continues to expand. As we have gone through the different microbe types, CDC has added a number of additional staff. Dr. Joe Sexton, Dr. Judith Noble-Wang. We've also had Branch Chief Rebecca Pines from EPA BEAD Microbiology Lab join us, as well as some additional industry folks having the necessary expertise as we proceeded down through the different microbes.

I can't thank this team enough. They have been with us for several years now, meeting every other Thursday, which is, you know, a significant volunteer time. And outside of the meetings, they're always sending additional journal articles and references and ideas to me as well. So many thanks to all of these very busy, important people that would take the time out to be part of this effort.

Go ahead, Tajah.

So a quick overview on where we're at really. There were five documents or policies you asked us to prepare, one for each microbe type, and

then, along the way, the experts had a lot of ad hoc recommendations about test methodology, test strains, et cetera. So I've captured those. They'll go in a sort of separate general recommendations report to EPA as well.

So I'm thrilled to tell you that we have finished drafting the policies for EPA for all of the microbe types except bacteria. We've finished consensus building on the bacteria and are now in the drafting phase. So I'm hoping that will finish by August, and also the general recommendations report tracking right behind that.

With all of these, we start out first with a public literature review and a sharing of all the diverse group of experts that we have on the call. We have the EPA test lab; we have the CDC test labs. We have a number of the key contract laboratories that do this testing for industry, as well as many industry members who have laboratories that they themselves use to test in the United States, as well as in other countries, all bringing this information forward to us.

So we review that cache of information and then proceed forward to build consensus on the recommendations for the various prerequisite claims

that could support the idea of a pre-registered claim for a future emerging pathogen. And those decisions, consensus-building decisions, are found in your appendix in great detail, surface type by surface type, microbe type, et cetera. And that is the work that went into drafting these policy documents.

Go ahead, Tajah.

So just a little more detail. Tajah pretty much covered where the viral stands. It's been written and out of the committee's hands for some time. As EPA went through each recommendation, there was a series of interactions on asking questions and citations and those types of things. We understand that EPA has accepted the majority of the workgroup's recommendations, and we look forward to it to be published behind the viral sanitizer policy, as was decided.

As far as the technical changes made to this document, really the viral prerequisites that have been being used since the 2009 version of this remained the same, but we did add a number of additional organisms that could be prerequisites and we dramatically changed a lot of the registration documents and the process there as well.

And we kept that same process as we went into the next four and five microbe types, all with the sporeformers, the mycobacteria, the fungi, and the yeast, which we were able to pair together in a single document. Those drafts have now been submitted to EPA to start that same review process that Tajah walked you down through earlier. So the workgroup is just awaiting the questions that we expect to come as came in the prior documents, as well to collaborate with that, and the workgroup also gladly will help with responding to public comments once these are published for public comment.

From the standpoint of the technical area, we really were starting brand new. We didn't have a preexisting policy like with the viruses. So we went through and established prerequisites for all the different surface types where it was possible and we also covered all types of microbes. So for the fungi, can tuberculocidal claims cover fungi, can sporadicidle claims predict for efficacy in these areas, and went through each microbe type against the microbe types to determine where those predictive possibilities are that can have strong support for this preregistered claim.

In some cases, we didn't feel like there was strong support either from the literature or from our experience, and in those cases we've declined to offer that as supporting evidence for a prerequisite. There were a few things that fell in a gray area where we felt like we did not have sufficient evidence to support a recommendation in a national policy, but we did provide advice to the agency or will provide advice to the agency where, in the case of a serious supply chain issue where there isn't sufficient product to meet the need, some areas where we thought they could step out a little bit further to add more products by using other prerequisites.

This is very similar to what was done and has been historically done by EPA as there's reports from the field that there's insufficient product to go along. So we did offer those -- we called them case-by-case recommendations where EPA would have this consideration internally, and then could advance the types of products that could be used in this way via the website tool as needed.

And in some cases, particularly in the sporeformers, they are at sort of the top of the food chain, very difficult to kill, we don't have

many registered, and so to say what we can predict for a sporeformer was very, very challenging. So of all of the categories we've done so far, this is the one where we will have the fewest products available to us.

We have proposed some new test organisms and some new test strains for companies that would like to join in this area so that we do have more items accessible to us in the case of a future pandemic in this space.

As I said earlier, the bacteria is still very much underway. The consensus building just finished last week, and we are getting the drafting of the policy underway. So hoping to have that draft out to the workgroup for review, oh, maybe by the first of July, and hoping to have the iterations of those drafts and stuff done and over to EPA in August.

With that, I believe we are concluding, unless, Tajah, do you have any final comments, or Anastasia?

TAJAH BLACKBURN: Nothing additional for me. I think this wraps up the work that's been completed over the last six months, and highlighting, of course, some of those things that

were still in the pipeline that we worked through during this period of time. So we now can address any questions or comments that PPDC has. Thank you.

JEFFREY CHANG: Thank you, EPIC team. We can now move it over to the discussion period. Please raise your hand and I will call you.

Lisa?

LISA DREILINGER: Thank you. So first, I just want to say thank you to another very passionate PPDC workgroup that I've been lucky enough to be a part of, but I've not really arguably contributed technically on this last round, because it's way above my head. But I have enjoyed the discussions that I've been a part of and I've enjoyed watching the final document come through and commenting on it.

My question is really for I'm not sure who or for discussion for the PPDC. So obviously, the viral sanitizer document is slated for, I believe, later this year and then the recommendations for the viral emerging pathogen document, as Rhonda noted, would be following that, and then there's the yeast and fungi document. But we have obviously not talked about bacteria, which are also, I would say, a concern often. I mean, I see alerts come through

all the time for food that's contaminated or other -- obviously, we're not worried about food, but like general outbreaks of bacteria. Those are not emerging. Obviously, there is emerging bacteria as well.

And I guess what I'm trying to figure out is where we go from here. This group is going to sunset and the work's been so critical and so important to the future of where we're going and how we want to be ready to deal with the next emergency, whatever that looks like, and I guess what I'm trying to figure out is, one, does there need to be a workgroup formed to discuss emerging bacteria, and the second is, how are we going to make sure, after this group is disbanded, that the work that they've done gets published, and if EPA needs support in order to do that, how are they going to go about it?

Maybe it's a Tajah question; maybe it's an Ed question; maybe it's a conversation for PPDC or maybe it's requiring a vote of some sort to figure out if we're ready to redirect this group but maybe not disband it.

TAJAH BLACKBURN: And I can just step in briefly, because we've had those conversations all along, because -- I mean, not only do I enjoy the

nerd sessions and what happens when we have those discussions, I mean, because they're really, really exciting, but, you know, where do we go from here is the mindset. And I guess we can't operate in perpetuity under PPDC, but are there provisions or, you know, other opportunities that we can work outside and still have, you know, aspects of this group meet occasionally to address questions that come up and, as Rhonda mentioned, this back-and-forth exchange that we had with the revised expanded EVP.

So we are thinking about those types of things. We don't -- when it sunsets in November, we don't want the group just to totally disband. We want to still have, you know, an opportunity to engage with that group. But we are kind of preparing and having those conversations now.

But if PPDC, Ed, others, can think of other directions in which the group can go, then we would definitely like to entertain those as well. Thanks, Lisa.

LISA DREILINGER: Thanks, Tajah. I think what I was thinking of -- I remember when we voted on it, I guess it was last November, we voted on continuing and going outside of just viruses,

right, and I love where we ended up, but we didn't do everything outside viruses. We only did one next subset. So is there still that energy to talk more about what an outbreak for bacteria looks like or are we going to stop at spores or is it enough. It's really, I guess, for discussion.

RHONDA JONES: Yeah, Lisa, I just want to jump in here, too, and just clarify with everybody. A far as the workgroup coming to consensus on a recommendation and drafting the future EPA policy, we have completed everything at this point and moved it to EPA, except for bacteria, but we will finish bacteria before we sunset in November.

LISA DREILINGER: Okay.

RHONDA JONES: That doesn't get us through the whole part of the EPA process, but at least the consensus building of the expert part will be done, so just to be clear about that.

LISA DREILINGER: That's good. Thank you.

JEFFREY CHANG: Ligia?

LIGIA DUARTE: Thank you. I just want to support what Lisa was saying. I would definitely support the continuation of the work that this workgroup has done. It's very critical. But I also wanted to just urge EPA to expedite the review of

the recommendations being proposed by this workgroup. I think in light of emerging pathogens, it's crucial to have these effective tools in place and measures readily available in case of another public health emergency. And so recognizing resource shortages, I'd just encourage prompt action from the agency to ensure that we're better prepared in the future.

Thank you.

JEFFREY CHANG: Ed?

ED MESSINA: Yeah, just to shed some light on kind of the process part of this. So, you know, the advantage of a FACA, which is what we have here is it's an opportunity where a federal agency can actually get consensus opinion or get opinions from multiple stakeholders and through the FACA process, you know, have that be treated out in the open with, you know, the sunshine it deserves and everyone sort of getting to see how that process works. That's the advantage.

The subgroups are great, because what they can do is -- and they are informal under the FACA rules. They are recognized. They are there to advise the larger FACA group, PPDC members in this case, on, you know, recommendations that then the

PPDC group can then vote on and then forward to the agency.

They are supposed to be short-term and discrete parts of that process. So the longer that they sort of last or stick around and then start grabbing, you know, additional sort of charge versions, then you run into the need to actually establish an official subworkgroup under the FACA, which then has processes where, you know, people get appointed, they get reviewed, right? So that's an option.

The other option, which we've done in this case, is to disband the prior workgroup once those charge questions are done, and then have the PPDC recommend and pass whether a different workgroup dealing with similar issues, but different components of that issue, is formed and then takes that charge on. And that's essentially what happened with this group, which is first there was the development of the EVP, which helped us actually be responsive to COVID, right. So an example of how this PPDC group and FACA has really helped the agency in many cases and, in particular, being responsive to COVID, because we had developed a emerging viral pathogen policy before COVID hit and

we were able to activate it, which was amazing, right?

So the question would be once November passes, if there's interest in a different aspect from PPDC members to have a subgroup look at, that's well within sort of the purview of this group. So I just wanted to interject some process parts to this. So again, thanks for the work and -- and is there anything -- are there questions or things that need to get forwarded to the agency from the subworkgroup?

It looks like maybe the next one -- the next PPDC meeting, you will present the final report and then seek its motion to get forward to the agency, and then also seek to sort of end the November -- you know, seek to end this committee, and then maybe there is a motion to form a new one that looks at a different charge question. That's maybe something you guys could think about in the next six months before the next PPDC meeting.

JEFFREY CHANG: Anyone else? We do have seven minutes, so...

ED MESSINA: We have seven minutes and we haven't scheduled a break for anyone until 5:00 p.m. So maybe, Jeffrey, we can taken advantage of

that.

JEFFREY CHANG: There's a five-minute break at 3:30.

ED MESSINA: Oh, there is?

JEFFREY CHANG: Yeah.

ED MESSINA: At 3:30, oh, okay. Got it.

(Pause)

JEFFREY CHANG: Maybe we'll just call on people by alphabetical --

ED MESSINA: No, I think whatever discussion needs to happen can happen. If we'd done, we can give people a break and then come back for the Emerging Pesticide Resistance Management Workgroup 2, because there was a Workgroup 1.

JEFFREY CHANG: All right. Okay. Well, we can take a break for, I guess, 10, 11 minutes, and then return at 3:35 for the next workgroup. Thank you.

ED MESSINA: Thanks, everyone.

(Break)

JEFFREY CHANG: Okay. Let's now pivot for an update from our Pesticide Resistant Management Workgroup. For that we are joined by Nikhil Mallampalli, Biological and Economic Analysis Division in OPP, and Cameron Douglass with USDA,

Office of Pesticide Management Policy. Welcome.

PESTICIDE RESIDENT MANAGEMENT #2 WORKGROUP UPDATE

CAMERON DOUGLASS: Thank you, Jeffrey. Thank you, everyone. Let me share my screen.

All right. Hopefully, everything is good. So good afternoon, PPDC. Thanks for the opportunity today to present the work of the second Resistance Management Workgroup.

JEFFREY CHANG: Sorry, I don't see your slides.

CAMERON DOUGLASS: Oh, no. Let me try again. Did that work?

JEFFREY CHANG: Yep.

CAMERON DOUGLASS: Okay. Better. All right. So what I'll be presenting today is a summary of the recommendation that we've detailed in our workgroup's final report work, which was shared with the PPDC membership on Monday. So hopefully, folks have had a little bit of a chance to look through that.

So what we're presenting today is not an update, as was mentioned in the agenda. It really reflects the culmination of the work of this workgroup. And at this end of this presentation, I'll ask that the PPDC vote on allowing this

workgroup to submit our final report to EPA and also to sunset our workgroup.

So I wanted to begin by taking a quick moment to thank the 20 individuals who participated in this workgroup over the course of the past 18 months or so. We've been very fortunate to have a diversity of views and perspectives represented by our members and I think that really shows in our recommendations, as does all of their hard work.

So it likely goes without saying to those who are PPDC members, but pesticide resistance is a growing problem with increasing and real consequences regardless of the affected sectors. As an example, in agriculture, we're already starting to see cases of resistance that are resulting in increased production costs and significant changes to production practices, not to mention changes, and some would argue, increased exposure to farmworkers and adjacent communities from use of some agricultural pesticides.

Similarly in the public health realm, we're seeing an increasing number of cases and increasing concerns with antibiotic resistant microbes. All of these issues, this workgroup would argue, are tied back to failing to successfully

manage pesticide resistance on a collective basis. Given that this is PPDC, the focus today is on what EPA could be doing to better address resistance management in the view of this workgroup.

And so we want to argue today that EPA needs to prioritize resistance management alongside their important work on the Endangered Species Act and other current agency priorities. Effective resistance management would, in our view, not only directly align with EPA's longstanding mission of protecting both human and environmental health by optimizing and, arguably, minimizing overall pesticide use, but could actually reduce the OPP's long-term workload by diminishing the constant need for new products to be registered as old ones simply become ineffective.

Resistance management is not a new issue for PPDC, as you can tell by our workgroup's title, and this is the second workgroup to be working on this topic. The first workgroup was stood up in 2021, and after working on the issue for over a year, issued a report in 2022 that made five recommendations. These five were: That EPA should explore changes in pesticide labels; second, that EPA should conduct a thorough review of EPA policies

and regulations that impact resistance management; thirdly, the EPA should expand collaboration and outreach efforts with other federal agencies, such as USDA, the Centers for Disease Control and Fish and Wildlife Service; fourthly, that EPA should explore cooperative agreements, updated training materials and grant programs; and, finally, that EPA should explore the creation of incentive programs to promote resistance management.

Following the discussion of the presentation of these recommendations, PPDC members at the time expressed interest in having another workgroup continue the effort to that first workgroup, and that was the genesis of our workgroup.

Our workgroup was approved by PPDC in the spring of 2022, so about two years ago, with the following three charge questions: Assist EPA in developing implementation strategies from the first workgroup recommendations; secondly, to develop a framework for the quantification of risks and benefits from resistance to conventional active ingredients; and, finally, to explore leveraging, integrated pest management, or IPM, strategies for resistance management.

Because of the COVID-19 pandemic and changes in PPDC leadership at the time, it took our workgroup a little while to really get going. Indeed, we have really only been meeting regularly and working in earnest on our recommendations for the past year or so.

In that time frame, though, I think we've come up with an ambitious and far-reaching set of specific recommendations for EPA. With an eye towards tying our recommendations back to the original charge questions issued to us by PPDC, we tried to group our more specific recommendations into several themes that we think directly address the charges put to us by PPDC.

So in response to the charge questions asking us to assist EPA in further implementing recommendations from the first workgroup, we've identified a number of specific recommendations to better strengthen internal and external relationships that could support EPA's resistance management efforts, and perhaps, most importantly, we would recommend creating a specific position within the Office of Pesticide Programs who could help coordinate these efforts internally and externally.

In response to the second charge question that asked us to develop a pesticide resistance cost-benefit analysis framework, we have not only done so, but we've gone a little bit further and provided recommendations as to how EPA could prioritize which active ingredients would best benefit from these analyses. And some additional recommendations also suggest how EPA could work with external stakeholders to improve sources of data on pesticide resistance to support these analyses.

Lastly, integrated pest management, or IPM, really became a central theme across almost all of our specific recommendations, but we more specifically make several recommendations to EPA on how we believe the agency could better encourage the commercialization of unconventional pesticides, including biological control agents, biopesticides, and devices. So as I go through our specific recommendations, I'll present them in the context of these four recommendation themes.

Also, as I walk through these more specific recommendations on the following slides, keep in mind that in response to requests from EPA management, we have both categorized our specific recommendations according to the workgroup's

perception of the ease of implementation in the context of both resources and time, but also complexity. And, again, in response to EPA requests, have tried to prioritize our specific recommendations for those that we think are most important, simply. Recommendations that we think are the highest priority are bolded on the following slides.

So beginning with our first theme of strengthening partnerships, we have three specific recommendations that the workgroup believes are both minimally challenging for EPA and high priorities. Firstly, as many of you know, EPA already has formal relationships in the form of liaisons to several professional or scientific societies, including the American Phytopathological Society, the Entomological Society of America, and the Weed Science Society of America.

These relationships have unarguably been very constructive both for EPA and for the academic societies that the liaisons represent. And the workgroup would suggest that there are other professional societies that EPA should establish similar formal relationships with, two examples of which could include the Agricultural and Applied

Economics Association and the American Public Health Association.

More broadly, we recommend that EPA leverage relationships with professional scientific societies to more collaboratively and proactively work on resistance management, including developing a better understanding of pest management practices for pesticide resistance management across disciplines, and also for EPA to hold internal discussions as to how BMPs produced by these professional societies could be better reflected on pesticide labels.

Secondly, staying within this theme of strengthening partnerships, EPA also has existing relationships with industry-affiliated resistance, action committees and has long collaborated with these RACs in the past on important labeling improvements. Looking forward, this workgroup would suggest that there are additional opportunities for EPA to work with the RACs on how to foster innovation and resistance management, either through jointly designed grant programs or community-based resistance management networks as just two examples.

Similarly, our workgroup would broadly recommend that EPA could work more proactively with

federal partners and other external stakeholders who are already working on resistance management education and training to ensure the pesticide users are consistently receiving the highest quality information on current best practices for resistance management. Along these same lines, we believe there are opportunities for EPA to collaborate with external stakeholders who offer grants to better ensure that these funding opportunities really foster innovative pest management -- pesticide resistance management tools. Such stakeholders not only include commodity groups and applicator-affiliated organizations, but also USDA-funded regional IPM centers and academic consortia, such as the Center for Regulatory Science and Agriculture.

JEFFREY CHANG: Cameron?

CAMERON DOUGLASS: Yes.

JEFFREY CHANG: Do you mind just slowing down your speech a little for our translators? Thank you.

CAMERON DOUGLASS: Of course. Sorry. We have two recommendations also in the vein of strengthening partnerships, that the workgroup believes would be much more challenging for EPA to

implement. The first of these is the recommendation that EPA, leverage existing participation in the Federal Integrated Pest Management Coordinating Committee, which is chaired by my Office of Pest Management Policy colleague, Alyssa Arnold, to request the initiation of a national roadmap for pesticide resistance management that would better ensure coordination across federal agencies and departments on resistance management issues.

Years ago, this committee, the FIPMCC, led the development of the national roadmap, for integrated pest management, which has arguably been instrumental and very useful in promoting IPM adoption and progress within the Federal Government.

Our final recommendation in the theme of strengthening partnerships is, in the workgroup's view, perhaps most critical to ensuring that any of the other workgroups' recommendations are actually successful, and this would be the creation of a new position or perhaps, more realistically, shuffling of existing FTEs or position equivalents to create what we are calling a Resistance Management Coordinator within the Office of Pesticide Programs. There are precedents already for this type of position within the Office of Pesticide Programs,

including point people who have been designated to lead coordination on Endangered Species Act and e-labeling efforts.

And this workgroup believes that the creation of this Resistance Management Coordinator would be key moving forward to OPP's ability to strengthen existing partnerships and build the new ones that will be critical to successful progress on resistance management. In addition, this coordinator could be critical to ensuring internal accounting for resistance management and assessments and decisions.

So shifting gears a little bit, the next theme of our recommendations was developing a cost-benefit analysis framework for use by EPA, so that the agency can, in some cases, quantitatively incorporate resistance into its weight of evidence approach that it uses for regulatory decision-making. We have two specific recommendations within this theme, the first of which is to suggest that EPA collaborate proactively with regional IPM centers on the development of crop profiles and pest management strategic plans that explicitly, and when relevant, quantitatively account for the costs or benefits of pesticide

resistance.

These crop profiles and PMSP documents are regional and crop-specific production guides produced by these regional IPM centers in collaboration with producers and academics and are already very valuable sources of information on pest management and IPM. But we see these documents as potentially being important sources of information on how growers and regulatory agencies, such as EPA, could better account for pesticide resistance.

The second specific recommendation in this theme is that EPA quantitatively account for resistance management implications in appropriate regulatory decisions. Members of our workgroup, led by Dr. George Frizvold from the University of Arizona have developed a framework for how EPA could go about doing such a cost-benefit analysis and has also proposed a prioritization system for helping EPA decide which active ingredients might warrant and most highly benefit from this type of analysis. This prioritization scheme reflects an appreciation for EPA's need to maximize its resources and the benefit of conducting these cost-benefit analyses only when they can be most impactful.

As our workgroup deliberated on our

recommendations and, in particular, discussed the recommendation that EPA needed to more quantitatively account for the costs and benefits of pesticide resistance, the concern was raised that existing sources of data on the occurrence of pesticide resistance are not optimal to support either quantitative accounting of pesticide resistance by EPA or, arguably, to effectively support the real-time management of resistance when it occurs in fields, public health care settings, or really anywhere that pesticides are used.

So our workgroup ended up making several recommendations that touch on how we believe EPA could improve existing data on pesticide resistance.

Firstly, we suggest that EPA ensure that they are comprehensively reporting in the incident database system, which we would applaud EPA for recently making public and available online, data that is already submitted by pesticide registrants in fulfillment of their obligation under FIFRA 682, to report confirmed cases of resistance as adverse incidents. We would also suggest that EPA could proactively work to understand, and when appropriate, help support new pesticide resistance surveillance tools.

Ed, earlier, and Mano and other PPDC members referred to a lot of the work that is going on with antimicrobial resistance and there's a tool called the National Antimicrobial Resistance Monitoring System, co-run by FDA and CDC, that has existed for decades in health care, and our workgroup believes this NARMs tool could serve as a model for the development of similar surveillance tools in agriculture and other industries where pesticides are used.

Relatedly, we would recommend that EPA work with federal partners and other external stakeholders to collaborate on the standardization of field level checklists that could be used to screen suspected cases of resistance. These types of decision support tools are already in use by many agronomists in agriculture and by practitioners in public health care settings and represent the reality that pesticide users and others dealing with resistance in real time often cannot wait for confirmation of resistance in laboratories or greenhouses. They have to make practical and rapid decisions on how to respond to cases of resistance based on their experience and evidence that they see in their fields.

Standardization of such decision support tools could be useful in helping to practically manage resistance and could possibly inform broader work on the development of a pesticide resistance, surveillance system for agriculture and other sectors of our economy in which pesticides are used.

The final theme of our recommendations most directly embodies the IPM principles that we feel are suffused throughout many of our recommendations. Our workgroup would argue that in order to support management of pesticide resistance, which is worse with conventional pesticides, EPA needs to ensure that they are facilitating innovation and commercialization of nonconventional pesticide pest management tools.

So we first recommend that EPA undertake a critical assessment as to whether existing regulatory incentive programs, such as the reduced fees that we see for registration of some biological control agents or biopesticides through BPPD, or the Biopesticides and Pollution Prevention Division, in the EPA are adequate, and whether additional incentives, such as expansion of currently limited voucher programs could better promote commercialization of nonconventional active

ingredients and pesticide devices.

Another critical but, arguably, minimally challenging recommendation we make is that EPA needs to expeditiously publicize updates to the process for additions to the list of minimum risk pesticides under FIFRA Section 25B. Three years ago, EPA published a notice in the Federal Register asking for public comment on a proposal to update the 25B list and make the process for doing so more efficient. But there's been no update from EPA on this effort since.

In this workgroup's view. FIFRA 25B, the list of minimum risk pesticides offers an ideal pathway to legal use of some nonconventional pesticides, such as pathogens with specificity for certain weeds for whom there's limited commercial viability, very little risk, and enormous potential for public benefit.

To round out this theme, our workgroup recommends that EPA broadly work to improve partnerships with external stakeholders to facilitate the development and -- sorry, the development of nonconventional pesticides and pesticide devices. There is rapidly increasing interest in the biological control of pests in

biopesticides and in innovative RENI-based pest control technologies, but very little knowledge amongst those innovating in these fields of the potential regulatory requirements for legally commercializing such tools.

There is lots of investment in these nonconventional pesticide -- pest control tool and proactive outreach and education with these industries by EPA could help to ensure efficient review and commercialization of these tools within the guardrails of EPA's existing regulatory system.

Relatedly, we would recommend that BPPD consider forming a classification committee to guide nonconventional pesticides through the registration process. This could be even an expansion of the current cross-division, bioclassification committee that already exists between BPPD and the Registration Division.

To conclude, we want to collectively reiterate that pesticide resistance poses real threats to sectors of our society that we all depend on, whether it's agriculture or public health and that resistance is already affecting all of us whether we acknowledge it or not. This problem is growing because we aren't doing enough to

constructively address pesticide resistance. Time and time again, we have seen that resistance management only becomes a priority when it's too late arguably to effectively do anything about it.

The upside, though, and to try to end on a positive note, is that we actually know a lot about how to successfully manage resistance and generally we find that those solutions that work are multi-disciplinary and grounded in principles like integrated pest management that are already widely adopted. So hopefully, this workgroup's recommendations can spur on some progress by EPA on resistance management and inspire the rest of us collectively to critically assess what more our own organizations could be doing to not only help EPA, but, in our own views, to promote pesticide resistance management.

With that, I'll close and both happily take any questions that PPDC members have of our workgroup's work and also ask that PPDC consider two motions, allowing us to submit our final report to EPA for their consideration and, secondly, a request to sunset the work of this second version of the resistance management workgroup.

JEFFREY CHANG: Thank you, Cameron.

Ed, should we go into the motion first?

ED MESSINA: Discussion first, Jeffrey, and then we can do motions if anyone wants to make a motion.

JEFFREY CHANG: Okay. Got it. Understood.

ED MESSINA: Thanks.

JEFFREY CHANG: All right. We will go into the discussion period now. If you could raise your hand and I will call on you.

Rosemary Malfi?

ROSEMARY MALFI: Hi, Cameron, thank you so much for the presentation. That was super-informative and very interesting and, in some ways, I feel like resistance management is something that kind of is a commonality for all of us, right? Like everyone is concerned about that problem because it makes our tools less effective and because it poses an issue for pesticide reduction. And I really appreciate the way that you laid that out. It was very, very organized.

I think some of the questions that came up for me -- and I am a newcomer here, so forgive me if I'm asking things that folks already know. But you mentioned incentives and like a voucher program and

I'm kind of curious to hear a little more detail about the ways you think those kinds of tools could be used to, you know, promote integrated pest management and alternative practice.

And then I guess a second piece of that, which I don't know if you can answer or if maybe Ed would be able to answer that. I know there was an MOU between EPA and USDA and it just strikes me that some things might be outside of the exact purview of EPA that would really tackle this problem, right? Like we need farmers, growers to adopt some of these practices and, you know, you could make the registration process easier for an organic, you know, pesticide or product, that doesn't necessarily mean it's going to, you know, have wide adoption. We need other kinds of incentive programs to help folks do that and to make those choices.

So, yeah, I would just love to hear kind of your thoughts and comments on that.

CAMERON DOUGLASS: Yeah. I mean, in response to your first question about incentives, I think the sort of driving concept there was that EPA should do with whatever it can to increase -- you know, we always talk about a toolbox a lot in pest management science -- the toolbox of nonconventional

pesticides that growers have. And I think, as you put it, that first question is very much tied to that second one where the rest of us have a very important role in trying to improve the adoption of those tools once EPA has approved them.

So we know we made a motion to sunset the work of this workgroup, but I, myself, certainly hope to continue to carry out a lot of this work through, you know, the federal IPM coordinating committee and other federal stakeholder groups that I participate in. And I think we hope that, you know, our recommendations and this discussion will spur similar discussions about what other external stakeholder groups can do to better or improve moving forward on resistance management.

ROSEMARY MALFI: Thank you. Just I'll tack a comment onto the end of that, which is, you know, there seems like there's an opportunity for, you know -- and I know things can be siloed, but there's an opportunity for EPA and USDA to work together, potentially through something like the NRCS Program, to kind of boost some of the incentives that are already there to help growers, you know, adopt some practices that would help combat resistance management, and that can even be

some, you know, mechanical basic things like crop rotation.

And I also want to -- I had to bring up treated seeds because it's, you know, something that's been a point of contention, and I think, you know, sort of authority over pesticide-treated seeds is a little bit in question, and I do want to point out that, you know, it is a major source of prophylactic pesticide use right? They're being used continually every year, not necessarily in response to a pest threat, but, you know, sort of just in case there's a pest threat, and that's even in places where, you know, the research shows that pest incidence is very low, like for relevant pests. And we need ways of helping farmers to adopt like untreated seeds or seeds that are -- that don't have insecticides on them.

And there are two problems there. One is, you know, we need incentive programs to help people make those as choices, but, also, those choices are very constrained by what is currently available. Many farmers report that they can't get the variety of corn that they want as an untreated -- or, you know, as an untreated type. So there are just numerous challenges there and I think that there's a

real opportunity for EP and USDA to collaborate in tackling some of those barriers.

CAMERON DOUGLASS: I appreciate those comments.

NIKHIL MALLAMPALLI: I just want to add that EPA does participate with that FIPMCC Committee right now and we'd be happy to continue the conversation there, too.

JEFFREY CHANG: Anastasia?

ANASTASIA SWEARINGEN: Hi, thanks. So a really interesting update, you know, we don't usually, as the antimicrobials industry, participate in these workgroups, but we noticed that your recommendations go pretty far beyond conventional pesticides, particularly beyond agricultural use pesticides to extrapolate some of these recommendations to products that would be outside of that field.

I just want to understand how you brought in expertise from those other types of pesticide user groups. I know no one from our industry group was part of that, and I don't know that those recommendations are really applicable or relevant for those types of use patterns and products. They're very different in their modes of action and

use patterns, and I just want to understand, you know, why the report went further than just the agricultural use without bringing in the expertise from some of those other types of users and industry partners.

CAMERON DOUGLASS: Yeah, I appreciate that comment. I think, you know, we wanted to try to go beyond a narrow focus on agriculture, and, you know, the first workgroup had a lot of weed scientists on it and so there was a bit of a theme in the recommendation that was really focused on agriculture. And so I think the second workgroup, we wanted to try to tackle something that was a little bit more broadly applicable.

I think your point about perhaps not necessarily doing the stakeholder outreach that we should have is a valid one. You know, we did speak with experts at CDC and FDA, who work on at least antimicrobial issues as it relates to human and animal drugs. I know that's very different than some of the products you're talking about. So I think your point about needing to have done a little bit more outreach is a fair one and I think that's something that we can try to address moving forward.

ANASTASIA SWEARINGEN: Thank you.

JEFFREY CHANG: Nathan?

NATHAN DONLEY: Great. And apologies in advance. I'm in a hotel room and my internet connection is kind of spotty. So if I go in and out, just holler at me.

Well, I do want to, you know, lend support for the scope of your work here. I think your workgroup has done a good job here and it's nice to see you all wrapping up your work product and I want to thank everyone for the work they've put in.

And I want to, once again, say I think the most important aspect of resistance management is pesticide reduction. Pesticide reduction can take many forms. It doesn't mean just canceling pesticides. It can mean, you know, IPM -- true IPM, not IPM in name only, which we're seeing happen quite a bit more often now. It can mean things like rotating different modes of action in different years instead of always combining them year after year.

But the pesticide overuse and, as Rosemary said, prophylactic use are certainly the biggest threats to having effective pesticides when they're actually needed, and it seems that that principle may have guided this group in a few of your

recommendations. But I would certainly like to see it stated a bit more explicitly than it is currently.

And, let's see, oh, yeah, 682. So we've been really vocal that the agency needs to initiate rulemaking on 682 regs on multiple fronts to require a whole lot more information from the registrants than what they're admitting to EPA. And while I think the greatest need for that is with incidents of harm to humans and wildlife, incidents of pesticide resistance are a really important aspect of 682 as well and, you know, right now, I would hazard to guess that most incidents of pesticide resistance are not reported to EPA by registrants, because they fail to kind of meet that very high reporting bar that's currently written into the regs.

So I think a recommendation to update the 682 regs would, I think, be a very worthy one and a very important request to get the agency even more information than it's currently getting right now. And as a bonus, it would align with asks of the agency, such that, you know, I think they could accomplish multiple important things with one rulemaking.

And as far as a recommendation to include pesticide resistance incidents on the incident data system, I think it's a good one. I think they need to be publicly available. I would just ask that your recommendation for that include an ask to EPA that they reach out to stakeholders before doing so. One worry I have is there's currently only one code for harm to plants and I imagine the pesticide resistance incidents would kind of be lumped into like incidents of drift and volatility and so that could make the database a little bit more difficult to use. So I think a new code would need to be added. And, anyway, if EPA consulted stakeholders before making such a change, I think it would be -- it would be good. So I would just say that.

And the last thing is, you know, you guys are going to submit this report soon, so I'm not -- there's really no ask here other than, you know, I would love to see the exploration of how registrants can be compelled to do more here because a lot is being asked of the Government, a lot is being asked of individual farmers when it comes to doing something about resistance, and a lot of that is well placed. The registrants, who I think objectively have played a big role in creating this

mess, need to do a lot more here, and they have the resources to do a lot more here. So I'm not sure what that ultimately looks like, but it's something that just strikes me as needing to happen.

So for what it's worth, that's all for me. Thank you.

JEFFREY CHANG: Hardy Kern?

HARDY KERN: Hey, everyone. Sorry, it looks like my laptop camera is no longer working today. So it's just the disembodied voice of myself over a hummingbird. So apologies for that.

Thank you so much, Cameron. That was a really helpful report-out and I really appreciate the recommendations that were in there, especially the evaluations of the different regulatory barriers and the incentive structures for IPM. I think that's really interesting. And to echo what Rosemary said, evaluating unnecessary, duplicative or -- and/or duplicative pesticide applications, such as seed treatment, coupled with over-the-top or soil drenching with essentially, you know, the same active ingredients is something that we would love to see included in this.

And jumping off of what Nate said, with

the inclusion possibly in the pesticide incident database, did your group at all talk about how that might be reported, or what type of threshold would count as a, you know, pesticide resistance event? Did that come up at all in your discussions?

And this is my first PPDC meeting as a member, so I apologize if this has been covered in previous talks.

CAMERON DOUGLASS: No, it hasn't, and it's a good question. We certainly discussed those types of more detailed kind of implementation side of that data and simply kind of ran out of time for working out those details and reaching a consensus on that. So we sort of left the recommendation in our report at a little bit higher level. But, again, I think it's one of the issues that I hope we can continue to work on, whether it's through PPDC or other platforms.

HARDY KERN: Gotcha. That's fantastic. This is definitely something we'd like to be engaged in on. Appreciate all the work. This is great. Hummingbird out.

JEFFREY CHANG: Marc Lame?

MARC LAME: Yes. You know, working with Nikhil and Cameron was really a joy. These guys

were great leaders of this group and really, really were able to put things together well, and I'm going to stick with that.

I'm going to start with the idea that I would encourage everyone to adopt up this report, more so to even read the report, because there's so much more in it. I've been hearing about resistance management for about 45 years, not to make myself sound too old, but that's pretty old. So I've been hearing about it and the one thing being part of this group -- and I was encouraged to be part of it -- at first, I didn't want to be, but being part of it, I realized how important this is. I mean, it is -- it's not -- as Cameron said, it's not just an agricultural commodities production thing for the ag business industry. It's also public health.

And because resistance means more pesticide, more pesticide means more exposure, and so there's going to be more public health problems, in particular with disenfranchised communities. And so, you know, I wanted to take the time to make sure that people understood how important that was and how linked these are. Forty-five years ago, resistance management and integrated pest management were born from the same needs and the needs were

that we were failing to control pests with the tools that we had, and the tools that we had, by using them so much and relying on so much, not only caused resistance, but caused environmental problems and health problems. And so these things had to be dealt with together.

Our group rightfully dealt with the regulatory side of integrated pest management. Yet, from the people who have commented so far, I've heard words like more need for adoption, more need for innovation to compel registrants, and all of that is about changing behavior. And so we need to look at that part of OPP that does more outreach and education, even in a nonregulatory sense.

But more that there is the pesticide environmental stewardship branch and, you know, we didn't deal with that too much, but, yet they are the outreach folks when it comes to IPM and could do it as well with resistance management. And so there needs to be some prioritization there. Yet, it's my understanding that the pesticide environmental stewardship program has a different status now, which could possibly be not working as in it's not there anymore. So that's concerning to me and I wanted to at least add that comment of the

nonregulatory side of the agency which is under-recognized and certainly underfunded.

JEFFREY CHANG: Daniel?

DANIEL MARKOWSKI: Hello, I'd like to just bring up a point. I don't know if the workgroup considered this, but -- and I certainly don't have -- anyone that really has an answer, but maybe we'll make Ed come up with the answer.

My concern with pesticide resistance isn't just resistance within the species, but it's to a specific class. We all know that class rotation is the primary way to manage resistance. But if you're dealing with a species like my members do, that fly, if you have a lot of a certain class of pesticides being used in one program, one county, you know, relatively close by, you rotate to that new class because you see resistance. You're rotating to a class that they're already -- the mosquitoes are highly, you know, subjected to.

So is there some mechanism within the incident reporting to just report nationwide, you know, general use trends so that you know what classes of pesticides are being used around your application area? Has that been considered? And if not, how could we consider that? I'm just throwing

it out there.

CAMERON DOUGLASS: Yeah, I think my basic response to that would be that it's not part of the incident database system. EPA doesn't directly report pesticide usage data. Obviously, you know, the National Agriculture Statistic Service within USDA does. There's some proprietary sources of those data. I think it's certainly a good question. How to tackle that one, I'm not quite sure.

DANIEL MARKOWSKI: Yeah, like I said, I don't think there's an answer for it because I've been advocating for a national database just for mosquito, you know, pesticide use and resistance data, and it's a very problematic thing to do, to say the least. So just something to consider like, you know, pie in the sky, down the road, what would we do, because I know that within our industry it's a big concern. We have mosquitoes resistant to pesticides that, for mosquito control, we've never used in that area. So they're being impacted by some other use type. Whatever that may be, I don't know.

Thank you.

JEFFREY CHANG: Ligia?

LIGIA DUARTE: Thank you. Yeah, I just

wanted to express some similar concerns to what Anastasia raised in terms of the scoping of this and the potential impact that these recommendations could have on antimicrobial uses considering that, you know, the expertise wasn't consulted there for those categories and use patterns. I do think that if there are restrictions that are imposed on antimicrobials based on nonantimicrobial uses that that's certainly a concern. And so the agency should certainly consider that.

I also have some reservations with some of the recommendations in terms of impacting registration requirements and considering the resources that the agency already is lacking currently and how that can further impact agency resources. So I just wanted to throw that in there as well as a consideration. So thank you.

JEFFREY CHANG: Any other comments?

(No response.)

JEFFREY CHANG: Should we move to the motions, Ed?

KIMBERLY NESCI: Jeffrey, I had a quick question.

JEFFREY CHANG: I'm sorry.

KIMBERLY NESCI: And it's more a process

question because I'm new to the PPDC. The question I have is so, as we're talking, I'm sort of jotting down what I'm hearing is maybe caveats to the recommendation or additions to the recommendation from the workgroup like PSP branch to sort of enhance awareness in a nonregulatory, like Marc mentioned, and limiting the scope of the recommendation to ag uses because of the expertise in the group.

As part of the functioning of the PPDC, how are those recommendations sort of incorporated into the decision-making process for the greater PPDC?

ED MESSINA: I mean, one option -- this has happened in the past -- is if the PPDC group doesn't have enough to move all the recommendations forward, you can make a motion to have a subset, you can make a motion to have the workgroup reconsider some of the recommendations in light of some of the discussions. So there's a myriad of options for the PPDC members to move this forward or send it back to the subcommittee.

KIMBERLY NESCI: Okay. That's helpful, Ed. I'm not suggesting we send it back. I just am hearing some tailoring of the recommendations.

ED MESSINA: Yeah. So, subcommittee chairs, do you have any suggestions for tailoring if there were to be any?

NIKHIL MALLAMPALLI: I wouldn't want it to be just us tailoring it. We would have to have some sort of meeting with the workgroup and go over it. It's a pretty dense report. Ed, is there a way for PPDC to weigh in after the meetings in written format or --

ED MESSINA: Well, it's on OPP -- I mean, so it would be the subworkgroup asking PPDC members to forward to EPA for consideration.

So the next step is, you know, through motions or whatever, you know, is the full PPDC willing to put their report forward, do they want to wait and, you know, take it back and read it and then have that be done at the next meeting? Do they want revisions? Are they good with maybe sending it forward with some caveats, you know, some language someone wants to throw out there like, you know, we recommend the full report go forward, noting some caveats as part as the discussion that, you know, that the antimicrobial work needs to continue or needs to be changed or full support, or, you know, whatever folks want to propose for language for --

to capture this discussion.

Does that answer your question, Nikhil?

NIKHIL MALLAMPALLI: Yeah, I mean, sure. It sounds like a question for PPDC to consider.

ED MESSINA: Exactly.

I think Marc had his hand up or is that legacy?

MARC LAME: No, I have my hand up.

ED MESSINA: Great.

MARC LAME: First, with regard to this current conversation, basically, I think people need to read the report. It's these -- you know, you can only put so much on these slides, and I think that Cameron covered it and -- but in the report, it does discuss some of the nonregulatory stuff. So I'm satisfied that it's there. I don't see that as an addition, although I think like everything should begin and end with integrated pest management. But that's just me, you know, having fun.

But seriously, I was not trying to change that. I was just trying to get across that there is a report out there that's a robust report and it has this stuff in it.

Furthermore, I'm a medical entomologist, and we had another medical entomologist who also

specializes with disinfectants from the University of Arizona. So the group was not without expertise when it came to those type of pesticides. And so, you know, we had that.

And, furthermore, you know, to say that the EPA doesn't have resources so it shouldn't have policies regarding something as important as resistance management with all of the pesticides is -- you know, that's, quite frankly, ridiculous. I mean, we're here to advise with regard to policy and resistance management is a very important subject that needs more robust policy at this point. And there's no doubt in my mind that it cuts across all of the sectors of pesticides, the innovative ones just as much as the ones that are more conventional.

So, you know, I just wanted to respond to those comments and to add in I think it's looking pretty good as it is personally.

KIMBERLY NESCI: That's helpful, Marc. Thank you.

ED MESSINA: Daren?

JEFFREY CHANG: Oh, wait, Gary had one. Gary had a comment.

ED MESSINA: Oh, Gary's first? Sorry.

JEFFREY CHANG: Yes.

GARY PRESCHER: Yeah, thanks. Looking at this, the timing of it, I'm uncomfortable -- I haven't quite digested everything in this regarding how it would impact the folks that I'm representing here. So I just wanted to kind of say I would like some more time to really digest the recommendations and read the whole thing through and then counsel with the folks that I represent.

So, you know, I realize that kicking the can down the road is sometimes not what we want to do, but having worked in the workgroup 1, I mean, this is such a big, broad area that -- and it's important, you know. And there are many things in here I can agree with just top of mind looking, you know, on IPM and those types of things.

But I guess I would speak for thinking about delaying this until the next meeting, so we can have a little bit more -- so I can and the group I represent can have a little bit more time to digest everything in here appropriately, and then maybe providing some way for suggestions for tweaking. Some of that was already talked about a little bit here.

And then, lastly, I recognize there's probably expertise on the workgroup for the

microbials but the ag products is kind of the focus where this started and, here again, it was really easy to get in the weeds to talk about too many things, tried to do too much too soon with this topic. So I would encourage the group just to kind of stay focused on the ag products here for right now, and long term, if the microbials wanted in on the action, you know, they can figure out how to do that one way or another with or without the team. That's my comments.

JEFFREY CHANG: Daren?

DAREN COPPOCK: Thank you. I'm new to the PPDC, also, and so I don't have the benefit of all of the context and prior workgroups and reporting. And I did skim the report yesterday, but I am far from having read and digested the entire thing.

There's a lot that's good in here, and so I don't want the co-chairs to feel like we're poking holes in your achievement here because there's -- you've done a lot of good work. But it would benefit from some additional time. What concerns me most is when I hear from people that say there are potentially impacts here that impact my constituency and we either haven't carved them out or given them input into the process. And I wouldn't want to be

in that situation and so I don't want to put anybody else in that situation So it would be -- I think it would be good for us to either bring that expertise in so that the recommendations can represent everyone or carve those constituencies out and focus it like Gary just said, on the ag uses.

It would be helpful if we try to keep these broad if the antimicrobial or microbial folks could give us some specific information about which proposals are concerning to them and that way we could do a better job of making a good carve-out. But I'm not sure we're ready to pass it in its current form today.

JEFFREY CHANG: Mano?

MANOJIT BASU: Thanks. Thank you, Jeff. And Daren said everything I wanted to say. Again, a big thank you to Cameron, Nikhil, Marc, and everyone else on the workgroup. This is a lot of work. I know several of the CropLife America members are part of the workgroup as well. So again, excellent work here. But if you could just get some time to read, digest what's in there, share with the broader membership, that certainly would be helpful.

I know from a -- correct me if I'm wrong, from a process point of view, we established or

reestablished this workgroup in November, of which automatically gave them a year time. That's how I guess the PPDC workgroups are. And then November is when we do review the final reports, also, as well as I decide on extension or sunsetting. So if we have that time, I think that would just help do the outreach and educate membership for several of the organizations here. So that time would certainly be helpful

But, again, thank you for all the great work that the workgroup has done.

JEFFREY CHANG: Anastasia?

ANASTASIA SWEARINGEN: I'm just going to echo the support to give more time and make the offer that those of us in the antimicrobials industry are certainly happy to talk with this workgroup and explain kind of what's going on in this space with the development of different methods to explore resistance in the antimicrobial use space and how it could be tailored to either carve-out and retain that focus on ag or what might be appropriate to include in the future for an antimicrobial-specific look at resistance. So thank you.

JEFFREY CHANG: Kim?

KIMBERLY NESCI: Well, I guess I'm hearing a proposal, so let me see if I'm capturing it correctly. I'm hearing the PPDC wants to keep the report, you know, commends the workgroup for all of the work that has been done because it's clearly quite a lot. What I'm hearing is most of us want to review and digest the information, have the opportunity to talk with the people that we represent. The Antimicrobial Group representatives might want to have a separate side conversation with the workgroup and that, at the meeting in November, we have a facilitated sort of PPDC member discussion to obtain consensus on final recommendations. Is that right? Did I -- is that how this works being new to the PPDC?

ED MESSINA: That works, but we'll let others chime in. You could have -- interpret that as a motion and have somebody second and then vote on whether that's what folks want to do or keep the discussion going.

KIMBERLY NESCI: I mean, do folks generally agree that that's what their -- I see Kim Brown.

KIM BROWN: Well, I mean, that's kind of what I'm hearing. I mean, this is my first PPDC,

but in the interest of moving along, first off, I did read the document as best I could in the amount of time, and it's a great document. So I really commend the group for the efforts that you all put forward. But I really like the idea just like what Kim just said. So I'd actually -- if we could formalize what Kim said as a motion, I'd happily second that to move the process along and we can have a little bit more discussion if somebody else has got something to add.

JEFFREY CHANG: Bob and David, are those hands for a motion or a comment?

BOB MANN: Yeah, I was going to say that if Kimberly could put her comment into the form of a motion, I would be happy to second it.

KIMBERLY NESCI: Well, I could do that.

JEFFREY CHANG: David?

KIMBERLY NESCI: David, yeah.

DAVID SHAW: Yeah, I think I can support the motion, obviously depending on exactly the wording. I think we do need to be sure that we provide the latitude of the group, given the original charge. It sounds to me like the existing workgroup and the work that they've done might want to have the option of being able to pair it down to

a more ag pesticide focus, because I think what we have heard this afternoon is that there's probably the need for, at some point in time, maybe a separate workgroup that really does bring in the right expertise to focus on the antimicrobials.

JEFFREY CHANG: Marc?

MARC LAME: Yeah. So I get the thing about speaking with ag and bringing in more debate on the antimicrobials, and that's fine with me, at least the antimicrobial stuff. I have some real concern when it comes to just ag, you know, we have mosquito control, any kind of vector-borne disease stuff that's going on right now. You know, I mean, we have rodenticides. We have lots of stuff that's going on, affecting millions and millions of people, many of whom are underserved and have nothing to do with antimicrobial. I mean, so that can be carved out or debated.

But sticking to ag is, you know -- resistance management is just so much more than that, and if we leave it at that, we're -- I don't think the agency will be able to expeditiously deal with its mission, not to mention ESA.

JEFFREY CHANG: Kim?

KIM BROWN: Yeah, I'm just going to chime

in really quickly. I agree with Marc. I think that in the interest of moving this foward, it sounds like -- and I'm going to go back to what Kim said, maybe what we do is charge this committee to take this back and work with those microbial folks -- Anastasia volunteered to help -- and you all kind of vet it out between now and November to see if maybe there's a way to word it so that it doesn't -- if microbials don't fit into it, then you can kind of find a way to word it to not make it all-encompassing of that group as well.

But I do agree with Marc's statements. So I don't really know how to make the motion to move that forward. Maybe Kimberly can do that. So since you kind of started it, Kimberly, why don't you do that and I'd be happy to second it?

KIMBERLY NESCI: Yeah, I can sort of restate what I heard because I think I've tailored it a little bit from the first statement. But I think I would move that the antimicrobial experts get with the workgroup to talk about their specific needs and, at the same time, the PPDC workgroup members consider the full report as it is, based on our stakeholder viewpoints, and that we all reconvene -- so this is a motion -- and that we all

reconvene at the next meeting in November to discuss any tweaks as a result of the conversation with the antimicrobial experts and then vote on the -- facilitate a discussion about the other recommendations and then vote in November.

ED MESSINA: Is there a second?

KIMBERLY NESCI: Sorry. I tried to simplify it, but not successfully.

ED MESSINA: Is there a second or a suggestion for modification?

BOB MANN: I'll second the motion. Bob Mann.

ED MESSINA: Okay. All in favor, raise your hands, and Jeffrey will do a count.

JEFFREY CHANG: Yes, and please keep them up until I tell you to put them down, so I can get an accurate read.

ED MESSINA: And, Jeffrey, for the transcript, you may want to read the name of folks or --

JEFFREY CHANG: Okay.

ED MESSINA: You're going to, you know, think about the transcript that's coming and how you want to capture whose hand is raised.

JEFFREY CHANG: Sure, I can read off the

names. Kim Brown, Karen Reardon, Grant Morris, David Shaw, Keith Jones, Brian, Alanna Bares, Walter Alarcon, Marc Lame, Anna van de Zalm, Jill Schroeder, David Heimer, Robert Neilsen, Kimberly, Nesci, Bob Mann, Ligia Duarte, Daniel Markowski, Wendy Sue Wheeler, Terry Kippley, Daren Coppock, John Wise, Anastasia, Mano Basu, Lisa Dreilinger, Emma Torres, Andrew Architect, Claudia Arrieta, and that gives us 27.

GARY PRESCHER: Prescher votes yes, too.

ED MESSINA: The motion passes. And Gary -- Gary votes what?

GARY PRESCHER: Yes. I don't seem to have a raise my hand function here.

JEFFREY CHANG: Okay, 28.

ED MESSINA: Okay. With that confirmed, I just --

MILY TREVINO-SAUCEDA: This is Mily and you didn't say my name, and I don't know if you caught my --

JEFFREY CHANG: Okay. Mily Trevino, 29.

KIMBERLY NESCI: I can (inaudible) in the chat. I don't know if it's inappropriate to use, Jeffrey, the chat, but I can write what I -- the motion if that's helpful.

JEFFREY CHANG: Sure.

(Pause)

ED MESSINA: So just to confirm, the motion was seconded and passed and we'll have the record reflect that.

Jeffrey, it looks like we're also out of time for the public part. We'd like to close the session if you're good with that.

JEFFREY CHANG: We have 20 minutes for the public session. Is that okay, Ed?

ED MESSINA: Yeah, I thought it -- didn't it start at 4:35?

JEFFREY CHANG: It was supposed to start at 4:35, but we have until 5:00.

ED MESSINA: Okay, great.

PUBLIC COMMENTS

JEFFREY CHANG: Okay. So we are nearing the end of our first day of the two-day PPDC meeting, and we would -- we want to give the members of the public who have listened a chance to provide comments. Please raise your hand if you registered to provide comments, and we are -- when you are ready to speak, our technical support team behind the scenes will promote each registered commenter to panelists, which will allow you to unmute your line.

You will receive a prompt to unmute. Please accept it. Please wait until I call on you, going in order of those listed on the screen first, to turn on your mic, then deliver your remarks slowly and clearly.

When you are making your comment, please state your name and affiliation, if you have one. We ask that you limit your remarks to three minutes. I will show a slide when you have 30 seconds left. Again, please keep your remarks within the maximum time allowed. When the timer makes it to zero, I will allow you to finish whatever statement you are making and then I will cut you off so we can make sure that everyone who has signed up to share comments has the opportunity to do so.

So up first, we have Doug Johnson. Doug, are you there?

DOUG JOHNSON: There we go. I just got the unmute message. Thank you. Doug Johnson, I'm the Executive Director of a nonprofit organization, the California Invasive Plant Council. And we serve land managers in California who are protecting natural areas from invasive plants as part of their job and they use herbicides, of course. And I was very interested to hear this discussion this morning about the labels and label reform.

And I just wanted to -- it's probably already on your radar screen, but something that has become a challenge for our members is that there seems to be some confusion in the regulatory sector between the state and the counties on which herbicides can be used in wildlands, and that has to do with labels in some cases saying they can be used in natural areas, that particular product. In other cases, just saying things like noncrop. And so while many folks might interpret noncrop to mean be able to be used in wildland areas, not all county commissions -- you know, agricultural commissioners in this case necessarily will make the same call.

So I think the idea of having a controlled vocabulary standardization on where a given herbicide can be used would be extremely helpful, and that's probably a big lift and I'm not an expert on all the systems in place, but if we can move in that direction that would be extremely helpful. Thanks so much.

JEFFREY CHANG: Thank you.

John Bottorff?

JOHN BOTTORFF: Yes. Can you guys hear me?

JEFFREY CHANG: Yes.

JOHN BOTTORFF: Oh, excellent. Good afternoon, my name is John Bottorff with CleanEarthforKids.org, and I want to thank you for this opportunity to speak at the committee. Though the presentations today were really informative, what I did not hear was the plan or any mention to eliminate or even reduce the use of synthetic pesticides.

So is there a workgroup or where is the workgroup on helping farmer transition to chemical-free methods? Where is the strategy to use organic and regenerative farming? And where are representatives for organic and regenerative farming on this committee? Were organizations like The Soil Institute or the Rodale Institute invited?
The vast majority of this committee is directly or indirectly funded by the pesticide industry, and that industry is tied at the hip with the fossil fuel industry. Ninety-nine percent of synthetic pesticides and synthetic fertilizers come from fossil fuels. They are petrochemicals.

I would ask all of you to read the book, Economic Poisoning: Industrial Waste and the Chemicalization of American Agriculture by Professor Adam Romero of the University of Washington. The

book lays out how, at the turn of the century, the mining, oil production, and chemical manufacturing industries create a market for their toxic waste into farming. These industries created the belief that we can't grow food without their toxic chemicals, a campaign that the petroleum industry has pushed hard since the 1940s. The petrochemical industry does not want organic or regenerative agriculture because they don't make products from it.

We are poisoning our children, our environment, our water, and ourselves so these industries can make their profits and this has to stop. The millions and millions of gallons and pounds of pesticides used in our country every year all come from fossil fuels. If the EPA wanted to be serious about climate change, then they have to address the use of synthetic pesticides and fertilizers. It's a false narrative that these petrochemicals are needed and necessary to grow our food, a narrative pushed by industry for their own purposes.

And I'm talking specifically about pesticides. The U.S. is very, very behind in regulating the use of pesticides. Approximately

one-third of the annual U.S. pesticide use are pesticides with active ingredients banned in the EU. The EPA routinely registers for use pesticides with ingredients widely considered around the world to be dangerous to human health. For example, multiple studies in California showed 13 agricultural pesticides they examined increased children's cancer risk up to two and a half miles away from the application site, but only five are classified as restricted use by the EPA, but 11 of those 13 are banned or not approved in other countries and 10 of those are banned in at least 28 countries.

Any pesticide, any chemical that causes cancer, especially in children, has to be banned, not regulated, not monitored, not minimized, not risk-reduced, but banned, banned for all uses. If you want to reduce risk for a toxic chemical, you stop using it. You stop the risk by stopping the use.

The mission of the EPA is to protect human health and the environment. So CleanUpForKids.org asks the EPA and this committee to prioritize people before profits and get us off the toxic pesticide treadmill and get farmers back in natural methods. Thank you.

JEFFREY CHANG: Thank you.

Lewis Brown? Is there a Lewis Brown?

(No response.)

JEFFREY CHANG: How about Virna Stillwaugh?

(No response.)

JEFFREY CHANG: William Jordan?

VIRNA STILLWAUGH: Jeff?

JEFFREY CHANG: Yes, Virna?

VIRNA STILLWAUGH: I'm here.

JEFFREY CHANG: Okay.

VIRNA STILLWAUGH: Sorry I didn't understand the process. Okay, yeah, good afternoon, I'm Virna Stillwaugh. I am the Vice President for Scientific Affairs on the Northwest Horticultural Council. I will represent growers, packers and shippers of apples, pears, and cherries in Washington, Oregon, and Idaho.

The fruit growers in the Pacific Northwest grow their crops using science and research-based practices. They perform integrated pest management practices, including scouting, the use of economic injury levels and economic thresholds before applying pesticides. They following insecticide resistance management programs by rotating pesticide

active ingredients, use high-precision equipment, and decision models to allow targeted and reduced pesticide applications. So they do a lot to reduce the use of pesticides.

Growers do not use pesticides unless they are needed, and in some cases, they have eliminated the use of some of these products, because they are more expensive than other control tactics. For example, for antibiotics and fungicides, they are used judiciously with established resistance management programs and we do resistance surveys in these states to determine if there is resistance from certain diseases that these products are used against.

So today, the surveys show that there is no resistance to these compounds in tree fruit in the Pacific Northwest. So we support the continued use of science and risk assessment regulatory policies of pesticides, including antibiotics and fungicides are important tools for fruit production and are needed in the (inaudible) against pests and diseases. Tree fruit growers in the Pacific Northwest want to continue to produce quality and healthy crops, but need to be able to out-compete insects, disease, and weed pests to obtain good

crop yields that result in an abundant and affordable food supply for all, while at the same time protecting the environment, the public.

So we welcome the continued opportunity and engagement from EPA and PPDC to (inaudible). It's important to hear growers' input, to know and learn what growers are actually doing to manage resistance and to reduce the use of pesticides, and we appreciate that EPA extends this opportunity.

Thank you for all of the great presentations and the updates and that's it. Thank you very much.

JEFFREY CHANG: Thank you, Virna.

William Jordan?

WILLIAM JORDAN: Hi there. My name is William Jordan. I am the Pesticide Team Lead for the Environmental Protection Network, and I want to talk about three topics, the budget, the Resistance Management Workgroup, and the Label Reform Workgroup.

On the budget front, it should be pretty clear that when you reduce the EPA staff levels by nearly 30 percent and when you cut the amount of money that they can spend on contracts, they're not going to be able to do everything that

they're required to do on the timelines that the statutes demand they do that, and every stakeholder that's spoken so far today has asked for EPA to do even more.

So I think it would be really smart for the full PPDC to spend some time thinking about what does OPP need in order to be fully funded to carry out its responsibilities and to look collectively at how to make that happen, including, at the very least, all of the stakeholders joining in some sort of message to the Congress asking them to increase the funding to the minimum level that's required in PRIA.

With regard to the Resistance Management Workgroup, it's a really solid piece of work, and my colleague, Steve Jones, had a lot to do with that. I want to underscore two ideas that are in the report of the workgroup. The first is the importance of a resistance management coordinator in OPP. If there's not a dedicated position for that, at least a significant part of one staff person's time, it's not going to get the kind of attention that it needs. And as so many of you have already said, resistance management is a critical issue for Pesticide Program, broadly speaking.

The second is the need for good data. OPP understands very well that it's best to base its policy and regulatory decisions on sound data, and what's required in the 682 regulations is just not going to get the kind of information about resistance incidents that people need. There are opportunities to revise the 682 regs or even to use the authority in Section 159.195 to direct specific companies to provide information on resistance issues, incidents that are not covered by the more general regulations.

And, third, I think that as the group goes back and reconsiders its report, it should also take a look at the issues that Nathan Donley talked about of putting more responsibility on registrants.

The Label Reform Workgroup has done good work; it's a good start; a lot of good progress, but there needs to be more attention paid to the user experience and how to translate the good work that OPP does on labeling into labeling that users can understand and readily use. That means looking seriously at the use of web-distributed labeling and building a system, also, that is 100 percent compliant in terms of not just having things submitted digitally -- there's a big difference

between a PDF and a Word document and a document that -- a file that is tagged with metadata that EPA can manipulate, use, and use to compare data and extract information for use in risk assessments.

So there's a lot of important work that the Label Reform Workgroup has an opportunity to tackle in the next six months or a year.

Thank you.

JEFFREY CHANG: Thank you, William.

We have made it through the full slate of public comments. A sincere thank you to our workgroup chairs who presented today, to our PPDC members, members of the public who listened in and shared their views, and to all the support staff that made today's session possible.

We will reconvene at 11:00 a.m. tomorrow using the same Zoom for Government link as today. That's it for me. Thank you for your participation today, and I will hand it over to Ed Messina to offer final words and adjourn the meeting.

Ed?

ED MESSINA: Thanks, everyone. I know that everyone on this committee has got other jobs and is very busy. Thank you for what you do in representing your respective stakeholders, and as I

mentioned, the process that we have here for reviewing pesticides and enabling growers to have products that they need to combat pests.

So thanks everyone for your time. Thanks for those who listened in on the channel. Hopefully, it was informative for you, and I look forward to another great day tomorrow with lots of great topics. Have a great evening, everyone.

(Day 1 adjourned.)