U.S. ENVIRONMENTAL PROTECTION AGENCY (EPA)

TOXIC SUBSTANCES CONTROL ACT (TSCA)

Public Webinar
Managing Unreasonable Risks for 1-Bromopropane under the Toxic Substances Control Act (TSCA)

September 30, 2020

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INTRODUCTORY REMARKS

VINCENT BROWN: Good morning and welcome to this public webinar presented by the U.S. Environmental Protection Agency on 1-Bromopropane: Risk Evaluation and Risk Management under TSCA Section 6. My name is Vincent Brown from Battelle, which is the 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 U.S. EPA.

NIVA KRAMEK: Good morning, everyone. Thank you for joining EPA's Office of Pollution Prevention and Toxics webinar on Managing Unreasonable Risks for 1-Bromopropane under the Toxic Substances Control Act. My name is Niva Kramek. I'm the Associate Chief of the Existing Chemicals Branch in the Chemical Control Division. My role will be to facilitate today's webinar. We expect about 200 people on the line.

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. That's K-R-A-M-E-K.N-I-V-A@E-P-A.G-O-V. And please also email Vincent Brown at brownv@battelle.org. That's B-R-O-W-N-V@B-A-T-T-E-L-L-E.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 1-Bromopropane Risk Management website. Today's agenda is also on that website.

Today's webinar will start with presentations from several people from EPA. Then, after the presentations, for those people who signed up to make remarks, we'll have a period for 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 properly through Webex so the operator can unmute you.

Again, if there are technical issues, please email me at kramek.niva@epa.gov and also Vince Brown at brownv@battelle.org.

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're interested in further dialogues on risk management. With that, let's start the webinar. Our speaker this morning is Yvette Collazo, the new Director of the Office of Pollution Prevention and Toxics. Thank you, Yvette. Please start your remarks now.

BACKGROUND ON RISK EVALUATION AND UNREASONABLE RISK FINDINGS FOR 1-BROMOPROPANE

YVETTE COLLAZO: Good morning. Thank you, Niva, for the presentation. It's a pleasure to be here today, and I'm opening today's webinar to emphasize how much we value your input. This is a usual forum for the Agency, for EPA, to obtain public comment on the implementation of

TSCA and risk management of bromopropane or 1-BP. Before I turn it over to my colleagues, Ana and Joel, I want to leave you with a few thoughts.

With the amendments to TSCA that were enacted in 2016, we've been building a new regulatory program from the ground up. We've taken some big steps in that process over the past several months by issuing our first three risk evaluations. The first one was methylene chloride, which we held a webinar on earlier this month. And the second risk evaluation is the 1-BP, which you will hear about shortly.

In those two risk evaluations, we identified unreasonable risk to workers, occupational non-users, as well as consumers. Now, we're taking the next step in the process by moving to risk management. As you know, when unreasonable risks are identified, TSCA requires the Agency to undertake a rulemaking process to address the unreasonable risks. Well, EPA wants you involved early in that process.

We'll be using today to bring you up to speed on the key provisions of TSCA as it

relates to risk management requirements, inform you about the unreasonable risk findings for 1-BP, and outline the next steps in the process. I want to emphasize that now is a critical juncture for you to be involved. We need and appreciate your input, expertise, and feedback to help shape the ways we're going to address the unreasonable risks we found.

You will hear from Ana and Joel 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 our continued collaboration. Thank you.

DR. ANA CORADO: Good morning. Thank you, Yvette, for the introduction. I'm Dr. Ana Corado, and I'm the point of contact for the risk management of 1-bromopropane. I'm joined today by the Chief of Existing Chemicals Branch, Joel Wolf. And we will be presenting an overview of the 1-bromopropane risk evaluation and the next steps for risk management. We are looking forward to your comments. Next slide.

The topics that we will be covering today during this presentation include a background on the risk evaluation process, the unreasonable risk findings, and the risk management requirements under TSCA, and then Joel Wolf will talk about the type of information that we'll use during risk management, principles of transparency during risk management, and where to find additional information. Next slide.

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 risk to health or the environment. Such evaluation should be done without consideration of cost or other non-risk factors and should include unreasonable risk to potentially exposed or susceptible subpopulations relevant to the risk evaluation. TSCA requires completing the risk evaluation process within three to three and one-half years.

The slide has a diagram illustrating the risk evaluation process and the timeline. 1-Bromopropane was one of the first ten chemicals and was not subject to prioritization. The risk evaluation of 1-BP has been completed with a determination of which conditions of use present unreasonable risk. Therefore, now we are in the risk management action step of those conditions of use with unreasonable risk. Next slide.

The final risk evaluation of 1-BP was published August 11, and it was the combination of a process that included the publication of a draft risk evaluation, problem formulation, and the scope document. Public comments were received during the process. This draft risk evaluation received 32 public comments and was peer reviewed by the Science Advisory Committee on Chemicals last September. Information regarding the final risk evaluation and additional materials can be found in the dockets listed in Slide 5.

Slide 6 provides general information on 1-bromopropane. 1-BP is a liquid volatile

chemical that is produced and imported into the U.S. It is used as a reactant in the manufacturing of other chemical substances, and it is incorporated into formulations of other products.

Other conditions of use identified by EPA include distribution in commerce; industrial, commercial, and consumer uses; and disposal of 1-BP. Some of those industrial and commercial uses of 1-BP include use as vapor degreasing, in adhesives, and in dry cleaning. Other consumer and commercial products that use 1-BP as solvent includes jet cleaners and degreasers for electronic and metal products and for automotive paint products. The total production volume of 1-BP in 2015 was 26 million pounds.

Slide 7 shows the life cycle diagram for 1-BP. This diagram is from the risk evaluation and illustrates the different conditions of use identified and evaluated by EPA. Next slide, please.

As a result of the risk evaluation, EPA determined that 1-BP does not present an

unreasonable risk to the general population or the environment under the conditions of use. Also, EPA determined that the conditions of use listed in this slide do not present unreasonable risk of injury to health or the environment. The conditions of use are manufacturing, both domestic manufacture and import, processing as a reactant, incorporation into articles, repackaging and recycling, distribution in commerce, commercial and consumer uses in insulation for building and construction materials, and disposal.

This determination is considered a final Agency action, and the risk evaluation is the order required under TSCA. However, EPA found several conditions of use that present unreasonable risk to workers and occupational non-users during occupational exposures and to consumers and bystanders during consumer use. The unreasonable risk was based on cancer and non-cancer adverse effects from acute and chronic inhalation and dermal exposures to 1-BP. EPA used developmental toxicities based on post-implantation loss in animal studies as the most

sensitive end-point for non-cancer adverse effects.

Slide 10. The conditions of use that present unreasonable risk are listed in the following slides, including when 1-BP is processed into formulations, mixtures of reaction products, and in industrial degreasing operations in several types of vapor degreasers, including batch vapor degreasers, closed-loop, and also cold cleaners and in aerosol spray degreasers and cleaners.

Slide 11 lists other industrial and commercial uses that present unreasonable risk, including in adhesives and sealants, in dry cleaning solvents including spot cleaners and stain removers, in liquid cleaners and in other applications such as in automotive care product, anti-adhesive agents, and laboratory use.

Slide 12 contains the full list of consumer uses that present unreasonable risk. All consumer uses, with the exception of insulation, present unreasonable risk. Next slide.

As mentioned before, the unreasonable risk determinations for workers and

ONUs, occupational non-users, are mainly due to developmental toxicity from acute and chronic inhalation exposures and due to cancer from chronic inhalation exposures. In occupational settings, the risk evaluation calculated risk estimates for workers handling 1-BP and risk estimates for occupational non-users, which are workers in the vicinity doing other activities that do not involve handling 1-BP directly. In the risk evaluation EPA has reviewed use of personal protective equipment for workers, and EPA considered the fact that there is no OSHA PEL for 1-BP, although there is a recommended threshold limited value of 0.1 ppm from the American Conference of Governmental Industrial Hygienists.

In the case of 1-BP, many conditions of use present an unreasonable risk to workers, even when EPA assumes use of respirators with APF of 50. Also, dry cleaning uses present unreasonable risk due to dermal exposures since we don’t assume use of gloves in dry cleaning. And EPA does not assume that ONUs use PPE because they do not handle the chemical directly.

Slide 14 explains the basis for unreasonable risk for consumers and bystanders. EPA's determination is based on developmental toxicity from acute inhalation and dermal exposures, although EPA does not assume dermal exposure for bystanders since they do not handle the product containing 1-BP. Also, EPA does not assume use of personal protective equipment by consumers or bystanders. The unreasonable risk determination was based on the high-intensity use. But for many conditions of use, unreasonable risk was also presented for low and moderate intensity use.

With Slide 15, we start the presentation regarding the risk management requirements under TSCA. And I now will let Joel Wolf continue with the presentation.

RISK MANAGEMENT REQUIREMENTS UNDER TSCA; TYPES OF INFORMATION TO INFORM RISK MANAGEMENT; AND PRINCIPLES FOR TRANSPARENCY DURING RISK MANAGEMENT

JOEL WOLF: Thanks a lot, Ana. And thanks everyone for joining us today for this discussion on 1-BP and the risk management requirements under TSCA. For those of you that participated in the methylene chloride webinar a couple weeks ago, these slides are going to look very similar to you. And you'll hear many of the same topics discussed. But we want everyone to be starting with the same understanding and framework as we move into the risk management stage for conditions of use that have identified unreasonable risks.

Now that there have been conditions of use that have identified unreasonable risks, we now must address the unreasonable risk. And TSCA Section 6(a) lays out the pieces that we'll use to address the unreasonable risk. The rulemaking itself needs to be one year to proposal from the final risk evaluation and then two years from the final risk evaluation to a final ruling. Which for those of you involved with rulemakings, you know that that's an extremely fast-paced schedule,

taking into account all of the factors that we consider.

There are requirements that we need to take into account as we craft our regulatory approaches such as the alternatives, the statement of effects, which I'll talk about later. And then as you know and as Yvette indicated, we now have three risk evaluations that are final, with another seven expected by the end of the year, which will result in a significant amount of regulatory action occurring in the TSCA world. And we do recognize that for many of you these chemicals -- it's not just one chemical that impacts you -- that several of the chemicals have impacts in your manufacture, processing, and distribution realm.

And one of the key things for us, which we have done from the beginning in the risk evaluation process for the first ten -- and we're going to, obviously, continue on this webinar as one, and we've also already been having one-on-one meetings with stakeholders and others that could be impacted by regulatory approach -- is we're

meeting as often as we can because the process for us needs to be as transparent as possible. Otherwise, we put in place a regulation that isn't necessarily practical or addresses the issues that we need addressed to take care of the unreasonable risk.

Moving on to Slide 16, these are the seven components of Section 6(a). And in this as you can see -- and it looks rather basic, but there are a multitude of things we can do, and these are used individually or in relationship to each other. We can use more than one.

So we can prohibit, limit, or restrict manufacturing, processing, or distribution in commerce. For those of you who know the methylene chloride final rule on consumer paint and coating removal, we used the manufacturing, processing, and distribution together. There's also a recordkeeping, monitoring, or testing component, and we can regulate commercial use or disposal among other things.

Moving on to Slide 17, for the regulatory options we'll focus on manufacturing, processors, distributors, entities that are disposing of the chemicals and the commercial workplace itself, which could be the manufacturing workplace or the processing workplace. And I'll go into a little more detail as we talk about the different regulatory options or things that we would consider as approaches in the later slides. For consumers we could get at them by the manufacturing, processing, or distribution level. The compliance of requiring them to use PPE is a bit more challenging because we don't have direct access to that the way we do in a commercial sector, but there are a multitude of tools to address the consumer uses as well.

Moving on to Slide 18, these are examples of some of the regulatory options. We could set a concentration limit, which is the weight fraction. And we are aware that for a number of uses there are various weight fractions of the chemical based on SDS sheets that we've seen and engagement with stakeholders that --

making the numbers up -- could range anywhere from 45 to 80 percent. And so it could be -- and it appears that at 45 percent, and again that is a made up number, the product is still efficacious. We do recognize that there are other components of a formulation that may be important, so, again, it's important for us to engage with stakeholders on those kinds of limitations of the concentration. But if we just found that 45 percent weight fraction in a product addressed the unreasonable risk, that could be an approach that we could take.

We could also require labeling on a product that talks about limitations or ways to use the product or the health risks that result from the use of the product. We can also, obviously, prohibit manufacturing, processing, and distribution, which, again, is what occurred for methylene chloride in the consumer paint and coating removal rule. We can mandate workplace controls such as ventilation, engineering controls, administrative controls, and/or PPE at sites. And I know that you've seen in the risk

evaluations themselves that there is an expectation that there is a certain level of PPE already being used in certain sites or facilities that are manufacturing/processing. We can also require that ordinary business records are kept. We are not looking for additional records to be kept but the ones that you keep as a matter of course to do your business.

Moving on to Slide 19. Other approaches and one that we do and are looking at closely, which you also heard me mention for those of you who participated in methylene chloride, is existing chemical exposure limit, an ECEL. And for those of you familiar with the OSHA PELs, this is the same idea and approach in that we recognize that, for many workplaces, it'd be more appropriate to have this limit -- this ECEL, which would then allow the workplace to determine for themselves what is best for their workplace as it relates to ventilation, engineering controls, PPE, and other things. Because, in some cases, the workplace may already have things in place that we

are thinking of and that would and already are addressing the unreasonable risk.

And this allows flexibility to the workplace. In addition, it allows for technological innovation as opposed to EPA saying, "You will do this type of ventilation, this type of PPE." At the same time, we recognize that there is a difference in workplaces and that there will be some work sites where the ECEL is great. But there are other worksites where an ECEL is not, such as an auto repair shop or some place like that. So we recognize that we will need to have flexibility in our regulatory approaches. And, again, this is why we're reaching out and engaging with stakeholders both in this forum and in other forums and more directly meeting with people so that we get a sense of the workplaces where certain approaches would work best.

Again, we can require hazard communication programs. There could be monitoring required as a part of an ECEL. And then one of the other things is notification down the supply chain so the people are aware of limitations on a

chemical, which, again, is an approach that we used for the methylene chloride consumer paint and coating removal.

Moving on to Slide 20 and Section 6(c), as I mentioned before, we need to make a statement regarding the magnitude -- the statement of effects, the magnitude of the exposure to human health and the environment, and the benefits of the chemical for various uses and then the reasonably ascertainable economic consequences of regulatory approaches that we are proposing or thinking of proposing. And, again, I'm going to keep saying it. We're engaging with all of you to better inform this part of the process.

The transparency is extremely important as we develop these rules. Methylene chloride has over 50 conditions of use. We have 25 here with 1-BP. Well, not all in both instances have unreasonable risk. But we want to make sure that we are properly informed as we are developing our regulatory approaches.

Moving on to Slide 21, which is the Complex Consumer and Durable Goods Section

6(c)(2). And I know that for a number of the stakeholders this is very important and has been raised with us in multiple venues, and Congress clearly contemplated this and told EPA to be cognizant of this as you move forward with any regulatory approach. And we will certainly be taking this into account as we do our regulatory approaches.

Moving on to Slide 22, there are a number of executive orders that we need to comply with. Obviously, what we refer to as 12866 is the process whereby our federal partners get to review our rules, as many as you know, prior to them being released to the public, as well as when you move to the final rule stage. They review them as well.

There is also the small entities executive order 13272, which for some of you know it as the SBAR or -- and as I hope you are aware, a notice went out looking for SERs. And I believe today is the deadline for self-nomination of small businesses to be part of the panel for both methylene chloride and 1-BP. And because of the

pace of this rulemaking, the expectation is that the SBAR panel will occur in November, so just a few short months away where we will be discussing small businesses -- the potential impact of the regulatory approaches. And this is by no means an exhaustive list of the executive orders that we need to comply with.

So moving on to Slide 23 -- and I've briefly touched on it -- the engagement that we're doing with stakeholders and then the types of information that will help us -- and not that we don't already have a sense of many of the things that we're doing. We also recognize that there are nuances that we need to be cognizant of. And so if there is information on the types of controls that are already in place or the types of engineering controls or PPE that's being used or maybe there's some new technology on the horizon that we should be aware of, that's the type of information that we would like to know. And obviously, if are there substitute approaches, either a new method for doing something or a chemical substitute.

And I'm well aware that a number of these are solvents -- chlorinated solvents that are substitutes for each other. And we are very much aware that, in the first ten, there are a number of the chemicals that replace each other, and that in our next 20some of those chemicals could be replacements for these chemicals. And so we within EPA are certainly thinking of what the approach should be and the best approach, recognizing the implications across chemicals for the approach we take.

And then, of course, we're always -- and as Yvette said at the beginning, this is a new program being built from the ground up. It's four years old -- a little over four years now. But this is really moving into the first risk management part of the process, which is the last piece envisioned by the amended TSCA. And so the process and our approaches will continue to develop and change as we go, but by the time our first ten -- we have proposed rulemakings out there. Some of you may be aware of our PBT

rulemakings -- the tools under 6(a) will be on full display.

I did not mention the training certification and limited access program, which I did mention in the methylene chloride. That is an approach that we are thinking about for all of the chemicals. And it may be that only parts of the training certification and limited access are used. It's not that all three need to go hand-in-hand. It may be that there is just a limited access component of it, but you will see how we go about and be better able to inform. And I know a number of you have thoughts on processes and how to do things, which we're certainly open to hearing about. So we do look for the engagement.

Again, on Slide 24 it's the transparency, and I've mentioned this several times throughout. This is the engagement with the stakeholders -- with interested parties. We're looking for all perspectives. We have done engagements one-on-one with industry groups. We've engaged with the environmental groups and the unions, and we continue to expand our

dialogue. There's still an education process going on with TSCA, which is understandable. We expect the dialogue, and we want the process informed by all sides as we go forward.

And the input only makes the regulations better and our process better and more transparent. I mean, I personally feel that there's nothing worse than EPA closing its doors, working furiously, and then suddenly there's a public comment period and people are like "Oh, my god, what just happened? It'd been good if you had talked to us about this. We could have given you valuable insights." So please do reach out and we are actively continuing to reach out.

Moving on to Slide 25 is the coordination and the engagement. I don't want you to think that we are only engaging externally. We do engage within EPA, and we engage actively with our federal partners, OSHA, CPSC. We talk with DOD. We talk with all of the federal families that can better inform what we are doing and how we are thinking about our approaches to risk management.

And moving on to Slide 26, there's clearly a theme here: Opportunities for Engagement. I, again, appreciate all of you that have joined us today for the 1-BP webinar. We expect that we'll be doing these webinars after every risk evaluation is final to make as many people as aware as possible.

And you are also, obviously, actively reaching out. We pay attention to the commenters on the risk evaluations, and we comb through those to reach out to people that clearly have an interest in what is occurring. So we use a multitude of ways to identify interested stakeholders and entities that we should be engaging with.

As I mentioned, the SBAR panel is expected to convene in November. We'll also have more of our formal consultations, which are the tribal -- with the tribes and then state and local governments, which will also be occurring this fall. So it'll be a frenetic fall for all the chemicals that finish and have final risk evaluations.

And now I am on to Slide 27, which is just the general information where you can find information about TSCA, also about the risk management activities of 1-BP, as well as the other chemicals. And then Ana you can reach out to, and please do reach out directly to her. On our current chemical risk management website you can also find the contacts for any of the chemicals. And they are your gateway to engaging with the Agency. And then there's also -- many of you I'm sure engaged with Doug Parsons on numerous times regarding a lot of our stakeholder engagement.

So with that, that's the general regulatory approach and the things we're doing. And, again, we sense our desire to have transparency in the process and engagement with stakeholders as we craft our regulatory approaches. And with that, I will turn it back over to Niva.

PUBLIC COMMENTS

NIVA KRAMEK: Great. Thank you, Joel and Ana and Yvette. We will now begin the public comment period. I'm going to turn the control over to the operator who's going to introduce the speaker and open their line. And then the operator will continue this until all the speakers who signed up have completed their remarks.

VINCENT BROWN: Okay. Thank you. This is Vince Brown from Battelle. We have Olga Krel on the agenda, but she is not connected in a way that we can find her. So we may ask for her later. If she can hear us now, we need her to register in Webex with her name and email, and then we can unmute her. Let me go find now Robert Sussman.

ROBERT SUSSMAN: Yes, he's here.

VINCENT BROWN: Robert Sussman, please go ahead.

ROBERT SUSSMAN: Okay. Good morning to everybody. I'm Bob Sussman of Sussman & Associates, and I'm speaking today on behalf of Safer Chemicals Healthy Families. According to

EPA's final evaluation, there is a high likelihood that pregnant women and fetuses will suffer severe harm as a result of short-term exposure to 1-BP. These serious risks exist for both 1-BP-containing consumer products and similar products used in workplaces.

1-BP is a component of several liquids, spray aerosols, household products with significant dermal and inhalation exposures, including degreasers, spot cleaners, and stain removers. These and related products are also used in commercial and industrial applications, including as vapor and aerosol spray degreasers, adhesives, sealants, spot cleaners and dry-cleaning chemicals. These uses are largely uncontrolled, occur at hundreds of small facilities, and result in large exposures to thousands of workers, mostly women. According to EPA, half the workers at these facilities are women. Studies on 1-BP show severe effects resulting from prenatal exposure during gestation, as well as post-natal adverse developmental

effects that manifest at various stages of development and can span multiple generations.

The final risk evaluation identifies two serious developmental effects: reduced litter size and post-implantation loss that have been observed following brief, acute exposures. According to the evaluation, virtually all the consumer and commercial products containing 1-BP present unreasonable risks to human health based on its acute effects on fetuses and mothers. EPA's evaluation found that actual exposures to these products were above or alarmingly close to toxic dose levels resulting in small or nonexistent margins of exposures two or three orders of magnitude lower than the EPA benchmark MOE. These are eminent and severe risks that pose an immediate threat to pregnant women and their offsprings.

Our group strongly recommends that EPA ban the consumer and commercial products presenting these risks under Section 6(a) of TSCA. This is the only remedy that will reliably and effectively eliminate the danger of eminent acute

effects as required by the law. As EPA has previously found from methylene chloride and PCE, label warnings and personal protective equipment are insufficient to protect both consumers and workers in small, uncontrolled facilities.

We previously asked EPA to address the acute developmental risks of 1-BP in advance of the final rule in order to prevent avoidable harm to consumers and workers. EPA refused. Now that the evaluation is final, we renew this request.

EPA should issue a health advisory warning the public of 1-BP's risk to fertility and fetal development following acute exposure and urging women of childbearing age to avoid exposure to 1-BP-containing products. It should also make its proposed Section 6(a) rule immediately effective as authorized by Section 6(d) of TSCA so that acute exposures are controlled as soon as possible. Thank you for the opportunity to present these comments.

VINCENT BROWN: Great. Our next speaker is Kathleen Wolf. And it'll take me just

one second to unmute her. Kathleen, or Katy, Wolf, please go ahead.

KATHLEEN WOLF: Thank you. Good morning, everyone. I appreciate the opportunity to comment. My name is Katy Wolf, as you said. And I'm a consultant. 1-Bromopropane or n-propylbromide, nPB, came on the market in the 1990s. And it was adopted in many dispersive applications at the time. It replaced 1,1,1-trichloroethane in a whole range of applications. And 1,1,1-trichloroethane was banned because it caused ozone depletion.

It also replaced trichloroethylene and perchloroethylene, which were placed on EPA's hazardous air pollutant list, and methylene chloride, which was also on the HAP list and which OSHA had regulated more stringently. NPB was not on the HAP list and still has not been listed, nor has it been regulated by OSHA. I've worked on safer alternatives to halogenated solvents for more than 30 years. I've done field testing with alternatives to NPB 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, dry cleaning, and auto aerosol cleaning, I've seen the chemical used by many facilities in an uncontrolled fashion. In adhesive applications, I've seen workers become ill from exposure to the chemical. I strongly urge EPA to ban NPB in all unreasonable risk applications. A ban in my view is the best strategy for dealing with the chemical for four reasons. These are similar to the reasons I cited in my request that EPA ban methylene chloride in the last public meeting a couple of weeks ago.

First, there are demonstrated viable, safe, and cost-effective alternatives in all of 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 NPB applications would allow EPA to do a thorough job

at 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 allow EPA to delegate authority for enforcement to the states. In the case of TSCA, in contrast, EPA must enforce regulations adopted under the statute on its own. EPA unequivocally does not have the resources to enforce a range of different regulations of the uses of NPB, and a ban enforced through the producers and importers would be a simpler option. Setting an exposure limit, for example -- that ECEL that was discussed -- for different applications, for example, that would require EPA to enforce the level on thousands of different facilities, and it's just not reasonable to assume EPA would do that.

Fourth, there is a historical precedent 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 and cold cleaning applications such that NPB could not be used for these purposes in half of California. Because of certain California-wide regulations, NPB cannot be used in spotting chemicals in the dry-cleaning industry, automotive aerosol applications, or most adhesive applications. In summary, then, I urge EPA to adopt a ban on all of the NPB applications tagged as posing an unreasonable risk. Thanks a lot for your attention. I appreciate it.

VINCENT BROWN: Thank you. Unmuting now, Barbara Kanegsberg. Barbara, if you're there, please go ahead. I also had an Ed Kanegsberg on the roster. I'm not sure if it's Ed or Barbara. Your phone may be muted. Okay. We will loop back to Barbara Kanegsberg and look now to Nick Chartres.

DR. NICHOLAS CHARTRES: Can you hear me?

VINCENT BROWN: Nick Chartres, please go ahead.

DR. NICHOLAS CHARTRES: Good morning. Good morning, my name is Dr. Nicholas Chartres, and I'm the Associate Director of Science and Policy at the Program on Reproductive Health and the Environment at the University of California, San Francisco. Today, my comments will focus on how EPA has failed to address the comments from the Science Advisory Committee on Chemicals on the full systematic review methods used in the 1-bromopropane risk evaluations in its peer review of 1-BP and on incorporating quantitative methods for estimating non-cancer risk at each level of exposure and accounting appropriately for variability in the population for non-cancer endpoints. I have no conflicts to disclose.

In our comments to EPA on March 27, 2020 on the draft risk evaluation for carbon tetrachloride, we highlighted that EPA must address the comments from the SACC in its peer review of 1-BP and incorporate the recommended changes to its systematic review method prior to finalizing the evaluation and to future TSCA risk

evaluations. The SACC highlighted, among several concerns, that EPA had failed to achieve a fundamental best practices to systematic review, which included documenting how every reference identified in the literature search had been used in the draft risk evaluation, transparently applying a pre-defined eligibility criteria to the references in the literature search, and using protocols that outline the pre-establishment that's to be used throughout the systematic review process as required by EPA regulations under TSCA. EPA has failed to address our comments on these issues or address the non-science based and flawed systematic review methods that were applied in the evaluation of 1-BP as highlighted by the SACC.

This failure to apply best practices for systematic review in the 1-BP evaluation means that EPA is underestimating the risk of 1-BP and therefore leaving the public and the most vulnerable populations Congress explicitly mandated EPA to protect at risk from harmful chemical exposures. Again, we urge the Agency to use systematic review methods that have been

demonstrated extensively for use in environmental health and which have been endorsed by the National Academy of Sciences. That is the National Toxicology Program's OHAT method and the Navigation Guide to Systematic Review Method developed at UCSF.

VINCENT BROWN: Nick, this is Vince Brown. You're kind of breaking up. I don't know if your phone is on a bad connection or what. We can't hear you.

DR. NICHOLAS CHARTRES: Can you hear me now? Is that any clearer? Hello. Is that any clearer?

NIVA KRAMEK: Yes, Dr. Chartres, you sound much clearer now.

NICHOLAS CHARTRES: Thank you. What would you want me to -- just continue from where I am?

NIVA KRAMEK: Yes. Please continue.

DR. NICHOLAS CHARTRES: Okay. In relation to risk management as we highlighted in our comments to EPA two weeks ago regarding the risk evaluation and risk management of methylene

chloride, exposures experienced by the full population at any exposure level can result in an increased risk of adverse health effects. Full health effects for which there is some evidence of a relationship suggest, if possible, likely unknown, the risk should be quantified and to not estimate risk would assume zero risk. Human health risk assessment and risk management can be substantially improved by incorporating quantitative methods for estimating non-cancer risk.

This would increase the scientific rigor of risk assessment, increase its utility for risk management, provide that information to the public for non-cancer risk, and allow for capture of benefits for environmental policy making. Without incidents for non-cancer risk assessment, it is difficult to estimate the health benefit from pollution prevention, which is an important input in decision making and a key ingredient in cost-benefit analysis. This would also better arm long-term approaches for estimating cancer risks, which are expressed in a probability that is one

in 1 million risks, for example, in contrast to non-cancer risks which are based on a bright line that does not specify particular risk level, such as the reference dose of concentration. And it assumes that threshold response.

The reference dose in concentration does not estimate the probability or incidence of response to any dose. It also implies the exposure just below or just -- I'm sorry -- just below that dose has no risk and just above confers a substantial risk. Furthermore, additivity to background in terms of both health status and exposure model for chemicals supports that there are non-zero risk for population risk of non-cancer effects, and that's the transitional way from this bright line approach that is treated as a threshold and a transition toward the dose response method. It quantifies risk at doses within the experimental range as well as below it.

For any and every condition of use that EPA has considered that presents an unreasonable risk, it should quantify risk across multiple levels of exposure. Therefore, for the

points of departure, evaluating human health hazard from acute and chronic inhalation scenarios including developmental, reproductive system, and nervous system effects, EPA should incorporate probabilistic approaches in quantifying this risk.

Addis (phonetic) 2002 and Ginsberg (phonetic) 2012, as well as many others, have already demonstrated such methods. Finally, further phase risk estimates should be calculated to include factors that account for life stage vulnerability, co-exposures to other pollutants, genetics, pre-existing conditions, and social factors that include poverty and racial discrimination. For cancer endpoints, EPA must account appropriately for variability to population at each level of exposure. The 2009 NIH report "Science and Decisions: Advancing Risk Assessment" calculated the difference in mating birds higher in response to carcinogens differed by a factor of 25. Thank you very much for your time.

VINCENT BROWN: Okay. Thank you. We will now look to Gary Timm. Take me a second

to get him unmuted. Gary Timm, if you're there, please go ahead.

GARY TIMM: Yes, thank you. Good morning. My name is Gary Timm. I served as Chief of the Chemical Testing Branch in OPPT for ten years. Today, I am presenting comments on behalf of the Environmental Protection Network. EPN is an organization comprised of over 500 EPA alumni who volunteer their time to perfect the integrity of the U.S. EPA, human health, and the environment.

EPN submitted comments on the 1-bromopropane draft risk evaluation on August 30th, 2019. EPA has failed to address our substantive comments. It has not given an adequate explanation for not doing so. By failing to use appropriate methods in various areas of the risk evaluation, EPA is underestimating the risk of 1-BP.

As EPN noted before, the Agency is not using the best available tools by continuing to use the non-peer reviewed, flawed draft guidance document entitled "Application of

Systematic Review in TSCA Risk Evaluations" to identify, sort, select, and exclude studies and other information to be used in the risk evaluation and then to raise our quality and acceptability for inclusion in the assessment. The Science Advisory Committee on Chemicals review of the 1-BP chemical risk evaluation pointed out that the use of the TSCA systematic review process results in EPA failing to consider well-done studies. EPA must develop guidance that comports with standard practices. That is consistent with the recommendations received during the peer reviews currently underway by the National Academy of Sciences.

Until EPA develops a new systematic review process, the Integrated Risk Information System review process, the Office of Health Assessment and Translation, or Navigation Guide should be used in place of the systematic TSCA process. In the final risk evaluation of 1-BP, EPA correctly notes that it must consider aggregate exposure. That is co-exposure from

different pathways as required by Section 6(d) or (f) of TSCA.

However, the Agency then failed to do so stating that it could not consider aggregate exposure because it did not have physiologically based pharmacokinetic models for integrating exposures from dermal and inhalation routes. This is a feeble excuse as the Agency has managed successfully to conduct thousands of aggregate exposure assessment for food use, pesticides, and other chemicals over the course of the past 30 plus years. The failure to include aggregate exposures may result in a substantial underestimation of exposures to workers and consumers who come in contact with 1-BP.

On October 18th, 2019 EPN sent EPA a letter expressing our concern that EPA was taking too long to regulate serious, acute effects from the exposure to 1-BP. The draft evaluation concluded that 1-BP presents an unreasonable risk to workers and consumers for developmental and reproductive toxicity (audio skip) exposure. We noted that this finding was unlikely to change in

the final risk evaluation. This is alarming because women of childbearing age comprise half of the large population of consumers, bystanders, and workers that are exposed to 1-BP, and a single acute exposure during a critical window of development could cause irreversible, permanent damage to a developing fetus.

We suggested that EPA regulate 1-BP in two phases. The first phase would move quickly to address acute effects. A subsequent rulemaking would address chronic effects and any other effects not addressed by first phase. This suggestion was rejected by EPA. To underscore this point, EPA specifically notes in the final risk evaluation that even now it is not making an imminent hazardous finding under Section 7 of TSCA.

If an acute exposure that causes developmental and neurological effects does not qualify for making an imminent hazard finding, what does? In the final risk evaluation, EPA determined that 1-BP presents an unreasonable risk from inhalation and dermal exposures to consumers

who use 1-BP in dry-cleaning solvents, spot cleaners, stain removers, sealants, adhesives, and to occupational non-users and bystanders near these operations. As with EPA's risk evaluation regarding the cyclic aliphatic bromide cluster, EPA should not rely on the use of personal protective equipment in these uses. Assuming that workers will use PPE for the entire duration of the work activity throughout their careers, even when such equipment is not required, provided, or used, underestimates the risk to workers.

We urge EPA to ban all consumer and industrial/commercial uses of 1-BP for cleaning and degreasing uses and adhesives and sealants and dry-cleaning solvents for which EPA has found an unreasonable risk. Thank you for your attention and time.

VINCENT BROWN: Okay. I will now unmute -- sorry. Getting some interference. I'll now unmute Ben Gann or Gann. Take me just one second. Benjamin Gann, if you're available, please --

BENJAMIN GANN: Oh. Now can you hear me?

VINCENT BROWN: Yes. You sound great. Thank you.

BENJAMIN GANN: Perfect. Okay. I'll go. Good morning. I'm Ben Gann, Director in the American Chemistry Council's Chemical Products and Technology Division, or CPTD, which represents more than 60 chemical-specific groups focused on business of chemistry and issues relevant to the chemical manufacturers and downstream users. CPTD is pleased to provide comments on EPA's final risk evaluation for 1-BP, as well as the risk management process for conditions of use that were found by the Agency to pose an unreasonable risk.

First, EPA found no unreasonable risk to the environment for all conditions of use that were evaluated. The Agency also found no unreasonable risk to the general population for all conditions of use that were evaluated and that it was unlikely the general population would be exposed to 1-BP through surface water, drinking water, and sediment. Second, as EPA states in the

final risk evaluation, the Office of Chemical Safety and Pollution Prevention used its authority under TSCA Section 9(d) to coordinate with the Office of Air and Radiation regarding ambient air emissions of 1-BP.

The OAR, as part of its authority under the Clean Air Act, can regulate ambient air emissions of 1-BP. Earlier this year, EPA granted a petition to add 1-BP to the Clean Air Act list of air toxics. This will trigger separate regulatory processes for reducing air emissions of 1-BP under the Clean Air Act. Thus, the risk evaluation did not evaluate ambient air exposures to the general population.

Third, halogenated solvents such as 1-BP are used in industrial and commercial settings because they are essentially not flammable and reduce the overall fire risk. Although the final risk evaluation includes consumer uses of products that include 1-BP, it is unusual for products containing 1-BP to be marked as "for use by consumers". A significant need exists in the marketplace for cleaning solvents

with the wide solubility parameters and excellent cleaning capabilities of 1-BP. Limiting solvent choices could result in abrupt and significant change for industrial and commercial facilities that are designed to handle materials.

Fourth, half of the ten chemicals undergoing risk evaluations are halogenated solvents -- in the first ten that are undergoing risk evaluation. That includes 1-bromopropane. This is relevant because, as EPA explores the range of risk management options for 1-bromopropane, EPA should take into consideration a continued need for halogenated solvents and what are the available alternatives in the marketplace.

Fifth, exposure levels for each condition of use that were evaluated by EPA as part of its risk evaluation varied depending on volume, engineering controls, and the use of personal protective equipment. We are encouraged to hear that EPA is factoring in engineering controls and appropriate use of PPE as it considers risk management options, as engineering controls and appropriate use of PPE can and does

reduce the risk of exposure. Six and finally, as mentioned in its presentation this morning, EPA has a range of regulatory options it can consider in determining appropriate risk management actions for conditions of use that the Agency found pose an unreasonable risk that stops short of prohibition.

So on behalf of CPTD, we thank the Agency for the opportunity to speak today and look forward to continuing the discussion with EPA as it moves forward in the risk management process.

VINCENT BROWN: Thank you. We'll try again for Ed or Barbara Kanegsberg, just one second. Okay. You are unmuted. Barbara Kanegsberg, if you're there, please go ahead.

BARBARA KANEGSBERG: No comment today, sorry.

VINCENT BROWN: Okay. Thank you. This is Vince Brown. Niva asked me to go down the list of those who had registered to make public comments, but we've been looking for them and have not been able to identify their names and connect their audio on today's call. So we have an Olga

Krel. We have a Jean Warshaw. We have a Uyen-Uyen Vo, Anthony Tweedale, Tommy Burgess, and a Jen Jackson. And those conclude the names of those who had pre-registered to make public comments but with whom we were unable to connect with their audio. Back to you, Niva.

NIVA KRAMEK: Great. Thank you. I'd like to give an extra minute or two if anyone who has registered to provide a public comment has been unable to connect or make themselves identified. We're going to just give one more minute.

VINCENT BROWN: Hi. Thank you. Niva, this is Vince again. I should also read the names of those who had registered but for one reason or another had to cancel at the last minute. We had a Flora Ratpan. We had a Christopher Shaw, Amy Kyle, and a Albert Hartman. Those were folks who prior to the meeting had sent their regrets that they could not make public comment at this meeting.

NIVA KRAMEK: Yes. Again, if you've registered to make a public comment and you're on

the line by phone, we will not be able to identify you. And so please email me or Vince Brown. But it seems like there have not been any messages. And so I do want to thank the public commenters and all of you who participated in today's webinar on risk management for 1-bromopropane. An audio recording and a transcript of this webinar will be available at the 1-BP Risk Management website -- the website you received a link to in the emails that preceded this event.

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 dialogue on risk management under TSCA. So thank you again, and I am going to turn it back to Vince to close out the call.

VINCENT BROWN: Great. Thank you. That concludes today's Webex, and we will now end the event.

[MEETING ADJOURNED]