U.S. EPA Webinar on the Proposed Rulemaking of N-Methylpyrrolidone under the Toxic Substance Control Act (TSCA)

Transcript

Thursday, June 20, 2024

Commencing at 1:00 p.m. Eastern Daylight Time (EDT)

Sheerin Shirajan (ICF): Hello and welcome to the U.S. EPA webinar on the proposed rulemaking of n-methylpyrrolidone. We will get started shortly. Next slide, please. If you're having trouble with Zoom and are using the desktop app, please check your settings. If you're using a browser, we recommend either restarting or opening it with Google Chrome. For general questions on the rule, please email EPA at NMP.TSCA@epa.gov. If you have any technical questions, please utilize the Q&A box or email us at EPArulemaking@icf.com.

All attendees are pre muted. Note that the public remark session will take place after the presentation. Attendees who requested to make public remarks and who are present will be taken off mute one at a time and given 5 minutes to provide their remarks. More information regarding this session will be provided later in the webinar. The chat will be used for broadcast messages only. Please refer to the Q&A button on your Zoom dashboard to submit technical questions. Please also ensure your full name and affiliation are correct. If your name on Zoom does not align with your name at registration, please reach out to EPArulemaking@icf.com with your name as it currently appears in zoom and the email address you registered with. This will ensure that you're still able to provide your remarks.

The ASL and CLT interpreters have their cameras on throughout the entire webinar and will be pinned to the top left corner of your screen. We also have Korean interpreters in attendance today. If you require Korean translations, please click the interpretation button in your Zoom dashboard. This will take you to a separate audio channel where you can hear the interpreters. You may also mute the original audio to only hear the interpretations. The closed captions have been turned on and should be displayed at the bottom of your screen. Click and drag the captions to move their position in the meeting window. If you wish to hide these captions, move your cursor down to the meeting controls and click the hide captions icon on the right-hand side of the zoom dashboard.

An email before this webinar will be in your inbox from EPArulemaking@ICF.com. The email includes details regarding accessing the presentation slides. If you don't see communications from this email, please check your spam. This webinar is being recorded and will be available, along with the presentation slides, after the webinar has concluded. Please use the links posted in the chat to access these materials in the future. Please note that the comment period for the proposed rule closes on July 29. Submit comments at EPA-HQ-OPPT-2020-0744. Please use the link in the chat to access the rule. And with that, I'll pass it on to Sheila Canavan for opening remarks.

Sheila Canavan (EPA): Thank you so much. Good afternoon, everyone and welcome. My name is Sheila Canavan and I'm the Deputy Director of the Existing Chemicals Risk Management Division within EPA's Office of Pollution Prevention and Toxics. We're so glad to be able to host this event for you. I know for many of you who've attended our previous events following publication of proposed risk management rules for perchloroethylene, carbon tetrachloride, and trichloroethylene, as well as the final risk management rule for methylene chloride, this should be familiar territory. Today, I'm excited to welcome you to our event for the proposed rule for n-methylpyrrolidone or NMP.

As many of you are aware, TSCA requires EPA to issue rules to address unreasonable risk to human health or the environment from chemical substances and to apply the section 6 requirements to the extent necessary, so these risks no longer are unreasonable. The unreasonable risk findings from NMP stem from risk to health effects resulting primarily from skin contact, which we refer to as direct dermal contact, much more than from inhalation exposure. These well documented effects include reproductive and developmental effects as well as liver toxicity, kidney toxicity, immunotoxicity, neurotoxicity, skin irritation, and sensitization.

Under this proposed rule, the majority of uses will continue with appropriate controls in place. The proposal includes a combination of workplace controls, including controls to prevent direct dermal contact, prescriptive controls and prohibitions to protect workers and consumers. A key element to note here is that the proposed strict and common-sense worker protections will prevent unreasonable risk while still allowing for essential uses to continue such as the manufacture of materials like, Kevlar, semiconductor chips, and lithium-ion batteries. We've based this proposed rule on the extensive Risk Evaluation of NMP, which was published in December of 2020 and the Revised Unreasonable Risk Determination from December of 2022.

Many of you may have attended our webinar in February of 2021 which provided an overview of the risk evaluation and our key findings, and it is available on our website as well. We were able to develop and refine this proposed rule through consistent public engagement over the last 3 years, including stakeholder meetings as well as consultations with Tribes, small businesses, and people interested in environmental justice. I know some attendees of those meetings have joined the event today. To those of you who have written to us, met with us, and engaged since the first stage of the risk evaluation - thank you so much. We hope you see elements of your contributions in the risk management action we're proposing.

Our goal today is to explain in plain language the rationale for the proposed action, several of the key details, and to highlight specific areas where we're seeking comments to inform the final risk management rule. And I want to emphasize that point, we are sincerely interested in comments to consider as we work to finalize the rulemaking. Detailed comments that provide supporting information will be particularly important for the final rule development so that the Agency has a solid record basis for the final elements in its final rule. Please note that your continued participation is critical to helping us write and then finalize these regulations that are protective of health in the environment. We can’t emphasize enough our appreciation for your time and all the information you've provided us to date. On behalf of the Office of Pollution Prevention and Toxics, we continue to look forward to collaborating as we move ahead. I'm now going to turn it over to Anthony Rufka, who's on our risk management team for this rule. He's the next speaker and will lead you through the start of the presentation. Thanks, Anthony.

Anthony Rufka (EPA): Good afternoon, my name is Anthony Rufka. I'm a Risk Manager with the Environmental Protection Agency in the Office of Pollution Prevention and Toxics. I'm on the Rulemaking Team for the proposed regulation of n-methylpyrrolidone also known as NMP, under Section 6 of the Toxic Substances Control Act or TSCA. I’ll go off camera to conserve bandwidth for the rest of this presentation.

On the next slide, we have an overview of what we'll talk about today, starting with the purpose of the rulemaking, followed by some background. We will then cover the list of regulatory tools available under TSCA and how the Agency developed the proposed risk management actions to address unreasonable risk. Next, I'll be turning over the presentation to the Rule Lead, Clara Hull, who will review the proposed rulemaking for NMP in closer detail, the alternative regulatory actions, and benefits of this proposal. And finally, we will conclude with opportunities for comment and engagement, next steps, and additional resources. Next slide.

On to slide 3, a little bit of history of TSCA. On June 2016, Congress amended TSCA with the Frank R. Lautenberg Chemical Safety for the 21st Century Act. This new law requires EPA to evaluate and address unreasonable risk from chemicals currently in commerce under imposed statutory timeframes in order to protect the public while outlining a predictable and comprehensive path for the regulated community.

In 2016, NMP was identified for risk evaluation along with 9 other chemicals, and these chemicals are often referred to as the first 10. As required by statute, EPA conducted a risk evaluation for NMP to determine whether the substance presents an unreasonable risk without consideration of costs or other non-risk factors.

The risk evaluation underwent a scientific peer-reviewed process and public comment period. After incorporating feedback from the peer review and the public, EPA published the final risk evaluation and determined that NMP presents unreasonable risk under its conditions of use and proceeded directly to the development of risk management regulation to address those risks. Next slide.

The purpose of this rulemaking is to address the unreasonable risk identified in the risk evaluation of NMP. The rule will prevent consumer and occupational illness through strict workplace protection, prescriptive controls, and five prohibitions. This proposal is based on the risk evaluation and extensive public engagement since 2016, and we'll talk more about that later in the presentation. The proposal is currently open for public comment until the 29th of July 2024, we encourage folks to submit comments in the docket. This coming period is an opportunity to submit information for EPA's consideration as we develop the finding regulation. Next slide, please.

On to slide 5, we have a little bit of background on NMP. NMP is used in wide-ranging industrial, commercial, and consumer applications. Its physical and chemical properties such as a high boiling point, polar aprotic, and low volatility make it less likely to vaporize. NMP is used as a processing reactant or intermediate or incorporated into a formulation as a solvent in the production of electronics and petroleum products, polymers, and other specialty chemicals. And in a variety of commercial and consumer applications such as a paint and coating additive, an adhesive in sealants, in laboratory chemicals, and a solvent for cleaning or degreasing. In the risk evaluation, the Agency assessed these uses across the lifecycle of NMP from manufacturing, processing, distribution, use, and disposal and determined that 29 of the 37 conditions of use that were evaluated drive unreasonable risk of NMP.

NMP was designated as one of the first 10 chemicals for risk evaluation. The risk evaluation was published in December of 2020, which was then followed by the revised risk determination in December of 2022 and the proposed regulation was then published earlier this month. Next slide, please.

On slide 6, we provide more information of the unreasonable risk of NMP. As noted, EPA determined that NMP presents an unreasonable risk to workers, consumers, and bystanders. The 2020 risk evaluation unreasonable risk determination is based on developmental and reproductive effects. The health risks associated with NMP are in fact well established, with dermal exposure being the main driver of unreasonable risk. The risk evaluation identified non-cancer effects from exposure to NMP, including kidney, liver, immune, and nervous system toxicity, as well as irritation and sensitization. EPA determined that the best representative endpoint for acute exposure is developmental toxicity and for chronic exposure is reproductive toxicity. And thus, our proposed risk management rule is targeted to those risks and by addressing the most sensitive toxicity endpoints, we will also address the risk for other non-cancer health endpoints. Lastly on this slide from the 2020 risk evaluation, EPA did not find unreasonable risk to the environment. I'll also point out that the risk evaluation did not find any cancer effects. Next slide.

Slide 7 describes EPA's authority under TSCA. Under revised TSCA, EPA is required to address unreasonable risk and has the authority to apply restrictions throughout the supply chain. EPA can regulate manufacturers importers, processors, distributors, commercial users and businesses or facilities that dispose of NMP. It's worth emphasizing that while EPA cannot directly regulate consumers from using NMP, we can regulate manufacturers, processors, distributors and retailers and the supply chain to restrict the availability of it to consumers. And therefore, by regulating at key points throughout the supply chain, EPA can effectively prevent NMP from reaching consumers, thereby addressing the unreasonable risk to this population. Next slide, please.

On slide 8, we have what I like to think of as our TSCA toolbox for addressing unreasonable risk. Again, EPA has the authority to restrict manufacturing, processing, or distribution in commerce for the chemical as a whole or a particular use. This includes prohibitions as well as the ability to set limits on weight fraction or production volume for a chemical or particular use of a chemical. This is the authority that allows EPA to set inhalation exposure limits, prescribe engineering controls, administrative controls, personal protective equipment, or other workplace restrictions. Of course, any of these potential regulatory options would have to be supported by the findings in the risk evaluation. We can also require record keeping, monitoring, or testing, as well as regulating the commercial use or disposal of a chemical substance. Any of these regulatory options could be used alone or in combination so that the chemical no longer presents an unreasonable risk. Next slide.

Now that we've gone over EPA's authority and regulatory toolbox under TSCA, on slide 9 we are going to discuss how EPA went about ensuring that we are putting our best foot forward during the development of risk management approaches. Transparency is important through the whole TSCA risk evaluation and risk management process. Meaningful dialogue between the Agency and stakeholders is the foundation of finding risk management strategies that are going to work to protect human health and the environment and work for the regulated community. We hope this is a common ground between the Agency and our stakeholders. The deeper understanding we have of chemical uses, hazards and exposures, the better we can focus our efforts and ensure outcomes that reflect the way chemicals are actually being used. So, to develop this proposed regulation, we've engaged in one-on-one meetings, public webinars, comment periods, peer review, and consultations with state and local governments, Tribes, environmental justice communities, and small businesses.

For this proposed rule, this also meant ongoing consultations with other federal agencies such as OSHA and NIOSH, to promote a consistent and harmonized regulatory approach, to facilitate compliance, and to avoid duplicative requirements. We also convened a small business advocacy review panel with SBA and OMB to seek input from small businesses. Stakeholders were thus essential to the development of this proposal and will be essential to its finalization. So, for those who have already engaged with EPA on NMP, thank you for reaching out and providing input. And thanks to everyone in advance for any input you may provide as we move forward to develop a final rule. This is a good spot for me to remind everyone again that the comment period will be open till July 29. Next slide.

Onto slide 10. So, that being said, it is EPA’s first and foremost priority is to address the identified unreasonable risks. Congress included some considerations in the statute to guide us, including requirements to consider and address risk to potentially exposed or susceptible subpopulations, such as workers and consumers, consideration of the chemical’s particular effects, magnitude of exposure, the benefits of the chemical substance, economic impacts of the regulation, and availability of alternative substances or processes. This proposed regulation is supported by best available science and reasonably available information. Next slide, please.

On slide 11, we've arrived again at our overarching goal to develop regulations that address the unreasonable risk from NMP exposure with a practical and protective approach. To that end, you'll see the NMP proposal presents a familiar regulatory framework for occupational and consumer exposures by aligning with how OSHA regulates workplaces wherever possible. This proposal allows the majority of uses to continue with appropriate controls in place, mandates worker protection requirements for uses continuing, including controls to prevent direct dermal contact, meets TSCA requirements to address risk to the extent necessary so that it is no longer unreasonable, including risks to potentially exposed or susceptible subpopulations, and requires record keeping to ensure the rule is enforceable. Next slide.

That being said, I want to emphasize that this is a proposal based on the best information we have at this time. We're requesting comment on all aspects of the proposal and fully intend to consider all comments and if appropriate modify the proposal so that the final rule is as protective and practicable as possible. We'll talk about specific requests for comment throughout, but broadly we'd like to ask for input on the timelines in the proposal and the implementation of new requirements. Public comments submitted to the docket could result in changes to elements of the proposed regulatory action. For example, EPA finalizing shorter or longer compliance time frames. I will now turn this presentation over to my colleague Clara Hull, the Rule Lead for NMP.

Clara Hull (EPA): Thank you, Anthony and good afternoon, everyone. Again, my name is Clara Hull and I am the rule lead for NMP. I'm going to go ahead and turn my camera off to save bandwidth and ask that we move to the next slide, please.

So, on this slide you'll see a description of our proposed regulatory action to protect consumers and workers while allowing for the continued use of NMP and a variety of regulatory controls to mitigate any unreasonable risk. We'll dive into these more in the next few slides, but in summary, EPA is proposing to require strict workplace controls, including an NMP WCPP, which prevents direct dermal contact with NMP for most occupational conditions of use. We're also requiring prescriptive controls, which are mainly a combination of concentration limits and PPE for several occupational conditions of use. We're also proposing a prohibition on the manufacture, including import, processing, distribution in commerce, and industrial and commercial use of NMP for five occupational uses.

For most consumer products, we're requiring container size limits and labeling requirements for the manufacture, including import, processing and distribution in commerce of NMP products for those consumer uses. For just one consumer use, we are requiring a concentration limit on NMP for the import, processing, and distribution and commerce of that use. And as Anthony mentioned, we're also establishing record keeping and downstream notification requirements. Now, before I move on, I want to briefly mention some of the considerations that we've factored into determining how best to address risks from particular uses. EPA considered aspects of particular work activities that may create challenges to implement workplace controls. We also considered the magnitude of identified risks, the potential for regrettable substitution or transition to a more hazardous substances as well as challenges that may be involved with effectively using personal protective equipment and so on. Next slide, please.

So, on slide 14 we show you the Workplace Chemical Protection Program or WCPP, which EPA is proposing for many occupational uses, which generally includes manufacturing, including import, processing, industrial and commercial use, and disposal. This WCPP requires owners or operators to implement strict workplace controls in accordance with the hierarchy of controls, with a focus on direct thermal contact controls or DDCC to prevent direct skin contact with NMP, and to inherently reduce inhalation exposure by reducing the concentration of NMP in the air from volatilization and to prevent unreasonable risk to workers.

In an effort to reduce burden and provide familiarity with an existing framework for controlling exposures and occupational settings, the provisions of the WCPP do align with General OSHA guidelines, particularly in hazard communication and general PPE standards, and the WCPPs proposed in other TSCA Section 6 rules, such as our record keeping and implementation requirements. One difference between the OSHA guideline in the NMP WCPP is the applicability to owners or operators as applying more broadly than OSHA's employers and employees. An additional difference from the other proposed TSCA section 6 WCPPs, is that EPA is not proposing an NMP specific Existing Chemical Exposure Limit or an ECEL, and again, this is due to dermal exposure really driving the unreasonable risk.

EPA believes that many workplaces may already have highly industrialized or sophisticated controls and industrial hygiene practices in place and should be able to comply with the proposed requirements. EPA's uncertainties in other workplaces to comply with the WCPP requirements are the main driver for the other regulatory options. Next slide, please.

On slide 15, we're showing you that the proposed regulation for WCPP is for all of the conditions of use that are not subject to a prohibition or prescriptive control. Those generally include domestic manufacture and import, processing, which is processing as a reactant or intermediate, and incorporation into formulation, mixture, or reaction products in multiple sectors, as well as incorporation and articles, repackaging, and recycling. This also applies to industrial and commercial uses in many sectors, not all of which are listed on this slide, but are listed in the proposed rule, which again, include but are not limited to, the use of NMP as a solvent for cleaning and decreasing in electronic product manufacturing, as a processing aid in petrochemical manufacturing, in laboratory chemicals, and in disposal. EPA is also proposing the WCPP requirements for 2 mission or safety critical uses by the Department of Defense and the National Aeronautics and Space Administration, which would otherwise be regulated by prescriptive controls. Next slide, please.

What are the prescriptive controls that we are requiring? We're requiring these certain prescriptive controls for very specific uses where it's uncertain that preventing direct dermal contact through implementation of a WCPP or prohibition would be practicable. And this can include situations where you may have hands-on spray or brush application with liquid formulations. These prescribed controls are based on additional calculations from EPA's risk evaluation to determine at what percentage in formulation and PPE would mitigate the unreasonable risk-based on the range of concentration in products that are reasonably available on the market. So, EPA is requiring the following prescriptive controls: a concentration of no greater than 45% with appropriate dermal PPE and suitable respirators for various processing and industrial and commercial uses in paints, coatings, and adhesive products, a concentration of no greater than 30% with requirements for appropriate dermal PPE and suitable respirators for the industrial and commercial use in paints, coatings, and adhesive removers, a concentration of no greater than 5%.with appropriate dermal PPE for the industrial and commercial use in ink, toner, and colorant products, and a concentration of no greater than 1% with appropriate dermal PPE for the industrial and commercial use in soldering materials. As we mentioned earlier in this presentation, EPA is particularly interested in receiving comments related to these uses, and their potential for workplace controls and the potential for exposure to NMP during application. Next slide, please.

On slide 17, you see the five uses that are being proposed to be prohibited. EPA is proposing to prohibit: the manufacture, including import, processing, distribution and commerce, and use of NMP for the processing incorporation into articles in lubricants and lubricant additives, in the industrial and commercial use in antifreeze and de-icing products, automotive care products and lubricants and greases, as well as in metal products, and in cleaning and degreasing and cleaning and furniture care products, and in fertilizer and other agricultural chemical manufacturing processing aids and solvents. These are based on the Agency's consideration of alternatives, our uncertainty relative to the feasibility of exposure reduction, to sufficiently address the unreasonable risk across the broad range of work environments and activities, and the irreversible health effects associated with NMP exposures, as well as EPA's understanding that some of these uses may no longer be on going or have reasonably available alternatives on the market. For more information about the alternatives that EPA has identified, we have published the alternatives assessment in the NMP Public Docket as a supplemental reference. Next slide, please.

EPA did identify unreasonable risk to consumers from one of the eight identified consumer uses, which is the use of NMP in adhesives and sealants. Under TSCA, rather than regulate consumers directly, EPA can regulate upstream of those consumer uses and so is proposing to require a concentration limit of 45% on

NMP for the import, processing, and distribution in commerce for the use of NMP in consumer adhesives and sealants. Next slide, please.

On slide 19 we have the remaining consumer uses which EPA did not identify unreasonable risk to consumers. However, EPA did identify unreasonable risk to workers at the equivalent upstream commercial uses from increased exposure and more frequent use. So, to prevent those consumer products use into those commercial applications EPA is proposing a container size restriction of 16 ounces and labeling requirements for the following consumer uses: in paint and coating removers, adhesive removers, in paints and coatings and paint and coating additives, in cleaning and furniture care products, and in lubricant and lubricant additives. Next slide, please.

This slide describes some of our additional requirements to the proposed rule, mainly downstream notification and record keeping requirements. The downstream notification requirements are intended to spread awareness throughout the supply chain to commercial end users of the NMP restrictions under TSCA, mainly through safety data revisions. The record keeping requirements generally require owners and operators to retain normal business records and records related to the proposed rule requirements for 5 years to support and demonstrate compliance. Next slide, please. Thank you.

So, on slide 21, we're laying out that TSCA requires the Agency to consider an alternative regulatory action in addition to the proposed one. In this proposed rule, we considered one alternative regulatory action, which proposes requiring a WCPP for additional conditions of use that would otherwise have been prohibited or have prescriptive controls under the proposed action. And we're also proposing a prohibition instead of prescriptive controls for the industrial and commercial use and distribution for consumer use of NMP in adhesives and sealants. The alternative action does not require consumer product container size restrictions or labels. Additionally, the implementation of the alternative action for a WCPP is 6-months longer than for the proposed regulatory action. Otherwise, the alternative action for a prohibition follows the same compliance time frame as those for the proposed. I want to highlight that in the proposed rule in unit 4C, you'll find an overview table that summarizes the proposed versus alternative option for each condition of use. And again, that's in unit 4C. Next slide.

Now, slide 22 lays out our proposed compliance time frames, as I'm sure folks have been wondering when these restrictions would apply when the rule is finalized. Under TSCA, compliance dates must be as soon as practicable, while providing for a reasonable transition period. Where the WCPP and container sizes and labeling requirements, EPA is proposing compliance after 12-months of publication in the final rule. For the proposed prohibition and prescriptive controls, which again, those were the combination of a concentration limit and PPE, EPA is proposing a staggered compliance timeframe starting at 12-months and then extending by 3-months through each stage of the life cycle. As you can see here, that starts out at 12-months for manufacturers and staggers to 15-months for processors, all the way through ending at 24-months for commercial users after publication date in the final rule. This 24-month deadline for the prohibition and the staggered timeline is consistent with other recently proposed rules under TSCA Section 6. Next slide.

On slide 23 we touch on the benefits of this proposed rule, which I don't think I can overstate. The rule would reduce risk of adverse health effects for workers and consumers, with identified unreasonable risk in the risk evaluation. The proposed restrictions allow for many ongoing uses of NMP to continue with strict but common-sense controls in place and EPA believes implementation should be achievable with minimal disruption to most of these uses. Uses in critical infrastructure and national security, such as in semiconductor and lithium-ion battery manufacture will continue with these workplace controls in place so that the unreasonable risk is mitigated. We also believe this regulation will provide regulated communities with confidence in a protected and healthier workforce. Next slide.

Slide 24 includes, as we noted earlier, our interest in seeking requests for comment from the public. And our proposed rule includes requests for comment throughout, though they are all listed in full in unit 8 of the notice. This slide highlights a few of those topics which we are eager to receive information on, including the Workplace Chemical Protection Program and its various components, timeframes for implementation of the requirements, specific engineering or administrative controls that would address the unreasonable risk, the feasibility of alternatives to NMP and their availability, and the feasibility of the proposed concentration minutes. We're also seeking comment on the proposed *de minimis* value of 0.1% of NMP in products or formulations. And again, our full list of these requests for comment questions are in unit 8 of the proposed rule. Next slide.

Slide 25, we list some examples of that potentially useful information for key areas of our uncertainty, and this can be information from within the last 20 years containing any descriptions of commercial worker activities and associated sources of exposure, product formulation information, and any other relevant unpublished data. Public comments submitted to the docket could result in changes to elements of the proposed regulatory action. We want to hear about your ability to meet workplace controls and compliance timeframes and receive any detailed and robust data to support or substantiate any comments. Next slide.

On slide 26, we briefly show you our next steps as noted earlier, the public comment period closes in 39 days on July 29. Please submit comments to the docket for EPA's consideration as we develop the final rule which is expected to go out in 2025. This slide also includes estimated effective dates for the proposed prohibitions and restrictions, should the rule be finalized as proposed. Next slide.

On slide 27, we have links to additional resources, including to EPA's TSCA Risk Evaluation and Risk Management webpages and links to the dockets. Next slide.

This is my final slide, which does include a link to the docket where comments must be submitted for EPA's consideration. If you have any additional questions that were not answered today, please submit it to the docket or email EPA at NMP.TSCA@epa.gov. These links and the slides will be available on EPA's web page following the webinar. On behalf of the Office of Pollution Prevention and Toxics, we thank you again for your remarks today and your continued participation and engagement. It is invaluable to us as we work through the final rulemaking process. So, we look forward to hearing your public remarks today and receiving your written comments by July 29 in the NMP docket. With that, I'm going to pass it back to Sheerin to facilitate the public remarks portion of the webinar. Thank you so much for joining today and for your engagement with the Agency on this proposed rule. We look forward to hearing your input.

Sheerin Shirajan (ICF): Thank you, Clara. We will now begin the public remarks session. If you requested to make public remarks, please ensure that your name on Zoom is the same as the name you registered with. If you're currently signed on Zoom, under a different name and you registered to provide remarks, please email EPArulemaking@icf.com with your name as it currently appears on Zoom and the email address that you registered with. Attendees who requested to provide public remarks will be given 5-minutes to speak, we will call on speaker numbers to begin. Each speaker will be unmuted one at a time to make their remarks.

As a reminder, oral remarks presented during the webinar will not be included as part of the docket, and substantive comments should be provided in writing by July 29 to EPA-HQ-OPPT-2020-0744. The link to the docket is provided in the chat box. Before you begin your remarks, please state your full name and affiliation. A timer will appear on the top right corner of the screen. A time check will be sent to speaking attendees when they have 1-minute remaining. Next slide, please. Thank you.

Those who requested to speak have been added to a public remark group. As you see your name and number in the queue to speak, please be ready to provide your oral remarks. When it is your turn to speak and your order in the queue, you will see a pop-up message, please hit unmute when it's your turn to speak. Your 5 minutes will begin when you start your oral remarks. If you do not see the pop-up message when it is your turn, go to the bottom left of the Zoom dashboard and hit the unmute button to speak. If you continue to have issues, please email EPArulemaking@icf.com. Again, please state your full name and affiliation before providing your remarks. You'll have a total of 5 minutes to provide your remarks. We will now begin. Speaker number one, please unmute, state your name and affiliation, and begin your remarks.

Michael Anderson (IFS Industries): Thank you, my name is Michael Anderson. I have no comments that was inadvertently added to this distribution.

Sheerin Shirajan (ICF): Thank you very much, we'd like to invite the next speaker. Speaker number 2, please unmute, introduce yourself, and begin your remarks.

Heather Blankinship (NMP Producers Group): Good afternoon, my name is Heather Blankinship. I'm the Manager of the NMP Producers Group. On behalf of the NMP Producers Group, I would like to thank EPA for the opportunity to make comments regarding EPA's proposed risk management rule for NMP. The NMP Producers Group remains concerned that EPA's risk evaluation concluding that NMP presents an unreasonable risk is flawed. EPA's rationale is based on flawed data that peer-reviewed scientific experts have demonstrated are incorrect. The study on which EPA has chosen to base its chronic point of departure is the incorrect toxicology study and toxicological endpoint. The NMP Producers Group has submitted these concerns to EPA through all available channels. First during the public comment period for the draft risk evaluation.

Next, in supplemental communications, following the public comment period, before the final risk evaluation was issued, and most recently in a request for correction of information submitted to EPA under the Information Quality Act. At no point has EPA offered a scientifically coherent explanation for its decision. The NMP Producers Group is concerned that EPA's proposed risk management rule is based neither on the best available science nor a scientifically defensible weighing of the scientific evidence as required by TSCA section 26 because EPA has based its point of departure on both the incorrect toxicology study and toxicological endpoint. After EPA published the final risk evaluation relying on the poor-quality study, a blinded panel of 6 experts, 2 of which were former career EPA employees, reviewed the pivotal study Exxon (1991) and agreed that it was not a high-quality study and should not be considered for quantitative risk assessment.

The results of this assessment were subsequently peer reviewed and published in a scientific journal in February 2023 by Kerman et al. In May 2023, the NMP Producers Group submitted to EPA a request for correction of information in the risk evaluation. The NMP Producers Group requested that EPA consider the new information relating to the 2023 Kerman et al review. In addition to providing reminders that the final risk evaluation included questionable quality ratings for studies, as stated in public comments, that were not addressed formally. For example, in the 2015 Workplan Chemical Risk Assessment of NMP EPA stated, Sitarek and Stetkiewicz, (2008) was unreliable due to inconsistencies in the published data. However, in the final risk evaluation EPA rated the study as high quality without addressing the previously cited weaknesses. In addition, the Exxon (1991) study was rated reliable with restrictions in the 2007 OECD Screening Information Dataset Review, while two follow up studies, NMP Producers Group 1999A and 1999B, were rated reliable without restrictions. In the final risk evaluation, all 3 studies were rated as high-quality without qualification. EPA provided no explanation for the change in its quality rating of the Exxon (1991) study.

Collectively, these arguments support the view that flawed studies were used for the point of departure designation that ultimately led to several conditions of use being incorrectly designated as presenting unreasonable risk. The NMP Producers Group's request for correction was denied in August 2003. In its denial, EPA again failed to address the concerns raised by the NMP Producers Group that are supported by peer-reviewed science. EPA was quoted in March 2023 as stating publicly that the public comment period provided as part of the risk management rulemaking will allow for the correction of information and risk evaluations that does not comply with EPA's information quality guidelines. The NMP producers group urges EPA to consider and address the significant concerns it has raised in previous comments and in the request for correction. EPA is relying on non-reproducible science for its determination of unreasonable risk for NMP. EPA is required to use the best available science and the weight of scientific evidence, a regulation of the uses of NMP based on EPA's final risk evaluation does not therefore meet this requirement. Thank you again for this opportunity to express our views.

Sheerin Shirajan (ICF): Thank you for your remarks, we'd like to invite the next speaker. Speaker number 3, please unmute, introduce yourself, and begin your remarks.

Amy Cuccaro (General Motors LLC): Hello, this is Amy Cuccaro. I inadvertently added my name to this list, so I do not have any comments.

Sheerin Shirajan (ICF): Thank you for clarifying. We will now go on to speak at number 5, speaker number 4 is currently not in attendance. Speaker number 5, please unmute and introduce yourself and begin your remarks. Speaker number 5, you're not audible. We kindly ask that you unmute. Please contact EPArulemaking@icf.com if you would like to provide remarks and need additional support. We will now move to the next speaker. Speaker number 6 is currently not in attendance, so we will be moving on to speaker number 7. Speaker number 7, please unmute, introduce yourself, and begin your remarks.

Darius Sivin (International Union): This is Darius Sivin, I registered and I thought I might have comments to make, but in fact I don't. Thank you.

Sheerin Shirajan (ICF): Thank you, we'll move on to speaker number. 9. Speaker number 9, please unmute, introduce yourself, and provide your remarks. You are not audible. We kindly ask that you unmute.

Kassaye Workagegn (Unknown Affiliation): Yeah, this is Dr. Kassaye, I just have some comments. Normally I'm just on a [inaudible] but, I need to have some kind of comment on the general presentation and overview of the [inaudible]. First of all, I would like to appreciate the EPA for preparing and organizing this kind of, interesting webinar and I'll also appreciate for the presenter, which explained very well with regard to the health effects of NMP, and the risk, and the source, and overview of NMP. With regard to, having said this, I have some, maybe comments or questions with regard to the NMP and the presentation and [inaudible] from the presentation I can see they say that there is no unreasonable risk in the present aspect with regard to NMP, but I have a question with this topic. Is there any kind of increase in the concentration to the environment and if so, is there any bioaccumulation and [inaudible] concentration with regards to this chemical?

The second aspect is, you explained the source and the effects and some aspects with due regards to NMP, is there any [inaudible] to review the concentration with regard to biological and chemical and mechanical that maybe just for reduce the concentration for the use of this chemical particularly in painting and coating, even if it's just used in agriculture for corn sugar which can be used to reduce. We may just think about replacing this technical with agriculture and that aspect, that may be possible to do to reduce if used because it's a

really uptick chemical that harms the workers that are working in that industry, agriculture and the direct exposure with the chemical. The other aspect that maybe, the question is, is there any study or a plan to study, with regard to the current effects and the long-term effects and half-life effects that may be called the chemical and maybe just consider these bio[inaudible] effects of the chemical? And without maybe common separation average [inaudible] thank you for clarify, present to explain this [inaudible] and different environmental issues. Thank you very much.

Niva Kramek (EPA): Thank you, this is Niva Kramek from EPA. I'd like to remind all the participants who've been providing remarks that we do appreciate their remarks also being submitted to the docket as part of the comment period. And regarding the points raised by the last speaker, thank you for your remarks. I would like to emphasize that in the risk evaluation for NMP in 2020 we did evaluate risks to the environment. The conclusions were that NMP does not present an unreasonable risk of injury to the environment, but we would be happy to view your public comments on that and also provide you with links to the particular portions of the risk evaluation and risk determination that address those. I'd be happy to follow up by email if you contact us.

Sheerin Shirajan (ICF): Thank you, Niva. We have one more speaker. So, speaker number 10 please unmute, introduce yourself, and begin your remarks.

Michael Purser (Rosebud Company): Yes, my name is Michael Purser. I'm in Atlanta, Georgia and I am what you would characterize as an end-user of NMP products, and specifically that would be products that are used to strip old paints and old finishes. I am in the restoration and preservation business; I have been using NMP products for over 30 years and over the course of that time I have probably used I would estimate somewhere between 1,200 to 1,500 gallons in my line of business, my company is called Rosebud Company. And we specialize in the restoration of old wood floors and historic properties. Now, I totally understand the concern for the health concerns, the environmental concerns, and long ago took steps when I first started working with the product in the late 80's to take advantage of whatever health information was available. In 1993 I actually called on NIOSH to come in and monitor air quality on projects, they published in 1994. So, I'm very proud to say that we've been well out in front of a lot of these issues.

I was not aware that there were health problems until about, I would say around 2010, when the manufacturer informed me of this. And so again, I started looking into what the possible issues would be, it looked like it was more related to dermal contact and the effects of what I would call excessive contact, spills, unintended contact, that sort of thing and the impact it had on pregnancies and fertility. I do want to emphasize that we had already taken steps, and I'm a very small company, to make sure that, you know, I come from a background of working on wood floors, so when you come out of a building like that where you're around solvents, finishes, chemicals, you pretty much understand, almost from the get go, that you don't want this stuff on you. It doesn't make any difference what the solvent said, and so there's a tendency to protect yourself from the dermal contact and from the airborne vapors. And with the amount of experience that I've got, as I said, it goes back over 30 years, I make no bones about the fact that the dermal contact is by far the easiest to manage because in many cases it's nothing more than simply wearing protective gloves and protective shields.

Now, where I have concerns and I was reading through, and by the way I am a layperson when it comes to EPA terminology studies and that sort of thing, but where I was looking at this is several things jumped out at me and that is this reduction in the concentration of NMP in certain products. First of all, as I said, we work with chemical strippers where we're removing old finishes, that sort of thing, and I know for a fact that ours is at the 45% level. And when I saw that you would reduce that down to 30%, my question is, what is the driving force behind that? Is it being based on consumers and the exposure to consumer use? In other words,

going into a hardware store and buying it off the shelf or are you judging this on, you know, professionals like myself. I'm in the preservation and restoration where there tends to be a lot more focus on the numbers, so to speak, to protect ourselves. We're, you know, we're the ones that are exposed to it. We work in isolated areas; the public is not at risk of walking in on us. We're in areas where it's cordoned off and you're not allowed back there unless you're guided back there by one of us.

So I'm curious to know how you came to that determination and I'm concerned about that because based on my experience, if you reduce the percentage of the NMP you will likely reduce the efficacy of the product and I kind of understand what you're thinking here is like, well, if we reduce the percentage down to 30% that there's less likelihood or that there's less potency, but at the same time, you decrease the potency of the product. So, from the standpoint of somebody who's working with it, if you decrease that then you will more than likely extend the amount of time needed to do the restoration work because of poor performance. And you would also probably require different products to clean up the residue and this is where you get into, you're opening up Pandora's box there. So, I'm very interested in the reduction of the percentage and also in finding out if there are any certification or restricted-use areas where we could apply for and get some sort of, not a pass, but just, you know, we're using this in a different context. We are not DIY, and we are not reselling this product to the public. We're using it for specific products under very controlled circumstances. I appreciate your time. I appreciate your hard work and look forward to getting feedback from you. Thank you.

Sheerin Shirajan (ICF): Thank you very much. This now concludes our public remark session. As a final reminder, oral remarks presented during the webinar will not be included as part of the docket. Substantive comments should be provided in writing by July 29 at EPA-HQ-OPPT-2020-0744. The link can be found in the chat box and in your email from EPArulemaking@icf.com. I'll now pass it to Clara Hull for closing remarks, thank you.

Clara Hull (EPA): Thank you, Sheerin. So yes, we're now closing out this public webinar. I want to again thank all attendees today. Pardon me, one moment.

Niva Kramek (EPA): This is Niva Kramek from EPA filling in for Clara. Apologies for the unexpected interruption on our end and I would like to say again, thank you for your public remarks, your attention, your participation, and especially for your forthcoming comments on our proposed rulemaking. The docket is listed here. It is open and we would be very interested in receiving your comments in writing by July 29. The presentation will be on the website, and also you can reach us at any time at NMP.TSCA@epa.gov. That's the email address that has been put into the chat several times that reaches Clara and the rest of her team, and we would be very happy to hear from you. Thank you.