Transcription details:

Date:	15-Dec-2020
Event:	**Public Webinar: Trichloroethylene (TCE) Risk Evaluation and Risk Management**
Input sound file:	EPA Trichloroethylene (TCE) Risk Evaluation and Risk Management-20201215 1757-1.mp4

Transcription results:

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S1: 02:35 Good day, everyone, and welcome to this public webinar presented by the US Environmental Protection Agency on Trichloroethylene, or TCE, Risk Evaluation and Risk Management under the Toxic Substances Control Act, or TSCA. My name is Vincent Brown from Battelle, which is a contractor providing meeting support for today's meeting. This event is being recorded. The host 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.

S2: 03:17 Great. Thank you, Vince. Good afternoon, everyone, and thank you for joining EPA's Office of Pollution Prevention and Toxics webinar on Managing Unreasonable Risks for Trichloroethylene, or TCE, 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 is to moderate today's webinar. We're going to have approximately 400 people on the line, including attendees from Canada and New Zealand as well as 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: kramek.niva@epa.gov. That's K-R-A-M-E-K dot N-I-V-A at E-P-A dot gov. You can also email Vince Brown at brownv@battelle.org. That's B-R-O-W-N-V at B-A-T-T-E-L-L-E dot O-R-G. For today's webinar, we'll be advancing the slides through the presentation using Webex. You can also download the slides from the TCE risk management website. Today's agenda is also on that website.

S2: 04:35 Our webinar will start with a presentation from EPA. After the presentation, for those people who've signed up to make remarks, we'll have a period of public comment. We're limiting the remarks to five minutes per person. The webinar operator will introduce the speakers during the public comment period. If you've registered to make a comment, please be sure you're connected through the Webex so the operator can unmute you. Again, if there's technical issues, please send them in the chat or email me, kramek.niva@epa.gov, or Vince Brown, brownv@battelle.org. The agency will not be answering questions during the webinar. Please know there's a variety of other forms that will be described during the presentation if you have questions or if you're interested in further dialogue on risk management. With that, let's start the webinar. Our first speaker this morning is Brian Symmes,Aacting Director of the Existing Chemicals Risk Management Division. Thank you, Brian. Please start with your remark.

S3: 05:35 Thank you, Niva. Good afternoon, everyone, and good morning to those of you further west. My name is Brian Symmes, as Niva mentioned. I'm the Acting Director of the Existing Chemicals Risk Management Division within the Office of Pollution

Prevention and Toxics, and we are the division that is responsible for regulatory development under TSCA. I'm opening today's webinar with an emphasis on how much we value your input. This is a useful form for the agency to obtain public comment on both the implementation of TSCA and the risk management of trichloroethylene. For those of you who have attended these earlier webinars, you will hear much information that you have perhaps heard previously about our efforts. But today you're going to learn much more about the findings in the final risk evaluation for TCE and our work to develop proposed regulations under section 6(a) of TSCA.

S3: 06:35 Before I turn it over to my colleague Katie McNamara who will go through a presentation on the risk evaluation and risk management of TCE, I want to leave you with a few thoughts. With the amendments that TSCA enacted in 2016, we've in essence been building a new regulatory program from the ground up. We are focused on ensuring chemical safety, and indeed the way congress directors undertake this work, this is a process that we're going through. We've taken some big steps in that process over the past several months by issuing the first five risk evaluations: methylene chloride, 1-bromopropane, HBCD, carbon tetrachloride, and now TCE. In these risk evaluations, we identify whether they're unreasonable risk of injury to health or the environment. For TCE, we determined the unreasonable risk to workers, occupational non-users, consumers, and bystanders. Now, we're taking the next step in this process by moving to risk management. When unreasonable risks are identified, TSCA requires the agency to undertake a rulemaking process to address the unreasonable risks. So we want you to be aware of our work and through meetings like today's contribute to that risk management rulemaking under TSCA. We want you to be involved early in the process. We'll be using today to bring you up to speed on key provisions of TSCA's latest risk management requirements, inform you about the unreasonable risk findings for TCE, and then outline the next steps in our process.

S3: 08:16 Very importantly, throughout this process we'll be seeking input from you on potential risk management approaches, their effectiveness and any impacts those approaches might have on stakeholders. The feedback you provide us is very important as we develop regulations that we hope are both practical and protective. And today kicks off that process for TCE, so this is a critical juncture for involvement by all stakeholders. Again, we need and appreciate your input, expertise, and feedback early in the process, and that will help shape the ways we're going to address the unreasonable risks we've found. Thanks again for your interest in TSCA, and on behalf of the Office of Pollution Prevention and Toxics and our staff, we look forward to working with you. So I will hand it over to Katie for her presentation. Thank you.

S4: 09:14 Thank you, Brian. Good afternoon, everyone. My name is Katie McNamara, and I'm the point of contact for the risk management of trichloroethylene, which I will refer to as TCE throughout this presentation. I am the lead for the TCE rulemaking, and today I'll be presenting an overview of the TCE risk evaluation and the next steps for the risk management process. I am going to turn my video off just so that nothing happens with my audio and we can all follow along together. So with that, let's go to the next slide.

S4: 09:57 Slide 2 shows the agenda. During this presentation, I will provide you with a background on the risk evaluation process, the unreasonable risk finding and the risk management requirements under TSCA. I'll also talk about the types of information that we'll use during risk management, the principles of transparency, and where to

find additional information. I have to apologize to those of you that participated in the previous presentations for methylene chloride, 1-BP, and carbon tet since I'll be covering a lot of the same information that my colleagues presented, but hopefully you will leave here as an expert on TSCA. Next slide.

S4: 10:46 Slide 3 shows that TSCA requires EPA to evaluate the manufacture including import, processing, distribution in commerce, use, and disposal of existing chemical substances and identify those conditions of use which present unreasonable risks to health or the environment. The evaluation was done without consideration of cost or other non-risk factors and also included unreasonable risk to those potentially exposed or susceptible subpopulations relevant to this risk evaluation. TSCA also requires completion of the risk evaluation process within 3 to 3 and a half years. Next slide.

S4: 11:38 Slide 4 has a diagram illustrating the risk evaluation process and timeline. TCE was one of the first 10 chemicals and was not subject to prioritization. The box in the middle outlines the steps taken during risk evaluation. And at this point, the final risk evaluation of TCE has been completed, and EPA has determined which conditions of use present unreasonable risk. Therefore, now we are in the risk management action step of the process for those conditions of use with unreasonable risk. Next slide, please.

S4: 12:21 Slide 5 indicates that the final risk evaluation for TCE was published on November 25th, and it was the culmination of a process that included the publication of a draft risk evaluation, problem formulation, and scope document. Public comments were received throughout the process, and the draft risk evaluation received about 70 public comments and was peer-reviewed by the Science Advisory Committee on Chemicals in March of this year. Information regarding the final risk evaluation and additional materials can be found in the dockets listed here in slide 5, which you can also find on EPA's web pages by searching TCE risk management. Next slide.

S4: 13:12 Slide 6 provides the general information on TCE. TCE is a colorless liquid and a volatile chemical that is produced and imported into the US. It is used as a reactant in the manufacturing of other chemical substances, and it is incorporated into formulation of other products. Other conditions of use identified by EPA include the distribution in commerce, industrial, commercial, and consumer uses as well as the disposal of TCE. Some of the industrial and commercial uses of TCE include the use in vapor degreasing, use as a processing aid or in paints and coatings. And the consumer and commercial products that use TCE as a solvent include adhesives and sealants, paints and coatings, cleaning and furniture care products, and other miscellaneous uses, which I will list shortly. And the total production volume of TCE decreased from about 220 to 171 million pounds between 2012 and 2015. Next slide.

S4: 14:29 Slide 7 shows the life cycle diagram for TCE. And this diagram is from the final TCE risk evaluation, and it illustrates the different conditions of use identified and evaluated by EPA. Next slide. Slide 8 shows that as a result of the risk evaluation EPA determined that TCE does not present an unreasonable risk to the environment under the conditions of use. EPA also determined that the conditions of use listed on this slide do not present unreasonable risk of injury to health. And those 2 conditions of use out of the 54 conditions of use that EPA determined do not present an unreasonable risk are distribution in commerce and consumer use in pepper spray. This determination is considered a final agency action, and the risk evaluation is the order required by TSCA. Next slide.

S4: 15:38 We are on slide 9. EPA found that most conditions of use of TCE present an unreasonable risk during occupational exposures to workers and occupational non-users, which EPA refers to as ONUs, as well as to consumer users and bystanders during consumer use. The unreasonable risks were based on cancer and non-cancer adverse effects from acute and chronic inhalation and dermal exposures to TCE. EPA used the immune endpoints as the best overall endpoints selected for the non-cancer adverse effects, which I will go into more detail in the following slides. Next slide, please.

S4: 16:26 Slide 10 begins to outline the conditions of use that present unreasonable risk, including when TCE is manufactured, including imported and processed as a reactant into formulations, mixtures, or reaction products, incorporated into articles, repackaged, or recycled. TCE is also used as a solvent in industrial and commercial degreasing operations in several types of vapor degreasers, cold cleaners and in aerosol spray degreasers and cleaners, as a lubricant and grease as well an adhesive and sealant. Next slide.

S4: 17:14 Slide 11 is a continuation of the list of industrial and commercial uses that present unreasonable risk, including as a functional fluid, in paints and coatings, in several cleaning products, in arts and crafts materials such as spray coatings, in corrosion inhibitors and anti-scaling agents, in process solvents used during manufacturing, in ink, toner, and colorant products, in automotive care products, and in other miscellaneous uses such as hoof polish, gun scrubber, and pepper spray as well as disposal. Next slide.

S4: 17:59 Slide 12 begins a comprehensive list of consumer uses that present unreasonable risk, including in brake and parts cleaner and in several aerosol and liquid products such as degreasers and cleaners, gun scrubber, mold release, tire cleaners, lubricants and greases, and adhesives and sealants. Next slide. Slide 13 is a continuation of that list of consumer uses that present unreasonable risk. It's listing more adhesives and sealants as well as in cleaning and furniture care products and arts and crafts materials as well as in shoe polish, fabric spray, film cleaner, hoof polish, and toner aid. And I'd like to point out here that all consumer uses present unreasonable risk with the exception of the consumer use of pepper spray, as I had mentioned earlier. Next slide.

S4: 19:05 On slide 14, and as I mentioned before, the unreasonable risk determinations for workers and ONUs are based on the immune endpoints. What EPA determined were immunosuppression effects from acute inhalation and dermal exposures, autoimmunity effects from chronic inhalation and dermal exposures as well as cancer from chronic inhalation and dermal exposures. In occupational setting, the risk evaluation calculated risk estimates for workers handling TCE as well as risk estimates for occupational non-users, which are workers in the vicinity doing other activities that do not involve handling TCE directly. In the risk evaluation, EPA assumed the use of personal protective equipment for workers. EPA considers the fact that there is an OSHA PEL of 100 parts per million for TCE as an eight-hour time-weighted average. In the case of TCE, many conditions of use present an unreasonable risk to workers even when EPA assumed use of respirators with an assigned protection factor of 25 or 50 and gloves with a protection factor of 10 or 20. EPA does not assume respirator or glove use for some of the small commercial facilities that perform uses such as spot cleaning, wipe cleaning, shoe polishing, hoof polishing, or commercial printing and copying. Therefore, those uses present unreasonable risk due to the inhalation and

dermal exposures. And EPA does not assume that ONUs use PPE because they do not handle the chemical. Next slide.

S4: 20:53 Slide 15 explains the basis for unreasonable risk for consumers and bystanders. EPA's determination is based on immunosuppression effects from acute inhalation and dermal exposures. It's important to know that EPA does not assume dermal exposure for bystanders since they don't handle products containing TCE. Also, EPA does not assume use of personal protective equipment by consumers or bystanders. The unreasonable risk determination for consumer uses were based on the high intensity use, but for many of the conditions of use, the unreasonable risk was also presented for moderate intensity use. It's also important to point out that EPA did not evaluate chronic exposures to TCE for consumer users and bystanders because EPA considered the frequency of product use to be too low to create chronic risk concerns. Next slide, please.

S4: 21:59 At this point in the presentation we're on slide 16, and I will transition us to outline the risk management requirements under TSCA. So now that EPA has determined which conditions of use present unreasonable risk, EPA is required to take action so that TCE no longer presents unreasonable risk. Under TSCA, the statutory time frame for EPA to propose a rule is 1 year after the risk evaluation is completed and a final rule 2 years after the risk evaluation is completed. The other specific requirements include the consideration of alternatives when selecting certain risk management options and statement of effects. We'll be looking for input from stakeholders throughout the process as it's critical in the development of the rulemaking for TCE. This can be in the form of participating in public events or one-on-one meetings. So please reach out to me as I am your point of contact for TCE. And EPA expects a significant increase in regulatory activity due to the unreasonable risk findings across the conditions of use. Next slide.

S4: 23:25 Slide 17 lists the requirements for risk management activities provided by TSCA section 6(a) to address the final unreasonable risk determination. EPA has the authority to prohibit, limit, or restrict manufacturing, processing, or distribution in commerce. We can also require recordkeeping, monitoring, or testing as well as regulate the commercial use or disposal of TCE. And while this list seems limited, I'll highlight some of the many tools under each of these regulatory options that we could use to address the unreasonable risks. Next slide.

S4: 24:09 Slide 18 continues to show other options we have to work with. Section 6(a) of TSCA provides us the authority to regulate distributors, manufacturers, and processors as well as to regulate commercial uses and entities disposing of TCE for commercial purposes. And while EPA cannot directly regulate consumer uses, under TSCA, we have the authority to regulate at the manufacturing level or other key points in the supply chain which in turn can effectively address unreasonable risk to consumers. Next slide.

S4: 24:51 Slide 19 has examples of some of the tools I've mentioned I would highlight. For example, EPA can set a concentration limit so that certain formulations of products cannot exceed a certain percentage by weight of the chemical. So for example here, if we're aware of a condition of use where for a similar product one SDS sheet contains about 40% while the other shows 60% of the chemical in formulation, then we can require that no more than 20% of the chemical be allowed in the product in order for there to be no unreasonable risk. We can also require a specific label to describe the health effects and precautions that should be taken during use. And EPA can also mandate specific engineering controls such as ventilation requirements or use of PPE

at occupational sites. So with this option specifically, it's important for us to understand how different workplaces might be affected by this option. So this is where stakeholder engagement is really important to us. Next slide.

S4: 26:06 Slide 20 includes other regulatory options such as that EPA can require manufacturers, processors, and distributors to provide downstream notification throughout the supply chain. Another example that I'd like to highlight is that we can set an occupational air exposure limit. The general concept is much like the OSHA PEL or permissible exposure limit. And EPA could establish an ECEL, which is an existing chemical exposure limit. The new chemicals program at EPA has something similar, but it's called NCEL. But the ECEL could be an option for TCE because it allows for more flexibility in the workplace so that the workplaces can determine what the best method is for them and in order to meet that ECEL depending on if they already have the engineering controls in place or could meet the limit by using PPE. Although we do recognize that the ECEL is not the best option for all workplaces, so we need to be more specific for certain facilities. Additionally, we're trying to look at all the practical and protective regulatory approaches. And having said that, there may be instances where a use may need to be banned, and this could only apply to the consumer use while we go with a different regulatory approach for the industrial or commercial use. EPA could also require a hazard communication program. These options can be used alone or in combination to regulate the conditions of use with unreasonable risk. We likely won't use any option in isolation because we want to allow for flexibility in the workplace while also making sure that the regulatory approach is both practical and protective. Next slide, please.

S4: 28:05 On slide 21, in addition to the requirement to address the unreasonable risk, EPA is also required under section 6(c) of TSCA to consider and publish a statement of effects of the rule with respect to the magnitude of exposure to human health and the environment, the benefits of the various uses of the chemical, and the economic consequences of the rule such as effects on the national economy, small businesses, technological innovation, the environment, and public health as well as the cost and benefits and cost effectiveness of the proposed regulatory action and of regulatory alternatives. Next slide.

S4: 28:50 Slide 22 lists the executive orders relevant to the section 6(a) rulemaking. So in addition to the requirements under TSCA, EPA also needs to address several executive orders throughout the rulemaking process. EPA is also required to hold formal consultations with state and local governments, tribes, small businesses, and environmental justice communities in minority and low-income populations. Consultation and coordination for TCE will begin in the new year; an announcement can be seen on EPA's web page for TCE. And if you're interested in participating, then please reach out to me, Katie McNamara. I will share my contact details at the end of this presentation, but you can also find it on the TCE risk management web page. Next slide.

S4: 29:47 On Slide 23, as we move forward with identifying risk management options, we welcome any information that you may have regarding your views regarding the regulatory approaches and any effective methods to address the unreasonable risks. It's also important for us to be informed on current workplace practices to control exposures such as engineering and administrative controls. Additionally, please let us know of any critical or essential uses and future impacts if TCE is not available. We also welcome information on substitute chemicals and safe and effective alternatives.

	And as always we welcome suggestions on how EPA can improve the regulatory process or to be more transparent. Next slide.
S4: 30:44	With respect to the last point on transparency, slide 24 summarizes EPA's principles for transparency during the risk management process. We're looking to have proactive and meaningful engagement with our stakeholders. And in addition to the formal consultations, we're also conducting one-on-one meetings and webinars. So the goal of this dialogue today is to explain the risk evaluation findings, the risk management requirements under TSCA along with the options available to EPA to manage the unreasonable risks and what that means going forward. We're also looking to learn from stakeholders about the effectiveness of the different risk management approaches and the potential impacts on businesses and workers and consumers. And as our director mentioned, by having stakeholder input EPA can develop regulations that are both practical and protective. Next slide.
S4: 31:49	On slide 25, during the development of risk management approaches, in addition to consultation with stakeholders, at the invitation of the companies, EPA can conduct site visits to learn more about existing practices. And while doing so, EPA can develop our network of stakeholders to ensure regulatory approaches are fully informed and based on current conditions. Next slide. Slide 26 lists the opportunities for involvement that I've mentioned such as through one-on-one meetings, participation in webinars, and formal consultations. Of particular interest will be to participate as a small entity representative, so please let us know if you're interested. Your engagement and feedback is important, and we're relying on you to ask questions and raise concerns. Please bring things to our attention that may not have been considered and provide us with information we may not already have. We would really appreciate for this coordination and feedback to happen early on in the process. It will help us shape the ways we're going to address the unreasonable risks that EPA has identified for TCE. Next slide.
S4: 33:19	Slide 27 has the links to the web pages with additional information regarding TSCA and the risk management activities and has my contact information if you would like to get in touch with me, Katie McNamara. I'm the risk management chemical lead for TCE. To follow or register for other upcoming events, meetings, and webinars on TCE or other high-priority chemicals, you can follow the second link. And if you're interested to be a small entity representative for the formal consultations with small businesses, please email me at mcnamara.katelan@epa.gov with your information. I can spell that for-- if anyone is listening on the phone, it's M-C, N like Nancy, A, M like Mary, A-R-A dot Katelan, spelled K-A-T-E-L-A-N at E-P-A dot gov. Katelan is spelled a little bit differently than you may have seen before, but my email address can also be found on those EPA risk management web pages for TCE. And my colleague Doug Parsons is also available to coordinate outreach and engagement, especially if you're interested in meeting with us or if you have any other general risk management questions or concerns. So with that, thank you all for listening to my presentation today, and I'll turn it back over to Niva Kramek.
S2: 34:54	Great. Thank you, Katie. We're now going to begin the public comment period. When you're making your comment, please state your name and affiliation, if you have one. I'm going to turn control over to our operator, Vince. He'll introduce each speaker and then open their line. And then we'll continue this until all the speakers who've signed up have completed their remarks. So Vince, who is our first speaker?
S1: 35:20	Jake Adler, if you can hear us, please go ahead. Jake Adler.

S5: 35:27 Hi. Can you hear me?

S1: 35:29 Yes.

S5: 35:30 Okay. Actually, no comment at this time but thank you.

S1: 35:34 Great.

[silence]

S1: 35:46 [Katelyn Steven?]. [Katelyn Steven?], please go ahead.

S6: 35:51 Yeah. I'm sorry. I did not mean to sign up to make a comment but thank you.

S1: 35:54 Okay. Carrie Roberts. Carrie Roberts, if you would like to make a comment, please go ahead. Carrie Roberts.

[silence]

S2: 36:28 Hey, Carrie. You might be muted maybe on your phone or also through the Webex.

S1: 36:35 Carrie Roberts, please go ahead.

S7: 36:37 I have no comment at this time.

S1: 36:42 Thank you. Okay. We have Ashley Adams, if you would like to make a comment. Ashley Adams, please go ahead.

[silence]

S1: 37:32 Okay. Steve Risotto, if you would like to make a comment, please go ahead.

S8: 37:37 Yes. Thank you. Can you hear me okay?

S1: 37:39 Yes.

S8: 37:41 Good afternoon. I am Steve Risotto, senior director at the American Chemistry Council. ACC has followed the development of the TCE risk evaluation closely and has submitted multiple rounds of comments to the agency. Although they're not the basis for the risk determination, the final evaluation continues to include cardiac effects in its risk characterization. In so doing, EPA has ignored both its mandate to apply the best available science in a weight-of-the-evidence approach under TSCA and the consensus of its own science advisors. Rather than follow its methodology for systematic review moreover, agency staff have applied an ad hoc approach that upgrades those studies that support its conclusions and downgrades those that do not. The result is a final document that raises concerns about the integrity of the TSCA risk evaluation process and the seriousness with which EPA staff view the scientific consensus of its advisors. Further, by including risk estimates for the cardiac endpoint that are not the basis for the agency's determination of non-cancer risk, the final risk evaluation creates the potential for unnecessary confusion and concern and significantly complicates the agency's approach to risk management.

S8: 39:01 In its decade-long effort to promote the fatally flawed set of studies by a single group of researchers suggesting cardiac effects summarizing the 2003 publication by Johnson et al., EPA has offered a series of theories. In its 2011 IRIS assessment, the agency asserted that exposure via drinking water was somehow unique in explaining why inhalation and oral gavage studies did not report evidence of cardiac defects. This rationale was abandoned after it was not noted that the drinking water exposures were actually lower than those resulted from the other exposure routes. In a 2016 publication, EPA staff proposed the notion of genetic drift in the animal strain

suggesting that the Johnson et al. study may never be duplicated because the particular strain of animal no longer existed. The agency quietly abandoned this argument after it was noted that one of the studies that did not find cardiac defects was conducted at roughly the same time as some of the studies reported by Johnson et al.

S8: 40:06 In the draft TSCA evaluation released in 2019, EPA argued that the failure of a new GLP study to duplicate the Johnson finding was a result of use of an insensitive dissection method despite the fact that the method used in the new study is the one recommended by EPA, and the method used by Johnson et al. is not. The 2019 draft also suggested that hodgepodge of mechanistic studies in chick embryos, zebra fish, and mammalian cell models supported the finding of cardiac defects in humans without identifying what the mode of action or human relevance might be. This suggestion elicited significant protest among the science advisors charged with reviewing the draft. In the final risk evaluation, EPA now suggests that there remains concern among older mothers as a potentially susceptible subpopulation for the cardiac endpoint. The agency points to the results of two epidemiology studies despite the fact that both use proximity to a source as a surrogate for TCE exposure, a potential source of significant bias.

S8: 41:15 The risk evaluation process is mandated by the 2016 TSCA amendments which require EPA to use the best available science and the weight of scientific evidence when evaluating chemicals. The fact that EPA is principally relying on one study for its evaluation of cardiac effects, a study that has never been replicated and that has been discredited by the majority of the agencies' own science advisors undermines the scientific guideposts that the 2016 amendments were created to address. Although ACC recognizes that the risk evaluation for TCE is now complete, the agency should continue to refine its analysis as it embarks on the next phase of the process outlined in TSCA. During this next phase, we urge the agency to exclude consideration of the cardiac endpoint in the development of management measures to address the unreasonable risk that it has identified. We further encourage the agency to align all of its policies related to TCE exposure to the potential risks to the immune system that are the basis of the final risk determination for non-cancer effects of the substance. Thank you.

S1: 42:28 Great. Thanks. Kelsey Randall, if you're on and would like to make a comment, please go ahead. Kelsey Randall.

[silence]

S1: 42:47 Kelsey Randall, possibly your computer or phone is muted.

[silence]

S1: 43:05 Okay. Robert Sussman. Robert Sussman, please go ahead.

S9: 43:09 Yes. Can you hear me?

S1: 43:11 Yes. You sound great. Thank you.

S9: 43:14 Okay. I'm Bob Sussman of Sussman & Associates, and I'm offering my comments today as counsel for Safer Chemicals, Healthy Families. For years, our communities have been at risk from exposure to TCE. While EPA has well known of TCE serious risks, it has repeatedly failed to take action. The final EPA risk evaluation is disappointing in many respects including a failure to base risk determinations on the link between TCE and serious fetal heart malformations and to consider the high

prevalence of TCE in air, drinking water, and other environmental media which are a significant source of exposure and risk. Even with these omissions however, the final evaluation presents overwhelming evidence that short-term exposure to TCE causes suppression of the immune system, compromises resistance to infections and leading to autoimmune diseases. As the evaluation indicates, these effects can result from a serious exposure to TCE, and really all workers and consumers are acutely exposed to TCE at levels that are unsafe. Now that these risk determinations are final, we believe it is incumbent on EPA to take immediate action without waiting for completion of the TSCA section 6 rulemaking process.

S9: 44:55 First, EPA should issue and broadly disseminate a health advisory that warns the public of the danger of acute TCE exposure and urges consumers and workers to avoid such exposure. Second, EPA should immediately finalize its proposed 2017 bans under TSCA on TCE use for vapor degreasing and spot removal. Looking ahead to the rulemaking, we urge EPA to follow the principles of risk management under TSCA section 6 that Safer Chemicals recently submitted to the agency. There isn't time to cover all 12 of our principles, but I want to highlight a few that are particularly germane to TCE. First, EPA should ban consumer products presenting unreasonable risk of adverse health effects where there is no other regulatory option that effectively and reliable protects consumers. Secondly, industrial and commercial uses of chemicals presenting unreasonable risk should also be banned where workplace protections cannot reliably and effectively reduce exposures to levels sufficient to eliminate the unreasonable risk.

S9: 46:23 I also want to emphasize another core principle. EPA section 6(a) rules should be designed to create incentives to transition to safer, more sustainable alternatives. The regulated chemicals will be replaced with other members of the same chemical class or with inadequately studied chemicals that may have similar toxic effects. The net result will be regrettable substitution that fails to eliminate unreasonable risk. This is a particular concern for the many solvents among the initial 10 evaluations including methylene chloride, TCE, PCE, NMP, carbon tetrachloride, and 1-bromopropane. These chemicals have interchangeable uses and in some cases similar chemistries and toxicity profiles. EPA should not address each solvent in isolation but should design its rules to maximize protection of solvent users broadly and encourage a shift to safer solvents across the board. Thank you.

[silence]

S2: 48:01 Great. Thank you for your comment.

S1: 48:03 Gary Timm, if you're on and would like to make a comment, please go ahead. Gary Timm.

S10: 48:08 Yes. Thanks, Vince. How are you?

S1: 48:10 Fine.

S10: 48:12 Good afternoon. My name is Gary Timm. Today, I'm representing the Environmental Protection Network. EPN wrote EPA two letters concerning TCE, one on March 12th regarding EPA's draft risk evaluation of TCE and a second on December 9th regarding EPA's final risk evaluation. This afternoon, I would like to summarize two concerns that we expressed in our letters. First, the management of the risks of TCE is taking an inordinate amount of time resulting in a continuous exposure to vulnerable populations. On December 16th, 2016, EPA issued NPRM under TSCA section 6 to prohibit the manufacture, processing, distribution in commerce of TCE for aerosol

degreasing and spot cleaning and dry-cleaning facilities. And on January 19th, 2017, EPA issued NPRM under TSCA section 6(a) to prohibit the manufacture, processing, distribution in commerce and commercial use of TCE in vapor degreasing. EPA issued these NPRMs based upon the determination that these [inaudible] present an unreasonable risk to human health and significant non-cancer risks under both acute and chronic exposure scenarios and significant cancer risk from chronic exposures.

S10: 49:29 The adverse health effects noted include those resulting from developmental toxicity including cardiac malformations, developmental immunotoxicity, developmental neurotoxicity, and fetal death; kidney toxicity, immunotoxicity, non-Hodgkin's lymphoma, reproductive and endocrine effects, neurotoxicity, and toxicity to the liver. These effects are alarming not only because of their serious nature but also due to the low-dose levels at which they have been observed in animal studies and the fact that a single exposure during a critical window of fetal development may produce adverse developmental effects. EPA identified these effects many years ago in the IRIS Toxicological Review in 2011 and the 2014 TSCA Work Plan. Yet, despite knowing these risks for many years, these risks have not been addressed in a final rule to protect human health. EPA did not even have to wait to issue a final rule as it could have used the authority under TSCA section 6(d) to declare the proposed rule under section 6(a) immediately effective when a chemical is likely to resolve in an unreasonable risk of serious or widespread injury to health before completion of the rulemaking process. TCE meets this criterion.

S10: 50:44 Our second concern is that EPA is not utilizing the most sensitive endpoint in its risk evaluation. TCE-induced heart malformations and immunotoxicity in animals have been identified in the Johnson study as the most sensitive developmental endpoints for TCE. Although members of the EPA scientific advisory committee on chemicals had differences of opinion concerning the adequacy of the Johnson study, the study has been repeatedly vetted, reviewed, and discussed by EPA and external expert peer reviews and previous assessments, including its limitations. In each case, the study was found to be sufficient for hazard identification and those response analyses. Its results are also wholly consistent with the findings of many other studies. That indicates that congenital heart defects resulting from TCE exposures are a considerable issue. EPA identifies or disagrees rather-- EPN disagrees with EPA's decision not to use the most sensitive endpoint, cardiac malformations, as the basis for its derivation of the point of departure for TCE. If EPA selects a risk management option other than a ban, a rule to control exposure that does not use fetal heart defects as the toxicity endpoint for the POD for standard setting will not be adequately protective of human health.

S10: 52:03 In view of above-- in view of the above and EPA's findings, EPN urges EPA to do the following: first, finalize the two proposed rules to prohibit manufacture, processing, distribution in commerce, and use of TCE for aerosol, vapor degreasing, and spot dry-cleaning without further delay. Two, prohibit all uses of TCE in consumer products. Three, initiate a complete ban on the manufacture, processing, and use of TCE with the exception of its use of the closest intermediate-- with exposure controls because all commercial activities currently pose an unreasonable risk to human health. The fourth, immediately require manufacturers and processors to notify workers and downstream users of the hazards of TCE. And lastly, add TCE to the 5(b)(4) risk list. Thank you for this opportunity to provide comments.

[silence]

S1: 53:06 Okay. Kathleen or Katy Wolf, if you're on and would like to make a comment, please go ahead. Katy Wolf.

S11: 53:14 Good morning. Can you hear me?

S1: 53:17 Yes. Loud and clear. Thank you.

S11: 53:19 Great. My name is Katy Wolf and I'm a consultant. Trichloroethylene was designated as a carcinogen in the 1970s. I've worked on safer alternatives to halogenated solvents for more than 30 years. I've done field testing with alternatives to TCE with companies using the chemical in a range of different applications. This includes nearly all of the applications deemed by EPA to pose an unreasonable risk in the risk assessment. In vapor degreasing, cold cleaning, spotting chemicals, and aerosol cleaning, I've seen the chemical used by many facilities in an uncontrollable fashion over the years. I strongly urge EPA to ban TCE and all the unreasonable risk applications. A ban, in my view, is the best strategy for dealing with the chemical for four reasons. And these are similar to the reasons I cited in my request that EPA ban methylene chloride and n-propyl bromide [1-bromopropane] in the public meetings EPA held for them recently.

S11: 54:23 First, there are demonstrated viable, safe, and cost-effective alternatives in all the unreasonable risk applications. Second, since EPA does not have adequate resources to examine and develop a diverse set of different regulations for each of the applications that poses an unreasonable risk, a ban on the TCE applications would allow EPA to do a thorough job in regulating the uses. Third and related to the second reason, a ban is the most reasonable option for enforcement purposes. As EPA knows, many, if not all, of the regulations adopted by the agency under other statutes allowed EPA to delegate authority for enforcement to the state. In the case of TSCA, in contrast, EPA must enforce regulations adopted under the statute on its own. EPA simply doesn't have the resources to enforce a range of different regulations on uses of TCE, and a ban enforced through the producers and importers would be a simpler option. Setting an exposure limit, the ECEL that was mentioned in the presentation, for different applications would require EPA to enforce the specified level on thousands of facilities, which EPA would likely not be able to do thoroughly. It isn't really clear how EPA could even do the enforcement would EPA badge all the workers in the facility where TCE is used and check the badges when they inspect at the facility?

S11: 55:53 Four, there is a historical precedence for banning high-risk halogenated solvents that demonstrates there would be a successful outcome for this strategy. Many years ago, the South Coast Air Quality Management District established stringent VOC limits on vapor degreasing, cold cleaning, and aerosol cleaning applications such that TCE could not be used for these purposes in half of California. Because of the certain California-wide regulations, TCE can't be used in spotting chemicals in the dry-cleaning industry, automotive aerosol applications, or most adhesive applications. There's been a lot of movement in several different types of applications from one solvent to another over the last several decades, and another commenter mentioned it: EPA identified four halogenated solvents in the list of the first 10 priority chemicals, and these include TCE, perchloroethylene, methylene chloride, and n-propyl bromide. Suppliers and users have converted from one to another of the solvents when each has been increasingly regulated. EPA can stop this unproductive and dangerous shell game by banning all four of the solvents and all of the unreasonable risk applications. There are safer alternatives for virtually all applications of the four solvents, and they're cost-effective and viable. In summary then, I urge EPA to adopt the ban on all the TCE

applications that are posing an unreasonable risk. Thank you very much for your attention.

S1: 57:36 Thank you. This is the host, and, Niva, we do not seem to have any of the other public commenters as registered in our attendee pool. I can give it one last check here.

S2: 57:51 Yes, Vince, if you wouldn't mind going through the list. I would also like to note for anybody who has signed up to make a public comment, if you have connected by phone, all we see is your phone number, and we don't know who you are. So you could definitely email me, kramek.niva@epa.gov, and then we'll be able to connect your phone number to your name and unmute you or help you connect to the Webex. So Vince, why don't you call the names, and we'll see if there's either anyone we missed or maybe somebody who signed up to Webex with a different name than they registered with? Thanks.

S1: 58:34 I'm glad to do that. The names on my list are Hector A. Lora, L-O-R-A, Mohamed Aly, A-L-Y, Diane Lauricella, Mark Walker, Abdeljalil Mekkaoui, Jennifer Vasos, Bob Loblaw, Malene McElroy, and Cal Lleb, spelled L-L-E-B, Lleb. Everyone in the attendee pool is muted now, Niva, so if I call someone's name, they have no way of speaking out loud

S2: 59:41 So I will ask any of those names that Vince called, anyone who has pre-registered, if you could please send us a message in the chat or raise your hand. And for those of you who have been sending us questions by chat or raising their hand, today we're taking public comments from individuals who pre-registered, but we would be happy to meet with you separately and discuss, as Katie mentioned. And also there will be additional public consultations and in more interactive format in the future. But today, we're looking for the public comments for people who have registered.

[silence]

S2: 01:00:43 Okay. I'm going to take a minute and check my email and see if anybody has contacted me either with technical issues or any kind of problem. And I don't see any. Vince, would you mind going through some of the individuals who were called on before but maybe have had problems with their mute? I think one of them may have been Kelsey Randall.

S1: 01:01:22 Kelsey looked back and said she had no comment.

S2: 01:01:28 Great. Thank you.

S1: 01:01:29 Yeah. I had Jake Adler and Caitlin Stephen who said no comment. Carrie Roberts, no comment. Ashley Adams, no comment. So those were the only ones that were on the list that we've not heard from. And the others, I have six or eight on the public comment list, but we've not seen them in the attendee list, so we cannot identify them or unmute them at this time.

S2: 01:02:04 Okay. So I'll just ask for anybody who did pre-register to make a comment, if you are having technical issues, please let me or Vince know either by email or if you're able to chat or raise your hand using the "raise hand" icon. We can take registered public commenters today. Again, if you signed in by phone, it's hard to connect your name with your phone number. But if you email me, you can let us know that you would like to make a comment. This is also - I do want to emphasize - not the last opportunity. It's actually the start of our discussion on risk management for TCE, and I know that Katie and also Doug would be happy to hear from you and arrange meeting or to invite you to participate in future events. So I'm going to look one more time. And Vince, if you wouldn't mind checking through your list again?

S1: 01:03:18 Yep. I'm doing that.

[silence]

S2: 01:04:12 Okay. I see we do have a hand up from a public commenter. Vince, could you unmute his line, please?

[silence]

S1: 01:04:28 I'm sorry. Who do you want me to unmute? I missed it, Niva.

S2: 01:04:34 Oh, yeah. Sorry. Just John Kalmuss-Katz, please.

S1: 01:04:38 Roger. John Kalmuss-Katz, if you can hear me, please go ahead.

S12: 01:04:51 I did not raise my hand to speak. Thank you.

S1: 01:04:56 Maybe there's two people. We've got a Jonathan Kalmuss-Katz who may be different from John Katz.

S13: 01:05:06 I could hold if there's any sort of confusion.

S1: 01:05:10 Jonathan Kalmuss-Katz, please go ahead.

S13: 01:05:12 Thank you. And you can hear me?

S1: 01:05:15 Yes. You sound great.

S13: 01:05:16 Excellent. Thank you very much. So I'm John Kalmuss-Katz from Earthjustice. I've spoken at most of EPA's risk management meetings to date, and by now EPA knows our position on the TCE risk evaluation and the risk management process. Today, I urge EPA to reach out to voices who have not been as widely heard and who are not present at this meeting but who have an important perspective on the TCE risk management process. In the Ironbound neighborhood of Newark, residents live on top of a TCE groundwater plume, the result of contamination from an industrial facility that previously operated there. Because TCE is volatile, that contamination has migrated through the soil and into their homes where it's been detected in indoor air. TCE vapor intrusion is a widespread problem that EPA failed to consider in its risk evaluation because it claims that pathway was being adequately addressed under other EPA laws. During the risk management process, I encourage EPA to speak to the residents of the Ironbound and others who have been exposed to TCE through vapor intrusion and ask how effective they feel those other environmental statutes have been. TCE is also present in public water supplies across the country contaminating the water that millions of Americans drink and bathe in. These include communities like south side of Tucson, a predominantly Mexican-American area, that has fought to remove TCE from its drinking water and Columbia, South Carolina, where elevated TCE levels were detected in the water supply serving a mobile home park. EPA claims that we need not worry about drinking water contamination under TSCA because the Safe Drinking Water Act will handle any risks from TCE and drinking water. EPA should contact the communities whose water has been contaminated despite the existence of that law and solicit their views on risk management.

S13: 01:07:05 More than a million pounds of TCE are released into the air each year in communities like Carlsbad, New Mexico, and Westlake, Louisiana. In its risk evaluation, EPA ignored those releases as well claiming that they would be managed under the Clean Air Act. But these releases are occurring despite TCE's regulation under the Clean Air Act, and EPA made no effort to measure the risks that the Clean Air Act has failed to address. I encourage EPA to contact the communities who live next to major sources of TCE and

to consider their views as EPA develops the TCE regulation. These communities are not present today in part because EPA has made little to no effort to reach out to them and to inform them of their interest in the risk management process. EPA has previously taken a position because TSCA regulates chemical substances as opposed to individual facilities: EPA need not identify or consult with impacted communities. That approach is dangerously mistaken. Every chemical that EPA has evaluated under TSCA in addition to threatening workers and consumers also impacts communities that are exposed to the chemical in their air, drinking water, and soil. Congress required EPA to consider all exposures from a chemical's conditions of use when making unreasonable risk determinations and to eliminate any risks that are found to be unreasonable. I urge EPA to take that mandate seriously and to broaden its outreach so the communities most impacted by TCE are involved in the risk management process.

S13: 01:08:38 And finally, with respect to the ACC's comments about fetal cardiac malformations, we strongly disagree. There is broad agreement that TCE is associated with fetal cardiac harm and that the fetal cardiac endpoint is the most sensitive. EPA properly relied on that endpoint in its IRIS assessment, and EPA scientists reportedly relied on that endpoint as well in the draft risk evaluation until they were overruled by senior EPA staff. In its risk evaluation, EPA has calculated the risks that TCE poses to fetal cardiac malformations. The agency cannot meaningfully regulate TCE or satisfy the statutory obligation to eliminate unreasonable risk if it ignores the serious harms to developing babies' hearts. That's all I have. Thank you for the opportunity to speak.

[silence]

S2: 01:09:37 Thank you. And Vince, do you see any additional public commenters who were on the list and who may have joined very late?

S1: 01:09:46 No. I do not yet. I'll keep checking.

[silence]

S2: 01:10:22 Okay. And thank you, everyone, for your patience. We do want to make sure people who registered to make a public comment have that opportunity. I also do want to emphasize that we're looking forward to continuing this discussion and that we will have-- the slides are already posted online on the website that you can see on the cover slide. We will also be posting a transcript and an audio recording of today's webinar on that same website. So if you know people who would be interested in viewing or hearing this presentation, that will be available as soon as we can. So Vince, I'm just going to ask one more time if there are any additional names that seem to have appeared, any public commenters who have been registered?

S1: 01:11:17 No, Niva. I have not seen any. Thank you.

S2: 01:11:21 Great. So I would like to say to everyone thank you for your public comments and for participation in today's webinar on the risk evaluation and risk management of TCE. As I mentioned, an audio recording and a transcript will be available at the TCE risk management website, and we've provided contact information for Katie and Doug if you would like to arrange a meeting. We'll also be posting on that risk management website opportunities for future engagement on this chemical as well as other chemicals under risk management under section 6, and we really appreciate your participation in today's webinar. The team here in the Office of Pollution Prevention and Toxics looks forward to continued dialogue on risk management under TSCA. So thank you again. And I'm going to turn it back to Vince to close out the call.

S1: 01:12:12 Okay. That concludes today's meeting. I will close the Webex event now. Thank you.