Title: EPA Public Webinar on the Pre-Prioritization Process

September 30, 2024

2-3pm EST

Sarah Soliman, U.S. EPA: Hi everyone. I know people are just getting in and connected so we're going to give it just a minute and let everyone enter the room.

Alright, well, welcome everyone to today's webinar on Prioritization of Chemical Substances under TSCA.

We appreciate everyone spending some time with us today. We are going to have a presentation about the prioritization process and then we'll have some time for public comment.

Please keep yourself muted and as well as please keep your camera off during the presentation. It just kind of helps save on bandwidth.

We do have the chat box if you're having any technical issues. I will try and help you out through that.

Feel free to send me a message. And with that, I am going to turn it over to the other Sarah.

Sarah Au, U.S. EPA:

Good afternoon, everybody. Thanks, Sarah. My name is Sarah Au and I'm a lead toxicologist in the Data Gathering Management and Policy Division within the Office of Pollution Prevention and Toxics.

I appreciate you all joining us today as we present an overview of prioritization and some of our current pre-prioritization efforts that EPA is engaged in to evaluate the potential risk of existing industrial chemicals regulated under the Toxic Substances Control Act, also known as TSCA.

This is just a quick summary of the various topics that will be discussed today, including a high-level overview of TSCA authorities, requirements, and timelines for evaluating existing chemicals. I will also touch upon our approach for identifying the chemicals that may undergo prioritization, including the information sources, data gathering authorities that OPPT is implementing earlier in the data gathering pipeline, as well as other types of data that the public may be aware of that may help inform current and future prioritization and potential risk evaluation needs.

At the end, I will just wrap up the presentation with a list of available dockets where you may submit comments and information.

Under the Toxic Substances Control Act, the nation's primary chemicals management law, EPA has the authority to require reporting, recordkeeping, and testing requirements and restrictions relating to chemical substances and mixtures.

When TSCA was amended in 2016, which received bipartisan support, under TSCA Section 6 for existing chemicals, EPA is required to implement a prioritization process that will determine whether those chemical substances should undergo risk evaluation. And to determine whether there is unreasonable risk to the health or the environment without the consideration of costs or non-risk factors based on the weight of scientific evidence using the best available science.

Under TSCA, EPA is required to consider cradle-to-grave chemical life cycles in which a chemical may be regulated at any point in that process, and is broader in scope than media-specific statutes. EPA considers the potential exposure and effects resulting from any use.

Because TSCA considers a lot of factors throughout a chemicals lifecycle to determine potential exposure and risk, it takes approximately 6 years to initiate prioritization, conduct a risk evaluation for chemical substances that are designated as High-Priority Substances, determine whether there is unreasonable risk for identified conditions of uses and as warranted, impose restrictions to address the identified and reasonable risk.

This process takes a long time to identify or receive reasonably available and potentially relevant information and conduct the analysis necessary to address different requirements of each phase of evaluating risk for existing chemicals under TSCA.

There are tens of thousands of chemicals active in commerce and regulated under TSCA. All of them may be subject to risk evaluation under TSCA Section 6.

Throughout the 6-to-6-and-a-half-year process, there are many opportunities for engaging with communities and any interested persons that would like to provide feedback and information that will inform the existing chemicals information gathering pipeline.

As more information comes to light throughout this timeline, EPA is able to better identify potentially relevant exposure hazards and exposures.

This slide focuses on the Prioritization step specifically, which begins with the identification of chemical substances undergoing prioritization during initiation, which starts the clock on 9-to-12-month prioritization process.

There are 2 statutorily mandated, 90-day public comment periods during prioritization. Once a chemical is initiated, there is a binary decision that must be made where based on the public comments and screening review of reasonably available information regarding the prioritization criteria and considerations, whether a chemical meets the requirements to be high priority for risk evaluations or be designated as a Low-Priority Substance, for which a risk evaluation is not required at this time.

The 3-to-3-and-a-half-year timeframe for conducting the draft and final risk evaluations will begin for any chemical having a final designation as a High-Priority Substance.

As discussed in the previous slide, prioritization is a 9-to-12-month process where EPA identifies, proposes, and finalize the designation of a chemical substance as either High- or Low-Priority Substances.

There are considerations for both identifying the chemicals that will undergo prioritization as well as 7 considerations that must be met to make this determination, and those will be described in upcoming slides. In short, prioritization is a process for identifying which chemicals have sufficient, reasonably available information for determining whether there may be risk. For chemicals where there is a likelihood of there being risk, those chemicals will undergo risk evaluation once designated as a High-Priority Substance. For chemicals where it's unlikely for there to be due risk based on reasonably available information, those chemicals will again not undergo risk evaluation at this time. But this may change as we receive new information in the future.

Prioritization is expected to be an annual process where chemical substances are designated as High-Priority Substances to replace other High-Priority Substances that are completing risk evaluations.

EPA must first identify chemical substances that will undergo prioritization. For the identification of chemical substances that will undergo prioritization, EPA draws at least 50% of the chemical substances from the 2014 TSCA Work Plan.

This helps to ensure EPA satisfies the prioritization framework rules requirement that at least half of the ongoing risk evaluations are for chemicals that are on the 2014 TSCA Work Plan until all the substances on that list have been designated.

The 2014 TSCA Work Plan was updated from efforts begun in 2012 by EPA to characterize a subset of chemicals in commerce that may pose risks to human health and the environment to advance the existing chemicals program so that those at the highest potential for exposure and hazards are assessed.

These chemicals are not a finding by the agency that there is risk, but rather a jump off point to quickly identify existing chemicals that the agency should consider for risk evaluation. Of those that are identified from the work plan, there is a preference for those that are persistent and biocumulative in the environment, are carcinogenic and have demonstrated toxicological effects resulting from acute and chronic exposure. This is a starting point, by law, for at least half of our work.

After identifying the chemical substances that will undergo prioritization, EPA uses the same considerations listed here to determine whether a chemical substance is a high or low priority for conducting a risk evaluation.

And those considerations and criteria are: the hazard and exposure potential of the chemical substance, persistence and bioaccumulation, potentially expose or susceptible populations, storage near significant sources of drinking water, the conditions of use or significant changes in the conditions of use of the chemical substance, the volume or significant changes in the volume of the chemical substance manufactured or processed, and other risk-based criteria that EPA determines to be relevant to the designation of the chemical substances priority.

EPA's approach for identifying chemical substances that would undergo prioritization considered both chemicals that are on and off the 2014 TSCA Work Plan.

Data availability regarding exposure and hazard information are of great significance to reduce the likelihood that EPA may need to order testing to evaluate potential risk, and to determine whether the reasonably available information is in fact robust enough to support a risk evaluation that can be completed between the statutory mandated time frame of 3 to 3 and a half years.

Date availability was a strong consideration. Because it takes a long time to identify reasonably available information, assess gaps and data needs for a given chemical to support a test order before even getting the data.

EPA has largely coordinated with other EPA offices as well as other interested parties throughout the pre-prioritization timeframe. It will continue to do so throughout the prioritization process.

This slide indicates some of the information sources that may be used to inform different aspects of characterizing potential exposure.

Many of these sources are databases and contain both primary and secondary information. And it takes a long time to consider which information may be duplicative across many sources, as well as determine what may be potentially relevant. However, this type of data analysis must be conducted so that EPA can understand how robust the chemicals data landscape actually is, while also considering work already done to be efficient, inclusive and transparent. Monitoring information from various databases is particularly useful because there are instances when monitoring information available in peer-reviewed literature is unable to address the scope of what we are mandated to address under a statute as comprehensive as TSCA, where facility-specific releases must be characterized.

This slide is one of 2 that depicts a high-level summary of information on the 27 chemical substances currently being considered for future prioritization actions, including but not limited to existing assessments by and interests of other agencies and government bodies, and whether there are data submitted to OPPT under the Chemical Data Reporting or the Toxics Release Inventory.

These are indicators of whether there are hazard and exposure data using reasonably available information.

And on this slide, all of these chemicals are on the 2014 TSCA Work Plan.

As a continuation from the previous slide, as you can see here in the legend, those that are shaded in gray are from the 2014 TSCA Work Plan and those that are blue are chemical substances that are not on the 2014 TSCA Work Plan.

And as indicated before, reasonably available information was a priority when considering chemical substances for upcoming prioritization efforts.

As I said before, those that are gray are those that are on the 2014 TSCA Work Plan and those that are blue are not on the 2014 TSCA Work Plan and are being considered due to various agency interests, specifically hydrogen fluoride and 6PPD were chemicals of interest from the TSCA Section 21 petitions.

And Bisphenol S is of interest, should bisphenol A (BPA) undergo prioritization, since it's currently one of the main alternative phthalates being used on the market for BPA, which is a chemical on the 2014 TSCA Work Plan chemical.

There are many ways in which data may be collected under TSCA to inform prioritization, risk evaluation, and risk management efforts for existing chemicals.

TSCA Section 4 gives EPA the authority to require chemical manufacturers and processors to test chemicals using EPA approved test methods and guidelines where insufficient information exists, and testing is necessary to get the information and report the results to EPA, including test orders, test rules and consent agreements.

TSCA Section 8 gives EPA the authority to require reporting and record keeping of existing information such as chemical related data, records alleging significant adverse reactions to the health or the environment, unpublished health and safety studies and substantial risk of injury.

EPA will be requiring the reporting of health and safety data under TSCA Section 8(d), which includes data that may include monitoring or toxicological studies. This authority was used recently with High-Priority Substances that are currently undergoing risk evaluation. EPA intends on taking final action on

that rule for 16 chemical substances, including the 5 that are currently undergoing prioritization by the end of 2024.

This data will inform existing chemicals, processes, and related EPA activities, including but not limited to prioritization analysis needs.

The primary goal of the tier data reporting proposed rule is to be able to collect different types of information associated with TSCA Section 6 activities, including prioritization.

That way at different points of the Section 6 pipeline, EPA will be able to collect information as related to specific actions under TSCA.

The idea is that some information can be collected during pre-prioritization time frames to help determine also when a chemical may undergo prioritization in the future, and the final rule is anticipated in 2026.

By implementing this process to value the potential risk of existing chemicals, EPA is committed to reducing exposure to communities and individuals. To do so, having the most relevant information is crucial to better characterize how people are being exposed via different activities and environments, such as working, different workplace environments, consumers and those who stay at home, especially in this remote environment that we are in today.

Specifically, there may be types and sources of information that communities or individuals may have access to that EPA isn't aware of and would help us characterize potential exposure and hazard. If you and your community are aware of available citizen community science that EPA should consider when identifying potential chemical exposure, for example, please send that our way.

Some information that would be helpful for characterizing potential exposure includes monitoring and product data, use information activities or use patterns. Ultimately understanding how, and the frequency of certain activities and behaviors are conducted that may pertain to specific products or practices where chemicals are involved will help us characterize unique exposure scenarios.

TSCA applies to potential exposures that may occur anywhere in the supply chain, but not all releases associated with manufacturing, production, import, distribution, use or disposal products that fall outside of TSCA such as drugs.

Depending on how relevant the data are to the chemical exposure pathway, conditions of use or potentially expose population, this determines how the data may be used in the analysis. Concentrations of chemicals that individuals are exposed to at or near workplace are particular importance, and process operational descriptions can often inform this potential worker exposure such as the physical state of the chemical, type and size of containers carrying the chemical, and how and when the chemical may be transformed or reacted with other chemicals at a particular step in the manufacturing or processing steps.

Downstream facilities in which chemicals are incorporated into different products are particularly harder to characterize. Therefore, supply chain information is also crucial for characterizing commercial and consumer, potential exposures.

The goal is for EPA to design and implement a data gathering process that will inform annual prioritization and potential risk evaluation and management needs.

This will be done earlier and on a continued basis so that input information provided by various stakeholders and individuals can be considered.

And this will also help EPA identify data needs earlier in the process. As well as informing potential data call-in authority needs.

The earlier characterization of potential exposure and hazard of industrial chemicals will generally help with the intent to meet statutory deadlines and ultimately reduce chemical exposure.

Every year, potential chemical substance candidates that are being considered for prioritization actions will likely change annually and therefore having this information submitted to the agency is also useful for identifying chemicals that have sufficient data to make the "may present unreasonable risk" call during prioritization.

Starting tomorrow until October 31st, EPA will be accepting public comments and information on the information presented today and tomorrow during this 30-day public comment period.

For the chemical substances that are currently undergoing prioritization EPA is also currently accepting public comments and information on these chemicals in the prioritization process until October 23rd, 2024. Please submit chemical specific information and comments to those specific chemical specific dockets.

And with that, thank you for your time, everyone. I really appreciate your time and any comments that you may have. Thanks, Sarah.

Sarah Soliman, U.S. EPA: Beautiful. Thank you, Sarah! All right. So, in a few minutes, we are going to have our 1st speaker, but first, just a couple of things.

Note: we are doing this presentation as well tomorrow. So, if you've signed up for that, just…

Oh, actually that's a good question. Can you put the docket numbers back up, please?

Sarah Au, U.S. EPA: Sure.

Sarah Soliman, U.S. EPA: The presentation tomorrow is exactly the same. It's the same information. There's nothing new and it will probably be the same bad jokes for me as well.

So you just, you have been warned. Yes, we will be making things available. We will be having the recording, and we'll be posting the slides as well, I believe? Sarah?

Sarah Au, U.S. EPA: Yeah, so that's a great question. So tomorrow when the public comment period opens, we are also posting these slides there as well. So hopefully all the information that you need to provide in the information or comments will be available then.

But let me know also if you need me to go back on any slides as well today. I'm more than happy to do so.

Sarah Soliman, U.S. EPA: Alright. So, with that, I am going to have our 1st commenter. And that is going to be Paige Varner. So, Paige, you should be able to unmute yourself and for the next 3 to 4 min the floor is yours.

Dr. Paige Varner: Great, thanks Sarah. And thank you all for the opportunity to comment. My name is Paige Varner, Dr. Paige Varner and I'm a scientist with Environmental Defense Fund. The prioritization process under TSCA affects multiple decisions throughout the risk evaluation process that will ultimately influence the risk management of these toxic chemicals.

If a comprehensive consideration of all exposures and risk of these chemicals is not taken into account as mandated by the law, management decisions will be under-protective and will leave individuals and communities at risk, especially those who are overburdened by multiple sources of pollution and other stressors that contribute to negative health outcomes.

We'd like to highlight a few considerations EPA must take into account when making pre-prioritization or prioritization decisions to ensure a comprehensive look at the real world exposures and risks to communities.

First, EPA should consider chemicals that are used or released together that cause the same health effects at the pre-prioritization and prioritization steps so that EPA can conduct a cumulative risk assessment at the risk evaluation stage.

Communities living at the fenceline of industry are exposed to multiple chemicals that when combined exacerbate health effects.

Considering these chemicals individually will severely underestimate risks. To illustrate the importance of considering cumulative risk as a factor in prioritization, EDF conducted analyses looking at releases of TSCA workplan chemicals that have not undergone the TSCA prioritization process.

Our analysis showed that up to 63% of TRI releases of work plan chemicals from 2017 to 2022 are co-releases of chemicals that contribute to the same health harms. It is therefore imperative to consider the cumulative real world risk of chemicals beginning even before the official prioritization process.

Additionally, individuals at the fence line are too often communities of color and low-income communities that are more vulnerable to risks from toxic exposures due to the multitude of stressors that adversely affect their health.

Failing to consider environmental justice and community vulnerability will result in these communities continuing to be at risk from exposure to multiple toxic chemicals.

We conducted some additional analysis incorporating these considerations into the pre prioritization process that have been and will be submitted in written comments.

Lastly, past prioritization efforts and risk evaluations failed to account for all potential sources of exposure, including peak exposures from accidental releases, spills, transportation incidents like derailments and collisions and other peak releases like from facility shutdown and startup.

This is despite the fact that these releases and exposures are reasonably foreseen and therefore must be considered under TSCA.

However, EPA has typically only considered exposures from what it terms routine releases. Yet people are exposed to more than just routine releases as was tragically demonstrated over a year ago in East Palestine and is demonstrated by the over 270 chemical accidents in 2023 alone.

Consideration of accidental exposures is critical in the prioritization step because a failure to consider all reasonably foreseen releases and exposures could result in an inappropriate designation of low priority.

It is critical for EPA to consider such chemical releases from the outset. If EPA waits to incorporate exposure pathways until later in the TSCA process, the agency may not have sufficient time for it to use section 4 authorities together than data needed to property characterize the risk. EPA may then decide as we have seen previously to not include these exposures in its risk evaluation, by claiming it has insufficient information. This once again can result in an underestimation of the risks potentially including to potentially expose or susceptible sub-populations.

In conclusion, EPA should start to incorporate the consideration of cumulative risk and accidental releases at the pre-prioritization and prioritization stages so that it will be prepared to consider the cumulative risk of chemicals causing similar health harms and the risks from all reasonably foreseeing releases. Failure to do so can result in under protective regulations that continue to leave communities at risk. Thank you and we will submit written comments.

Sarah Soliman, U.S. EPA: Thank you, Paige. And yes, please, always written comments are great. All right, so our next speaker we have Mike Belliveau. I hope I'm saying that correctly. But, Mike, for the next couple of minutes, the floor is yours.

Mike Belliveau: Yeah, thank you both Sarah's. My name is Mike Belliveau. I am the director of an NGO called Bend the Curve.

And our mission is to transform the petrochemical industry so that it no longer harms people in the planet. And by further way of introduction, I was involved in a leadership role in the NGO campaign that went on for 7 years that led to the revision of the Toxic Substances Control Act being signed into law in 2016.

Under my previous employer we were plaintiffs in the lawsuit against EPA over the original framework, TSCA framework rules, which have since been significantly improved. And we greatly appreciate the Biden EPA's efforts to implement TSCA properly, including re-evaluation of the previous risk evaluations the prior administration did.

For general guidance, we think that you should continue to focus on plastics related chemicals. The reason being that, as you know, there's great public concern that's growing around plastic pollution, but also it provides you with synergy with other EPA programs, such as the national strategy to prevent plastic pollution, and synergy with the international negotiations that the United States has participating in. That should lead toward a global Plastics Treaty to reduce the production and toxicity of plastics.

More specifically with respect to the chemicals that are in the work plan list that you displayed earlier, we think that you should prioritize benzene, ethylbenzene, and styrene together, and assess their risk cumulatively.

We know that 85% of all benzene is used to make plastics. Half of that is to make styrenic plastics.

And, the process of making styrene go through ethylbenzene, 30% of all benzene ends up going to polystyrene plastic. And almost two-thirds of all styrene goes to that plastic as well. So that's a major concern.

And if you look at the styrene manufacturing plants in the United States, they're emitting significant quantities of benzene, ethyl benzene and styrene into the air. And there are likely other exposures of concern as well. If you look at the fence line monitoring data now available, for benzene, it's suggested that routine exposures are exceeding fetal toxicity advisory levels. So, there's a lot of data to work with, to consider those 3 chemicals together.

Second, certainly it's time finally, to prioritize and assess the health risk posed by bisphenol A, BPA, but we would encourage you to do that. In conjunction with other bisphenols.

You have clear authority under Section 26 C of TSCA, to assess categories of chemical substances as a group; certainly the bisphenols qualify and I was pleased to see you have bisphenyl S on the list as well.

You're probably aware that the European Food Safety Authority lowered their safety threshold for BPA by a factor of 20,000 fold, finally responding to the ample new science that has developed over the last few decades on the health effects of bisphenol A at very low doses.

Also, I want EPA to remember that you must assess the exposures, all exposures, to a chemical substance that has been prioritized, including exposures that may result from food contact materials even though food contact materials are not under your regulatory authority.

There's very clear direction provided in TSCA in that regard. And I'd urge EPA to adhere to that.

Lastly, I would encourage you to prioritize antimony and antimony compounds. About 60% of that metalloid substance is added to plastics. The highest uses are added to PVC plastic to enhance its flame retardancy. But also to other plastics that have been treated with brominated flame retardants to enhance their flame retardancy.

It shows up at in very high concentrations, relatively speaking, in household dust. The toddlers are exposed.

Another major use in consumer source of consumer exposure is the use of antimony trioxide as polymerization catalyst to make PET. Polyester plastic. We know that the antimony carries forward into the PET resin or polyester fiber and migrates from those materials, exposing consumers in many different ways, including in the beverages they drink from plastic, bottled beverages.

The California Office of Environmental Health Hazard found that, or we found, in testing that some of those exposures exceeded the OEHA Health advisory level for chronic toxicity of one part per 1 billion in drinking water, but in the beverage itself. So, it would be quite appropriate to take a hard look at antimony compounds.

And, yeah, I'll stop there and I appreciate the opportunity to share these views.

Sarah Soliman, U.S. EPA: Thank you, Mike. We appreciate the comments. We do have a little bit of time. So, I wanted to see if there was anyone else that wanted to make a comment, keeping comments to

about 3 minutes. If you look down at the bottom of your zoom you should see an option to raise your hand. Just a reminder, we're not really answering questions today.

We're just kind of trying to get the information out and start the comment period.

Let's see, I don't see any hands?

I know Mike and Paige are a tough act to follow.

Other Sarah, can you please show that? There we go. So, we'll leave that up for a minute.

Sarah Au, U.S. EPA: Sorry, I had to split it between 2 slides, folks. So, let me know if you need me to switch slides. And, I was, trying to address some questions or clarifications in the chat, Sarah.

So hopefully I didn't make it anything too complicated. But for Nathan Williams, regarding the xylenes, according to the workplan, they're listed as 3 separate isomers, with their own distinct CASRN numbers. And if you have information on those or thoughts on you know how we should consider these chemicals for future prioritization actions.

We love to have it. So thank you in advance.

Sarah Soliman, U.S. EPA: Alright, and I see Margaret has her hand up so Margaret, the floor is yours.

Oh, did we lose Margaret?

Oh. No worries, Margaret. Alright. So, well, it looks like if no one else has any comments, we can leave these slides up for a few minutes while people are taking a look, but remember it will all be posted on that docket when that docket opens tomorrow as well.

So, you don't have to memorize these. I promise it'll all be available for you.

I also had put my email in the chat. Higher up but I'll throw that in there again if anyone does have any questions feel free to shoot me an email and I will track down the answers best I can and with that, again, a reminder, the tomorrow's presentation is going to be exactly the same.

So, you are always welcome to come spend time with Sarah and I, but if not, then I just hope everyone has a great day and the closing date for comments is the 31st, correct? Halloween.

Sarah Au, U.S. EPA: Yes, spooky Halloween, is the last day for getting comments for these pre-prioritization candidates.

And apologies if the last 2 sides were confusing. I should have paused a little bit. So yes, for the docket ending at -0606 for a prioritization in the list of these 27 candidates, the docket will open tomorrow and will close on Halloween, October 31st

For the last slide was regarding the current prioritization actions and that is the second public comment period that we're currently in for the 5 chemicals currently undergoing prioritization and being proposed as High-Priority Substances.

And so different actions and different chemicals. But apologies if that was confusing. Thank you.

Sarah Soliman, U.S. EPA: Alright, well with that we will close out for today, but I hope everyone has a great rest of your day. And make sure you get those written comments in!

Thank you all so much.

Have a good day everyone.

Bye.