Transcript for U.S. EPA's Public Webinar:
U.S. EPA Public Webinar: Risk Management for Pigment Violet 29 (PV29)
February 23, 2021

Opening Remarks from Judy Kendall, U.S. EPA

Good afternoon, everyone, and thank you for joining EPA's Office of Pollution Prevention and Toxics seminar on Managing Unreasonable Risk for C.I. Pigment Violet or PV29 under the Toxic Substances Control Act. My name is Judy Kendall and I work in the Stakeholder Engagement Branch in the Office of Pollution Prevention and Toxics. We have about 100 people on the line today. During the webinar we'll be advancing the presentation slides using WebEx. You can also download the slides from EPA's PV29 Risk Management web page. Today's agenda, which is shown on your screen now, is also on that same web page. We'll start today's webinar with a presentation from EPA followed by a public comment period. EPA will not be answering questions during the webinar. Those who signed up ahead of time to make remarks will have five minutes to do so. Emily from Abt Associates will introduce each commenter in alphabetical order by first name. If you have registered to make a comment, please make sure that you're connected by phone properly through WebEx so that Emily can find your name in the list and unmute your line. Again, if there are technical issues please use the chat function in WebEx in the right-hand bottom corner of your screen or email Sarah Swenson at Swenson.sarah@epa.gov. With that, let's get started. Our first speaker this morning is Tanya Mottley who is the Director of EPA's Existing Chemicals and Risk Management Division in the Office of Pollution Prevention and Toxics. Tanya, please go ahead.

Introductory Remarks from Tanya Hodge Mottley, U.S. EPA

Thank you, Judy. Good afternoon, everyone. My name is Tanya Hodge Mottley and as Judy stated, I am the Director of the Existing Chemicals Risk Management Division in OPPT. I want to thank you for joining us. I am opening today's webinar to emphasize how much we value your input. This is a useful forum to insure everyone understands the risk management requirements under the Toxic Substances Control Act, the findings from the PV29 risk evaluation and for EPA to obtain public comment on risk management of PV29. You will learn today about the findings in our final risk evaluation and EPA's work to develop and propose regulations under section 6(a) of TSCA. Before I turn it over to my colleagues, I want to leave you with a few thoughts. With the amendments to TSCA that were enacted in 2016 and the arrival of the new Administration, the Agency is committed to ensuring the safety of chemicals used by all Americans. To that end, EPA will follow the science and the law. The new Administration is reviewing actions issued under the previous Administration. This review could result in additional steps to insure protection of human health and the environment. This review is being guided by various executive orders issued by the new Administration including those on environmental justice, scientific integrity, and regulatory review. EPA issued final risk evaluations for the initial 10 chemicals starting in June of last year and immediately began the risk management process. The PV29 final risk evaluation was issued in January 2021. The final risk evaluation shows that there are unreasonable risks to workers

and occupational non-users from 10 of the 14 identified conditions of use. EPA found no unreasonable risk to the environment, general population, bystanders, or consumers. I want to call your attention to the Agency's announcement from Friday, February 5th. This announcement informed people that the Agency is actively reviewing the final risk evaluation in light of statutory obligations and policy objectives related to using the best available science – as well as protection of human health and the environment. This process is ongoing at the Agency and we aim to keep stakeholders updated as decisions are made and as next steps are determined. It is important to know that during this review, outreach, and stakeholder engagements on risk management for the initial 10 chemicals with unreasonable risks will continue. The Agency is hosting this webinar so you can be aware of our work and through meetings like today's ensure that risk management rulemakings are guided by the law and informed by the best available science. We'll be using today to bring you up to speed on the key provisions of TSCA as it relates to the risk management requirements, to inform you about the unreasonable risk findings for PV29, and outline the next steps in the risk management process. Perhaps most importantly throughout this process we'll be seeking input from you on potential risk management approaches and their effectiveness and how best to ensure the safety of chemicals used by all Americans. Now is a critical juncture for you to be involved. Again, we need and appreciate your input, expertise, and feedback now, early in the process to help inform the ways we're going to address the unreasonable risks we found. You'll hear more from the EPA team about how you can get in touch and stay informed. Thank you again for your interest in TSCA and on behalf of the Office of Pollution Prevention and Toxics, we look forward to working with you. Thank you.

Presentation by Todd Coleman, U.S. EPA

Good afternoon, everyone. My name is Todd Coleman. I'm with the EPA's Office of Pollution Prevention and Toxics. I'm going to give a short presentation on PV29 and where the Agency has done work and where we plan to go on with work for PV29. So, with that, just jump right into it. This is the outline of what we're going to go through today: a little bit of background on the risk evaluation process under TSCA 21, findings from the risk evaluation for PV29, and we'll go over some of the risk management requirements under TSCA and this will be kind of a crash course in TSCA sections 6(a) and 6(c). And we'll do a little bit on the types of information to inform risk management, the principles for transparency in risk management in which we'll also include some more conversation about further opportunities for engagement with the Agency, and then we'll just go over a little bit more of additional information, some important contact info, and some hot links to the docket and materials the Agency has already generated for PV29. So, some of the basic risk evaluation statutory requirements. It's important to get the background on TSCA 21, where things stand, and what we are and are not allowed to do underneath the risk evaluation. So, EPA must evaluate risks presented by a chemical under the conditions of use and determine if the chemical presents an unreasonable risk of injury to health or the environment under the conditions of use. The Agency does this without consideration of costs or other non-risk factors, although as we'll talk about in a bit, the cost comes in later in the process when we start talking about risk management. And it is including unreasonable risk to potentially exposed or susceptible subpopulations determined to be relevant to the evaluation and the TSCA 21 requires that a risk evaluation be completed within three to 3.5 years. This is a really nice schematic that gives you a review

of where things go as soon as we start working with a chemical. So, it can come in one of three ways. We have to do prioritization and if a chemical is a high-priority chemical it will go right into the risk evaluation process. Then we had other statutory requirements for the first 10 chemicals. Then we had manufacturer requests coming in. All along this point of time we're going to deal with interagency collaboration. We deal with our colleagues within the EPA and the other offices and we also deal with other federal family organizations as we need to. So, after a chemical enters the risk evaluation stage, we have scope drafts for a 45-day public comment period on that draft scope and we take comments on it and then we'll put out a final scope. Once we do the hazard assessment, the exposure assessment, the risk characterization, and the draft risk evaluation, then we'll have another public comment period. We try to give the public a lot of time to comment and give us thoughts and insight as they see what the Agency's thinking. There are draft prioritizations or proposed prioritizations, then final prioritizations. You can see we do a draft scope, then a final scope. We'll do a draft risk evaluation and then a final risk evaluation meant to give the public plenty of opportunity to engage as they see what the Agency is thinking about a certain chemical. Some of our activities, our defining hazard or assuming or proposing, after the public comment period, we'll go into peer review, then final risk evaluation, and that's where we're at with PV29. We've done the risk evaluation process. We do have a final risk evaluation out. I'll talk a little bit more about dates and when things were published for PV29 in a bit, but that's where we're at. Now we're right down into the risk management area.

If after the risk evaluations there is no unreasonable risk, you can see that there is an exit and there would not be any risk management, but if there is unreasonable risk identified in the risk evaluation, it drops into a risk management action and that's where we'll start talking about those TSCA sections 6(a) and 6(c) pools to manage risk. Statutory deadlines are two to four years for that final rule, so, we've got a little bit of time but not an unreasonable amount of time to make sure that we put a final rule out to manage any unreasonable risks that we find in the risk evaluation. So, an overview of the risk evaluation explicitly for PV29. The final risk evaluation was published earlier this year in January. Fourteen conditions of use were evaluated. These conditions of use were identified using the CDR data and other publicly available forms of information to identify the conditions of use. The final risk evaluation follows a series of risk evaluation activities. As you saw before, we did prioritization, then we did everything else. For most of the chemicals, we did the first 10 or the manufacturer requests. All those things happen before the risk evaluation is actually rolled out. Plenty of opportunity for public interaction before the final risk evaluation is published. The PV29 draft risk evaluation was out in December of 2018, then we put out a revised draft risk evaluation October of 2020. We did a problem formulation in 2018 and a scope document in 2017. Public comments and external scientific peer review information informed the final risk evaluation. EPA counted up 49 public comments on the draft and the revised draft risk evaluation. On the peer review, we met to review the draft risk evaluation in June of 2019 and participated in a letter peer review for the revised draft risk evaluation in December 2020. All the documentation, all the public comments, everything is very transparent with the process. Everything is located in this docket right here. You can go to regulations.gov and then just search in the search box for that docket number, the EPA-HQ-OPPT-2018-0604 or the 2016-0725 on regulations.gov and it will give you all of the published documents for PV29 along with all the public comments. General information on PV29: so, that's kind of where we're at with PV29. We'll go over what it is. C.I. Pigment Violet 29 is the

Colour Index name used in sales of products containing CASRN 81-33-4. It's important to note that C.I. Pigment Violet 29 is assigned, copyrighted, and maintained by the Society of Dyers and Colourists and the American Association of Textile Colorists and Chemists. It is both produced in and imported into the United States. During the risk evaluation process, we started to go through the draft scope and figuring out where PV29 is used, imported, and manufactured. We identified conditions of use during various lifecycle stages of PV29: manufacturing, including imports, as we noted before, processing, distribution into commerce, and then use; industrial, commercial and consumer. PV29 is also recycled and disposed of. PV29 has a pretty wide range of uses but a lot of them are pretty adherent to the paints and coatings industry and plastic and rubber products, which we'll go over in a little bit. The percentage of PV29 that is used in those is pretty high versus the use as an intermediate in perylene pigments and the use in inks and consumer acrylic/watercolor paints. A point of note, the total aggregate production volume was between 603,420 pounds in 2015. We get that information from CDR.

So, a PV29 life cycle diagram. This is also in the final risk evaluation. The manufacturing/import 603,420 pounds of which each year. So, and then it's taken right from there and put into processing for use as an intermediate to create or adjust color of other perylene pigments. That's about 90 percent, and incorporation into formulation, mixture of reaction products is less than 10 percent. And then from there it goes over to its industrial, commercial, and consumer uses. As we noted, the paints and coatings and plastic and rubber products make up the predominant industrial, commercial, and consumer uses, with 10 percent split 5 percent between each of those two uses. And some of the smaller uses are merchant ink for commercial printing and then consumer watercolor and acrylic paints. As you can see the life cycle diagram also dumps down into recycling and disposal determinations of no unreasonable risk. So, as we noted when we put out the final risk evaluation, we had to make determinations of unreasonable risk and no unreasonable risk. EPA determined that PV29 does not present an unreasonable risk to the environment under any of the conditions of use. Under all 14 conditions of use there was no unreasonable risk to the environment. EPA also found there was no unreasonable risk to consumers, bystanders, or the general population in the use of PV29. EPA also found there is no unreasonable risk to industrial and commercial users of plastic and rubber products for automobile plastics and industrial carpeting. These no unreasonable risk determinations are considered final Agency actions and are issued by order pursuant to TSCA section 6(i)(1). So, these findings are final in the risk evaluation and they are driven by TSCA, so, can't really go back on those.

Now, the unreasonable risk determinations. This is what drives the risk management activities under TSCA. This is what we're going to talk about, that TSCA section 6(a) in a bit -- what this actually means for PV29, where it was found to be an unreasonable risk. So, of the 14 conditions of use EPA did find unreasonable risk to workers and occupational non-users or ONUs in 10 out of 14 conditions of use. And the sub-bullet shows a bit more of what those are, but I'll go into that in the next slide. Risk for workers and occupational non-users can come from long-term inhalation exposure and we'll talk a little bit more about that in a moment as well. EPA's determinations are based on unreasonable risks of injury to workers and occupational non-users during occupational exposures. The risk evaluation evaluated alveolar hyperplasia, inflammatory and morphological changes in the lower respiratory tract from chronic inhalation exposures. This is of important note at the bottom as well. EPA did not evaluate

cancer effects from chronic exposure because PV29 is not likely to be carcinogenic via genotoxic mechanisms. And that's kind of - it goes a little bit more into the deep science of it and it's all built out in the risk evaluation, but this is just going to give you a little flavor of where an unreasonable risk determination comes from and where it's set in. So, as I mentioned before, the 10 that we found unreasonable risk in kind of goes a little bit further into those: processing, the incorporation into a formulation, mixture or reaction products in paints and coatings; processing, again, in plastic and rubber products; processing intermediate in the creation or adjustment of color of other perylene pigments; recycling; industrial and commercial use in paints; automobile (OEM and refinishing); industrial and commercial use of paints and coatings, coatings and basecoats; industrial and commercial use of merchant ink for commercial printing; and then disposal. Then, the basis for the unreasonable risk determination, workers and the ONUs that were mentioned before. The unreasonable risk determinations for workers and ONUs are based on the following health hazards during occupational exposures of PV29. As I said before, long-term inhalation exposure which could cause alveolar hyperplasia, inflammatory and morphological changes in the lower respiratory tracts. Little bit of note on the PPE, personal protective equipment limit for PV29. OSHA has not set a permissible exposure limit for PV29. EPA assumes the PPE for respirable dust particulates will be used by manufacturing and processing workers – half face dust masks with APF of 10, and then industrial and commercial workers in painting and coating of automobiles are also expected to wear PPE, which is a supplied air respirator with APF of 25. EPA did not assume the remaining industrial, commercial and consumer use any PPE. Those are assumptions. And the EPA did not assume ONUs use PPE because they do not handle the chemical - the raw chemical.

So, with that, we'll jump right into the risk management requirements. As I said, we'll kind of go into a little bit of a crash course with TSCA and what our risk management options are underneath the 6(a). This might be repetition for some folks but maybe it's new information for others. Under TSCA, EPA is required to take action to address chemicals that pose unreasonable risks to human health or the environment. We found unreasonable risk with PV29 with respect to human health. So, that's what we're going to have to look at when we're doing risk management. EPA must issue a TSCA section 6(a) rule following risk evaluation to address all of the identified unreasonable risks within two years. That's a statutory mandate. We have proposed rule one year after the risk evaluation, final rule has to be out two years after the risk evaluation, and again, those timelines are not arbitrary. They are driven by TSCA. Specific requirements on consideration of alternatives, selecting among options, and statement of effects apply to risk management rules. The Agency will have a very large preamble with any rule, as many of you probably already know. This will be no different than that. We'll have a large preamble where we discuss our options and where things fell out and why we chose to go certain ways. We'll do a detailed economic analysis and we will also have statutory and an executive orders section that goes over all our statutory and executive order mandates, which we will talk about. Input from stakeholders is critical to the process. We'll talk a little bit more about how we're going to work to get more input from stakeholders as we go along. We're just starting the outreach for risk management underneath the PV29. So, we're beginning that process now and hopefully we have plenty of time to make sure that we get as much input from folks as we possibly can to have an informed risk management. There is a substantial increase in regulatory activities expected due to unreasonable risk findings across diverse

conditions of use. It's another note with the risk management requirements under TSCA 21 section 6(a), some of the regulatory options TSCA provides authority to regulate entities including distributors, manufacturers, and processors. An example of that would be the formulators who are working with PV29. Commercial users, the workplaces and the workers, and entities disposing of chemicals for commercial purposes -- your recyclers and your disposing facilities – those are the entities that TSCA section 6(a) allows the EPA to regulate or set regulatory requirements for using the risk management options. Some of the regulatory options.

Again, this might be repetitive for folks, but bear with me, we're not going to spend too, too much time on it. Just a little crash course in section 6(a). Some of the tools that we have in the TSCA section 6(a) toolkit. We can prohibit, limit, or otherwise restrict manufacture, processing, or distribution in commerce. We can prohibit, limit or otherwise restrict manufacturing, processing , or distribution in commerce for a particular use or for use above a set concentration. We can require minimum warnings and instructions with respect to use, distribution and/or disposal. We can require recordkeeping, monitoring or testing; prohibit or regulate manner or method of commercial use; prohibit or regulate manner or method of disposal by certain persons; direct manufacturers/processors to give notice of unreasonable risk determination to distributors, users and the public, and replace or repurchase. A couple of examples of regulatory options, because it kind of sounds like bureaucrats speaking when we go over what we can do, so, these are kind of some of the things that EPA has done with TSCA section 6(a) and that we would consider when we're doing any type of regulatory action for a chemical that poses an unreasonable risk. Some of it's pretty basic – providing a prominent label securely attached to an import container or product with specific directions, limitations, and precautions or that describes the health endpoints. Just so that users and folks that are sourcing these products are really aware of what's happening with this product and what kind of dangers it might pose. It's a giant labeling option we can use. We can prohibit importing, processing, and distribution for particular conditions of use with unreasonable risks. We have done that under TSCA section 6(a). It can be used. We can mandate specific engineering controls and PPE at occupational sites. We can require importers, processors, and distributors to maintain ordinary business records. It's a record keeping requirement with retention periods. We can require importers, processors, and distributors to provide downstream notification to help ensure regulatory information reaches all users in the supply chain, and that usually rolls with the recordkeeping requirement. If you're required to keep records and pass records on to downstream entities and folks still receiving or purchasing the product path to maintain those same records. And then we can set an occupational air exposure limit, for example, an existing chemical exposure limit. Examples of regulatory options - there's still more. We can require monitoring of exposures in occupational settings; mandate administrative controls and system requirements at occupational sites; mandate a training program at occupational sites and measures to limit access to the chemical; require a hazard communication program to educate workers on label directions, warnings, et cetera. These are all 6(a) tools.

This is an important one for TSCA Section 6(c) as I mentioned before. So, in order to promulgate any rule under 6(a), EPA must consider and publish a statement of effects of the rule based on the reasonably available information with respect to the effects and magnitude of exposure to human health and the

environment: the benefits of the chemical for various uses; the reasonably ascertainable economic consequences of the rule including consideration of the effect on the national economy, small businesses, technological innovation, the environment, and public health; the costs and benefits of the proposed and final regulatory action and one or more primary regulatory alternatives; and the cost effectiveness of the proposed regulatory action and one or more primary regulatory alternatives. This last bullet and all of its sub-bullets, as I mentioned before, with any final action with the Agency, we will do an economic analysis of some type. It will have to go into depth about the economic consequences of any options that we're considering and some of the alternatives under needs of consideration. So, the public's aware of the actual economic consequences of the rule. So, we have to consider human health and the environment. We also look at the economic consequences of any of the tools we're going to use under 6(a). As I mentioned a little bit earlier, in the preamble of any risk management activity, there will be what's called a statutory and executive order section in the preamble where the Agency will go over all the different executive orders that are considered in the development of any regulatory risk management option. I'm not going to go into depth about what each one of these executive orders is, but it's important to note that all these executive orders provide guidance to EPA on what has to be done in order to satisfy. In looking at them, the Regulatory Planning and Review Act, federal actions to address environmental justice; protection of children from health; environmental and safety risks; federalism; consultation and coordination with Indian tribal governments; activities that do not significantly affect energy supply, distribution, or use; consideration of small entities in Agency rulemaking and reducing regulation and controlling regulatory costs. The Agency has a lot of folks in the Office of Policy who are going to help the risk managers work to ensure that we satisfy these risk management activities or these executive orders and do the proper consultations and have the proper basis built into our economic analysis to ensure that we're looking at things such as working with children and how any type of risk management action is going to help with the protection of children, how environmental justice is being considered, the risk management options, and coordinating with Indian tribal governments. And a lot of this does also have to do with coordination and outreach, which we're going to talk about in a few more seconds. But we are, as I mentioned before, in the beginning stages of doing the outreach. This is our public webinar. We are planning on doing a roundtable with SBA and we will eventually get down into the federalism, Indian tribal government coordination, and one-on-one meetings with interested stakeholders as we need to.

Types of information that help to inform risk management: suggestions -- so, the Agency is always looking to have a transparent process for doing any sort of risk management options and looking at different ways we can manage chemicals to make the environment and human health operate in a safer way. So, in doing that, we like to get information from the public. We're always asking for feedback during the public comment periods but we take feedback pretty much at any point from prioritization all the way down to when we're developing the final risk management options. And what we're looking for is suggestions on effective methods EPA can use to address unreasonable risks, input on protective regulatory approaches, information related to controlling exposures including current work practices, engineering, and administrative controls. This is something that we work on with a lot of the interested stakeholders who are managing PV29 to get information on what they're actually doing to ensure that their workers and the environment are safe when they're using PV29. We've had really in-depth

conversations that I'm sure some of the folks on the webinar know about - how things are being monitored in the manufacturing facilities and how chemicals are transferred, what controls are in place. So, we're always looking for information on that. Always, always, always looking for information on how the chemical is being managed to ensure safety to human health and the environment, information on essential uses. The Agency wants to know if a use is completely essential and that also goes in line with working with some of our federal family -- the Department of Defense, the Department of the Interior, and other folks who have an essential use of a chemical where it can't easily be replaced or is built into the specifications for certain products and things that are required and considered essential uses, and the impacts if the chemical were not available. And some of that we look into the economic analysis as well: identification of uses that have been phased out or can be phased out and thus are no longer needed. Sometimes the Agency will identify uses that are historic and are no longer being used and when we put together these draft scopes and draft risk evaluations what we're signaling to folks is if you've got this use ongoing, we want to hear about it. But if you're going to tell us you moved on from using PV29 in between the CDR reporting time, we'd like to hear about that because sometimes the uses the Agency proposes to put risk management on it that have been naturally phased out. So, again, we're pretty far along in the process of PV29 but these are the types of information that we look for when we're going through the scopes and why it's so important for the public to engage us from the beginning on developing the background and all this scope and risk evaluation tools for the final risk management. Any information on substitute chemicals that are safe and effective alternatives. Sometimes it's really simple to substitute out a chemical. Sometimes it's really difficult. The Agency always wants to hear from industry, the folks actually using the product, the chemists that are actually formulating the blend and the proprietary chemicals that use this product, if there is a suitable alternative that can be effectively subbed out for a more dangerous or unreasonably risky chemical, and then suggestions on how the EPA can further improve its regulatory processes or be more transparent. That's kind of the overarching type of information that we're always looking to obtain. Principles for transparency during risk management, as I've mentioned several times. I don't mean to sound like I'm beating a dead horse. The Agency does really try to be transparent with where our heads are working on risk management and all the way throughout the process.

We try to provide transparent, proactive, and meaningful engagement. We're constantly reaching out to certain industry partners as we see a need to and we hope that folks are reaching out to us. We do have one-on-one meetings. We're doing a public webinar right now and required consultations with state and local governments, tribes back to the statutory executive order section in the preamble, where the Agency is required to reach out to state and local governments to accommodate, environmental justice communities, and small businesses. This bullet point kind of points the federalism executive order, tribes for the tribal executive order, the EJ executive order, and small business executive order. There's going to be an impact on small businesses. We always have found that extensive dialogue helps people understand the findings in the risk evaluation, the risk management process required by TSCA, and the options available for managing unreasonable risks. Obviously, we've gone through the process of doing the risk evaluation and drafts of scope. This kind of crash course in TSCA section 6(a) should be signaling to folks that these are the tools we have for managing the unreasonable risks to be identified with PV29 and this is the first step in us reaching out and trying to educate. And we're always available to try to

educate more on what TSCA is. We understand it's a complicated process. It's a complicated statue and so, anything we can do to help the public understand it a little bit better, is always really helpful for us so that folks aren't surprised or blindsided when they see what the Agency is considering in the way of risk management. We're always looking to seek input from stakeholders on potential risk management approaches, their effectiveness and impacts those approaches might have on business, workers and, consumers, and we look to get a lot of information in the public comment period after we put out a draft regulation under risk management. And then we're always looking for input on how the Agency can develop regulations that are practical and protective. Coordination and engagement. In developing the risk management approaches, EPA consults with stakeholders to learn about the conditions of use, existing engineering controls, personal protective equipment, available alternatives, or other programs to tailor effective risk management solutions. We usually start a lot of coordination and engagement really early on in the scoping period when we're identifying the users of PV29 and some of the downstream users of PV29 through the CDR and the public information searches. We start those consultations with those stakeholders at that point and then we hope to keep that consultation going on as we go forward. We do plant tours. We've been invited down for plant tours for other chemicals where we're walked through step by step how the chemical is created and in some ways managed, then sent off to other facilities for use. And it's important for us to understand exactly how every chemical is managed because every chemical is managed differently, so, we try to consult early with stakeholders and there should be a pretty hefty record of that in the public dockets for PV29 with all the public comments and all the different conversations that we reference back to on where we've met and toured with stakeholders to try to understand their manufacturing and processing facilities a little bit better. As I mentioned before, we conduct site visits to obtain detailed information on practices in chemical manufacturing, processing, and use. And then we develop an extensive network among all stakeholders to ensure the regulatory approaches are fully informed and based on current conditions. We try to keep a completely open dialogue with stakeholders who are using and processing PV29 who find it essential to their businesses, so that we know exactly how they're managing it at their facilities point in time, so again, we're not making assumptions based on old information that may be out there that we found publicly available but we're talking to the actual movers and shakers who are using these chemicals, processing the chemicals and so then we know exactly how it's being managed in real time. More opportunities for engagement. The Agency is always interested in one-on-one meetings and when we get to the final slide, there will be some contact information if folks are interested in one-on-one meetings. We meet on a company level, a one-on-one level, and then we also meet with a lot of trade groups who represent larger industries. We're happy to engage anyone who has some information for us or who would like more information on TSCA. Understand of course that a lot of the times that we interface with folks, we hope to get some more information and we like to have that information publicly submitted to the docket so that we can use that information in developing the risk management options and further refining our economic analysis. Webinars providing overviews of the final risk evaluations and unreasonable risk determinations. Other chemicals follow their risk evaluations as well. And then consultations seeking targeted feedback with states and local governments – that's the federalism executive order that I was mentioning before. The tribal, the small business, and the EJ executive orders as well. So, those consultations will be separate. We don't have overarching consultations to satisfy all those groups. We separate those so that we can have the right people in the

room speaking to the points that are relevant to those groups point in time. And again, when we do finally put out a risk management proposal that proposes regulatory options, we will speak to all the consultations that we had done with those groups so that folks can review that and its part of the preamble in the statute in the executive order section. So, this is a little bit more about the Biden-Harris Executive Order on Protecting Public Health and the Environment. EPA is actively reviewing the final risk evaluations to ensure they use the best available science and protect human health and the environment. And the Agency will keep stakeholders updated as decisions are made and the next steps are determined. It's a new executive order, as everyone is probably very aware, and the Agency is actively reviewing the final risk evaluations to make sure that we've got the best available science and we're doing everything we can to protect human health and the environment. So, again, as we make decisions, we'll keep folks updated. A little bit of general information for everyone: general TSCA, as I gave you guys a quick, terse, TSCA crash course. The general TSCA website does an even better job of it because it doesn't mumble and stutter as I do. So, feel free to just take that hot link and keep it on your browser so you can see all the different options and what we can do and then an Agency updates page where we talk about our current risk management activities. We try to update this as soon as things are going out. I am the point of contact for risk management for PV29 and if you had general risk management outreach, if you're interested in those one-on-one meetings, trade meetings, industry meetings, Doug Parsons is our meetings guru. He's been doing it for quite a while and he's really phenomenal at it - extremely responsive so, there's Doug's information as well. But feel free to reach out to me with any general questions or concerns with PV29. I'm happy to be a resource. I'm jumping ahead of myself. So, with that, that's my webinar. Thanks, everybody. I hope that wasn't too painful.

Public Comment Period

Andy Komai

This is Andy Komai. I work with United Autoworkers. I have been trained in industrial hygiene and I wanted to make the comment that there is this hierarchy of controls that we emphasize and we can't really rely on PPE respiratory protection to control paint exposure. So, we've done a lot of work around ventilation in paint booths in the heavy truck industry in North Carolina, Tennessee, Detroit, Ohio, where we do have worker exposure where we really can't rely on respiratory protection to reduce exposure. I just wanted to make that point real clear. Thank you.

Maryann Hoff

I am with PPG and my role is Director of Advocacy for Environment Health, Safety, and Product Stewardship Issues for the corporation. My comments today, which I really appreciate this opportunity, are more geared towards my experience as an industrial hygienist and my 30 years of experience in the paint/coatings industry. So, I welcome further discussion and collaboration on these points, but I wanted to highlight a number of issues with my comments. I really wish to encourage EPA to understand industrial hygiene principals and sampling considerations and also stress the importance of collaborating with OSHA, ACGIH, NIOSH, and others in the industrial hygiene community in order to help develop more robust risk management strategies. In the IH processes the previous speaker just alluded to, there

is a hierarchy. So, we go through our recognition evaluation control. It's the basic tenets of industrial hygiene. But before sampling, we need to understand the hazards of the substance. In the case of PV29, I understand it's the alveolar chronic exposure that can cause the non-cancer health effects. However, as a practicing industrial hygienist we really need an exposure limit to which to compare any air sampling. So, before I start talking about sampling, we really need an exposure. We need to understand what is the acceptable limit. So, reading the PV29 assessment it seemed that there was reference to carbon black as being an analog and if that is the case, the other part we need to understand is, are we looking at total dust, an inhalable fraction, or the respirable fraction? For PV29 there is no information on the inhalable fraction that I could see. There's total dust, and then EPA requested more information for the respirable. So, if the focus is going to be on respirable, I recommend setting an exposure limit for the respirable fraction and also, as far as sampling methodology, I know that EPA had a comment that the previous method wasn't done properly. The sampling was too short and actually, the sampling was incorrect. So, I think moving forward as we get into risk management, we really need to be on the same page from an industrial hygiene standpoint and an EPA standpoint. There are so many tenets of industrial hygiene that are so different from environmental management and environmental protection and monitoring. So, when data are collected for something as specific as PV29, it is very appropriate to only run the sampling pump when that material is being handled and then actually the concentration of air that is used to come up with the final milligram per cubic meter exposure is the air that would be breathed during the entire work shift. So, it would be a time weighted average for either the 10-hour shift or 12-hour shift as in the case of PV29. So, I'm bringing these up as examples that, like I said, we really need to be on the same page moving forward before we ask industries to start doing samplings. We need to understand why, what the limit is, how to sample the two methodologies that were referenced for PV29. The NIOSH 0600 method was the one for respirable, but they also used a total dust method for the total dust, which was NIOSH 0500. Two different methods, two different sampling rates. The other thing to point out is that when these procedures are followed, there can be no deviation. There was a reference on page 53 of the risk assessment that the larger sample air volumes would have been achieved if the sampling team would have arranged for longer sampling periods or used equipment that operated at a higher flow rate. But the 1.7 liters per minute is very specific to using a cyclone and capturing the respirable fraction. So, I'll stop there. There are so many other comments and considerations that I could probably go on to fill the time of the other remaining speakers, but once again, I do welcome a one-on-one discussion to further discuss the industrial hygiene aspects to work towards risk mitigation. Thank you.

Closing Remarks from Judy Kendall, U.S. EPA

Thanks for those public comments and for your participation in today's webinar on the risk management of PV29. There will be an audio recording and a transcript of this webinar available on the PV29 risk management website. The team here in the Office of Pollution Prevention and Toxics looks forward to a continued dialogue with you on risk management under TSCA. Thanks again for joining us today. That's the end of the meeting. Thank you.