

Transcription details:

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Transcription results:

[silence]

S1: 04:09 Good day. Welcome to this public webinar presented by the US Environmental Protection Agency. N-Methylpyrrolidone risk evaluation and risk management under TSCA section 6. My name is Meredith Fritz, assisted by Vincent Brown, and we are 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 Amy Shuman, the leader of this call for the US EPA. Amy.

S2: 04:48 Hello. Good afternoon to some and good morning to others. Thank you for joining EPA's Office of Pollution Prevention and Toxics webinar on managing unreasonable risk for N-Methylpyrrolidone, also referred to as NMP, under the Toxic Substance Control Act. My name is Amy Shuman. I am an environmental protection specialist in the existing chemicals risk management division. My role will be to moderate today's webinar. We have over 250 people on the line today, including some attendees from Canada, Germany, and France, just to name a few, as well as all 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 any technical difficulties, please email me at shuman.amy@epa.gov. That's S-H-U-M-A-N dot A-M-Y at E-P-A dot G-O-V. And also 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 will be advancing the slides through the presentation using Webex. You can also download the slides from the NMP Risk Management website that I just linked in the chat. Today's agenda can also be found on that website. Today's webinar will start with the presentation from EPA, then after the presentation, for those who find [inaudible], you will have a series for public comment. We are limiting those remarks to five minutes per person. The webinar operator will introduce the speakers during the public comment period. If you are registered to make a comment, please be sure you are connected properly through Webex so the operator can unmute you.

S2: 06:49 Again, if there are any technical issues, please email me at shuman.amy@epa.gov and also Vince Brown at brownv@battelle.org. You can also send a message in the chat regarding any technical difficulties or inquiries. The agency will not be answering questions during the webinar. Please know there are a variety of other forums that will be described during the presentation if you have questions or if you are interested in further dialogue on risk management. Our speakers today are Tanya Mottley and Eileen Sheehan. Tanya Mottley is the Director of the Existing Chemicals Risk Management Division and will provide opening remarks. Eileen Sheehan is the chemical lead and point of contact for NMP and will provide some background on risk evaluation as well as details of the findings of the risk evaluation for NMP. Ms. Sheehan will also explain the risk management requirements under TSCA, the types of information that are helpful, and discuss the importance of transparency in risk

management. Without further ado, let's start the webinar. Tanya, if you would kindly begin your remarks.

S3: 07:56

Thank you. Good morning or afternoon, everyone. My name is Tanya Hodge Mottley, and I'm the Director of the Existing Chemical Risk Management Division here in the office of Pollution Prevention and Toxics. Thank you for joining us. I'm opening today's webinar to emphasize how much we value your input. This is a useful forum to ensure everyone understands the risk management requirements under the Toxic Substances Control Act, the findings from the NMP risk evaluation, and for EPA to obtain public comment on risk management of NMP. You will learn today about the findings in our final risk evaluation and EPA's work to develop and propose regulations under section 6(a) of TSCA. Before I turn it over to my colleagues, I want to leave you with a few thoughts. With the amendments of the TSCA that were enacted in 2016 and the arrival of the new administration, the agency is committed to ensuring the safety of chemicals used by all Americans. To that end, EPA will follow the science and the law. The new administration is reviewing actions issued under the previous administration. This review could result in additional steps to ensure protection of human health and the environment. This review is being guided by various executive orders issued by the new administration, including those on environmental justice, scientific integrity, and regulatory review. EPA issued final risk evaluations for the initial 10 chemicals starting in June of last year and immediately began the risk management process. The NMP's final risk evaluation was issued in December 2020. This final risk evaluation shows that there are unreasonable risks to workers and consumers from 26 conditions of use. EPA found no unreasonable risks to the environment, general population, bystanders, or occupational non-users.

S3: 09:48

I want to call your attention to the agency's announcement from Friday, February 5th. This announcement informed people that the agency is actively reviewing the final risk evaluations in light of statutory obligations and policy objectives related to using the best available science as well as protection of human health and the environment. This process is ongoing at the agency, and we aim to keep stakeholders updated as decisions are made, and as next steps are determined. It's important to know that during this review, outreach, and stakeholder engagement on risk management for the initial 10 chemicals with unreasonable risk will continue. The agency is hosting this webinar so you can be aware of our work and, through meetings like today's, ensure that risk management rulemakings are guided by the law and informed by the best available science. We'll be using today to bring you up to speed on the key provisions of TSCA as it relates to the risk management requirements to inform you about the unreasonable risk findings for NMP and to outline the next steps in the risk management process. Perhaps most importantly throughout this process, we'll be seeking input from you on potential risk management approaches, their effectiveness, and how best to ensure the safety of chemicals used by all Americans. Now is a critical juncture for you to be involved. Again, we need and appreciate your input, expertise, and feedback now, early in the process, to help inform the ways we're going to address the unreasonable risks we found. You'll hear more from the EPA team about how you can get in touch and stay informed. Thank you again for your interest in TSCA, and on behalf of the Office of Pollution Prevention and Toxics, we look forward to working with you. Thank you.

S4: 11:35

Thank you, Tanya. Hello. I'm Eileen Sheehan, and I'm the point of contact for the risk management of n-methylpyrrolidone, which I will refer to as NMP. I will be presenting a new review of the NMP risk evaluation and next steps for risk management, and we are looking forward to your comments. Next slide, please. Slide 2 includes the topics

I'll cover during this presentation. I will provide you with a background on the risk evaluation process, the unreasonable risk findings, and the risk management requirements under TSCA. And then, I will talk about the type of information we'll use during risk management, principles of transparency during risk management, and where to find additional information. Some of the risk management information is very similar to the information presented in previous public webinars hosted by EPA, including the recent public webinars on TCE and perchlorate ethylene. Next slide, please. This slide outlines TSCA's statutory requirements for a risk evaluation. For NMP, the evaluation is now complete. TSCA requires EPA to evaluate the manufacture, including import, processing, distribution and commerce, use and disposal of existing substances, and identify those conditions of use which present unreasonable risks 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 sub-populations relevant to the risk evaluation. TSCA requires completion of the risk evaluation within three to three and a half years.

S4: 13:44

Next slide, please. Slide 4 displays a diagram illustrating the risk evaluation process and the timeline. NMP was one of the first 10 chemicals and was not subject to prioritization. The risk evaluation of NMP has been completed with determinations of which conditions of use present unreasonable risk. Therefore, we are now in the risk management step, at the bottom of the slide, for those conditions of use that present a reasonable risk. Next slide, please. As Tanya said, the final risk evaluation of NMP was published on December 30th, 2020. It culminates a process that includes the publication of a trapped risk evaluation, problem formulation, and scope document. Public comments were received during the process. The draft risk evaluation received 35 public comments and was also peer-reviewed by the Science Advisory Committee on Chemicals in December 2019. Information regarding the final risk evaluation and additional materials can be found in the dockets listed here on slide 5.

S4: 15:09

Next slide, please. NMP is a colorless liquid and semi-volatile organic chemical and a solvent that is produced and imported into the United States. It is used as a reactant in the manufacturing of other chemical substances, and it is incorporated into the formulation of other products. Other conditions of use identified by EPA include distribution in commerce, industrial, commercial, and consumer uses, and disposal of NMP. Some of those industrial and commercial uses of NMP include production of paints and coatings, use as a solvent for cleaning and degreasing, and in the manufacture of electronic products. Other consumer and commercial products that use NMP include adhesive sealants, adhesive removers, and automotive care products. The total production of NMP in 2015 was approximately 160 million pounds. Next slide, please.

S4: 16:29

So this diagram is from the risk evaluation, and it illustrates the different conditions of use identified and evaluated by EPA. This life cycle diagram depicts the conditions of use that are considered within the scope of the risk evaluation during various life cycles, including, and the font's a little small, but manufacturing and import, processing, distribution, use, and disposal. The production volume shown in the boxes are for reporting year 2015 from the 2016 chemical data reporting period. The life cycle diagram for NMP does not include specific production volumes for processing or repackaging because the information was considered confidential business information. Next slide please, slide 8 highlights, determinations of no unreasonable risk under various conditions of use. EPA determined that the conditions of use listed on this slide do not present unreasonable risk of injury to health, the environment,

and general population. The conditions of use with determinations of no unreasonable risk are distribution and commerce, industrial and commercial uses, in ink toner and colorant products, in soldering materials, and in fertilizer and other agricultural chemical manufacturing, and also multiple consumer uses, including paint and coating removers, adhesive removers, paint and coating additives, in automotive care products, in cleaning and furniture care products, and in lubricants and lubricant additives in consumer products

S4: 18:34

While EPA found previously risk for the consumer use of NMP in paint strippers and graffiti removers in a 2015 risk assessment, the final risk evaluation published in December found no unreasonable risk to consumers from paint and coating removers. Based on input from the Science Advisory Committee on Chemicals, our peer review committee, EPA used a different approach to analyze the dose-response information for acute exposures to NMP, and it resulted in the change to no unreasonable risk for consumers for that condition of use. Next slide please. On slide 9, you see EPA found multiple conditions of use that present unreasonable risks to workers during occupational exposures and one condition of use that presents an unreasonable risk to consumers during use. And Tanya mentioned this earlier: EPA found no unreasonable risk to occupational non-users and bystanders in the COUs.

S4: 20:05

Next slide, please. The conditions of use that present unreasonable risk are listed in these slides, including domestic manufacturing and import of NMP; the processing of NMP as a reacting intermediate in plastic material and resin manufacturing and other non-incorporative processing; the processing of NMP into formulations, mixtures, or reaction products; the processing of NMP into articles, including in lubricants and lubricant additives in machinery manufacturing, in paint and coating additives not described by other codes in transportation equipment manufacturing; and in other sectors such as plastic product manufacturing. The processing of NMP into articles as a solvent, including textiles, apparel, and leather manufacturing, and finally, processing and repackaging and recycling. Next slide please. This slide lists industrial and commercial uses that present unreasonable risk, including in paints, coatings, and adhesive removers, in paint and coating additives, in the manufacturing of electronic products, in electronics as a solvent for cleaning and degreasing. And the COU for paint additives and coating additives not described by other codes entails multiple manufacturing sectors, such as construction, machinery manufacturing, and paint and coating manufacturing. Please refer to risk evaluation if you're interested in seeing the full list of sectors.

S4: 22:06

Next slide please. Slide 12 lists other industrial and commercial uses that present unreasonable risk, including in processing aids, in adhesives and sealants, in commercial automotive care products, in laboratory use, in lithium-ion battery manufacturing, in cleaning and furniture care products, and in disposal. Next slide please. Finally, a slide with a very easy to read font. Slide 13 lists the single consumer use that presents unreasonable risk. And it is the consumer use in adhesives and sealants, in glues and adhesives. Next slide, please. As mentioned before, the unreasonable risk determinations for workers are based on developmental effects from acute inhalation and dermal exposures and based on reproductive effects from chronic inhalation and dermal exposures. In occupational settings, the risk evaluation calculated risk estimates for workers handling NMP and risk estimates for occupation non-users, also known as ONUs, who are workers in the vicinity doing other activities that do not involve handling NMP directly. No conditions to use present unreasonable risk to occupational risk to occupational non-users, as mentioned before. In the risk evaluation, EPA considered the use of personal protective equipment for workers.

And EPA considered the fact that there is no OSHA PEL, a permissible exposure limit, for NMP.

S4: 24:19

In the case of NMP, many conditions of use present an unreasonable risk to workers, even when EPA assumes the use of respirators with an assumed protection factor of 10, and the use of gloves with a protection factor of 5 or 10. It's important to emphasize that EPA does not assume occupational non-users use gloves, for instance, because they are not handling the chemical. Next slide, please. So we covered the basis for the risk determination for workers. This slide explains the basis for unreasonable risk for consumers. EPA's determination is based on developmental toxicity from acute inhalation and dermal exposure. EPA does not assume dermal exposure for bystanders in the vicinity of the consumer, so they do not handle the products containing NMP. Also, it's important to underscore that EPA does not assume the use of personal protective equipment by consumers. The unreasonable risk determination for the consumer use was based on a high-intensity use.

S4: 25:52

Next slide, please. With slide 16, we start the presentation portion that addresses, what are the risk management requirements under TSCA? Now that EPA has determined which conditions of use present unreasonable risk, EPA is required to take action so that NMP no longer presents such a risk. According to TSCA, EPA should propose a rule a year after the risk evaluation is completed and should finalize a rule two years after the risk evaluation is completed. There are other requirements, such as considering alternatives when selecting certain risk management options and a statement of effects, which I'll describe briefly later. I do want to emphasize though that stakeholder involvement is critical in the development of rulemaking. And I want to note that you'll observe increased regulatory activity due to the unreasonable risk findings across several conditions of use.

S4: 27:06

Next slide, please. So slide 17 lists the range of requirements provided by TSCA section 6(a) to address the unreasonable risk. I won't read every one, but among the regulatory options EPA could use to address unreasonable risk are: EPA could take steps to prohibit, limit, or otherwise restrict manufacturing, processing, or distribution and commerce, or require record keeping, monitoring or testing, or regulate the commercial use or disposal. There are many tools under each of these regulatory options that we could use to address the unreasonable risk. This just gives you an overview of some of them. Next slide, please. I would like to point out that section 6(a) provides authority to regulate distributors, manufacturers, and processors, for example, those making products that contain NMP, and we have the authority to regulate commercial users and entities that dispose of NMP for commercial purposes. Under TSCA, we have the authority to regulate at the manufacturing, processing, or distribution level in the supply chain to address conditions of use associated with consumers. These authorities allows the EPA to regulate [at?] key points in the supply chain to effectively address unreasonable risk to consumers.

S4: 28:53

Next slide, please. As mentioned before, in addition to the requirements to address the unreasonable risk, EPA is also required under section 6(c) of TSCA to consider and publish a statement with respect to the effects and the magnitude of the 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 national economy, effects on small business, technological innovation, the environment, and public health, also costs and benefits and cost-effectiveness of the proposed regulatory action and of regulatory alternatives. Next slide, please. Slide 20 lists the executive orders relevant to section 6(a) rulemaking. In addition to the requirements that I

already identified under TSCA; EPA needs to address several executive orders in the rule-making process. In particular, EPA is required to hold formal consultations with state and local governments, with tribes, small businesses, and environmental justice communities in minority and low-income populations.

S4: 30:25

Next slide, please. As we move forward with identifying risk management options, we would welcome information from you, as Tanya indicated. We're interested in information about effective methods to address the unreasonable risk, your thoughts and views on regulatory approaches, data and information on current work practices to control exposures, such as engineering and administrative controls, information on essential uses and impacts if NMP is not available, identification of uses that have been phased out or are no longer needed. And we also would welcome information on substitute chemicals and safe and effective alternatives as well as how EPA can improve the regulatory process or how we can be more transparent. Next slide, please. With respect to that last point, slide 22 summarizes EPA's principles for transparency during risk management. We're seeking transparent, proactive, and meaningful engagement with all stakeholders. In addition to the formal consultation with state and local governments, with tribes, environmental justice communities, and small business, we are conducting one-on-one meetings and webinars. The goal of the extensive dialogue is to explain the risk evaluation findings, the risk management required by TSCA, the options available to EPA to manage the risk, and hear from you about what that means moving forward. We want to learn from stakeholders. What is the effectiveness of the different risk management approaches? What are the impacts potentially on your business, on workers, on consumers? And as explained by Tanya Mottley, with stakeholder input, we aim to develop regulations that are practical and protective.

S4: 32:53

Next slide, please. Slide 23 addresses our coordination and engagement during the development of risk management. And that includes consulting with stakeholders regarding effective management solutions, such as engineering controls, personal protective equipment, and available alternatives, and other effective risk management solutions. Our engagement may also entail, when safe to do so, conducting site visits to learn more about existing practices, and developing a network of stakeholders to ensure regulatory approaches are fully informed and based on existing conditions. Next slide, please. So how can you get involved? You can get involved with us through one-on-one meetings - please let us know if you're interested in meeting with us - through participation in webinars such as this public webinar, through formal consultations with states, tribes, and environmental justice organizations and communities. And businesses, small entities, can participate as a small entity representative. Please let us know if you're interested. Again, your feedback is important. We want to develop regulations that are practical and protective. We're relying on you to ask us questions, to raise concerns, bring things to our attention that may not have been considered, and to provide us with information we may not already have. So now is a critical juncture for you to be involved. Again, we need and appreciate your input, your expertise, your feedback early in the process, as Tanya said, to help shape the way we're going to address the unreasonable risks we've found.

S4: 35:08

Next slide, please. Slide 25 has the links to web pages with additional information regarding TSCA and the risk management activities. It also has contact information if you want to get in touch with us. If you're interested in acting as a small entity representative for the formal consultations with small business, please email me. Eileen Sheehan, and my email's there. Also, my colleague, Doug Parsons, is available

to coordinate outreach and engagement, particularly if you're interested in meeting with us. I thank you for your time and your participation today, and I will now pass the presentation back to our moderator Amy Shuman to continue with the webinar and your comments. Thank you.

- S2: 36:08 Thank you so much, Eileen. We will now begin a public commentary. A kind reminder, if you have registered to make a comment, please be sure you are connected properly through Webex so the operator can unmute you. Again, if you're having technical issues, please email me at shuman.amy@epa.gov, and also Vince Brown at brownv@battelle.org. For those listening on the phone, I'll spell that out. shuman.amy@epa.gov, that's S-H-U-M-A-N dot A-M-Y at epa.gov. And for Vince Brown, that's B-R-O-W-N-V at B-A-T-T-E-L-L-E dot org. When you are making your comment, please state your name and affiliation if you have one. I am turning the control over now to the operator who will introduce the speaker and open their line. The operator will continue this until all the speakers who have signed up have completed their remark. Operator, if you would please begin.
- S1: 37:17 Thank you, Amy. The first public commenter we have on deck is Kerry McMichael. Kerry, you are unmuted. Please go ahead.
- S5: 37:27 Hi, yes. I was just wondering; can we expect that EPA will be working with OSHA to develop a permissible exposure limit in the future that companies will need to abide by?
- S2: 37:42 Thank you for your comment. Again, this is strictly a public comment forum. We will not be answering any questions. If you'd like to send us a question, please feel free to email Eileen Sheehan, who is the point of contact for NMP.
- S1: 38:00 Okay. The next public commenter is Sangita Agarwal. Sangita, you are unmuted. Please go ahead.
- S6: 38:14 Okay then, this is a nice presentation, and I am from India, associate professor in chemistry. And this is a very nice presentation, and many points just like dermal exposure of this, and many other, acute inhalation, and these other main points which are keeping in mind. And please follow the main as you discussed in your presentation. And as I have many good information from this, and so there are very proposed already rules for one year and after evaluation, and many other. So I don't want to [inaudible], but the dermal exposure is very important [inaudible]. Thank you [inaudible].
- S1: 39:20 All right. Next up for public comment is David Isaacs.
- S7: 39:30 Hi. This is David Isaacs. I'm with the Semiconductor Industry Association. Our group met with the presenters yesterday, and I think we had a good discussion on the finding of unreasonable risk. As workers in the semiconductor industry, we continue to be disappointed, and believe that the agency mischaracterized the risks present in our industry, and we're going to continue working to seek a correction and correct the record. We believe the data and other information we submitted was not properly reflected in the final risk evaluation, and we'll continue working with you in the risk management phase. But again, we believe there was a mischaracterization of the risks and we'll be continuing to work to get that remedy. Thank you.
- S1: 40:49 Okay. Next up is Nicholas Chartres.
- S8: 40:54 Hi, good afternoon. Can you hear me?

- S1: 40:56 Nicholas, you are unmuted.
- S8: 40:58 Thank you. Good afternoon. My name is Dr. Nicholas Chartres, and I am the Associate Director of Science & Policy at the Program on Reproductive Health and the Environment at the University of California San Francisco. Before I begin, I have no conflicts to disclose. As we have highlighted in our previous comments regarding risk evaluation and risk management one 1,4-dioxane methylene chloride [inaudible], exposure experienced by the full population at any exposure level can result in an increased risk of adverse health effects. For all health effects which there is some evidence of a relationship, so suggests if possible, likely, and known, the risk should be quantified. To estimate risk would assume-- sorry, to not estimate risk would assume zero risk. Human health risk assessment and risk mitigation can be substantially improved by incorporating quantitative methods for estimating noncancer risk. This would increase the scientific rigor of risk assessments, increase its utility for risk management, and also provide better information to the public for noncancer risk, while allowing full capture of benefits in environmental policymaking. Without evidence for noncancer risk assessment, it's difficult to estimate the health benefit from pollution prevention, which is an important input into decision-making and a key ingredient in the cost-benefit analysis. This would better align with the current approaches for estimating cancer risks which are expressed as a probability, for example, one in a million risk. In contrast to noncancer risk, which are based on a bright line that does not specify particular risk level, e.g. the reference dose or reference concentration, and assumes a threshold response. The reference dose and reference concentration does not estimate the probability or incidents of response at any dose. It also implies that exposures just below the reference dose [lack?] or reference concentration lack any risk, while those just above the reference dose of concentration confer a substantial risk.
- S8: 42:51 This is inconsistent with the numerous examples of dose response relationships at and below the point of departure, where there is essentially non-zero risk level for noncancer effects across a diverse population. Therefore, for the points of departure evaluating human health hazards from developmental acute effects and reproductive effects for chronic exposures, EPA should incorporate probabilistic approaches in quantifying risk instead of using an MLE for these noncancer endpoints in estimating the standard of the population at risk at different exposure scenarios and calculating the benefits of risk management under the unreasonable scenarios. That's all I have. Thank you very much.
- S1: 43:42 Thank you. [Bing Wang?] you next up to comment. You are unmuted. Please go ahead.
- S9: 43:53 Oh. Hi. This is Bing, [Bing Wang?] from AW [inaudible] company. We are a small company. This is a very good update for us, and it's very helpful for us to understand what we expect in the future for NMP. Thanks. That's it.
- S1: 44:18 Okay. Next up to speak is Luni Ramakrishnam. Give me one second to scroll. Luni, you are unmuted. Please, go ahead.
- S10: 44:32 I have really no comment. It's an educational information for me, and I have no other comment other than the fact that I found the presentation useful. Thank you.
- S1: 44:54 Thank you. Next up is Linda Loris. Linda, you are unmuted. Please, go ahead.
- S11: 45:03 Hi. Good afternoon. So I belong with a small manufacturer that uses NMP. Sometimes it comes in in a mixture. We're just trying to understand what the commentary is and

how we might look at the risks and determine what EPA is doing in the future. And that's it.

S1: 45:36 All right. Next up is Patricia [Stanislaus?]. Patricia, you are unmuted. Please, go ahead.

S12: 45:44 Yes. Thank you. Good afternoon. I don't actually have any comments at this point. This is more informational for me. I do have some questions, but I will pose them via the email options that were presented earlier. Thank you very much.

S1: 46:06 All right. Next up is Heather Blankenship. Heather, you are unmuted. Please, go ahead.

S13: 46:17 Thank you. B&C Consortia Management makes the following comments on behalf of the NMP Producers Group. The Group is concerned that the final risk evaluation includes a significant number of additional conditions of use designated as presenting unreasonable risk that go well beyond those presented in the draft risk evaluation. In particular, the Group was surprised that EPA assumes four-hour and eight-hour exposures when the industry provided specific information to EPA that demonstrated exposure durations are much shorter. Neither outcome is supported by the record. EPA has not met its burden for weight of the evidence in determining the point of departure in the risk evaluation. This significantly skews the conditions of use determined to present unreasonable risk. EPA states that its selection of the Exxon two-generation reproductive toxicity study to derive the point of departure is supported by a continuum of reproductive and developmental endpoints. The NMP Producers Group has communicated to EPA on numerous occasions and provided supporting evidence as to why the Exxon study is not the high-value study that EPA represents in the risk evaluation. Furthermore, as the sponsoring authority for NMP at the OECD SIDS Meeting in 2007, EPA is well aware that the international regulatory authorities rated the Exxon study quality as inferior, with a reliability score of two, as compared to studies conducted by the NMP Producers Group. Given this indisputable international consensus on study quality and results, we are unable to reconcile EPA's inferior quality rating in 2007 to its more recent high-quality rating. The data did not change, only EPA's view for a reason that EPA has not provided. Not surprisingly, this change has had a significant effect on the key endpoint for NMP.

S13: 48:13 The Producers Group supports following the hierarchy of controls when determining how best to protect workers from exposures to NMP. EPA is encouraged to consider specifying a range of engineering and administrative exposure controls as well as personal protective equipment that provides flexibility for manufacturers, processors, and end users to implement the controls best suited to their workplace. The Producers Group commented on the draft risk evaluation that it disagreed with EPA's approach of assuming no glove use, or use of gloves that are not protective against NMP when calculating margins of exposure. The Producers Group wishes to reiterate that, when determining risk management measures, EPA should use the NMP specific data on glove types and production factors that have been provided to EPA, rather than assuming workers will not use gloves appropriately. Where PPE is needed to provide protection beyond engineering and administrative controls, EPA is encouraged to consider allowing the use of protective gloves that have been tested and shown to protect against NMP-containing liquids. We refer EPA to the journal article by Chris Kirman in which physiologically based pharmacokinetic modeling suggests that the proper use of gloves can be effective at reducing internal doses of NMP. In this article, glove protection factors of various glove types are shown to range from 80 to 1,900, far greater than those used by EPA and its margin of exposure calculations. EPA is encouraged to adopt the workplace environmental exposure limit

for NMP that was peer reviewed in 2020 and reconfirmed in 2021 by the Occupational Alliance for Risk Science. These values are eight-hour time-weighted average of 15 parts per million per [inaudible], and 30 parts per million for short term. The NMP Producers Group appreciates the opportunity to make these comments today.

- S1: 50:23 Thank you. Next up we have [inaudible] Energy. [inaudible], you are unmuted. Please go ahead. [inaudible]? Okay, I will move on. Oh. [inaudible]? [inaudible]. Okay. If you don't get to make a comment, there are other ways to write your comment to EPA. So I will move on to the commenter who is Francisco Diaz. Francisco, you are unmuted. Please go ahead.
- S14: 51:32 Thank you, I don't have any comments . Thank you.
- S1: 51:43 Okay, thank you. As a reminder, if you joined by phone only and did not use the Webex link to login, you appear as a call-in user and we cannot see your name in our list. So if you have a comment to make, please use the Webex link to log in.
- S15: 52:14 This is Vince Battelle, one of the hosts. I wonder if [inaudible] had his phone or computer muted. It looks like he might have been trying-- he or she might have been trying to say something, but.
- S1: 52:24 Yes, I just [inaudible].
[silence]
- S1: 53:22 Amy, I don't see any other commenters who have pre-registered.
- S15: 53:31 Yes, and Amy, this is Vince Brown from Battelle. I have no emails from anyone else saying they're having technical difficulties. And Meredith and I have gone through the list of registered public commenters and do not see anyone else in the attendee pool at this time.
- S2: 53:53 Excellent. Thank you so much. For those who do have further questions or inquiries, please feel free to contact Eileen Sheehan. She is the point of contact and the lead for NMP risk management under TSCA. Her email address was posted on the last slide of the presentation, which can also be found on EPA's website for NMP risk management. With that, thank you all for the public comments and for the participation in today's webinar on risk management for NMP. An audio recording and transcript of this webinar will be available on the NMP risk management website. EPA very much appreciates your participation in today's webinar. And the team here in the Office of Pollution Prevention and Toxics look forward to a continued dialogue on risk management under TSCA. Thank you all again, and please enjoy the rest of your day or evening. I'm now turning it back over to the operator to close out the call.
- S1: 54:59 Thank you very much. Everyone have a lovely day.
[silence]