

U.S. EPA Webinar on the Final Regulation of Methylene Chloride under the Toxic  
Substance Control Act (TSCA)

Transcript

Tuesday, June 4, 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 Final Regulation of Methylene Chloride under the Toxic Substance Control Act (TSCA). We will get started shortly. Please note that all attendees are pre muted for this webinar. If you are having trouble with Zoom and are using the desktop app, please check your settings. If you're using any browser, we recommend either restarting or opening it with Google Chrome. The chat will be used for broadcast messages only. If you have questions about the rule that you would like EPA to address, use the Q&A button on your Zoom dashboard to submit questions in that box.

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Please note that after the presentation, there will be a requested information session where EPA will address questions previously submitted during registration. EPA may also address some questions through the presentation and others sent during the webinar in the Q&A box. Please note that time might not permit all questions to be addressed during today's session. More information about submitting a question will be provided later in the webinar. For any general questions on the final rule, email EPA at [MethyleneChlorideTSCA@epa.gov](mailto:MethyleneChlorideTSCA@epa.gov). If you have any technical questions during this webinar, please use the Q&A box or email us at [EPARulemaking@icf.com](mailto:EPARulemaking@icf.com).

An email following this webinar will be sent to your inbox from [EPARulemaking@icf.com](mailto:EPARulemaking@icf.com) with information on how to access the presentation materials. If you do not see this email in your inbox, please check your spam or junk. This webinar is being recorded and will be available with the presentation slides after webinar at the link pasted in the chat. The link to the docket for the methylene chloride rule is also pasted in the chat for your reference. Thank you very much and we will now move on to our opening remarks by Dr. Elissa Reaves.

**Elissa Reaves (EPA):** Good afternoon, everyone, and welcome. It is great to see such an excellent turnout for this webinar today. My name is Dr. Elissa Reaves. I'm the Director of the Office of Pollution Prevention and Toxics (OPPT) within EPA's Office of Chemical Safety and Pollution Prevention (OCSPP). Welcome to our webinar for the Final Rule of Methylene Chloride under the TSCA. For those that attended our previous webinars, welcome back. And for those of you joining us for the first time, we are glad to have you here. We are especially glad to have you all here for the discussions of this final rulemaking, which demonstrates EPA's commitment to protecting human health from existing chemicals.

As many of you are aware, the Toxic Substances Control Act, or TSCA, requires those of us at the EPA to address unreasonable risk from chemical substances to the extent that they are no longer unreasonable to human health under the conditions of use. Since 1980, at least 88 people have died from acute exposure to methylene chloride. Many others have also experienced severe and long-lasting health impacts, including certain cancers. Due to these well-documented health effects and based on a thorough risk evaluation, the EPA issued an unreasonable risk determination for workers for risk to workers, consumers, and the bystanders nearby. We have been working on methylene chloride for a long time, and I know many of you have provided comments, input, and your perspectives on this regulation.

Last year, we proposed to regulate all conditions of use of methylene chloride to address the unreasonable risk. This was a landmark action by the agency, and we appreciate all of your comments. Just last month, we finalized the methylene chloride regulation and Ingrid Feustel, the rule lead, will be discussing the details of the requirements in a few minutes. This final rule requires that companies rapidly phase down manufacturing, processing, and distribution of methylene chloride for all consumer uses, and most industrial and commercial

uses. There are substitutes for most of these uses of methylene chloride, and we have determined that prohibitions are necessary for these conditions of use. This final rule also establishes landmark worker protections. For a handful of highly industrialized uses, EPA has created a Workplace Chemical Protection Program or WCPP. This program will protect workers and others in the workplace from cancer and other adverse health effects caused by methylene chloride exposure.

This final rule allows several more uses under the WCPP than those originally proposed. The determination to allow additional uses to continue under the WCPP was largely due to information such as exposure monitoring data, safety practices, and process details that were provided to us at the EPA for consideration by organizations and people who may be in attendance today. Additionally, through stakeholder engagement with the regulated community, non-governmental organizations, trade organizations, unions, and public submissions, in this final rule, we also established a de minimis concentration. We included new or revised provisions to strengthen the WCPP and extended several compliance dates to ensure successful implementation.

I mention all of this to emphasize to you all how much my colleagues and I at EPA take into consideration the information we receive from you. I want to take a pause here and thank all those who participated in this process, those who met with us or submitted information during our public comment periods. I cannot overstate the importance of your engagement throughout the TSCA evaluations that bring us here. Again, it has been a journey getting to this point. The overall goal today is to explain to you, in plain language, the TSCA process that led us to the final regulatory action for methylene chloride and the requirements of the final rule. We will be providing answers to questions previously submitted.

Before we move on to our presentation, I want to introduce speakers from two different agencies, OSHA and NIOSH. They are already trusted sources of information regarding workplace chemical exposures and recognize the importance of EPA's methylene chloride rule for public health, and that there is particular interest from the occupational health community. We are also mindful that this rule applies to entities that are familiar with OSHA regulations, so we work closely, not only with the regulated community but also with our federal partners in NIOSH and OSHA to align EPA's approach to risk management with familiar limits of the OSHA regulation. I will now introduce our representatives from NIOSH and OSHA to provide us with a brief message. First, from the OSHA and the Department of Labor, Ms. Janet Carter, Senior Health Scientist with OSHA's Directorate of Standards and Guidance. Following Janet, Dr. Christine Whittaker, Director of the Division of Science Integration at NIOSH will be speaking. Janet, I hand it over to you.

**Janet Carter (OSHA):** Thank you and good afternoon, everyone. OSHA is pleased to join our EPA colleagues and the community of stakeholders in attendance at this event. We would also like to acknowledge the important step EPA has taken in promulgating its final risk management rule for methylene chloride under the Toxic Substance Control Act. This rule will strengthen protection for workers in industries where occupational exposures to methylene chloride occur in home renovation, chemical manufacturing, and a large variety of other occupations where products that contain methylene chloride are made and used. We also want to acknowledge EPA's efforts to consult our regulatory enforcement and technical personnel during the rulemaking process to take OSHA's experience and our technical expertise into consideration in their decision making on risk management policies. Additionally, we look forward to the continued work with our EPA colleagues in support of their rulemaking efforts under TSCA. Thank you so much. I now turn it over to Christine.

**Elissa Reaves (EPA):** Thank you, Janet. Christine, the mic is yours.

**Christine Whittaker (NIOSH):** Good afternoon. I am Christine Whittaker, Director of the Division of Science Integration at the National Institute for Occupational Safety and Health. I would like to offer my congratulations to EPA for the publication of the methylene chloride final rule. This is especially meaningful for me, personally, because I started my career at OSHA where my first assignment was working on the OSHA methylene chloride rule. That final rule was published in 1997. This current EPA rule updates and provides additional protections for workers. It has been exciting to see this process unfold. NIOSH staff have been pleased to take part in regular meetings with the EPA TSCA staff to discuss occupational risk assessment and occupational safety and health issues like exposure assessment, the hierarchy of controls, and proper personal protective equipment use. These continuing conversations have not only improved EPA's understanding of the details and nuances of occupational risk assessment but have also provided NIOSH staff with a deeper understanding of the issues and concerns that EPA faces. We look forward to continuing our discussions.

NIOSH, unlike OSHA or EPA, does not set regulatory occupational exposure limits. Instead, NIOSH offers recommended exposure limits. In addition, NIOSH produces a wide variety of communication products to assist employers in providing a safe and helpful workplace. For example, NIOSH publishes workplace solutions documents that describe recommended practices for specific hazards in specific workplaces. A recent example includes reducing workers' lead exposure during water service line removal and replacement. NIOSH also publishes the NIOSH Pocket Guide to Chemical Hazards, in which employers and safety and health professionals can find not only NIOSH recommended exposure limits, but also OSHA permissible exposure limits. NIOSH is currently exploring ways it could provide information on EPA TSCA regulations as they are developed. NIOSH joins OSHA and EPA in the goal of providing a safe and helpful workplace for all workers. Thank you.

**Elissa Reaves (EPA):** Thank you again, Janet and Christine for joining us. While they will not be taking questions today, we appreciate our colleagues' support during this webinar and throughout this rulemaking. Without further ado, our next speaker and webinar presenter, Ingrid Feustel.

**Ingrid Feustel (EPA):** Thank you so much, Elissa, and thank you to Christine and Janet for your remarks and for all the work that you do. Good afternoon, everyone. My name is Ingrid Feustel. I am with EPA's Office of Pollution Prevention and Toxics, and I am the lead staff member on this rulemaking. Today, I am pleased to give an overview of the Regulation of Methylene Chloride under the Toxic Substances Control Act, which was finalized last month.

Today's webinar will start with some background, including a very high-level overview of the Toxic Substances Control Act or TSCA, an overview of the methylene chloride rulemaking, including the rulemaking process and EPA's proposed regulation of methylene chloride. Then we will spend the bulk of our time discussing the final regulation of methylene chloride. I know as a part of the registration for this webinar we asked for your questions. I will be trying to answer as many of them as I can throughout the presentation, and immediately after the presentation we will provide a brief requested information session.

In June of 2016, Congress passed the bipartisan Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act to significantly amend TSCA. These are amendments mandated the agency address risks from chemicals currently in commerce in a way that was predictable for the regulated community and would provide much-needed protections for human health and the environment. Methylene chloride was identified as one of the first ten chemicals to undergo a chemical risk evaluation under the new law, which requires EPA to identify all the conditions of use of a chemical and evaluate the risks, then address those risks such that they are no longer unreasonable.

This is a lengthy process with numerous formal and informal opportunities for public engagement. The timing of each step is determined by statutory deadlines, which set a swift pace for the agency. This is the process for all EPA initiated risk evaluations under TSCA, not just methylene chloride.

Starting with prioritization, EPA announces candidates for prioritization and has 12 months to determine whether that chemical is a low priority chemical or a high priority chemical. This step includes a period for public comment and if a chemical is determined to be a high priority, then it moves on to the next phase. The next stage is risk evaluation, and it typically takes three to three and a half years, a period which includes lots of public engagement, public comment periods, and a scientific peer review. EPA conducts thorough analyses on all reasonably known and foreseeable uses of the chemical to determine whether it presents an unreasonable risk to human health and the environment. If EPA finds unreasonable risk, TSCA mandates that we move to the next stage to address those risks, and that is risk management. EPA has two years to propose and finalize a rule for a chemical substance that poses unreasonable risk, and we can choose from a suite of risk management tools to address those risks. I will talk more about those tools later in the presentation.

TSCA set up some requirements for how we address any unreasonable risks that we identified, including a consideration of alternatives to the chemical, the inclusion of a regulatory alternative in the proposal, statement of effects, and an economic analysis. Input from stakeholders is essential throughout the various stages of the rulemaking process, including between the proposed and final rule stage. EPA additionally coordinates across its internal offices such as the Office of Land and Emergency Management, Office of Air and Radiation, and Office of Water, and other federal agencies including the Consumer Product Safety Commission, OSHA, NIOSH, Department of Defense, NASA, and Department of Energy, tribal representatives, state and local governments, various industries, and non-government organizations.

When promulgating a rule, EPA has the authority to regulate manufacturers, importers, distributors, processors, commercial users, and entities disposing of commercial chemicals. EPA cannot directly regulate consumers. However, if unreasonable risk is identified for consumer use from products containing a chemical, EPA may regulate upstream uses such as manufacturing, distribution, and processing to prevent the unreasonable risk to consumers. TSCA allows EPA to regulate at key points upstream of the chemical supply chain to address any unreasonable risk downstream to consumers.

Here on slide six, we have our toolbox. Once we have identified risks, TSCA section 6(a) gives us a suite of options for addressing those unreasonable risks. It allows the EPA a range of tools from prohibitions for certain uses to labeling, to regulating manner or method of disposal or use. Which could entail, for example, setting occupational exposure limits. Any of these tools may be applied alone or in combination to address risk such that they are no longer unreasonable.

Now, we are moving from a general TSCA overview to talking about methylene chloride and this major rule promulgated under the new law. As a quick review, methylene chloride is a solvent with a wide range of uses from off-the-shelf commercial products and even some toys, to manufacturing applications including the manufacture of other chemicals. However, the hazards of methylene chloride are well established. Sadly, there have been 88 recorded fatalities since 1985 due to methylene chloride use, with the most recent fatality taking place in June 2023. In June 2020, EPA released a risk evaluation that determined methylene chloride presents an unreasonable risk to human health, driven by all but one of its uses. Those short-term risks include potentially lethal neurotoxicity and liver and cancer effects resulting from chronic exposures.

As Elissa mentioned, EPA has been working on methylene chloride under TSCA for a long time. Before the June 2016 Lautenberg Chemical Safety Act to TSCA, EPA completed a risk assessment on the use of methylene chloride as a paint and coating remover. A particularly hazardous use, which resulted in the 2019

prohibition on consumer use of methylene chloride as a paint and coating remover. Then, under the Lautenberg Chemical Safety Act in 2016, EPA designated methylene chloride among the first 10 chemicals to undergo TSCA risk evaluation, which required EPA to assess all uses of methylene chloride and address any unreasonable risk we find via rulemaking. That risk evaluation was published in 2020, along with a final revised risk determination in 2022.

In May 2024, EPA proposed a prohibition on all consumer and commercial use with a handful of exceptions, where in lieu of a prohibition, EPA would finalize a risk-based worker protection program which we are calling a WCPP, for Workplace Chemical Protection Program. As a high-level overview of the WCPP, it includes an occupational exposure limit of 2 parts per million over an eight-hour time weighted average and 16 parts per million over a 15-minute time weighted average. The WCPP also includes supporting requirements such as monitoring and record keeping. EPA also proposed two time-limited exemptions from the prohibition, which in contrast to those uses that fall under the WCPP, would only continue for 10 years. EPA's proposed alternative action, including additional uses continuing under the WCPP and longer compliance time frames for the WCPP and prohibitions. EPA requested comments on both of those topics as part of its proposal. And that proposal was published on May 3rd, 2023, with a 60-day public comment period.

As you might have seen on the previous slide, we received almost 40,000 public comments which were extremely valuable to the development of the final regulation. A vast majority of those comments came from mass mail campaigns and petitions asking EPA to move quickly to protect workers and consumers from methylene chloride. Additionally, around 200 of those comments were NGOs (non-governmental organizations), trade associations, unions, academics, and the regulatory community. All entities and individuals provided suggestions on certain provisions were included in EPA's final rule response to comments document. This information is available in the docket for anyone looking for in-depth responses to comments submitted on the proposal. Unit III of the final rule preamble highlights comments which resulted in significant substantive changes to the proposal.

We touched on some of this earlier, but it bears repeating that TSCA provides guidelines for a rigorous decision-making process when it comes to the development of the final rule. For each use of methylene chloride, we considered all reasonably available information when determining which of the tools under TSCA 6(a) we should use to address risks such that they are no longer unreasonable. That includes looking at alternatives, existing safety practices, and processes for each use, as well as the magnitude of the risk associated with each of those uses. EPA's goal is to promulgate regulations that are both practical and protective, and we believe this final regulation has hit the mark.

That all brings us to our approach for this final rule. As in the proposal, EPA will prohibit all consumer use of methylene chloride as quickly as possible, and we will prohibit the industrial and commercial uses of methylene chloride where an exposure limit cannot be implemented safely. There were two specific uses in which EPA determined needed a longer phase out period. I will expand more about both timeframe changes in a few slides. In addition, there are five uses which were prohibited at proposal, which we are now finalizing under WCPP. The five uses were also included in the proposal. We will talk about that in detail on slide 19. This rule also finalizes the proposed 6(g) exemption for certain NASA uses.

First, I want to talk about the applicability of this final rule. The Toxic Substances Control Act includes a definition of chemical substance that excludes food, food additives, drugs, and medical devices, as well as pesticides. In other words, if methylene chloride is being used in a way that meets those criteria, it is not subject to these final regulations. This includes instances when methylene chloride is present as an impurity due to coffee decaffeination. We received many questions about that particular use. The criteria also includes

instances where methylene chloride is used in the manufacture of pharmaceuticals. While this definition might seem straightforward, there is some nuance here. If you are unsure about whether your use meets the TSCA definition for a chemical substance, we recommend contacting us at EPA for confirmation.

The final rule also includes a *de minimis* threshold for compliance. If methylene chloride is present in formulation at less than 0.1%, that formulation would not be subject to any requirements of this regulation, including prohibitions, workplace protections, or record keeping. While presented on the slide, we received questions about the presence of methylene chloride in articles and how the *de minimis* applies to those situations. There is a lengthy discussion of this in the response to the comment document that I encourage you to review if this question is relevant to you. In short, this rule did not identify unreasonable risks from articles containing methylene chloride, but there may be some risks in the manufacturing of some articles, such as in plastic or rubber product manufacturing where the risks during manufacturing would be managed by a WCPP. This also includes uses of methylene chloride in other ways during article manufacturing, such as use in decreasing or finishing products for fabrics and textiles, both of which would be prohibited by this final rule.

This rule prohibits all use of methylene chloride in consumer products. This includes degreasers, adhesives, and automotive care products. You will notice the list on slide 14 does not include paint and coating remover, and that's because consumer use of methylene chloride as a paint and coating remover was already prohibited back in 2019.

The final regulation additionally prohibits all industrial and commercial use of methylene chloride unless that use is specifically identified as subject to the Workplace Chemical Protection Program, which I will talk about in a few slides. For both consumer and commercial uses, regulated entities have some time to sell through their existing stocks and move to alternatives.

There were two uses where EPA found a little bit of additional time might be necessary to move to those alternative products. The first is the furniture refinishing sector, where folks who are doing refinishing of wooden pieces of historic, cultural, or artistic significance have five years to transition away from methylene chloride. However, to take advantage of that five-year extension, there needs to be existing safety controls in place, including local exhaust ventilation and minimum respiratory protection, which must be air supplied. All other furniture refinishing, which does not meet those two criteria, will be prohibited after two years. The second use where more time might be necessary is in adhesives and sealants for structural and safety critical aircraft, space vehicles, and turbine applications. For this use, EPA is not requiring the use of the WCPP or other interim controls during the phase-out period. For those interested in the rationale for these two extensions, it can be found in the preamble of the final rule in Unit III.c.1. and 2.

I will not spend too much time on slide 17, but please be aware that the regulation includes a 10-year exemption from the prohibitions for certain emergency uses of methylene chloride in support of NASA's mission. This exemption is for 10 years and requires folks to try to comply with the WCPP and can only be extended by rulemaking.

I promised I would talk a bit more about the timeframes. EPA understands that in some cases, complying with the new requirements will be disruptive. We have tried to structure a phase-out into the rule to ease the burden where possible, while still providing protection to workers and consumers. These timeframes are longer than those that were proposed. To that end, beginning in February 2025, it will be prohibited to distribute methylene chloride containing products to retailers. As a reminder, a retailer is any distributor with at least one consumer customer. Those retailers will have three months to sell through their stock. After one year, it will be prohibited to sell any methylene chloride containing products to consumers. We advise

members of the general public to always check their labels and avoid methylene chloride containing products where possible and ensure if you must you are using products in a well-ventilated area.

In May 2025, manufacturers may no longer produce methylene chloride for any of the prohibited end uses, and by April 2026, most industrial and commercial use will be prohibited. For those two uses on the previous slide with extended deadlines, they will continue until May 2029. For any prohibited end pieces, regulated entities do not meet the WCPP or ECEL during that phase out period.

The rule is not a complete prohibition. For a handful of uses, EPA is issuing a Workplace Chemical Protection Program or WCPP. As I mentioned earlier in the presentation, TSCA requires us to address identified risks to human health such that they are no longer unreasonable. The law specifies that this includes potentially exposed or susceptible subpopulations and identifies workers as one of those populations. Since EPA's unreasonable risk determination identified risk to workers, we are obligated, through rulemaking, to address those risks.

Due to the breadth of the charge given to EPA by Congress, these regulations address risks from all occupational exposures, including some folks who would not normally be covered by OSHA requirements. For that reason, you will see terms like owner or operator instead of employer and potentially exposed persons instead of employees in the text of the regulation. However, while the charge to EPA under TSCA is different than the requirements of the OSH Act, EPA consulted with OSHA and NIOSH extensively throughout the development of its workplace protections. The WCPP will look familiar to anyone currently complying with those requirements, including exposure limits and provisions to support their implementation. That said, I want to emphasize that this rule does not replace or modify any existing regulations under other statutes.

Slide 20 contains the list of uses which will continue with strict controls under the Workplace Chemical Protection Program as part of this final rule. This list includes manufacturing and import for the uses which will continue under the WCPP; Processing, including processing as a reactant in the manufacture of other chemicals, processing into formulation for uses which will continue under the WCPP, recycling and repackaging; as well as disposal for all those uses as well. Those uses are: use as a laboratory chemical, use as a paint encoding remover only for safety critical corrosion sensitive components of aircraft and spacecraft, industrial or commercial use as a bonding agent for solvent welding, use as a processing aid, including as a heat transfer fluid for industrial processes, and use in battery separator manufacturing, use in plastic and rubber product manufacturing, including interfacial polymerization, and finally, use as a solvent inside a closed manufacturing process where the methylene chloride will be reclaimed and recycled. These uses are continuing under the WCPP because EPA is confident based on reasonably available information, including information submitted during the comment period, that they can address the unreasonable risk by meeting EPA's risk-based exposure limit.

We received many questions regarding the uses of methylene chloride. I wanted to go through them all and spend a little extra time talking about laboratory use in particular. I want to clarify that this rule does include academic, government, and research laboratories, including research and development that happens in those settings. We will talk more about this in the information session after the presentation, so please stick around.

EPA's Workplace Chemical Protection Program for methylene chloride includes two occupational exposure limits that I mentioned earlier, an existing chemical exposure limit or ECEL of 2 parts per million over an 8-hour time weighted average, and an EPA short-term exposure limit of 16 parts per million over a 15 -minute time weighted average. Note that these values are in order of magnitude lower than the current Permissible Exposure Limits (PELs) under OSHA. EPA has determined as a matter of risk management policy that

ensuring exposures remain at or below the EPA ECEL will eliminate any unreasonable risk of injury to health. Since we received a few questions on this, I want to emphasize that both of these limits are measurable and for the uses that are under the WCPP, EPA is confident that these limits are attainable. The WCPP requires monitoring, record keeping, and dermal and respiratory protection by providing exposure limits without prescribing specific controls. EPA's WCPP provides flexibility to regulated entities to meet the exposure limits in a way that is feasible for their business within limits, which I will talk about on slide 22.

We discussed the ECEL of 2 parts per million and the EPA STEL of 16 parts per million. To meet those limits, the WCPP relies on the familiar framework established by current practices for methylene chloride. That includes initial monitoring followed by periodic monitoring of either 3 months, 6 months, or 5 years depending on the monitoring results in comparison to an action level, ECEL, or STEL. The rule also requires exposure to be reduced according to the NIOSH hierarchy of controls wherever feasible, and where not feasible, to include a description of why those controls are not feasible in the exposure control plan. It also provides respirator selection criteria to protect workers from any remaining risks. EPA will issue a compliance guide soon, which will lay out all these details.

The final rule extends the time to set up WCPP in comparison to the proposal. There will be up to one year to do their initial monitoring. That is by next May 2025. Three months after that, based on that initial monitoring, owners and operators need to set up their regulated area and provide potentially exposed persons with PPE to ensure no one is exposed above the ECEL or STEL. Another three months after that, it all needs to be written up in an Exposure Control Plan. We had a question about whether existing documentation under other rules such as the laboratory standard under OSHA can be used to meet the Exposure Control Plan requirement, and the answer to that is yes, so long as the document includes all the requirements and information outlined in this rulemaking. I will talk a little bit more about this in the information session. This is another area where you can expect help from the forthcoming compliance guide.

The final rule requires manufacturers, processors, and in some cases distributors to update their Safety Data Sheets (SDS) to provide notice of the restrictions. The final rule provides the text that should be added to the SDS in Sections 1 and 15. The other record keeping requirements include normal business records and records related to the WCPP monitoring and compliance.

I want to take a second to zoom out and talk about the benefits of this final rule. This final regulation of methylene chloride is a landmark achievement in protecting human health and the environment as envisioned by the 2016 bipartisan amendments to the Toxic Substances Control Act. This rule includes practical provisions and timeframes to aid in successful implementation, and it will protect both consumers and workers from the severe risk of methylene chloride through either prohibition or strict workplace controls. On slide 26, we have an overview of the compliance dates for all of the various provisions of this final rule, including the prohibitions and the Workplace Chemical Protection Program, so that these can all be found in one place.

On slide 27, we have helpful links to both EPA and OSHA resources on methylene chloride, including the TSCA hotline, which is the best phone number for those looking for clarification on the provisions in this final rule. One of the best ways to get updates from us is to subscribe to email updates, so I would recommend that for anyone interested. And finally, you can always reach me and my team with general questions through our email, [MethyleneChlorideTSCA@epa.gov](mailto:MethyleneChlorideTSCA@epa.gov). Thank you so much for your attention. I tried to answer as many of your questions as I could through the course of the presentation, and we have a few more that I would like to speak about. I will hand it off to Sheerin for any housekeeping and to move into our information session.

**Sheerin Shirajan (ICF):** Thank you very much, Ingrid. We will now begin the requested information session. Questions submitted previously during registration and via email to [EPARulemaking@ICF.com](mailto:EPARulemaking@ICF.com) will be addressed as time permits. Questions have been grouped and may be reworded for clarity. EPA may also answer some questions received during the webinar. Note that questions will be read aloud and answered individually and if you have any other questions about the final rule, please email EPA at [MethyleneChlorideTSCA@epa.gov](mailto:MethyleneChlorideTSCA@epa.gov). We will begin the session now.

First, EPA received many questions related to laboratory use of methylene chloride and how it is regulated under TSCA. Although the information in the presentation may have addressed several of these questions, we would like to give this topic special attention. Because of the large volume of questions, we consolidated them into a few topics.

First, general applicability. Many participants asked EPA to clarify: what provisions of this rule apply to use of methylene chloride in laboratories?

**Ingrid Feustel (EPA):** Thank you. Under this final rule, industrial and commercial use of methylene chloride as a laboratory chemical will continue with strict protections under the Workplace Chemical Protection Program. For the purposes of this rulemaking, EPA emphasizes that industrial and commercial use of methylene chloride as a laboratory chemical includes and applies to research, government, and academic institutions, as well as industrial and commercial laboratories. This includes use of methylene chloride in a laboratory process or in specialized laboratory equipment for instrument calibration and maintenance, chemical analysis, chemical synthesis, extracting and purifying other chemicals, executing research, development, test and evaluation methods and similar activities such as use as a solvent, reagent, analytical standard or other experimental use. This includes use of methylene chloride in EPA analytical methods. To reiterate, methylene chloride used in the manner I just described will continue under the WCPP. The requirements for the WCPP are in the final rule in Unit IV.a.1. I'd like to emphasize that these requirements protect people exposed in the workplace, referred to as potentially exposed persons, which includes more than workers. It would also include students, interns, visitors, or any others as relevant.

**Sheerin Shirajan (ICF):** Thank you. Moving on to the next question. Laboratories currently comply with the OSHA laboratory standard at 29 CFR 1910.1450 and, it follows, the methylene chloride standard at 29 CFR 1910.1052, particularly where the action level is routinely exceeded. How does EPA's new rule relate to these existing regulations?

**Ingrid Feustel (EPA):** This is an excellent question, so thank you to all who submitted it. What I hear in this question is a lot of expertise about how to comply with existing regulations and a strong desire to keep workers and other folks in the lab safe. Laboratories are required to be in compliance with the OSHA chemical specific methylene chloride standard, 29 CFR 1910.1052, and the OSHA laboratory standard at 29 CFR 1910.1450. EPA's methylene chloride rule under TSCA does not modify those requirements. The performance-based measures of the WCPP will address the contributions of laboratory use to unreasonable risk identified by EPA for methylene chloride under TSCA section 6. There are a few key differences between OSHA's and EPA's approach to note. The first obviously is the lower exposure limits, which must be met to comply with EPA's rule, and are necessary to address unreasonable risk under TSCA. The timeframe for meeting these new limits, as I mentioned, is just over a year, so, August 2025. EPA's WCPP additionally requires monitoring at least once every five years. While it requires records for monitoring and other documentation to demonstrate ECEL compliance, EPA's regulations do not include a requirement for medical surveillance.

**Sheerin Shirajan (ICF):** Thank you. The next question asks: How will the rule apply to research and development activities?

**Ingrid Feustel (EPA):** TSCA section 6 does not include an exemption for research and development. To the extent that research and development activities are encompassed by the description of industrial and commercial use of methylene chloride as a laboratory chemical, which was found to contribute to the chemical's unreasonable risk, those uses will continue with worker protection requirements under the WCPP. Activities that do not fall under that use or one of the other uses subject to the WCPP such as processing as a reactant are prohibited by this final rule.

**Sheerin Shirajan (ICF):** Thank you for clarifying. Relating to the WCPP, numerous people ask questions about how to comply with the WCPP requirements in a laboratory setting. What additional clarification can EPA provide?

**Ingrid Feustel (EPA):** Thank you for the question. First, as I mentioned during the presentation, I want to highlight that EPA will be publishing a small entity compliance guide which will be helpful to anyone trying to comply with this final rule, not just laboratories and not just small entities, so please look out for that guidance. Just like the OSHA methylene chloride standard, EPA's WCPP provisions require initial monitoring, including the use of similar exposure groups where appropriate, and requirements for setting up a regulated area, which the agency defines as an area established by the regulated entity to demarcate areas where airborne concentration of a specific chemical substance exceed, or there is a reasonable possibility they may exceed, the applicable Existing Chemical Exposure Limit or EPA Short Term Exposure Limit. I know we also had a question about the use of fume hoods in the context of the WCPP requirements. While a properly working fume hood should be sufficient for meeting the exposure limits, labs will need to conduct initial monitoring to demonstrate the extent to which fume hoods mitigate exposure to methylene chloride, and proceed to the appropriate periodic monitoring based on that result. This monitoring could occur as infrequently as every five years if monitoring is below the action level.

EPA believes that it is possible to use methylene chloride safely in a laboratory setting with the appropriate safeguards as required by the WCPP. That said, if laboratories are not able to comply, they would be in violation of the rule if they use methylene chloride without following the requirements of the WCPP.

**Sheerin Shirajan (ICF):** Thank you. Moving on to the next topic, you say EPA also received many questions about the WCPP outside of laboratory use. Similar to the last topic, while information in the presentation may have addressed several of these issues, we would like to provide additional clarification related to monitoring, the exposure control plan, and implementation time frames. First question, is there a requirement to put in place a WCPP, or comply with the WCPP, for companies that intend to comply with the prohibitions by the 720-day timeframe?

**Ingrid Feustel (EPA):** Thank you for the question. No, this final regulation by EPA does not require the implementation of an interim WCPP during the phase out periods for the prohibitions.

**Sheerin Shirajan (ICF):** Thank you for clarifying. The next topic related to the WCPP has to do with monitoring. There are several questions: If initial monitoring indicates results below the action level, is the WCPP still required? How does the EPA view the integration of multipoint real-time, indoor air quality monitoring systems in industrial settings, especially those capable of detecting methylene chloride at parts per billion levels? Can employee exposure monitoring conducted after the rule was proposed be considered objective data and used as initial monitoring for the final rule? And finally, if monitoring results for

potentially exposed persons are below the ECEL, which is 2 parts per million-time weight average and 16 parts per million the Short-Term Exposure Limit, is a written exposure control plan required?

**Ingrid Feustel (EPA):** Thank you. These are all great questions. For initial monitoring, depending on the results, owners and operators may need to increase or decrease the frequency of periodic monitoring, or adopt new exposure controls. Even if monitoring below the action level, the WCPP at 40 CFR 751.109, and associated recordkeeping requirements in section 113, is still required because EPA's occupational exposure limits and the related workplace exposure control monitoring and exposure plan are considered part of the WCPP for the continuing uses. Regarding real time monitoring, the methylene chloride rule does not require real-time indoor air quality monitoring in occupational settings. However, if such systems meet the accuracy requirements for measuring EPA's occupational exposure limits, EPA does not see any reason at this time that they could not be integrated into the monitoring used to meet the WCPP requirements.

Next, regarding monitoring and objective data: owners and operators must generally perform initial occupational exposure monitoring before May 5, 2025, for the private sector, or November 9, 2026, for federal agencies and contractors acting on behalf of the federal government to assess a potentially exposed person's exposure profile. Occupational exposure monitoring data from within the previous five years of the publication date of the methylene chloride rule can serve as initial monitoring data, including after the rule was proposed. Objective data sampled after May 8, 2019, can be used in the case where the owner operator demonstrates that occupational exposure monitoring data represents the highest exposure likely to occur under the condition of use and that methylene chloride can't be released above the ECEL action level or EPA STEL. In that circumstance, there are record keeping requirements identified in 751.113(c).

Finally, regarding the need for an exposure control plan: yes, anyone using methylene chloride under the WCPP needs an exposure control plan as part of compliance with the requirements. If you are monitoring below the action level, the exposure control plan can be a useful way to document best practices and provide additional certainty to regulated entities that they are complying with all WCPP and record keeping requirements.

**Sheerin Shirajan (ICF):** Thank you. The last question on the WCPP also relates to exposure control plan: Can an existing Chemical Hygiene Plan, such as those as required per Cal/OSHA 5191, be used as an exposure control plan under the Workplace Chemical Protection Program?

**Ingrid Feustel (EPA):** Thank you. EPA has no issue with using elements of an existing Chemical Hygiene Plan written to meet the requirements of Cal/OSHA 5191(e) or OSHA's 1910.1450(e) to meet the requirements for an exposure control plan. In fact, we encourage regulated entities to make use of information, tools, and procedures that are already in place, so long as they have the required elements of the exposure control plan required by this rule.

**Sheerin Shirajan (ICF):** Thank you. For our next topic, EPA received several questions related to whether a particular use of methylene chloride would be considered a chemical substance under TSCA, or whether agencies such as the Food and Drug Administration would have authority to regulate those uses.

First, there are many questions about the use of methylene chloride in the decaffeination of coffee. How might that be affected by this rule?

**Ingrid Feustel (EPA):** Methylene chloride used in the decaffeination of coffee that is manufactured, processed, or distributed in commerce for such purposes is not covered by the provisions of this rule because

it is a food additive, and thus excluded from TSCA. FDA interprets the Federal Food, Drug, and Cosmetic Act as covering the methylene chloride used in decaffeination as a food additive at all stages of the decaffeination process. If you have additional questions about how FDA regulates the use of methylene chloride as a food additive for this use, please contact FDA.

**Sheerin Shirajan (ICF):** Thank you. Next question. What is the impact to a registered medical device, which contains 2 milliliters of methylene chloride as a solvent for a liquid bandage?

**Ingrid Feustel (EPA):** Registered medical devices under 21 CFR 820 that are manufactured, processed, or distributed in commerce for such purposes are not considered chemical substances under TSCA and therefore not subject to this final rule.

**Sheerin Shirajan (ICF):** Thank you. Lastly on this topic, will EPA's regulation on methylene chloride extend to pharmaceutical manufacturing practices, including as a solvent in tests used on pharmaceutical ingredient or product testing?

**Ingrid Feustel (EPA):** TSCA excludes drugs, as defined by the Federal Food, Drug, and Cosmetic Act, that are manufactured, processed, or distributed in commerce for such purposes. Any use of methylene chloride in pharmaceutical manufacturing that meets this exclusion's requirements is outside of the definition of a chemical substance under TSCA and therefore not subject to the final rule.

**Sheerin Shirajan (ICF):** Thank you very much. This now concludes the Requested Information Session. We hope the session has provided additional useful information. Many of the questions EPA received helped inform the detailed information in the presentation – such as questions about compliance dates and which requirements or prohibitions apply to specific uses such as a solvent in adhesives, in cold cleaning, and in furniture refinishing.

We appreciate your questions and encourage you to check EPA's website for guidance materials and updates. And to use the resources listed on the last slide. Related links have been posted in the chat box. Additionally, this presentation, including recording of slides for download, will be available at EPA's website. Thank you again to our speakers and attendees. This now concludes today's webinar.