

Transcription details:

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Transcription results:

[silence]

S1: 01:34 The EPA meeting on 1,4-Dioxane risk evaluation will begin in about three minutes.
[silence]

S1: 04:44 Good day. Welcome to this public webinar presented by the US Environmental Protection Agency. 1,4-Dioxane Risk Evaluation and Risk Management under TSCA Section 6. My name is Meredith Fritz, assisted by Vincent Brown, and we are from Battelle. Battelle is a contractor providing meeting support for today's meeting. This event is being recorded. The hosts may use Webex chat to share announcements with all attendees, but attendees will not be able to respond to the chat. I will now introduce Niva Kramek, the leader of this call for the US EPA. Niva?

S2: 05:23 Thank you. Good afternoon, everyone, and thank you for joining EPA's Office of Pollution, Prevention, and Toxics webinar on managing unreasonable risks for 1,4-Dioxane under the Toxic Substances Control Act. My name is Niva Kramek. I'm a team lead in the Existing Chemicals Risk Management Division. My role will be to moderate today's webinar. We have approximately 200 people on the line, including attendees from across the United States. I'm going to provide an overview of the technical aspects of the webinar and what to do if you need assistance. First, if you experience technical difficulties, please email me at kramek.niva@EPA.gov and also Vince Brown at brownv@battelle.org. For today's webinar, we'll be advancing the slides through the presentation using Webex. You can also download the slides from the 1,4-Dioxane Risk Management website. Today's agenda is also on that website.

S2: 06:25 Today's webinar will start with a presentation from EPA. Then after the presentation, for those who signed up to make remarks, we'll have a period for public comment. We're limiting those remarks to five minutes per person. The webinar operator will introduce the speakers during the public comment period. If you have registered to make a comment, please be sure you're connected through the Webex so the operator can unmute you. Again, if there are technical issues, please email me at kramek.niva@epa.gov, and I'll spell that out, K-R-A-M-E-K dot N-I-V-A at E-P-A dot gov, and also Vince Brown at brownv@battelle.org. I'll spell that out B-R-O-W-N-V at B-A-T-T-E-L-L-E dot O-R-G. You can also send a message in the chat regarding any technical difficulties. The agency will not be answering questions during the webinar. Please know there are a variety of other forums that will be described during the presentation if you have questions or if you are interested in further dialog on risk management. With that, let's start the webinar. Our first speaker this morning is Tanya Mottley, the director of the Existing Chemicals Risk Management Division. Thank you, Tanya. Please start your remarks now.

S3: 07:51 Good afternoon, everyone. My name is Tanya Hodge Mottley, and I'm the director of the Existing Chemicals Risk Management Division in the Office of Pollution Prevention

and Toxics. I'm opening today's webinar to emphasize how much we value your input. This is a useful forum for the agency to obtain public comment on the implementation of the Toxic Substances Control Act and risk management of 1,4-dioxane. Today we will discuss the findings of our final risk evaluation and EPA's work to develop proposed regulations under Section 6 of TSCA. But before I turn it over to my colleague, Cindy, I want to leave you with a few thoughts. With the amendments to TSCA that were enacted in 2016, we have been building a new regulatory program from the ground up. As with many things in life, the way EPA works to ensure chemical safety and indeed the way Congress directed us to undertake this work is a process. We've taken some big steps in that process over the past several months by issuing all of our first 10 risk evaluations for methylene chloride, 1-bromopropane, HPCD, carbon tetrachloride, trichloroethylene, NMP and more. Today we are focusing on 1,4-dioxane with a final risk evaluation issued in early January 2021. In each of these risk evaluations, we identified whether there are unreasonable risks of injury to health or the environment.

S3: 09:24

For 1,4-Dioxane, we have determined there are unreasonable risks to workers and occupational non-users. Now we are taking the next step in the process by moving to the risk management phase. When unreasonable risks are identified, TOSCA requires the agency to undertake a rulemaking process to address the unreasonable risks. I want you to be aware of our work and, through meetings like today's, contribute to the risk management rulemaking under TSCA. The agency wants you involved early in the process, and I thank you for joining us in today's meeting. Excuse me. We'll be using this opportunity 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 1,4-Dioxane and to outline the next steps in the process. Perhaps, most importantly, throughout this process, we'll be taking input from you on potential risk management approaches, their effectiveness, and any impact those approaches might have on stakeholders. Your feedback is important to us as we develop regulations that are practical and protective. Today kicks off that process. Now is a critical juncture for you to be involved. Again, we need and appreciate your inputs, expertise, and feedback now early in the process to help shape the way we are going to address the unreasonable risks that we've found. You'll hear from Cindy more about how you can get in touch and get involved. Thank you again for your interest in TSCA. On behalf of the Office of Pollution Prevention and Toxics, we look forward to working with you. Thank you.

S4: 11:11

Thank you, Tanya. Hi, my name is Cindy Wheeler, and I work in the existing chemicals risk management division at EPA, and I am going to be talking this afternoon about our 1,4-Dioxane risk evaluation and our risk management activities under TSCA section 6. Next slide, please. Okay. On slide 2, there's an agenda for my presentation that I will be talking about. I will be giving you some background on the risk evaluations, the findings from the risk evaluation for 1,4-Dioxane, general risk management requirements under TSCA, the types of information that can inform risk management, our principles for transparency during risk management, and some additional contact information. Next slide, please. On slide number 3, risk evaluations, statutory requirements; EPA must evaluate the 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. That has to be without consideration of cost or other non-risk factors, and it must include unreasonable risks to potentially exposed or susceptible subpopulations determined to be relevant to the evaluation. And TSCA finally requires the risk evaluation to be

completed within three to three and a half years. Next slide, please. And I'm going to turn my video off so we can concentrate on the slides.

S4: 12:52

This is slide number 4, and it provides a flow-chart illustrating the risk evaluation process and the timeline. We move from prioritization to high priority chemicals, manufacture requests. 1,4-Dioxane was one of the first 10 chemicals which sort of got jump-started by the statute. Risk evaluation involved all of these elements: hazard assessment, risk exposure assessment, risk characterization. We published a draft risk evaluation for public and peer-review comment, and we have now published the final risk evaluation. Next slide, please. On slide number 5, I'm going to give you a little overview of the risk evaluation for 1,4-Dioxane. The final risk evaluation was published on January 8th of this year. There were 24 conditions of use evaluated and the final risk evaluation followed a series of risk evaluation activities, including a supplemental analysis published in November 2020 for public comment, the draft risk evaluation published in June 2019 for public comment and peer review, the problem formulation document published in June 2018, and the scope document published in June 2017. Public comments and external scientific peer review informed the following risk evaluation. We received 34 public comments on the draft risk evaluation. The peer review, the Science Advisory Committee on Chemicals, SACC, met to review the draft evaluation in July of 2019, and we also received 16 public comments on the supplemental analysis that was published in November of 2020. The final risk evaluation and supplemental materials are in this docket, EPA-HQ-OPPT-2019-0238, and we have some additional materials in another docket, EPA-HQ-OPPT-2016-0723. And that's what regulations backed up. Next slide, please.

S4: 15:15

And now I'm on slide 6. This is some general information on 1,4-Dioxane. It is a clear, volatile liquid used primarily as a solvent. EPA identified conditions of use during various life cycle stages, such as manufacturing which includes import, processing distribution and commerce, use, and disposal. 1,4-Dioxane is also found as a by-product in commercial and consumer cleaning products and other products. 1,4-Dioxane is used as a catalyst, an intermediate and [inaudible] solvent in the production of other chemicals including agricultural chemicals and plastic. 1,4-Dioxane is also used in laboratory applications, functional fluids such as metalworking fluid, film cement, printing inks and dry film lubricant. The total annual production volume of 1,4-Dioxane in 2015 was approximately one million pounds. Next slide, please. Slide 7: determinations of no unreasonable risk. EPA determined that 1,4-Dioxane does not present an unreasonable risk to the environment and to the general population under the conditions of use. EPA further determined that 11 of the 24 conditions of use of 1,4-Dioxane do not present an unreasonable risk of injury to health or the environment. There is no unreasonable risk to terminations or considered final agency actions, and they are issued by order pursuant to TSCA Section 6(i)(1). Next slide, please.

S4: 16:49

Slide number 8: the determinations of no unreasonable risk. Distribution and commerce, industrial and commercial use in functional fluids and spray polyurethane foam, and eight consumer uses. Used in textile dye, antifreeze, surface cleaner, dish soap, dishwasher detergent, laundry detergent, paint and floor lacquer, and spray polyurethane foam. Next slide, please. This is slide number 9: the unreasonable risk determination. EPA determined that 13 of the 24 conditions of use of 1,4-Dioxane presents an unreasonable risk of injury to health. EPA's determinations are based on unreasonable risk of injury to workers during occupational exposures. EPA's risk evaluation identified unreasonable risk for liver toxicity from acute inhalation and dermal exposures and olfactory epithelium effects and increased risk of cancer from

chronic inhalation and dermal exposures to 1,4-Dioxane. Next slide, please. Slide 10 lists the conditions of use for which EPA has found unreasonable risk. Here we have manufacture. That includes domestic manufacture and import/repackaging. We have four processing conditions of use: repackaging, recycling, processing as non-incorporative use, and as a reactant. And then we have some industrial and commercial use. Used as an intermediate, as a processing aid in laboratory chemicals, in adhesives or sealants, in printing and printing compositions, in dry film lubricant, and in disposal. Next slide, please.

S4: 18:49

This is slide 11, the basis for the unreasonable risk determination for workers. The unreasonable risk determination for workers are based on the following health hazards during occupational exposures, liver toxicity from acute inhalation and dermal exposure and olfactory epithelium effects and increased risk of cancer from chronic inhalation and dermal exposures. With respect to personal protective equipment, the OSHA permissive exposure limit or PEL for 1,4-Dioxane, which was established in 1971, is 100 parts per million. Many conditions of use presented an unreasonable risk to workers even with the use of gloves with a protection factor of 20. No unreasonable risk to workers due to acute and chronic exposure, but that assumes the use of respirators with an APF of 50 in industrial and commercial settings. EPA does not assume that occupational non-users use personal protective equipment because they do not handle the chemical. Next slide, please. Now, moving on to risk management requirements on slide 12. Under TSCA, EPA is required to take action to address chemicals that present unreasonable risk to human health or the environment. EPA must issue a Section 6(a) rule following risk evaluation to address all identified unreasonable risk within two years. The proposed rule must be issued one year after the risk evaluation, and the final rule must be issued two years after the risk evaluation. There are specific requirements on the consideration of alternatives, selecting among options, and the required statement effects that apply to the risk management rule. An input from stakeholders is critical to this process. Next slide, please.

S4: 20:50

Slide 13, that's half the Section 6(a) regulatory options. This is our toolbox for addressing unreasonable risk under TSCA Section 6. EPA may prohibit, limit, or otherwise restrict manufacture, processing, or distribution and commerce. We may prohibit, limit, or otherwise restrict manufacture processing, distribution, and commerce for a particular use or for use above a set concentration. EPA may require minimum warnings and instructions with respect to use, distribution, and/or disposal. EPA may require record-keeping, monitoring, or testing. EPA may prohibit or regulate the manner or method of commercial use and the manner or method of disposal by certain persons. EPA may direct manufacturers processors to give notice of the unreasonable risk determination to distributors, users, and the public and replace or repurchase. Next slide, please. Slide number 14, continuing with the regulatory options, TSCA provides the authority to regulate entities, including distributors, manufacturers, and processors, for example, formulators, commercial users, workplaces, and workers, and entities disposing of chemicals for commercial purposes. Next slide, please. Slide number 15. This is TSCA section 6(c). This is the statement of effects that EPA must consider and publish with any rulemaking under TSCA Section 6(a). So we must consider and publish based on recently available information the effects and magnitude of exposure to human health, the effects and magnitude of exposure to the environment, the effects of the chemical for various uses, and the reasonably ascertainable economic consequences of the rule, including consideration of the likely effect on the national economy, small business, technological innovation, the environment, and public health. The costs and benefits

of the proposed 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. Next slide, please.

S4: 23:20

Slide 16 lists some executive orders that are relevant to TSCA Section 6(a) rulemakings. I'm not going to read through all of them, but here we have executive order 12866 which involves regulatory planning and review, executive order 1298 which addresses environmental justice, executive order 13045, protection of children from environmental health and safety risks. And also federalism, co-ordination with Indian tribes and other entities. Next slide, please. Slide 17, these are the types of information that tend to be very useful in informing risk management. So, EPA would be looking from stakeholders for suggestions on effective methods that we can use to address the unreasonable risk. We'd look for input on protective regulatory approaches, information relating to controlling exposures including current work practices, engineering, and administrative controls. Information on essential uses and the impact of the chemical were not available. Identification of uses that have been phased out or can be phased out and thus are no longer needed. Any information on substitute chemicals that are safe and effective alternatives and suggestions on how EPA can further improve its regulatory processes or be more transparent. Next slide, please.

S4: 24:57

Slide number 18, this is EPA's principles for transparency during risk management. EPA is looking for transparent, corrective, and meaningful engagement from stakeholders. We are holding one-on-one meetings, public webinars, and the required consultations with state and local governments, tribes, environmental justice communities, and small businesses. We believe an extensive dialogue will help people understand the findings in the risk evaluation, the risk management process required by TSCA and the options available for managing unreasonable risk. EPA is seeking input from stakeholders on potential risk management approaches, their effectiveness, and the impacts those approaches might have on businesses, workers, and consumers. Stakeholder input can help the agency develop regulations that are practical and protective. Next slide, please. Slide 19, coordination and engagement. In developing risk management approaches, EPA consults with stakeholders to learn about conditions of use, existing engineering controls, personal protection equipment, available alternatives, or other programs to tailor effective risk management solutions. EPA conducts site visits as necessary to obtain detailed information on existing practices in chemical manufacturing, processing, and use. We have not been doing that recently due to the pandemic, but we are looking forward to doing that again in the future. EPA also developed an extensive network among stakeholders to ensure regulatory approaches are fully informed and based on current conditions. Next slide, please.

S4: 26:47

And this is slide 20, opportunities for engagement. EPA is always happy to meet one-on-one with stakeholders. We are providing webinars with overviews upon our risk evaluations and the unreasonable risk determinations, and we are also doing our consultations which seek targeted feedback with states and local governments, tribes, small businesses, and environmental justice organizations and communities. Next slide, please. And this is additional information. These are some websites that may be of interest to you. The general TSCA, that's a description of how TSCA works and how certain chemicals are being managed under it. Current Chemical Risk Management Activities is another website of interest. And we have a 1,4-Dioxane risk management website, and I am the main contact for the 1,4-Dioxane risk management activity. That's my name and email and phone number up there. And general risk

management outreach. And also contact Douglas Parsons one of my coworkers at parsons.douglas@epa.gov, and he can be reached at 202-564-0341. I'm Cindy Wheeler again, wheeler.cindy@epa.gov, and my phone number is 202-566-0484.

And I believe that is the last slide. So that concludes my presentation, and I will now turn it over to Battelle to start calling on the public commenters.

S1: 28:45

Great. Thank you, Cindy. And we will now begin the public comment period. When you're making your comment, please state your name and affiliation if you have one. So, at the beginning of your public comment, please do state your name and any affiliation. I'm going to turn control over to the operator, Vince, who will introduce the speaker and open their line. We'll then continue this until all the speakers who have signed up have completed their remarks. Again, please limit your remarks to five minutes per person, and don't forget to include your name and affiliation.

S5: 29:23

Okay. Thank you. This is Vince Brown from Battelle. I'm the Webex host. And just a word, if you registered to make a public comment, but you connected by phone only, I will not be able to find you and unmute you in the attendee roster. If you would care to make a public comment, please refer to the email of invitation and log in through Webex. That way, I will see your name and be able to unmute you. What I'll do is call each name in turn and then unmute your line and introduce you at that time. The first one on my list is Manuel Gomez. Manuel Gomez, if you can hear me, please go ahead.

S6: 30:05

Yes. Should I start?

S5: 30:07

Yes, please.

S6: 30:10

I am Dr. Manuel Gomez, a retired veteran of the Occupational Safety and Health Administration, the US Chemical Safety Board, the EPA, the American Industrial Hygiene Association, and other health and safety entities. I am here to recommend, to urge that the EPA assume primary responsibility for developing and issuing occupational health standards for chemicals that are found to present unacceptable workplace risk on the TSCA assessment procedures and require timetables instead of surrendering that primary authority to OSHA. I speak today with a focus on 1,4-Dioxane because the agency has determined that its occupational risks are the most severe, but my arguments apply equally to any chemical for which EPA finds a reasonable risk on the TSCA. Since its founding 50 years ago, OSHA has been unable to issue occupational health standards in anything even close to a timely manner. And it has even sometimes been entirely unable to do so, as was the case with the failed proposed standard to protect workers from ergonomic hazards. While obviously not a chemical hazard, that experience illustrates how difficult it would be if OSHA were to attempt the standard for Dioxane or other chemicals under TSCA. It goes without saying, of course, that OSHA and NIOSH and sometimes other agencies must participate actively in the process with their expertise. And I understand there's already an MOU between EPA and OSHA to collaborate for this purpose. But the regulatory action should come under EPA authority and mandatory TSCA timetables, so the standards have a chance of becoming reality in a reasonable time frame.

S6: 32:09

In 2012, GAO report documented that the time to develop standards averaged more than seven years for OSHA. And in a failed OSHA effort to modernize 300 or so of its roughly 500 permissible exposure levels for chemicals a few years ago, OSHA reported that, and I quote, "Most have not been updated since 1971, and many are based on science dating back to the mid-to-late 1960s," end of quote. Not to mention that there are tens of thousands of other chemicals in commerce to which workers are

potentially exposed, all with an enforceable exposure standard or any other means of enforceable protection. So, and I quote OSHA once again, "Workers are essentially covered by the same PELs as they were 40--" actually now 50 years ago. "And while OSHA has been given no new tools to control workplace exposures, it has had to conduct increasingly resource-intensive analyses that have slowed the PEL rulemaking process to a crawl. Since 1971, OSHA has been successful in establishing or updating PELs for only about 30 chemicals," end of quote. And I also want to mention that OSHA's current PEL for Dioxane is more than 350 times the permissible level under California's OSHA standards. In addition, there is strong evidence that there are an estimated 60,000 premature deaths through occupational disease each year compared to some 10,000 deaths through accidents. While both figures are unacceptably high for a developed country like ours and preventable, the occupational disease deaths are typically silent and, thus, often receive less attention.

S6: 34:06

Considering the urgency to address the massive public health impact of occupational disease, we can at least begin to make a dent if EPA undertakes regulatory action under TSCA procedures and timetables when a chemical is found to present occupational risk, as is the case with Dioxane and others. EPA is in a far better position to issue a standard in a timely manner in collaboration with other agencies, and it should take the regulatory lead under its authority rather than OSHA. Occupational health standards issued under EPA TSCA authority and mandate will certainly face legal and political obstacles that I cannot review in five minutes, but what is certain is that the new TSCA Act has court-enforceable timeframes which would, at the very least, exert pressure for more timely protection for workers than can be obtained under OSHA. Thank you.

S5: 35:12

Okay. Thank you. Wanted to clarify an earlier statement I made. If you've been watching the slides, and you're a public commenter, then you are already in Webex, and we will be able to find you. My comment about the calling people was only for those who use the phone only and not the Webex website. The next speaker is Steve Risotto. And as soon as I can get him unmuted-- Steve, if you're there, please go ahead.

S7: 35:46

Yes. Good afternoon. Can you hear me?

S5: 35:47

Yes.

S7: 35:49

All right. Thank you. Good afternoon. I am Steve Risotto, senior director at the American Chemistry Council. ACC has followed the development of the 1,4-Dioxane risk evaluation closely and submitted the results of a 90-day mode of action study to help inform the agency's consideration of the chemical. The results of that study, which have now been published in two peer-review journal articles, provide strong biochemical, histopathological, and toxicogenomic evidence for an early mitogenic response occurring at doses that exceed the metabolic clearance threshold of the animals. This non-genotoxic mode of action is acknowledged in EPA's 2005 cancer risk assessment guidelines and is especially relevant to the liver in sensitive rodent strains such as the mouse strain under consideration here. These two new studies also support a lack of any primary genotoxic insult associated with the mouse liver tumors. We encourage EPA staff to continue to investigate the cancer mode of action for 1,4-Dioxane as it develops risk management measures for the conditions of use of the chemical. Despite agreeing that the available data do not suggest the genotoxic mode of action for cancer, and that substantial evidence exists for a threshold MLA, EPA has continued to apply its default assumption of a linear low-dose response in evaluating the potential cancer risk associated with exposure to 1,4-Dioxane.

S7: 37:20 As we have previously noted, this approach is in direct conflict with that taken by Health Canada, the World Health Organization, and the European Union. In the draft risk evaluation released in the summer of 2019, EPA staff excluded data for female mice, when the study conducted at the Japan Bioassay Research Center as reported by [inaudible] et al. in a 2009 publication. As a result, the oral cancer slope factor in the draft evaluation was five times higher than that calculated in the 2013 assessment conducted for the Integrated Risk Information System, or IRIS. In explaining this decision, the draft risk evaluation noted that the female mouse data exhibited a low control group incidence and a 70% response rate at the lowest dose, followed by a plateau. The draft risk evaluation further explained that the analysis excluded the female mouse results from [inaudible] et al. because of the modeling gymnastics required to generate the cancer slope in the IRIS assessment, concluding that the data were unsuitable for risk model. EPA did not seek comment on its decision to exclude the female mouse data in the draft from the science advisory committee on chemicals last fall, nor did the committee offer any comments on this decision. Nevertheless, EPA staff reached out to the Japanese researchers for individual animal data in order to conduct the time-to-tumor analysis of the female mouse data that is the basis for the cancer slope factor in the final risk evaluation. This analysis has not been subject to peer review or to notice and comment. In fact, the change was not identified as part of the agency's supplemental analysis for consumer and surface water exposures, which was issued from an abbreviated comment period in December.

S7: 39:11 In reviewing the data provided in Appendix K of the risk evaluation, however, we note that only a 50% survival rate in the control group. That result combined with the background incidents of liver tumors among controls suggests that a time-to-tumor analysis is not adequate for assessing the female mouse data. While EPA ACC recognizes that the death risk evaluation for 1,4-Dioxane is now complete, the agency should continue to refine its analysis as it embarks on the next phase of the process outlined in TSCA. We believe that the data, collected as part of our 90-day study provides strong support for mitogenic threshold MOA for cancer and raise additional questions about the findings reported by [inaudible] et al. that are the basis of the agency's cancer risk evaluation. Thank you.

[silence]

S5: 40:11 Great. Thank you. Our next public speaker is Shakil Saghir. Shakil, if you can hear me, please go ahead.

S8: 40:24 I don't have any comments at this time. Thank you.

S5: 40:27 Okay. Thank you. Our next commenter is Claudia Walecka-Hutchinson. Takes me just a second here. Claudia, if you can hear me, please go ahead.

S9: 40:50 Can you hear me? This is Claudia.

S5: 40:51 Yes. Go ahead.

S9: 40:53 I have no comment at this time. Thank you.

S5: 40:54 Okay. Thank you. Our next is Vasilis Vasiliou.

S10: 41:11 Do you hear me? Okay.

S5: 41:12 Yes. Yes. Vasilis, please go ahead.

S10: 41:16 Okay. My name is Vasilis Vasiliou. I'm the chairman of the environmental health sciences from the Yale School of Public Health. And I listened to all the comments and

everything. I just have to tell you we have a paper, which is under revision right now, which we have seen that there is DNA damage by 1,4-Dioxane. Unfortunately, it's not published yet, but we do have substantial more evidence about the action of 1,4-Dioxane in males now that it might require more molecular mechanisms. And unfortunately, it's not published data, but I just want to increase the concern that we don't have a complete mode of action, at least at the molecular level, of this chemical. And that's all I have to say. And there are two more papers published in 2020 from other groups that indicate that 1,4-Mioxane has a genotoxic effect. With that being said, the dogma is that Dioxane may offer two types of action, one is mutagenic, and the other is genotoxic. But we do have DNA damage detected in our studies. That's all I have to say. And we hope that our paper will be published very soon, a series of papers indeed.

S5: 43:04 Okay. Thank you. Our next public comment person is Adrienne Esposito.

S11: 43:19 Yes. Thank you. Can you hear me?

S5: 43:21 Yes. Adrienne, please go ahead.

S11: 43:23 Yes. Thank you. My name is Adrienne Esposito. I am the executive director of Citizens Campaign for the Environment. We are a 120,000-member organization throughout New York and Connecticut. I just wanted to make two points. One is that I noticed in your presentation that you only evaluated exposure risk from one personal care product, which was-- excuse me, two, laundry and dish soaps. But you did not seem to, at least in the presentation, take into consideration dermal exposure or inhalation from other personal care products including shampoo, bath gels, baby bath products, all of which have 1,4-Dioxane in them. CCER organization did an independent study and had a laboratory certified by New York State test 80 different common household products for adults and for children. The vast majority of those products, 80%, had some level of 1,4 dioxane in them. Some were quite high, reaching up to 17,000 parts per billion. So my comment relating to that is that a dermal exposure, if someone uses a bath gel and then a shampoo and then washes the dishes with the dish soap and then puts the baby in the bath with the bubble bath, that also has 1,4-Dioxane, now the dermal exposure levels can be anywhere between 20,000 and 50,000 parts per billion in one day and every day thereafter. And it doesn't seem to be any evaluation of those personal care products and human dermal exposure.

S11: 45:12 My second comment is on the issue of 1,4-Dioxane in drinking water. I am sure being with the EPA you know that Long Island has a sole-source aquifer for our drinking water. And we unfortunately had the highest level of 1,4-Dioxane out of all the testing that the EPA did in the 4,400 supply wells across the country. And we had the highest levels of 1,4-Dioxane, some ranging as high as 33 ppb, and that drinking water well was closed. But that leads to the concern of not only a public health risk, obviously, there's a great deal financial concern with filtration of 1,4-Dioxane and the excessive cost of that. So I don't see any risk associated with these types of exposures coming from drinking water, particularly in areas that drink from aquifers. That, of course, is a direct exposure, it's very concerning, and I'm not sure what the EPA is doing about that. Maybe it just wasn't in the presentation, but that is an extreme concern and consideration for populations that drink from aquifer systems. Thank you very much.

S5: 46:39 Great. Thank you. Our next speaker is Douglas Troutman. Douglas, if you can hear me, please go ahead.

S12: 46:53 I can. Thank you very much. You can hear me?

S5: 46:56 Yes.

S12: 46:57 Thank you. No further comment at this time. You may move on to the next commenter.

S5: 47:05 Thank you. Next will be Nicholas Chartres. Nicholas, if you can hear me, please go ahead.

S13: 47:17 Can you hear me?

S5: 47:18 Yes.

S13: 47:20 Thank you. Good afternoon. My name is Dr. Nicholas Chartres, and I'm the director of science and policy at the Program of Reproductive Health and the Environment at the University of California, San Francisco. Today my comments will focus on the need for EPA to incorporate quantitative methods for estimating non-cancer risk that leads to a level of exposure, the incorrect decision made by EPA regarding the scope of the risk evaluation and that several pathways of exposure to 1,4-Dioxane could be excluded from the risk evaluation and how they are critical to risk management and benefits cost analysis considerations. And finally, that EPA should use its rulemaking authority to ensure that employers are provided proper and necessary protective personal equipment needed to protect workers from the health risks of 1,4-Dioxane. I have no conflicts to disclose. As we have already highlighted in our comments regarding the risk evaluation and risk management of ethylene chloride and 1BP, exposures experienced by the full population at any exposure level can result in increased risk of adverse health effects. Pro-health effects which there is some evidence of a relationship, so suggested, possibly, likely, known, the risk should be quantified. To not estimate risk would assume zero risk. Human health risk assessment and risk mitigation can be substantially improved by incorporating quantitative methods for estimating non-cancer risk. This would increase the scientific rigor of the risk assessments, increase its utility for risk management, better provide information to the public for non-cancer risks, and allow for capture of benefits through environmental policymaking. Without incidence to non-cancer risk assessment, it is difficult to estimate the health benefit from pollution prevention which is an important input into the decision-making and a key ingredient in the cost-benefits analysis.

S13: 49:05 The reference dose for reference concentration does not estimate the probability or incidence of response to any dose. It implies that exposure just below the reference dose lack any risk, while those just above the reference dose for concentration confer substantial risk. This is inconsistent with the new risk examples of dose-response relationships at and below the point of departure where there's essential non-zero risk levels for non-cancer effects across a diverse population. Therefore, for the points of departure evaluating human health hazards from liver toxicity from two exposures and olfactory epithelium effects, EPA should incorporate probabilistic approaches in quantifying risk instead of using it in [inaudible] these non-cancer endpoints in estimating the percent of the population at risk at different exposure scenarios and calculate the benefits risk management under the unreasonable scenarios. EPA mistakenly also included its several pathways of exposure to 1,4-Dioxane could be excluded from the risk evaluation. We urge EPA to revisit this decision regarding the scope of the risk evaluation. Issues regarding the excluded pathways are also important to risk management and benefits cost analysis considerations. Several of the regulatory options that may be considered for 1,4-Dioxane may affect the exposure pathways are excluded from risk analysis. For example, a ban on a condition

of use 1,4-Dioxane could be expected to reduce releases to water and, ultimately, to reduce drinking water exposure to 1,4-Dioxane.

S13: 50:33

Reduced drinking water exposures to 1,4-Dioxane resulting from any regulatory options are potentially an important benefit category that must be quantified and monetized. It's also important to recognize that removal of 1,4-Dioxane from drinking water with existing technologies is very difficult, energy-intensive, and expensive. TSCA regulatory options to prevent pollution of drinking water with hazardous chemicals may be much more effective and much more cost-effective for reducing drinking water exposures than treatment of contaminated water, and this should be part of the consideration in selecting a preferred regulatory option. Finally, the EPA risk evaluation of 1,4-Dioxane includes expensive assumptions regarding-- sorry, extensive assumptions regarding the worker's use of personal protective equipment with little or no supporting evidence. For a number of conditions of use, the finding about no unreasonable risk was dependent on the use of this PPE assumption. EPA should use its law-making authority to ensure that employees are provided proper and necessary PPE needed to protect workers from the health risk of 1,4-Dioxane, including those employees associated with the conditions we're used but were found not to pose an unreasonable risk. Because of the very significant hazards posed by 1,4-Dioxane, it is critical that EPA put the force of TSCA behind requirements, the PPE provision, maintenance, kit testing, and training. Thank you very much.

S5: 51:54

Great. Thank you. Our next public commenter is Deidra White. Deidra, if you can hear us, please go ahead.

S14: 52:11

Can you hear me?

S5: 52:12

Yes.

S14: 52:13

Okay. Great. Hi, my name is Deidra White. I'm with the Association of State Drinking Water Administrators, or ASDWA, and ASDWA is the non-partisan professional association representing the administrators of the 57 state and territorial drinking water programs that implement the Safe Drinking Water Act and provide assistance and funding for public drinking water systems. We are hoping that the Biden administration's actions will change OCSPP policies that have disregarded considerations for drinking water and other exposures and specifically re-open the risk evaluation for 1,4-Dioxane to include them. ASDWA has provided multiple comments on TSCA actions, where we have urged EPA to use a holistic approach to consider potential impacts to drinking water, human health, and the environment from chemicals throughout any part or all of the chemical's life cycle from manufacturing to processing, distribution, and disposal. I'm going to reiterate some of our comments on one of the 1,4-Dioxane supplemental analyses that focus on the impacts to both groundwater and service water sources of drinking water and affect the actions and decisions of state and state drinking water programs as they need to consider impacts for ensuring public health protection. Contamination of drinking water sources from 1,4-Dioxane is extensive. This is shown by the results of the third unregulated contaminant monitoring rule where 1,4-Dioxane from industrial wastewater streams, wastewater treatment facilities, produce water, groundwater discharges, and landfill leachate has contaminated those sources. In our comments, we've provided information about actions and impacts in the states of New Hampshire and North Carolina, though many other states have seen significant impacts and have had to take action without a federal drinking water standard.

S14: 54:10

States have also seen a co-occurrence of 1,4-Dioxane with chlorinated solvents in groundwater plumes and have experienced issues with oil and gas and hydraulic

fracturing-produced water, water reuse, and disposal via POTWs or wastewater treatment plants and underground injection control injections. The determination by EPA not to include drinking water exposures in the 1,4-Dioxane risk evaluation, we believe, is fundamentally flawed because the Siward does not adequately assess and effectively manage these exposures. By not including these exposures, EPA is, essentially, passing the burden and cost of removing 1,4-Dioxane from drinking water on to the public water systems and their customers. Removal of 1,4-Dioxane with conventional water and wastewater treatment processes are generally ineffective. Advanced oxidation appears to be the best treatment process using a combination of ozone, hydrogen peroxide, and ultraviolet light but is very expensive to construct and operate and is not economically feasible for many water systems, especially the small ones. 1,4-Dioxane also has significant potential regulatory implications for safe [inaudible] agencies and water systems as this contaminant is on EPA's fourth contaminant candidate list. And EPA recently announced its decision to continue the evaluation of 1,4-dioxane without making a preliminary regulatory determination in order to review the TSCA risk evaluation and consider the upcoming Canadian guideline technical document. In this regard, as were also requested that EPA explain why the office of water is relying on the TSCA risk evaluation to make a regulatory determination for 1,4-Dioxane when OCSPP is excluding drinking water exposures from its analysis. And I will close with emphasizing that projecting drinking water sources and preventing contamination is essential for sustaining safe drinking water supplies, protecting public health and the economy, and the environment. Thank you.

S5: 56:30

Thank you. Our next public speaker is Richard Dennison. Richard, if you can hear me, please go ahead.

S15: 56:39

Yes. Can you hear me?

S5: 56:40

Yes.

S15: 56:42

Great. Thank you. My name is Dr. Richard Dennison. I'm a lead senior scientist at Environmental Defense Fund. I will provide this comment on three issues today. The first is that the extreme difficulty of removing 1,4-Dioxane through treatment and the slow degradation demand risk management measures that eliminate its use or presence altogether and, at a minimum, eliminate all release. EPA's risk evaluation acknowledge that very little Dioxane is removed through wastewater treatment and yet its rate of degradation is, quote, "slow or negligible," end quote. This persistence means that any releases will remain in the environment and lead to human exposure. State and local government and, as you just heard from Deidra, water utility and agency associations have all raised concerns about the limited ability of treatment to remove 1,4-Dioxane once it is present in water. And they need to address the problem upstream by restricting its use and presence in products and waste streams. Advanced treatment technologies are required to achieve any significant removal, yet these systems are expensive, rarely used, and cost-prohibitive in many cases. For this reason, it is essential that EPA adopt the risk management measures that, to the maximum extent possible, eliminate the use or presence of 1,4-Dioxane, instituting bans rather than relying on measures that seek to reduce its release or exposure after release.

S15: 58:26

The second point, EPA can and must address risks associated with the conditions of use and the exposures that the prior administration illegally excluded from its risk evaluation. EPA's final risk evaluation failed to acknowledge or address the risks of numerous Dioxane usage and exposures. These include drinking water exposures, including from legacy sources such as groundwater contamination, that are

particularly of concern to communities of color and low wealth. The prior administration falsely asserted it could ignore drinking water exposures based on the purported coverage by the Office of Water under the Safe Drinking Water Act. This ignored the fact that one, there was no regulation of 1,4-Dioxane under the Safe Drinking Water Act. And two, just last March, the Office of Water refused to initiate the very process that could have eventually led to such a regulation, instead deferring to the risk evaluation LPPT was conducting which excluded those very exposures by asserting the Office of Water had addressed them. EPA also ignored down-the-drain releases from use and disposal of formulated products containing 1,4-Dioxane as a by-product. Millions of workers using or disposing of such formulated products on the job were also ignored. These include workers employed in industrial laundries, in carwashes, in building maintenance, housekeeping, painting, or automotive services, or as insulation installers or in construction jobs. All of these workers are likely more highly exposed and chronically exposed than consumers are because they use such products more frequently, for many more hours a day, and in higher strength formulations.

S15: 01:00:24

Finally, EPA ignored fence line communities that are exposed to air, water, or waste-related releases of the chemical. To cite but one example, a recent article from Chemical and Engineering News identified 1,4-Dioxane as contributing the greatest risk among those emitted by a chemical facility in the Harrisburg/Manchester neighborhoods of Houston, Texas. Combined exposures from multiple conditions of use or sources were also ignored. Just two examples, EPA did not consider a consumer who used more than one product containing 1,4-Dioxane each day, for example washing a load of clothes and cleaning a kitchen or bathroom surface. They also ignored workers that are exposed both at work and also at home as a consumer through product use. Notably, TSCA section 6(a) explicitly requires EPA to address combinations of activities that present risk in deciding on appropriate risk management measures. My last point is that TSCA requires EPA to select risk management options that entirely eliminate unreasonable risk. Several TSCA provisions are relevant.

S15: 01:01:43

Section 6(b)(4)(a) states that risk must be determined without regard to costs or other non-risk factors. In selecting among risk management options that are sufficient to eliminate all unreasonable risk, Section 6 (c) lists factors that EPA must consider. These include the effects of the chemical on health and people's exposure to it. EPA must also consider the benefits as well as the costs of regulatory options selected, and alternatives considered. Those effects and exposures and benefits may absolutely include those that go beyond the effects, exposures that were considered in the risk evaluation. This is especially critical in light of the gross exclusions from the risk evaluation that I have just described. Finally, sections 6(b)(4)(a) and (c)(1) require EPA to ensure that its regulation protects all potentially exposed or susceptible subpopulations. The prior administration's ignoring of risks to those populations is not a basis for EPA not to ensure that its risk management regulations are sufficient to address those risks. Thank you.

S5: 01:03:05

Great. Thank you. Our next speaker is Jonathan Kalmuss-Katz.

S16: 01:03:16

Can you hear me?

S5: 01:03:16

Jonathan, please go ahead.

S16: 01:03:20

Thank you. Can everybody hear me?

S5: 01:03:22

Yes.

S16: 01:03:24

Okay. Good Afternoon. I'm Jonathan Kalmuss-Katz Just from Earthjustice. Today I'd like to focus on just two recent executive orders issued by President Biden and what they mean for the task or risk management process. On January 21st, one day after the inauguration, the Biden administration issued a memorandum to all federal agencies on modernizing regulatory review. The memorandum called for agencies to take into account the distributional consequences of regulations and to ensure that rules do not inappropriately burden disadvantaged, vulnerable, or marginalized communities. Six days later, the president issued another executive order calling on federal agencies to, quote, "make achieving environmental adjustments as part of their mission by developing programs, policies, and activities to address the disproportionately high and adverse human health, environmental, climate-related, and other cumulative impacts on disadvantaged communities." These orders build on President Biden's campaign commitments to make environmental justice a focal point of his administration. They're also directly relevant to EPA's top score and the risk management process. The only way for EPA to comply with those orders in its risk management role for 1,4-Dioxane and to meaningfully protect disadvantaged communities is to consider the risks to communities exposed to the chemical from their drinking water, air, and soil. Communities of color from east Los Angeles to Statesville North Carolina face disproportionate exposure too, and that's increased risks from 1,4-Dioxane. Regrettably, the Trump administration failed to consider those risks in its 1,4-Dioxane risk evaluation leaving a gap that EPA must fill during risk management. To satisfy TSCA's mandate to eliminate unreasonable risks to potentially exposed and susceptible sub-populations and to avoid perpetuating historic patterns of environmental racism, EPA must evaluate 1,4-Dioxane's risks to those communities and address those risks in its risk management role.

S16: 01:05:29

President Biden's order on modernizing regulatory review also calls on federal agencies to fully account for regulatory benefits that are difficult or impossible to quantify. Fully accounting for such benefits will require EPA to consider populations in exposure pathways that were excluded from its risk evaluations, such as workers who use products containing 1,4-Dioxane, people exposed to 1,4-Dioxane in their drinking water, and people who are exposed from multiple pathways or conditions of use. Critically, the Biden administration's acknowledgement that certain benefits are difficult or impossible to quantify reinforces the need for EPA to identify and consider non-monetized benefits when deciding how to regulate chemicals under TSCA to pursue risk management approaches that offer the greatest public protection as opposed to solving the lowest [inaudible]. In sum, TSCA gives EPA broad discretion to issue health protection risk management roles despite the prior administration's flawed risk evaluations. President Biden's new executive order should guide EPA's use of that discretion particularly with regard to the rules environmental justice impacts. And this may require EPA to conduct additional analyses of chemical exposures and regulatory benefits during the risk management process. TSCA not only permits but compels EPA to conduct those analyses and to fully protect workers, consumers, and the public from 1,4-Dioxane's unreasonable risks. Thank you.

S5: 01:07:03

Okay. Thank you. Our next public commenter is Roger Rayle. Roger, if you can hear me, please go ahead.

S17: 01:07:18

Can you hear me?

S5: 01:07:20

Yes. You sound fine. Thank you.

S17: 01:07:23

Okay. Well, my name is Roger Rayle. I am a citizen volunteer of watching over the [inaudible] government, [Danhouw?] 1,4-Dioxane site in Ann Arbor side township

Michigan for going over 27 years. I wasn't going to make a public comment, but I noticed on slide 10 that conditions of uses that present an unreasonable risk under the industrial commercial included disposal. So disposal of Dioxane is a risk under industrial commercial settings. It's not clear whether that includes home studies because as many prior speakers combatted, there are laundry products and other products that go down the drain, and if you live in an area with wells, like I do, you'd have septic fields, and your disposal is going to go back into the groundwater, and it's not going to be-- we know from the government site that Dioxane, once it gets anaerobic in groundwater doesn't breakdown on its own. So this also is a problem because people are using products with high concentrations of Dioxane, and they may not know what dioxane is in their products. They would have to do some type of research on every product they buy. Where it would be behooved, you guys, to regulate that in the products. Even if you're not getting-- you're saying the exposure, the use of the product might not be-- you might not get exposure but over the long term as you dispose of the stuff into the groundwater through septic fields and even through water treatment plants, there is exposure there through disposal. It seems like that route has been ignored. Non-commercial, non-disposable-- I encourage you to correct that and keep the Dioxane out of the products that people use, and maybe we won't have any more Long Island tanks in the future. Thank you.

S5: 01:09:47

Great. Thank you. I think it's back to Niva Kramek now.

S2: 01:09:52

Yes. Thank you, Vince. This is Niva from EPA. We have a few people who registered to make a public comment but don't appear to be in the Webex. So if you have registered to make a public comment, and your name has not been called, we are looking for the name that you used - is that right? - to register with. So if you are preregistered and would like to make a public comment, please send a message in the chat to either All Panelists or Vince Brown or myself. I'm going to take one minute and check my email and see if anybody has had any issues logging on, or anybody on the phone has been emailing to say they want to comment. But I do not see any of those. Vince, have you been contacted by anyone who would like to make a public comment?

S5: 01:10:45

No.

S2: 01:10:52

Okay. So yet again, if you have registered to make a public comment, please send us a chat right now. This is last call for any preregistered public commenters. There are a few, and we just want to make sure that everybody has had the opportunity to make their comment. Okay. And Vince, can you move it to the slide with the contact information on the end slide. Thank you. If you have not had an opportunity to make a comment, or you'd like to follow up with us, as Cindy mentioned her contact information is there along with additional information on TSCA generally, our current chemical risk management activities, and our point of contact for general risk management outreach is Doug Parsons, and his information is there. We're very interested in continuing this engagement with you on 1,4-Dioxane risk management, and we really want to thank you-- yes, Vince?

S5: 01:12:03

Sorry, Niva, didn't mean to interrupt. We have a Yvonne Watson who would like to make a comment, if that's all right with you?

S2: 01:12:08

Fantastic, yes, thank you.

S5: 01:12:12

Yvonne Watson, if you can hear me, please go ahead.

S18: 01:12:15 Thank you. I'm Yvonne Martinez Watson. I'm the chair of the Environmental Justice Committee, Environmental and Social Justice Committee for the Angeles Chapter of the Sierra Club. I'm very concerned about the lack of consideration of the risk in groundwater supplies for urban areas and rural areas as well. I happen to live in an environmental justice community that has been impacted by 1,4-Dioxane, PFOS, PFOA, and radiation in our groundwater. I live in a home that has been supplied directly with groundwater that has these contaminants. I also live less than a block away from a large hospital which I can only assume has also been receiving water supplies contaminated with these contaminants. I find it very alarming that all these risk assessments talk about health effects to the outside of the body, but I don't see anything about what happens if you actually ingest this chemical. And then to hear all the other speakers talking about how there's all these cumulative effects, that's even more alarming. And it just seems to me that if you're really concerned about getting input from environmental justice communities, then that is something that should have been considered, otherwise it rings pretty hollow to say that you're trying to get input from us if you haven't even considered what might be happening to people's health when they're actually drinking this stuff. I hope that you will reconsider this and keep in mind that there are large populations, especially large Hispanic Latino populations, black communities, and others that are being affected disproportionately by COVID, and these types of environmental contaminations make us a whole lot more susceptible to other things and make us more vulnerable to these types of damage to our bodies. Thank you very much for the opportunity to comment.

S5: 01:14:39 Thank you. Niva?

S2: 01:14:46 Yes. Thank you for the comment. And again, anyone else who is registered to make a public comment, if you haven't had the opportunity or if you have used a different name for registering through Eventbrite and the Webex, please do send a message to Vince Brown, the host of the Webex, you can send a message through the chat or to All Panelists, All Panelists through the chat. I will again look at my email and pause for a moment to see if anyone has gotten in touch.

S2: 01:15:26 Okay. I haven't received any messages. Vince, do you have anyone else?

S5: 01:15:31 No, nothing here, thank you.

S2: 01:15:34 Okay. Thank you. And again, you can see our website for general TSCA and for risk management activities under Section 6 plus 1,4-Dioxane specifically are here, also Cindy Wheeler's contact information - you heard her speak earlier - and our general risk management outreach contact, Doug Parsons. We really do want to hear more from you and continue the conversation for the risk management of 1,4-Dioxane. We appreciate the public comments and your participation in today's webinar, especially those of you who made comments and also the many of you who were listening. An audio recording and a transcript of this webinar will be available at the 1,4-Dioxane risk management website, the same link that is in the chat, and where you can access the slides right now. We will, as soon as possible, make the transcript and recording available. I want to emphasize the EPA very much appreciates your participation in today's webinar, and the team here at the Office of Pollution Prevention and Toxics looks forward to a continued dialog on risk management. So thank you again, and I'll turn it back to Vince to close up the call.

S5: 01:16:44 Great. Thank you, Niva. That concludes today's session on 1,4-Dioxane, and I will now end the Webex.

