

Chemical Watch Events & Training TSCA Developments 2024
March 5, 2024
Remarks, as prepared

Thank you so much for having me speak to you today.

I've been representing EPA at Chemical Watch events for more than three years now – and I always appreciate the invitations.

And I think--three years in--this is a good opportunity to look back at the history of chemistry and chemical regulation to think about where we've been, why we are where we are, and how we're going to move forward.

Necessity often drives innovation. And chemistry's no different. So many of the key advances in chemistry over the past 150 years happened because people needed to find substitutes for natural resources that were rapidly being depleted.

For example, celluloid, one of earliest plastics that was invented more than 150 years ago, was developed in part because people were trying to find substitutes for ivory. And that's because elephants were being hunted in vast numbers due to the widespread use of ivory in billiard balls. Yes, billiard balls. Billiards had become so popular that according an 1867 article in the New York Times, elephants were at risk of becoming endangered.

So I guess Harold Hill was partly right in *The Music Man*. Billiards were “trouble with a capital T”- trouble for elephants, at any rate. The problem got so bad that billiard manufacturers actually offered a reward to anyone who could make a substitute for ivory. A New York man named John Wesley Hyatt apparently saw this offer and started working to create a substance that would ultimately become celluloid that would also be used in billiard balls and many other products for decades to come.

About 60 years later, fully synthetic plastics would take the United States by storm, transforming the way we live our lives.

In the 1930s, the U.S. was using half of the world's natural supply of rubber, most of which came from Southeast Asia.

But after Pearl Harbor, Japan cut off access to much of the natural rubber supply, and rubber was critical to the war effort – not to mention all the other things we used it for.

So, scientists and engineers got to work and did what they do best: they innovated. The U.S. government worked with industry and research labs to create synthetic rubber that could be produced at a commercial scale. In four years, U.S. production of synthetic rubber went from 231 tons a year, to 70,000 tons... *a month!*

Necessity is the mother of invention, as they say. New advances in chemistry like plastics and synthetic rubber were game-changing. Not only did they help win the war, they also transformed America in the years after the war, as these innovations were increasingly incorporated into our homes, our food, our cars, our kitchens, our offices, our toys - everything.

We were less successful at figuring out how to protect human health and the environment from some of their negative consequences.

A few decades after World War II ended, people started to realize that deadly toxic smog events in Pennsylvania, the Cuyahoga River catching fire for a mind-blowing 13th time, improper dumping of toxic chemicals in the Love Canal neighborhood, and the emergence of a cancer cluster in Woburn, Massachusetts, were all caused by our collective failure to manage the way chemicals are made, used, and disposed of.

So in the 1970s and 80s, as our awareness of that collective failure increased, the EPA was created and Congress enacted laws like the Clean Air Act, the Clean Water Act, and the Superfund law.

These were and are absolutely game-changing statutes that improved Americans' lives in real and important ways.

But when it came to chemicals, the Nixon Administration understood it wasn't good enough to just try to clean up the air we breathe, the water we drink and the land we live on *after* it was already contaminated. So they asked Congress to enact a comprehensive chemical law – the Toxic Substances Control Act.

As the Nixon White House Council on Environmental Quality told Congress in 1971, EPA needed the authority to assess and regulate “the flow of potentially toxic substances throughout the entire range of activity - from extraction to production to consumer use and to disposal.” CEQ also said: “We should no longer be limited to repairing the damage after it has been done; nor should we continue to allow the entire population or the entire environment to be used as a laboratory.”

But the original 1976 Toxic Substances Control Act that Congress ended up passing was too weak – it grandfathered in the thousands of existing chemicals that were already in commerce without requiring additional review. And when EPA tried to use its authority to ban asbestos, a court overturned the ban and rendered the law almost powerless to regulate existing chemicals.

The 1976 law also *allowed* EPA to regulate new chemicals, but if EPA didn't know enough about a particular chemistry to take action within 90 days, that chemical *STILL* went right into

commerce. Between 1976-2016, EPA only finished formal risk reviews on about 20% of all new chemicals.

As a result, while the air, water and land were being cleaned up through the successful implementation of laws like the Clean Air Act, the Safe Drinking Water Act, the Clean Water Act and the Superfund law, the law that was supposed to manage the way chemicals were made and used in the first place was failing. In the decades that followed, we know what happened: many toxic chemicals were used without any restrictions at all, people kept getting sick and even dying due to exposures to chemicals like TCE, and “forever chemicals” like PFAS became ubiquitous in our bodies and our environment.

We can't re-write history and travel backwards in time to fix these mistakes, but we could – and did - re-write the law so that history wouldn't repeat itself. TSCA was amended in 2016 to give EPA additional authority that the original law had lacked. So now, we HAVE to make sure that new chemicals can be used safely before they can enter commerce. And we HAVE to go back and look at existing chemicals to make sure people are protected.

And that's exactly what we've done over the past three years. While our ability to implement new TSCA has been hampered by a lack of funding, I'm really proud of the work that we've done. And as we move forward, we'll continue to foster innovation for new chemistries that have the potential to transform our lives for the better, just like synthetic rubber and plastics did in the 1930s and 40s. But we also have the responsibility to ensure that these innovations can be launched without some of the negative consequences we saw in the past.

When I started at EPA three years ago, we were very clear about our approach to TSCA. This is a comprehensive chemical safety law, and we're going to implement it comprehensively.

It has to be comprehensive to protect people from health risks like cancer, for example. Our work is a key component of President Biden's Cancer Moonshot. Deputy Administrator Janet McCabe has said that if you look at the agencies that are working on cancer, many of them are figuring out how to detect cancer earlier. Many are figuring out how to treat it better. But EPA is the only agency that can actually use the laws we administer to prevent cancers caused by environmental exposures from occurring in the first place. And so much of that power lies in TSCA. Seven of the first 10 chemicals evaluated under TSCA cause cancer. Some cause many different types of cancer. We have an urgent obligation to protect people from these risks.

And that brings me to some of the arguments I've heard about EPA's work in the past couple of years. I've heard from some of you that you don't think TSCA should be about workers – you think OSHA is enough. Some of you have said you don't think TSCA should be about people breathing air or drinking water that have been contaminated with chemicals – and that laws like the Clean Air Act and the Safe Drinking Water Act are enough. But if TSCA isn't about protecting workers who are exposed to chemicals INSIDE facilities, and it's also not about protecting communities who are exposed to chemicals OUTSIDE facilities, I struggle to understand just who it is the law is supposed to be protecting.

What the Nixon Administration asked for back in 1971, and what Congress intended when it amended TSCA in 2016, was to create a law to comprehensively protect human health and the environment from chemical risks. And to do that BEFORE the Superfund sites were created, and BEFORE the drinking water was contaminated. And that's what we're delivering on.

So let's get into some specifics. This year is going to be a very busy one for EPA. And I know that we've been saying that for years, but this one's going to be especially busy.

Protecting people from existing chemicals continues to be a major priority for us. This year we're going to finish proposing 9 of the first 10 chemicals reviewed under the new law, and finalize most of them.

We've already proposed rules for methylene chloride, TCE, carbon tet, PCE, and part 1 of asbestos. And we'll soon propose a rule for NMP.

These six rules would protect more than 1.5 million workers and 15 million consumers from well-documented risks from these chemicals - proving that the new law has delivered on its promise. Our proposed rule for 1-BP is with OMB right now. So are our final rules for part 1 of asbestos and methylene chloride.

We've heard concerns from industry about how we're handling worker risks in these rules, and we know this is an area where working together earlier in the process is critical.

That's why we're working to improve the TSCA occupational exposure assessment process.

Last year we held two workshops on this topic with a wide range of participants from industry, the public health and environmental community, academia, labor groups, and other federal agencies. The workshops focused on identifying ways to improve exposure assessment for workers and how we identify occupational exposure scenarios using a variety of data sources.

We're scheduling a third workshop focused on exposure data and modeling for late spring of this year. We think this will help us better shape the risk evaluations and rules that are to come,

But we know that there have been some concerns with the worker safety measures in the rules we've already proposed, so I'd like to spend a little time talking about that.

First of all, we have to write rules that are supported by the science and the law. So if we're going to say that a use of a chemical can continue safely, we need to be able to defend that in court if we're sued. And that means having information about worker exposure, how a chemical is being used, and measures that are being taken to keep workers safe.

We haven't always had that for the first 10 chemicals we've been working on rules for. In fact, I was previously told by some companies that they didn't want to come talk to us because they hoped we just wouldn't notice their use of the chemical existed. But I'm happy to say that we're largely beyond that now – many companies have come in after our proposals were released, given us a lot of extremely useful monitoring data and other information, and you'll definitely see some shifts in the final rules for some of the uses of some of the chemicals.

We've also heard concerns about some of our proposed existing chemical exposure limits, with people saying that we've chosen levels that can't be easily monitored or implemented.

First, when we conduct a risk evaluation, we're not ALLOWED to consider costs and other non-risk factors. So yes, when we calculate the starting point - a draft, risk-based occupational exposure value in the risk evaluation - we're also not looking at those sorts of things.

But for some of our first 10 chemicals, we know that many companies are already meeting or close to meeting those risk-only levels. For others, we've heard from companies that maybe the right analytic method to measure them isn't yet available, but it will be soon – so in cases like that, maybe our solution would be to provide a longer compliance time in the final rule. And in other cases, perhaps other adjustments will be needed for other reasons. The point is, when EPA proposes a risk-based occupational exposure value, it's not the end of the conversation; it's only the beginning.

We know that getting these rules right is really important. A huge part of amending TSCA in the first place was about protecting people from chemicals that have been making people sick for decades. Now, we're finally doing it.

We also have a busy slate of risk evaluations planned for the rest of the year.

We've moved to a system where we'll prioritize 5 chemicals every year, which will help make the entire TSCA lifecycle more sustainable. For the first time ever, we talked to industry, environmental organizations, Tribal nations, state and local governments and other federal Agencies BEFORE we chose which 5 to pursue. And we're really trying to frontload the data and other information we need for these 5 chemicals, so we can build a more efficient risk evaluation machine that might even meet a statutory deadline one day!

We've already released a draft risk evaluation for TCEP. The draft risk evaluations for formaldehyde and part 2 of asbestos are coming very soon. This year, we'll be finalizing formaldehyde, asbestos part 2, TCEP, dioxane, 2 phthalates and 1,1-

dichloroethane, and releasing drafts on 1,3-butadiene and several others of our next 20 chemicals.

Like I said, busy year!

On the new chemicals side of our program, we made really significant strides last year in terms of hiring more staff and making our evaluations more efficient. We still don't have the resources we need; but the results are undeniably improving.

In FY 23, we completed 70% more risk assessments compared to FY 22. Since June, we've more than doubled the monthly average number of completed risk assessments as compared to the year before. And we've cleared out about half of our older back-logged cases.

These gains were made possible by our hardworking staff, and the fact that we were able to hire twenty more of them in the last year and a half.

We've gone from 2 human health assessors to more than a dozen. The path to an efficient and effective new chemicals program is in large part a matter of resources.

But we've also made the program more efficient by making procedural improvements and standardizing some of our reviews.

This effort is particularly important when we're talking about chemicals that are critical to the Biden-Harris domestic manufacturing agenda. We're doing everything possible to make sure that the \$640 billion dollars in private sector investments that have been announced due to the Bipartisan Infrastructure Law, the CHIPs Act and the Inflation Reduction Act go forward quickly.

For example, we've created a standardized review approach for mixed metal oxides, which are used for batteries, electric vehicles, semiconductors, and renewable energy generation. We've prioritized the review of new chemicals in the semiconductor, EV battery, biotechnology, and other key sectors that we need to realize all the new jobs being created through the Biden Administration's domestic manufacturing. We are now reviewing these chemicals in a third of the time compared to other sectors.

We've developed a framework for reviewing new PFAS, which will ensure the continued availability of these chemistries for sectors that plan to use them in ways that won't result in environmental releases, like the semiconductor sector, while generally expecting to prohibit new PFAS from being used in a way that will result in environmental releases or exposures.

And we've worked closely with the semiconductor sector to create a predictable regulatory path for dozens of the new chemistries they need to operate, and hope to expand that collaboration in the coming months.

These approaches are working – and strike the balance between fostering innovation and protecting human health and the environment.

As we finalize our procedural rule for new chemical reviews and continue to get more experience implementing these more standardized reviews, I think our new chemicals program is only going to get more efficient.

But while I'm proud of the progress we've made towards more timely and efficient new chemical reviews, our resource shortfalls

have ultimately prevented us from implementing some of these improvements as quickly as we'd like. The President's budget continues to lay out the needs of our program, and with the resources we're asking for, we'd be able to work through the backlog more quickly and ensure that we can evaluate new chemicals both comprehensively and quickly.

We've also committed to continuing to make some additional changes that will help make everything move more quickly and more predictably. We've already followed through on some of these commitments.

We've been able to create a tiger team of people who will be able to speed up the re-work of applications when they've gone through most of the review process but something minor changes in what the company sends in towards the end. We know this is one of the most frustrating ways an application can get delayed. We'll also be able to publicly track improvements in the speed of review of cases like that on our website.

We're continuing to work on science policies that reduce animal testing and help make our reviews more efficient. In January we released a framework for faster and less expensive non-animal testing for new chemicals that are corrosive to your eyes. Next up will be policies on skin irritation and skin sensitization.

And there's more to come. Assuming EPA's funding isn't cut, we've created a new position for someone whose job it will be to re-vamp and lead the sustainable futures program, which used to exist under old TSCA to help industry with more training and technical assistance to speed up reviews.

We've also committed to incorporating the latest science on chemical categories into our SOPs, which will increase speed and

consistency of reviews. We're prioritizing this work because it's the fastest way to both protect people AND speed up the process. Finally, we've committed to sending an engineer to pre-submittal meetings with submitters if the submitters ask for one to be there. The engineer can talk submitters through the sort of engineering information that would be most helpful to include in their submission, which will help avoid rework.

I know there are still frustrations about the time it takes us to review new chemicals, but we are very clearly making progress.

And I think it's important to think about how much it's ultimately costing the American people to clean up the messes caused in part by the insufficiencies of the original law. Just take PFAS as an example. Think about how different the country might look if EPA had the authority and responsibility to have gotten the data it needed and imposed protections from the start - like, maybe only use the PFAS foam when there's an actual fire, instead of endlessly training with it – we could have avoided a great deal of contamination and exposure.

Because of the insufficiencies of the old TSCA, I'd argue that everyone – taxpayers, industry and of course people's health – is paying a much higher price than they would have had EPA had the tools, responsibility and resources to properly review PFAS from the start, before they entered commerce. When it comes to chemicals, an ounce of prevention is worth a TON of cure – we want to move more quickly with new chemicals, but it can't come at the expense of creating a future potential pollution problem like PFAS.

Ultimately, protecting human health and the environment is a collaborative effort and we all benefit from working together. Together, we can help advance the technologies of the future, without repeating the failed chemical safety policies of the past.

Thank you so much for having me and enjoy the conference.