S. HRG. 117–526

TOXIC SUBSTANCES CONTROL ACT AMENDMENTS IMPLEMENTATION

HEARING

BEFORE THE

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

UNITED STATES SENATE

ONE HUNDRED SEVENTEENTH CONGRESS

SECOND SESSION

JUNE 22, 2022

Printed for the use of the Committee on Environment and Public Works

Available via the World Wide Web: http://www.govinfo.gov

U.S. GOVERNMENT PUBLISHING OFFICE

50–067 PDF WASHINGTON : 2023

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

ONE HUNDRED SEVENTEENTH CONGRESS

SECOND SESSION

THOMAS R. CARPER, Delaware, *Chairman*

BENJAMIN L. CARDIN, Maryland
BERNARD SANDERS, Vermont
SHELDON WHITEHOUSE, Rhode Island
JEFF MERKLEY, Oregon
EDWARD J. MARKEY, Massachusetts
TAMMY DUCKWORTH, Illinois
DEBBIE STABENOW, Michigan
MARK KELLY, Arizona
ALEX PADILLA, California

SHELLEY MOORE CAPITO, West Virginia, *Ranking Member*
JAMES M. INHOFE, Oklahoma
KEVIN CRAMER, North Dakota
CYNTHIA M. LUMMIS, Wyoming
RICHARD SHELBY, Alabama
JOHN BOOZMAN, Arkansas
ROGER WICKER, Mississippi
DAN SULLIVAN, Alaska
JONI ERNST, Iowa
LINDSEY O. GRAHAM, South Carolina

MARY FRANCES REPKO, *Democratic Staff Director*
ADAM TOMLINSON, *Republican Staff Director*

C O N T E N T S

TOXIC SUBSTANCES CONTROL ACT AMENDMENTS IMPLEMENTATION

WEDNESDAY, JUNE 22, 2022

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
Washington, DC.

The Committee, met, pursuant to notice, at 10:01 a.m. in room 406, Dirksen Senate Office Building, Hon. Thomas R. Carper (Chairman of the Committee) presiding.

Present: Senators Carper, Capito, Whitehouse, Markey, Kelly, Padilla, Inhofe, Sullivan, and Ernst.

OPENING STATEMENT OF HON. THOMAS R. CARPER, U.S. SENATOR FROM THE STATE OF DELAWARE

Senator CARPER. Good morning, everyone.

Let me begin by welcoming our witness, no stranger in this room, Dr. Michal Freedhoff, and thank you, Michal, for joining us today for an important hearing. Michal, we are pleased to welcome you back to the EPW Committee as the Assistant Administrator for the Office of Chemical Safety and Pollution Prevention.

As we gather here today, I believe today is the sixth anniversary of the enactment of the Toxic Substances Control Act legislation, among others. Senator Inhofe, myself, and a lot of folks worked on it. David Vitter, Tom Udall, all kinds of people worked on it. It was a great bipartisan triumph at the time.

As we gather here today, my hope is that this hearing will offer us a much needed and timely opportunity to explore one of the more daunting challenges that we face, and that is protecting our health and the health of our families while also preserving the capacity of chemistry to enrich our lives and spur innovation.

Given the complexities of this task and the intricacies of the science that accompanies it, not just anyone can do that. It should come as no surprise that the miracle of modern chemistry comes with potential risks and rewards.

In many cases, industries have invested large amounts of resources and expertise to develop the chemicals that surround us in our everyday lives and make our lives better. Having said that, they are not the ones we expect to tell us all we need to know about the potential shortcomings or negative health impacts that those chemicals can pose.

So, we turn, as we often do, to our government to serve as our watchdog and our protector of our people. In this case, it is the EPA. And through the Toxic Substances Control Act, or TOSCA as we affectionately call it, Congress has vested the responsibility of

protecting Americans from chemicals that pose an unreasonable risk to us and our environment with EPA's Office of Chemical Safety and Pollution Prevention.

With that being said, I am not sure we have found a person more qualified to lead that effort than the witness before us today. Dr. Freedhoff is a Ph.D. chemist who has spent countless hours working with many of us to create a law that can actually provide the protections that Congress intended when TSCA was initially enacted in 1976, but fixing the law is only half the story.

The harder part is dealing with the complexities, with the competing interests, and daunting mechanics of implementing that law. Senator Inhofe, Senator Markey, and a number of our colleagues on both sides likely recall the high expectations that accompanied our shared sense of accomplishment and relief at enacting the Lautenberg Act in 2016.

Still, no matter how capable the leadership at EPA is, the agency simply cannot meet these expectations without adequate support from Congress and from the Administration. Implementing TSCA requires experts and financial resources to rigorously test literally thousands of chemicals, quickly turn around risk assessments and chemical reviews, and establish the protection against those chemicals that can put our lives and our livelihoods at risk.

As Dr. Freedhoff will point out in her testimony today, EPA's staff has continually faced the high expectations and workloads that we created in 2016 armed with flat budgets. To be fair, this is a shared responsibility. Faced with the previous Administration's efforts to strip the agency of critical personnel and resources, we in Congress did not respond by providing EPA with the budget increases that this law requires. To put it frankly, we collectively dropped the ball.

Not surprisingly, today, the agency is missing deadlines and delaying decisions, which contribute to growing grievances. Advocates are frustrated with EPA's delayed pace in reviewing and regulating harmful chemicals. Meanwhile, those in industries are disheartened by having to wait sometimes a year or more for new chemicals to be approved or not approved.

It is clear that no one is happy with the current situation. This leaves advocates and companies feeling compelled to look for nefarious explanations for those unmet aspirations and expectations: Faulty science, regulatory overreach, skirting the law, and inappropriately close ties between EPA staff and industry.

Fortunately, there is a fundamental solution to all of this. I am going to say that again: Fortunately, there is a fundamental solution to all of this, and that is to provide the agency the resources it needs to get the job done, the job we all want them to do, the job that we all need for them to do.

We might be pleasantly surprised to see how much better both the law and EPA start to look if the Congress and the Administration actually work together going forward to ensure that the agency has the qualified people on board, with the resources needed to meet the letter of this new law.

My suggestion is that we give them that chance. We need to do more. I have committed to working together with members of this Committee to ensure that we provide the agency with the resources

they need in fiscal year 2023 and to then hold EPA accountable, going forward, in protecting us from harmful toxics while allowing chemistry to usher in a new world of clean energy and life saving technologies.

Dr. Freedhoff, we look forward to hearing from you today, in no small part, because you have quite a tale to tell us. Before we hear from you, though, I want to hear from our Ranking Member, Senator Capito for her opening remarks.

Senator Capito.

OPENING STATEMENT OF HON. SHELLEY MOORE CAPITO, U.S. SENATOR FROM THE STATE OF WEST VIRGINIA

Senator CAPITO. Thank you, Mr. Chairman, and welcome back to the Committee, Dr. Freedhoff. It is nice to have you here.

Today, we are holding a hearing, as the Chairman has said, on EPA's ongoing implementation of the Toxic Substances Control Act, TSCA. In 2016, Congress passed in a bipartisan way, overhauled the TSCA Program, strengthening EPA's authority to evaluate and regulate new and existing chemicals. These were a significant, as you know, working then, a significant bipartisan achievement.

Among other changes, the revised TSCA Program established legally enforceable deadlines for EPA decisions. These deadlines are a key facet of the new TSCA, and one I would like to particularly focus on today. The Chairman has already talked a bit about this.

Since being confirmed in your role, you have repeatedly stated, including in your testimony today, that a lack of resources is the reason EPA has repeatedly missed statutory deadlines. With regard to existing chemicals, you have said, "It shouldn't come as a surprise that we expect to miss every single deadline for the final risk management rules for these first 10 evaluations and every single deadline for the next 20 risk evaluations."

Well, I have to be clear here. It does come as a bit of a surprise to hear a blanket pronouncement such as this, in particular, when the EPA's appropriations over the past few years have been developed in a bipartisan way.

You have blamed the root cause of TSCA's delay on the prior Administration gutting the program, but we are 18 months into the Biden administration. Compared to 2016, you have dozens more full time equivalent employees working within the TSCA Program, and user fees have risen by over 600 percent.

In 2021, EPA issued 146 final determinations on new chemical submissions, fewer than any other year of the prior Administration. The Obama administration, which was tasked with standing up the entire new TSCA Program, issued 92 determinations from June 23, 2016 until the end of its final year in office.

In contrast, as of last month, your office has issued final determinations only 23 times for 2022 submissions over a comparable amount of time. And that is really the crux of the issue that we will be talking about today.

Previous administrations were able to do more with fewer resources. I guess the question would be, why is that? It seems that internal changes pushed by the Administration to the TSCA Program are undermining EPA's ability to meet its statutory obligation. Ten risk evaluations finalized between June 2020 and Janu-

ary 2021 have all now been reopened, adding to a more supposedly already overstretched staff's plate.

According to your previous statements, impacted communities will now have to wait until at least 2025 to see an eventual risk management rule for these high priority chemical substances.

In your requests for more robust funding to the TSCA Program, you continually point to the increased workload that your office is facing. It kind of seems to me that a lot of the workload is self-generated mission creep of the TSCA Program that is not required by the statute.

Under the Biden EPA, risk evaluations must now include exposure pathways covered by other EPA administered statutes like the Clean Air and Clean Water Act, as well as assess fence line community exposure.

Your office has revised risk evaluation models to make highly questionable assumptions that OSHA standards are insufficient and that workers are not routinely wearing PPE.

Finally, the agency is no longer issuing risk findings for individual conditions of use but is adopting a "whole chemical" approach.

Taken together, these policy changes have created a situation where existing chemicals under review will most certainly face an unreasonable risk determination going forward. This expansion of your office's work beyond what TSCA requires has exacerbated the workload issues and is at odds with the intent of the statute.

In addition, it seems staff resources have been diverted to programs without existing authorizations, like IRIS and Safer Choice, with EPA prioritizing elective programs over statutorily authorized programs.

I don't have to tell you this, but in today's turbulent economic times, the importance of reliable, efficient domestic supply chains for key technologies like semiconductors and batteries has become increasingly apparent. Even feedstocks essential for the Biden administration's renewable energy priorities, like batteries and solar panels, are being held in regulatory limbo. Delays in approving new chemical submissions directly impact our economic and national security, and ultimately, will help fuel inflation and scarcity.

We can all agree that everybody will benefit from getting this TSCA implementation on track. I look forward to hearing what specific actions you plant to take administratively, beyond just asking for additional resources, to fulfill the office's statutory obligations in a timely and cost effective manner.

Thank you. I yield back.

Senator CARPER. Thank you, Senator Capito.

We now turn to our witness, Ms. Freedhoff.

We welcome you.

Michal is currently serving as the Assistant Administrator of the Office of Chemical Safety and Pollution Prevention at the Environmental Protection Agency. Prior to her confirmation in that position, in June 2021, she joined EPA as a Principal Deputy Assistant Administrator for the Office of Chemical Safety and Pollution Prevention in January 2021, right after the inauguration of the President.

Dr. Freedhoff has more than 20 years of Government experience, most recently, as the Minority Director of Oversight for this Committee. She began her congressional service in 1996, in then Congressman Ed Markey's office as Congressional Science and Engineering Fellow, after receiving a Ph.D. in physical chemistry at the University of Rochester. Dr. Freedhoff has also served on the staffs of the House Science Committee, the House Select Committee on Energy Independence and Global Warming, the House Energy and Commerce Committee, and the House Natural Resources Committee.

Her environmental expertise spanning a range of policy areas for legislative work includes the 2016 reauthorization of TSCA, the 2019 legislation to address PFAS contamination, fuel economy provisions in the 2007 Energy Independence and Security Act, and a law requiring the creation of an online data base of potential consumer product safety defects.

Somehow, in the midst of all that, colleagues, she managed to bring four children, four babies into the world and raise them, four children any of us would be proud to claim as our own.

Once, you worked as a member of our team here on this Committee.

I used to say that she never slept. My guess is she probably still doesn't sleep now.

I don't know how you do it all, but we are here to figure out how we can enable you and the folks that you lead to do your jobs even better today.

With that, your statement will be entered for the record, and then we will start some questions. Thank you. Please proceed. Welcome.

STATEMENT OF HON. MICHAL FREEDHOFF, PH.D., ASSISTANT ADMINISTRATOR, OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION, U.S. ENVIRONMENTAL PROTECTION AGENCY

Ms. FREEDHOFF. Good morning, Chairman Carper, Senator Inhofe, Ranking Member Capito, and other members of the Committee. Thanks for inviting me to testify on EPA's implementation of the Toxic Substances Control Act, or TSCA.

It was exactly 6 years ago that many of us gathered at the White House to witness the historic amendments to TSCA being signed into law. For nearly 40 years, TSCA had largely failed to serve its purpose: To protect people and the environment from the risks of dangerous chemicals. I was proud to be a part of that bipartisan group that negotiated the Lautenberg Act.

I was also proud a few months ago to propose the rule to ban the ongoing uses of chrysotile asbestos, more than 30 years after the previous failed attempt became the emblem for why we needed to rewrite the law. Unfortunately, on amended TSCA's sixth birthday, I think we can all also agree that things aren't yet working as everyone had hoped. Despite the best efforts of our dedicated staff, we are missing many of our statutory deadlines, our scientific peer reviewers and the courts have been critical of our work, and the public lacks confidence in our chemical safety efforts to date.

Having the public's trust is essential to realize the promise of TSCA reform. It is in everyone's interest for the public to be able to trust EPA when it says that a chemical that industry makes and sells is safe, or when EPA writes a rule, to say how that chemical can be safely used. For the entire 6 years since the law was enacted, the agency has faced some major challenges, and central to all of them was a lack of resources.

The 2016 TSCA amendments told EPA in no uncertain terms to scale up. The program's workload skyrocketed virtually overnight and doubled again several years later. But in the law's first 4 years, EPA never once made a congressional budget request for new resources to implement the new work. As a result, budgets for the new law remain just about exactly the same as the budget for the old, broken law. Although the new law gave EPA the authority to collect fees from chemical companies, we have only collected about half as much as Congress intended.

The President's fiscal year 2022 budget request was the very first one that requested additional TSCA funding, but the agency didn't receive everything we asked for. In our 2023 budget request, we have asked for an increase of almost $64 million and 201 FTE for the TSCA Program. That is based on an extensive analysis of how much the law will actually cost to implement the way Congress expected it to be implemented.

We will also update the fees rule and are doing all that we can to increase efficiencies and improve our processes. But the truth is, the years of compounding budget and workload challenges have taken their toll. The last Administration missed the deadlines for 9 of the first 10 risk evaluations, and for just about the entirety of the new law's existence, we have struggled to complete new chemical reviews as quickly as Congress intended.

It is simple, elementary school math. We won't do more with less. We will do less with less. For instance, we are working as quickly as we can to put measures in place to protect people from exposures to dangerous chemicals like trichlorethylene, methylene chloride, and asbestos. The deadlines for those final rules and those first 10 chemicals are in just a few months, and we won't make a single one of them. Without additional resources, we won't get more than a handful of those rules on the books before 2025 or beyond.

We are conducting about two dozen risk evaluations with statutory deadlines that start to hit later this year. Absent the resources in the President's budget, it is unclear whether we will even be able to complete half of them before 2025. There will be real consequences if we don't get those resources. Communities, workers, children, all of us, really, will go even longer without the health protections we need and deserve.

Congress also wanted our new chemical reviews to be both protective and fast, but our budget for new chemicals now is actually less than it was before the new law because about 15 percent of the new chemical staff were permanently moved by the previous Administration to work on risk evaluations. With more work and less staff, we will continue to fall short of Congress's expectations.

It is also very clear to me that added resources are not just about meeting deadlines. Resources will also let us build the infrastruc-

ture of a well run, sustainable program. We are focused not just on getting the chemicals reviewed and the rules written, but in ways to build that infrastructure, maximizing use of the scientists and the resources we do have, and because science is the backbone of everything we do at EPA, we are reaffirming our commitment to scientific integrity across the board.

The path forward is clear. We need to implement the law that Congress wrote, and to do that, we need to build a foundation for a sustainable program, one that delivers the promised health and environmental protections, one that brings the predictability that stakeholders expected it to bring, and one that can endure for years to come. I am confident that, with sufficient resources, the law can and will deliver on those promises.

Thank you again for the opportunity to testify, and I look forward to your questions.

[The prepared statement of Ms. Freedhoff follows:]

TESTIMONY OF
MICHAL ILANA FREEDHOFF, ASSISTANT ADMINISTRATOR
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
U.S. ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE
SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

JUNE 22, 2022

Good morning, Chairman Carper, Ranking Member Capito, and other Members of the Committee. I appreciate the opportunity to speak with you today regarding the Agency's implementation of the Toxic Substances Control Act or TSCA, as amended in 2016 under the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

Six years ago to this day, many of us gathered at the White House to witness the historic amendments to TSCA being signed into law. I had the great privilege to engage directly on those legislative reform efforts, and I keep a framed picture of the June 22nd ceremony in my office. We celebrated the end of a very long process, and the start of a new one as the words we wrote would be put into action. But we also celebrated the promise of what the new law would achieve. Unfortunately, and despite the tremendous efforts of EPA's career staff over the past several years, we will continue to fall short of that promise without additional resources to support the program.

For nearly 40 years, TSCA had largely failed to serve its purpose – to protect people and the environment against the risks of dangerous chemicals. Originally signed in 1976, TSCA took its place among a relatively small group of bedrock environmental laws like the Clean Air Act,

Clean Water Act and Safe Drinking Water Act. It fairly quickly became clear, however, that the law was broken. EPA attempted, unsuccessfully, to use its TSCA authorities to ban asbestos in the 1980s, a chemical widely known to cause cancer. The failure became a clarion call for TSCA reform and prompted the years of discussion and debate that followed. Ultimately, a strong federal chemical safety law became a common goal that united Republicans and Democrats, the chemical industry, the public health and environmental community, and so many others.

I was proud to be a part of that bipartisan group that negotiated the Lautenberg Act – a law that addressed the fundamental flaws in TSCA and has the promise to deliver long overdue protections for the American people. I was equally proud a few months ago to propose the first risk management rule under the new process – a rule that, if finalized, would ban almost all ongoing uses of chrysotile asbestos more than 30 years after the previous attempt. Not only is that proposal a victory for public health, it's also historically symbolic. It's proof that TSCA, as amended, can effectively address unreasonable risks to human health and the environment from chemicals in commerce.

As the members of this Committee well know, the end product of the TSCA negotiations was a careful compromise. On one side, the law provided EPA with strong authority to oversee chemicals: new mandates to systematically prioritize and evaluate chemicals against a purely risk-based safety standard; new deadlines for both the risk evaluations and the risk management actions that follow, creating a continuous pipeline of actions that would advance EPA's understanding of chemicals and drive forward progress on reducing unreasonable risks; new tools and authorities to help EPA collect the data it needs to support implementation; and new

requirements to ensure that more information on chemicals is made publicly available. On the other side, the law promised strong federal chemical safety regulations that would be expected to discourage, and in some cases prevent, states from setting divergent standards that might complicate the flow of interstate commerce, giving companies the certainty and predictability they needed to continue to innovate. Ultimately, the success of this compromise rests on trust. It is fundamentally in everyone's best interests for the public to be able to trust EPA – an agency charged with protecting health and the environment – when it tells the public a chemical is safe, or writes a rule to say how a chemical can be safely used.

I think about the TSCA reform negotiations often and carry that context forward in my current position leading the Office of Chemical Safety and Pollution Prevention at EPA. My goals are simple. EPA needs to implement the law that Congress wrote. And to do that, the Agency needs to build a foundation for a sustainable TSCA program. One that can and will rise to meet the inevitable challenges. One that delivers the promised health and environmental protections to the American public. One that can be trusted to bring both the protections and the predictability that stakeholders expected it to bring. And one that can endure for years to come.

On amended TSCA's 6th birthday, I think we can all recognize that the law is not yet working as everyone had hoped.

Despite the best efforts of EPA's dedicated staff, in most circumstances, the Agency is missing statutory deadlines to review and ensure protections for new and existing chemicals. EPA's scientific peer reviewers and the courts have been critical of some of the work so far. And the

public lacks confidence in the Agency's process. I'd like to share with you some of the reasons that brought us here, and our plans to turn things around.

The 2016 TSCA amendments told EPA, in no uncertain terms, to scale up. From zero comprehensive existing chemical risk evaluations to ten in the first six months, and then to twenty just three years after that. From zero to ten risk management rules for the chemicals we evaluated, with more on the horizon. From formal risk determinations on around 20 percent of new chemicals to determinations on 100 percent. To reset the TSCA inventory of over 84,000 chemicals with new active and inactive designations. To enhance our scrutiny of confidential business information claims. The new responsibilities in amended TSCA meant that the program's workload skyrocketed virtually overnight, and then would double again several years later. Clearly, the program would need considerably more money and support.

But for the first four years of the new law's existence, EPA never once made a Congressional budget request that would have added resources for TSCA implementation. And Congressionally enacted budgets for the new law with all of its new sweeping authority and obligations remained just about exactly the same as the old broken law. Both the EPA Office of Inspector General and the Government Accountability Office have consistently pointed out the Agency's failure to assess and plan for resource needs. It turns out they were not wrong – the last Administration wouldn't even authorize senior managers to do a workforce or budget analysis of what it would take to implement the new law. We did that as soon as we could after taking the reins in 2021.

The amendments did give EPA new authority to collect fees from chemical companies to defray some implementation costs. However, the rule establishing that fee structure wasn't finalized until late 2018 and didn't impose any fees whatsoever on the highest cost activity: the first ten TSCA risk evaluations. On top of that, EPA's baseline cost estimates that drove the fee amounts were based on the costs of implementing the old, unamended law. As a result, the program's fee revenue hasn't come close to collecting 25 percent of authorized implementation costs as Congress expected. Instead, it's been roughly half that – 13 percent on average – and that's 13 percent of an already too low baseline.

The years of compounding budget, priority setting, policy and workload challenges have put the program at a serious disadvantage. Not only do we need to play catch up on various past actions or inactions, the Agency's obligations under TSCA are continuing to grow quickly. It should come as no surprise that EPA missed the statutory deadlines for nine of the first ten chemical risk evaluations completed by the last Administration, and it should also come as no surprise that for just about the entirety of the new law's existence, the Agency has struggled to complete new chemical reviews as quickly as Congress intended. To implement the 2016 TSCA amendments, EPA needs the additional resources provided in the fiscal year 2022 and 2023 budgets.

The President's fiscal year 2022 budget request was the first one since the new law was enacted that requested additional funding to implement it, and although the Agency did not receive everything it asked for, the program did receive a small increase of $4.9 million. This will enable the agency to hire a small number of additional staff and make some incremental progress toward enhancing quality of actions and better adhering to statutory intent and timelines

applicable to pre-market review of new chemicals, chemical risk evaluation and management, data development and information collection, and review of confidential business information claims. In EPA's fiscal year 2023 budget request, the Agency asked for an increase of almost $64 million and 200 FTE for the TSCA program, which reflects the budget and workforce analysis that the program conducted last year and that is further described in the report regarding EPA's capacity to implement TSCA that we expect to send to Congress soon. The Agency also expects to issue a supplemental proposal to update the fees rule this Fall. Moreover, EPA is holding itself accountable by increasing efficiencies and making process improvements based on lessons learned from the first years of implementing the law. All of these things are critically needed to help perform the job Congress expects EPA to do.

There will be real consequences if the program does not have these resources. EPA will need to reprioritize its chemicals work. Even with our heads down and noses to the grindstone, EPA expects to miss many significant statutory deadlines. For instance, the Agency is working as quickly as possible to put measures in place to protect people from exposures to chemicals such as trichlorethylene, methylene chloride, and asbestos – which have caused deaths or serious risks to human health. The deadlines for the final rules on the first ten chemical fall between mid-2022 to early 2023, and EPA won't make any of them. Without the resources requested in the fiscal year 2023 President's Budget, EPA will not get more than a handful of those rules on the books before 2025 or beyond. The Agency is currently conducting 23 risk evaluations – 20 that were initiated back in late 2019 and three more at the request of manufacturers – plus part II of the risk evaluation for asbestos and the supplemental evaluation for 1,4 dioxane. The deadlines for final risk evaluations on the next 20 existing chemicals fall between late 2022 and 2023. EPA has not

completed a draft risk evaluation yet for a single one. Absent the resources requested in the fiscal year 2023 President's Budget, it is unclear whether EPA will even be able to complete half of them before 2025. And the Agency is doing its very best to complete new chemical reviews as quickly as possible. Without the funding requested in the President's Budget, though, EPA will simply not be able to get these done in the time that Congress expected or that industry needs.

Resources like money and people won't just allow EPA to produce more evaluations and rules, more quickly. Resources will give the Agency space to be thoughtful and thorough about how to set up a well-run program based on policies that are consistent with the statute. In my short time at EPA, it's been abundantly clear that the Agency needs to make scientific, infrastructure, organizational and other investments in the TSCA program in addition to those financial ones. EPA needs to establish standard operating procedures and better train its staff to carry out various new tasks with consistency and order. EPA needs to grapple with statutory terms, phrases or provisions that are still relatively novel. EPA needs to update our scientific policies, processes and models and adjust our regulatory frameworks to align with our new responsibilities under TSCA. EPA needs to improve the way it communicates scientific and risk findings to the public. And EPA needs to modernize its information technology infrastructure to facilitate all of the Agency's work most efficiently.

You have heard the analogy "building the plane while flying it." In the first few years of the new law, there was not enough effort devoted to the building part – and while that may have provided a short-term benefit of allowing the program to meet certain deadlines in the face of inadequate resources, it did a disservice to the longer-term sustainability of TSCA implementation. Investing

in this effort now will increase consistency internally, prevent the same issues and delays from reappearing over and over again, and increase transparency for both the regulated community and the communities EPA is charged with protecting. Taking the time now will help the flights run smoothly and on time in the future.

Again, having the public's trust is essential to realize the promise of TSCA reform, and unfortunately, trust in the TSCA program is low. For example, in identifying various concerns on the first ten risk evaluations, the Agency's scientific peer review committee noted that EPA's work to date "does not instill confidence that objectivity is being maintained in Agency assessments as part of TSCA." Without building up the public trust in EPA's work to evaluate chemicals and manage risks, the public will not have confidence in the safety of chemicals and the products they use in the marketplace. By implementing TSCA as Congress intended and building a foundation for a strong chemical safety program, it is my hope that EPA can, over time, regain the public's trust and confidence.

I would like to share some highlights of what EPA has already accomplished and what the Agency is working towards now – a testament to the resiliency, dedication, and creativity of EPA's career staff.

I will start with EPA's risk evaluations. The last Administration finalized ten existing chemical risk evaluations, identifying unreasonable risks across most of the uses for each and every chemical. A great deal of work and analysis was done as part of these risk evaluations, and I commend EPA staff for their substantial efforts. However, certain policy decisions in the last

Administration raised the potential that those risk evaluations underestimated the risks and fell short of the law's requirements.

One of these policy decisions was the lack of consideration in our risk evaluations for how people could be exposed by breathing or drinking chemicals on the hypothetical grounds that EPA could address those exposures using other statutory authorities - an approach which likely left exposures to both the general population and to fenceline communities near industrial facilities that may have disproportionately high exposures unaccounted for. To help address this concern, EPA developed and released an initial version of a screening methodology. The Agency's expectation is that if the screening shows that there are "no likely added fenceline community risks" for a substance, or if the rule we are already contemplating based on the existing risk evaluation would adequately address these risks, EPA would be able to move to rulemaking quickly to put the necessary protections in place. But if the screening methodology tells the Agency that the last risk evaluation won't support a risk management rule that will sufficiently protect these communities, EPA will perform additional analysis and formally supplement the risk evaluation to support a risk management rule. And moving forward, the Agency will add ways to analyze potential environmental justice concerns and other types of exposures, and incorporate these upfront into future risk evaluations.

Additionally, prior risk evaluation work generally assumed that all workers are always equipped with and appropriately using sufficient personal protective equipment, even though some workers may not be subject to OSHA requirements and many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being

"outdated and inadequate for ensuring protection of worker health." EPA is updating the way the Agency makes risk determinations to reverse that assumption and to more appropriately determine risks to workers, which were identified as "potentially exposed or susceptible subpopulations," in all of the first ten risk evaluations. This is an area where EPA must improve its risk communications practices since the Agency also recognizes that many companies effectively address worker and bystander safety requirements. As EPA implements this policy shift, the Agency will strive to both clearly communicate when either existing OSHA requirements or best industry practices are sufficiently protective and propose occupational safety measures in the risk management process that are consistent with them.

EPA has also worked to strengthen the science used in the Agency's risk evaluations by revising the systematic review protocol that describes how EPA will identify and use the "best available science" that the Agency's risk evaluations must be based on. EPA put its draft protocol for systematic review out for public comment and peer review in December last year. And the Agency is in the process of updating the framework rule that established procedures for how EPA carries out TSCA risk evaluations – a proposal the Agency expects to help ensure that, moving forward, EPA's evaluations reflect the 9th Circuit's decision on legacy uses and other topics, and otherwise align more closely with Congress' intent.

To support EPA's risk evaluation efforts, the Agency has significantly ramped up use of the data gathering authorities in TSCA. Earlier this year, EPA issued another set of test orders for eight of the next 20 chemicals, asking for additional information on avian and aquatic hazards and

consumer exposure. Getting high quality, timely data in response to these requests will go a long way towards moving the risk evaluations forward using the best available science.

The President's requested increase for TSCA, if enacted this fall, will be the type of investment the TSCA program needs to shift the trajectory and get it back on the right track
EPA is, therefore, taking a long hard look at the resources we do have, the expertise of the scientists we do have, and the risk evaluation procedures we do have, and expect to soon communicate which of the next 20 risk evaluations we will be able to complete first, and which we will need to pursue longer term. The Agency is looking for ways to maximize efficiencies – using the best available science, including modeling, to address identified data gaps; employing a range of acceptable peer review practices in accordance with EPA and OMB guidance; and exploring how best to use authoritative, recent governmental assessments (along with systematic review protocol and peer review recommendations as guidelines) to develop TSCA evaluations. With the requested resources, EPA could complete risk evaluations sooner. The Agency also could get an earlier start on conducting analyses of potential alternatives to uses that present risk concerns. But the hard truth is that without a sustained increase in the resources available to the program, EPA will not be able to meet all of the statutory deadlines for conducting 20 or more concurrent risk evaluations, either now or in the future.

EPA also has a lot in the works on the risk management front. Risk management for existing chemicals is and will remain a very high priority. After all, the purpose of TSCA reform was to provide EPA with the authority to protect people from the unreasonable risks posed by chemical substances. Methylene chloride will likely be the second chemical the Agency will propose a risk

management rule for, following EPA's proposed ban on almost all ongoing uses of chrysotile asbestos earlier this Spring.

The statutory deadline for risk management actions under TSCA means that all of EPA's rules underway are due to be finalized before the end of this year. The Agency will not be able to meet a single one of those deadlines. However, with the exception of 1,4-dioxane, which EPA has determined requires some additional analysis before moving to the risk management phase, I am hopeful that funding levels included in the President's fiscal year 2023 budget request would enable the Agency to finalize risk management rules for most if not all of the remaining nine of the first ten chemicals in 2023 and 2024. Internally, EPA is doing everything possible to move forward expeditiously – reinforcing a rigorous commitment to expedited schedules, anticipating and being proactive in resolving issues, and undertaking concurrent reviews where possible – while the Agency works to advance EPA's mission of protecting human health and the environment.

EPA also continues to try to make strides in our New Chemicals Program to ensure that new chemicals are safe before they get to market – and that the Agency also reviews the safety of those new chemicals quickly. As with EPA's existing chemical risk evaluations, the Agency announced some new policies to ensure that actions on new chemicals will appropriately protect workers, and are more aligned with the statute. And EPA is working to update its procedural regulations to align the Agency's processes with the 2016 amendments. Longer term, the Agency is continuing to build out the science policies and standard operating procedures, and further strengthening the science of the program through the collaborative research program with EPA's

Office of Research and Development and other federal partners. This research program will allow the Agency to innovate on the approach EPA uses to group and draw conclusions about similar chemicals in a systematic, transparent, and reproducible way.

It is no secret that challenges in the New Chemicals Program have led to delays and frustrations. For five or more years and counting, there have always been several hundred new chemical submittals in the Agency's review queue. Let me say that I fully appreciate the value of chemical innovation. New chemistries can spark new technologies and processes, open up new markets, and help power the nation's battery, semiconductor and other industrial sectors. New chemicals are sometimes designed to replace older, riskier chemicals, and may serve as substitutes for chemicals regulated elsewhere under TSCA. To better support the New Chemicals Program and these ends, EPA is looking for ways to streamline processes where possible, make the Agency's tools, guidance and forms more understandable, and become more efficient in its reviews. Earlier this year, with these goals in mind, EPA announced a biofuels initiative to standardize the review of these new chemicals while still ensuring that necessary protections are in place before new chemicals can hit the market. The Agency is exploring similar approaches to expand into other chemistries and industry sectors.

The lack of sufficient resources for the program under the revised TSCA has an outsized impact on the New Chemicals Program. Before the 2016 amendments, only 20 percent of new chemicals were issued risk determinations – and now they are required for 100 percent. In addition to the enacted budget levels and planning issues described earlier, it turns out that about 15 percent of the new chemicals staff was moved to work on existing chemical risk evaluations in 2019-2020 – a move that was then formally cemented in the office's reorganization in the fall of 2020.

Attracting and retaining staff has been challenging – in part because of the stress of the heavy workload – and today the program only has about two human health assessors available to do certain critical aspects of each of these hundreds of reviews. The program's IT system also regularly breaks down, impairing the staffs' ability to get their work done on a day-to-day basis, exacerbating delays, and adding to overall frustrations. EPA has heard from submitters a desire to have more training, more pre-notice support and to have technical staff available for consultations. The Agency has heard from the public a desire for greater transparency, more insight into EPA's review process, and timely sharing of relevant information. The Agency wants to do all these things. We all want the process to work better. And no one wants to sacrifice quality or safety for the sake of speed, or vice versa. EPA's ability to improve quickly hinges on adequate funding – but you can be assured that rebuilding the staff capacity in the New Chemicals Program is the Agency's highest personnel priority.

On top of all of this, I want to reaffirm my commitment to scientific integrity across all aspects of the TSCA program. Science is the backbone of our work at EPA and is essential for earning and maintaining the public's confidence in our decision-making. One of my top goals at EPA is to promote the highest level of scientific integrity, and we've already taken strong actions to this end.

Finally, I want to touch briefly on per- and poly-fluorinated substances, or PFAS, and some of the actions my office is working on to address the urgent public health and environmental threat they pose to communities across the country. The Agency's work in this area is an important part of EPA's broader "PFAS Strategic Roadmap" which reflects a whole-of-agency approach to this

issue. One of the biggest challenges EPA faces is that most of the hundreds of PFAS that are in commerce have limited or no toxicity data. When the Agency cannot characterize the health effects of these substances, it cannot effectively regulate them. If EPA continues to work on this one PFAS at a time, the Agency will never be able to fully understand or address the risks from these substances in any sort of reasonable timeframe. Under the National PFAS Testing Strategy, which builds upon the work of this Committee in the 2020 National Defense Authorization Act, EPA has grouped PFAS into categories, identified important gaps in existing data, and is selecting representative chemicals within identified categories for testing. Congress gave EPA new authority in TSCA to order manufacturers to develop this new information, and the Agency is using it. EPA's first test order under the Strategy went out a couple of weeks ago and will provide important information on the health effects of certain PFAS, including one used to make commercial firefighting foams.

The Strategic Roadmap describes many additional important efforts – both within OCSPP and across the Agency. For example, EPA is working to finalize a new PFAS reporting rule under TSCA section 8 and to enhance collection of PFAS data through the Toxics Release Inventory or TRI program – both requirements of the 2020 NDAA – which will ultimately provide EPA with better data to inform future research, monitoring, and regulatory efforts. The Agency established a stewardship program for certain previously granted PFAS submissions, and continues to leverage its TSCA authorities to prevent both dangerous new PFAS from entering the market and significant new uses of old PFAS. In addition, EPA is looking back at past decisions on PFAS in the New Chemicals Program, and to using all available tools to take actions that will reduce or limit exposures to those that may already be out there.

I am truly proud of everything my office has accomplished and how far we have come since 2016. I am hopeful that a healthy dose of reality will serve everyone far better than an over-promise-but-under-deliver fiction. The TSCA story arc is far from over. And if we can all recognize that sufficient resources, and robust management of the program are essential to building the foundation for a sustainable program – and make those necessary investments – I am confident that the law can and will deliver on those promises. Thank you again for the opportunity to testify today and I look forward to your questions.

Senate Committee on Environment and Public Works
Hearing Entitled, "Toxic Substances Control Act Amendments Implementation."
June 22, 2022
Questions for the Record for The Honorable Michal Freedhoff Ph.D.

Chairman Carper:

1. I was pleased to learn of EPA's strong actions to better account for risks to workers in your assessments under TSCA, and to ensure that your rules afford them the protections they deserve. But I've also heard some criticisms that EPA has gone too far, and that your approach is duplicative of Occupational Safety and Health Administration (OSHA) regulations already on the books.
    a. Would you help us to better understand what you and your staff are doing to address risks to workers exposed to chemicals, and how that aligns with EPA's responsibilities under TSCA

RESPONSE:

TSCA requires EPA to consider risks to relevant "potentially exposed or susceptible subpopulations" when we do risk evaluations – and workers are clearly an example of a subpopulation that may be identified as "potentially exposed or susceptible." Consistent with that mandate, we've been looking at - and identifying unreasonable risks to - workers in individual TSCA risk evaluations. TSCA also requires EPA to address the unreasonable risks it identifies in risk evaluations through the risk management process.

EPA and OSHA meet regularly and are closely coordinating efforts to ensure protections for workers are both consistent and practical. Because OSHA rules don't apply to self-employed or State and local public-sector workers that aren't covered by State OSHA plans and because many of OSHA's chemical-specific rules are decades old and do not reflect current science (and even OSHA has acknowledged that these are "outdated and inadequate for ensuring protection of worker health" – see https://www.osha.gov/annotated-pels), EPA cannot just assume that all workers will be properly covered by OSHA rules and move on. Moreover, as EPA considers risk management options for worker protection, EPA seeks to select options that provide a high level of confidence that there will not be unreasonable risks. EPA is also cognizant that respiratory and eye and face protection safety violations are almost always on OSHA's annual top 10 list of most frequent safety violations (see https://www.osha.gov/top10citedstandards) and EPA factors this into decisions about how to best protect workers.

The Agency also knows, however, that many companies comply with and even in some cases go beyond what OSHA requires to protect workers. When TSCA risk management rules include requirements to protect workers, EPA expects to strive for consistency with OSHA rules and industry best practices whenever possible, leveling the playing field for all companies, and will ensure that all workers are protected against unreasonable risk no matter where they live or who employs them.

2. This question goes to the issue of what is "good" science. Perhaps a good example is your decision to consider risks of a chemical broadly rather than consider so-called "conditions of use" when you assess the risk of a chemical. As I understand it, "conditions of use" refers to the processes or protections that companies might use to minimize releases and exposures to the chemical. I believe you would assert that the decision to consider risk broadly is the scientifically sound way to proceed. I understand the industry feels good science dictates that you consider "conditions of use" in these risk evaluations.
    a. Would you help us understand this disagreement over how science should be used to assess chemical risk?

RESPONSE:

Science is the backbone of everything we do at EPA, and I'm firmly committed to strong science and scientific integrity to support an effective and sustainable TSCA program. The issue you describe, however, is not about science, but rather risk communication.

To clarify, EPA has considered and will continue to consider the "conditions of use" of a chemical in all of its risk evaluations, as the law requires. TSCA defines "conditions of use" as the circumstances "under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." TSCA section 6 further requires EPA to conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." (emphasis added).

The previous Administration made several policy decisions that are important to understand. First, they excluded consideration of certain exposure pathways for certain chemicals (e.g., exposure to the general population from breathing or drinking contaminated air or water) and interpreted the statute to allow Agency discretion to effectively narrow the scope of TSCA risk evaluations. Second, they decided to make risk determinations on each individual condition of use separately instead of considering the entirety of the risks posed by the "chemical substance."

We are now including the previously-excluded exposure pathways in our risk evaluations to ensure that those assessments are comprehensive and will not leave potential risks on the table – something that our scientific peer reviewers have consistently supported and encouraged. And secondly, we have started to revise some of our risk determinations to reflect a risk determination on the "chemical substance" as a whole under TSCA section 6(b), as opposed to each individual "condition of use" in isolation.

This approach to making risk determinations does not mean that all uses of a chemical are dangerous. For many chemicals, there are risky uses, less risky uses and perhaps even some uses that are not risky at all. We will clearly identify conditions of use that drive the unreasonable risk, and conditions of use that do not drive the unreasonable risk, in our "whole chemical" risk determinations. Our goal is to be as clear as possible on which uses of the chemical are driving

the unreasonable risk determination for the chemical substance, and thus where we'd expect to focus efforts in the TSCA Section 6(a) risk management rulemaking to eliminate the unreasonable risk presented by the chemical substance. The ultimate message the Agency wants to be able to send to the public is that we've done a comprehensive TSCA risk evaluation, managed unreasonable risk, that people can have confidence in our work, and that they can rest a little more easily at night knowing that they are now protected.

3. Recently, EPA took the important step of requesting that its Science Advisory Board provide advice on incorporating "cumulative impact" assessments into decision making to account for the fact that people and communities often experience multiple chemical and non-chemical stressors impacting their health, well-being, and quality of life. For example, exposure to multiple phthalates would be considered together to reflect the best science and actual exposures, and considering cumulative impacts would mean people that are exposed to phthalates and have limited financial resources, access to education, health care, etc.
    a. What are OCSPP's plans for considering cumulative impacts in upcoming risk evaluations?

RESPONSE:

There are multiple definitions of the term "cumulative risk assessment." The definition in EPA's 2003 Framework for Cumulative Risk Assessment (U.S. EPA, 2003) is "an analysis, characterization, and possible quantification of the combined risks to health and/or the environment from multiple agents and/or stressors." This could include the evaluation of multiple chemicals that jointly exert a toxic effect. EPA's Office of Research and Development also just finalized a report with regarding recommendations for advancing the Agency's cumulative impact research going forward.

TSCA does not explicitly require EPA to conduct cumulative risk assessments. However, when conducting risk evaluations, TSCA does require EPA to consider all reasonably available information and to ensure that risk determinations are based on the weight of scientific evidence and best available science. TSCA also gives EPA the authority under TSCA section 26(c) to take "any action authorized" under any provision of TSCA, in accordance with that provision, with respect to a category of chemical substances or mixtures. The definition of "category" is broad and may include substances that share similar structure, or physical, chemical, or biological properties. Where appropriate, EPA might use this authority to assess and consider the combined risk from multiple chemical substances (e.g., when there is an interrelated group of chemicals or mixtures). In some instances, the best available science may indicate that conducting a cumulative risk assessment is appropriate to ensure that risk to human health and the environment is adequately characterized.

EPA's Office of Pollution Prevention and Toxics (OPPT) is currently working to develop some proposed principles for cumulative risk assessment under TSCA. Once ready, we plan to seek scientific peer review (e.g., from the Science Advisory Committee on Chemicals (SACC)) and

solicit public comment, and to potentially incorporate feedback into a more detailed framework for conducting cumulative risk assessment under TSCA.

b. How does EPA intend to address cumulative risks in the new chemicals program, particularly to fence line communities, workers and other potentially exposed or susceptible subpopulations?

RESPONSE:

TSCA explicitly requires EPA to consider risks to "potentially exposed or susceptible subpopulations" in carrying out its new chemical reviews under TSCA section 5 – including risks to subpopulations like workers or fenceline communities – and we expect to continue and enhance our considerations in this area. With respect to exposures from multiple chemicals or non-chemical stressors, such considerations can help EPA to identify "potentially exposed or susceptible subpopulations" that may have increased vulnerabilities. However, the Agency's determination on risks under TSCA section–5 - and any risk management action taken in response - are focused on risks from the new chemical substance itself. OCSPP is working collaboratively with other offices at EPA to ensure the new chemicals program is utilizing the best available science in its reviews and that approaches are appropriately aligned across the Agency.

4. When Congress amended TSCA in 2016, it granted EPA new authority to gather the information it needs to conduct risk evaluations, including the authority to issue chemical testing orders. I am pleased to see this administration begin to use that authority, but significant data gaps remain for many of the chemicals that are currently undergoing risk evaluation.
    a. Does EPA plan to issue additional testing orders for chemicals that are undergoing risk evaluation?

RESPONSE:

EPA has issued 18 test orders for chemical substances undergoing risk evaluation. The Agency does not, at this time, anticipate issuing additional test orders for chemicals currently designated as high-priority substances because such orders would be unlikely to generate data in time for use in the forthcoming risk evaluations. However, moving forward, the Agency is actively working to ensure we collect data – including through use of our TSCA section 4 test order authority – sufficiently early in t process to support our prioritization, risk evaluation, and risk management efforts.

b. Does EPA plan to issue testing orders for mixtures, or combinations of chemicals that people are exposed to, including combinations of chemicals that are found in the same consumer product or released in the same community?

RESPONSE:

TSCA section 4 provides authority for EPA to require testing on mixtures when "the effects which the mixture's manufacture, distribution in commerce, processing, use, or disposal or any combination of such activities may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture."15 U.S.C. § 2603(a)(1)(B).
EPA described its expectations with respect to testing of PFAS mixtures in response to a citizen's petition under TSCA section 21. That response (and the discussion on mixture testing at Unit III. B) is available on EPA's website: https://www.epa.gov/system/files/documents/2021-12/pfaspetitionresponse.pdf. EPA does not have expectations to require mixture testing for any of the chemicals undergoing TSCA risk evaluation at this time.

c. Chemical manufacturers have pushed back on the few orders that EPA has issued. What is EPA's response to industry opposition?

RESPONSE:

The ability for EPA to issue testing requirements by order was new in the 2016 amendments. Because the previous administration didn't exercise this authority in a significant way, we are now – in many ways – still building the policies, processes and infrastructure of the test order process. Developing section 4 test orders is a complex and resource-intensive process involving many scientific and regulatory considerations. The new authority is an important tool in EPA's toolbox to be able to support TSCA risk evaluations and to get the information it needs, especially in light of the aggressive deadlines in the law. The staff working on this are actively working to identify ways to make the process go more smoothly. EPA has developed a document to help external stakeholders better understand the Agency's process for developing, drafting, and issuing section 4 test orders, available here: https://www.epa.gov/system/files/documents/2022-03/issuing-a-section-4-order-24-march-2022.pdf. In addition, EPA published its policy with respect to identifying manufacturers subject to test orders here: https://www.epa.gov/system/files/documents/2022-08/Policy_Manufacturing_Processing_August_2022.pdf

Senator Merkley:

1. Dr. Freedhoff, I recently introduced the Alan Reinstein Ban Asbestos Now Act of 2022, which would ban eight recognized asbestos fibers. The TSCA Part 1 proposed rule for asbestos is focused on only one fiber – chrysotile– and only six specific conditions of use.

   What is the basis for these limitations? Do you agree that it would be better for public health if all fibers and all conditions of use were banned?

RESPONSE:

Under the previous Administration, EPA narrowed the scope of the TSCA risk evaluation for asbestos by only reviewing certain uses of one fiber type of this chemical, chrysotile asbestos. In 2019, a court ruled that the agency unlawfully excluded "legacy uses" and "associated disposal" from consideration as "conditions of use" under the TSCA Risk Evaluation Rule, resulting in the need to expand the agency's review of asbestos. In response to this court decision, EPA chose to finalize part one of its risk evaluation of asbestos and then turn to part two to address the legacy uses. Interested stakeholders challenged the agency's failure in part one to consider the risks of other asbestos fibers, conditions of use, health effects, and pathways of exposure, and EPA entered a settlement agreement to consider these issues in part two. The draft scope for part two of the risk evaluation was released in December 2021 and includes legacy uses and associated disposal, other types of asbestos fibers in addition to chrysotile, and the use of asbestos in talc and talc-containing products. EPA will publish the final risk evaluation by December 1, 2024, and proceed with additional risk management action to address any unreasonable risks identified.

2. EPA's Part 1 proposed risk management rule for asbestos includes a two-year phase-out date for asbestos use in chlor-alkali production. My bill reflects this timeline. However, at my recent subcommittee hearing on the bill, I heard from stakeholders that this might not be feasible. Can you elaborate on why it may or may not be feasible for the chlor-alkali industry to transition from asbestos diaphragms in two years?

RESPONSE:

The comment period for EPA's proposed risk management rule ended on July 13, 2022, and the Agency has received more than 150 comments. Comments are publicly available in the online rulemaking docket here: https://www.regulations.gov/docket/EPA-HQ-OPPT-2021-0057/document?documentTypes=Proposed%20Rule. A number of stakeholders have provided comments regarding the implications of a 2-year phase-out for use of asbestos in chlor-alkali production. Some have argued that chlorine is essential to disinfecting drinking water and the production of various other goods, and that EPA's proposed timeline for phase-out of asbestos in the chlor-alkali industry will have significant negative implications for public health and the economy. EPA is continuing to carefully review these and other comments and expects to provide a formal response to comments as part of the rulemaking process.

3. The Fiscal Year 2023 budget request seeks a 66% increase in funding for EPA's Toxics Risk Review and Prevention Program. As you know well, this program is responsible for protecting Americans from dangerous chemicals like asbestos through its authorities under the Toxic Substances Control Act, as amended by the bipartisan 2016 Lautenberg Act.
   Given the expanded responsibilities that Congress tasked EPA with in the 2016 Lautenberg amendments, we all expected the agency would need more resources to get the job done. The vision for this program was always that 25% of agency costs would be covered through services fees, but the previous administration grossly undercounted the resources needed for this program. Dr. Freedhoff, the administration has taken an

important step in re-evaluating the TSCA Service Fees Rule, which sets industry fees authorized under TSCA.

a. How will a new fee approach help ensure that industry contributes its fair share of the costs of this program?

RESPONSE:

Ensuring the Agency had enough money to implement the law was a key principle of TSCA reform that everyone supported, and it is correct that Congress also told EPA to collect up to 25% of certain TSCA costs from fees. But the first fees rule didn't become effective until fiscal year 2019, and the cost baseline for setting those fees was based on the costs of implementing the 1976 law – not the 2016 amended version of the law that provided the Agency with substantially increased requirements and responsibilities.

The costs of the first ten risk evaluations – the most expensive actions that could have been subject to the first TSCA fees rule - were also completely excluded from being subject to fees in that rule. As a result, the Agency did not come close to collecting 25% of even that artificially low costs baseline; instead it was around 13%.

The law requires us to update the rule every three years, and our supplemental fees will soon be released for public comment. Consistent with Congress' direction in the FY22 appropriations bill to "properly consider full costs…in line with the Lautenberg Act's intent," EPA expects the updated fees rule would provide the Agency with 25% of the full costs of implementing relevant provisions of the new law. See Joint Explanatory Statement: https://docs.house.gov/billsthisweek/20220307/BILLS-117RCP35-JES-DIVISION-G.pdf. Ensuring sufficient funding is something that all stakeholders supported, including industry, when the 2016 amendments were enacted – and that's also exactly what Congress told EPA to do in the last Appropriations bill.

b. What are the consequences for families and communities from underfunding this program?

RESPONSE:

The promise of TSCA reform was to deliver to the American people long-overdue protections against dangerous chemicals. The additional resources requested in the President's 2023 Budget Request, together with establishing and collecting fees that reflect the actual estimated cost of EPA's TSCA work, are critical to ensuring the success of the TSCA program and keeping families and communities safe. But fundamentally, it is in everyone's interests, including industry's, that EPA has the resources and other processes in place that will allow it to be able to make credible determinations on chemical risks and provide regulatory certainty to the public and stakeholders in accordance with our statutory deadlines.

Ranking Member Capito:

1. You mentioned in your testimony that there are only two health assessors working within the TSCA program. Please provide an accounting of the number of full-time employees currently working within the TSCA program, organized by job title, area of expertise, and program office.

RESPONSE:

To clarify, as indicated in EPA's testimony, there were only two health assessors currently in the New Chemicals Division at the time of the June 2022 hearing. "Human health assessor" is not an EPA job series or title, but was intended to generally refer to staff scientists with background and expertise in and current responsibilities for human health risk assessments in the new chemicals program. In addition to the two permanent health assessors, since the hearing, EPA has temporarily moved some existing employees with the appropriate technical and scientific training from their current positions into the New Chemicals Division to help address the current shortage of human health risk assessors. EPA has now successfully filled temporary (i.e., "detail") positions for a total of seven employees currently working to perform human health risk assessments for the next 3-4 months.

The New Chemicals Division has been allocated additional FTE following the March, 2022 enactment of the last Appropriations bill, and some of these new recruits have started to be onboarded (pending the completion of applicable background check and other requirements). We anticipate that by Spring 2023, we will hopefully have 11 human health assessors on board.

The employee accounting (Enclosure A) is organized by division and branch within the Office of Pollution Prevention and Toxics.

2. What role do health assessors have in chemical reviews under the TSCA program?

RESPONSE:

Under TSCA, EPA is required to review and make an affirmative determination on the safety of new chemicals before they can enter the market. EPA uses an integrated approach that draws on knowledge and experience across disciplinary and organizational lines to conduct new chemical reviews. EPA conducts a full life-cycle risk assessment of the substance, including chemistry, engineering, environmental releases, environmental fate, exposure (workers, general population, consumers and environment) and hazard (human and ecological) assessments, and then integrates those components into a risk assessment to inform the determination of whether the chemical poses or may pose an unreasonable risk to human health or the environment under the conditions of use. Human health assessors play an integral role in the assessment of human health hazards and risks as part of this process.

3. Do the health assessors do other work that could be addressed by other Agency employees?

RESPONSE:

The two health assessors referred to at the hearing in OPPT's new chemicals division are already devoting 100% of their time to carrying out new chemical reviews (including both pre-manufacturing notice and low volume exemption reviews). They are not performing other tasks that could be given to other employees to take on.

4. How many health assessors were working under the TSCA program during 2016?

RESPONSE:

The TSCA program with EPA's Office of Pollution Prevention and Toxics (OPPT) underwent a substantial reorganization in 2020. As part of that process, the human health assessors within the "Risk Assessment Division," which previously provided assessment to support both the new chemicals and existing chemicals assessments were assigned to one of two new divisions. Human health assessors that went to the New Chemicals Division conduct risk assessments to support the New Chemicals Program and those that went to the "Existing Chemicals Risk Assessment Division" conduct risk assessments to support the Existing Chemicals Program. In 2016, the "Risk Assessment Division" had approximately 17 employees with expertise in human health risk assessments supporting both new and existing chemical programs in OPPT. In 2020, following the reorganization of OCSPP, of 289 total employees in OPPT, 28 employees had responsibility for conducting TSCA human health risk assessment activities, including eight focusing on new chemical risk assessments, 19 on existing chemical risk evaluations, and one on cross-cutting issues.

5. What is the average tenure of a health assessor working under the TSCA program?

RESPONSE:

EPA has not analyzed personnel records to generate an average tenure of a health assessor working under the TSCA program. However, we have observed high levels of employee turnover across the office in recent years following the TSCA amendments.

6. Why do you think the Agency is having a difficult time retaining these types of employees and please identify any changes you are considering to ensure a sufficient number of health assessors are employed within the TSCA program?

RESPONSE:

The role of a health assessor in the TSCA new chemicals program is a challenging one. Congress gave EPA a relatively short window of time to review submissions and assess risks from new chemicals. This is no small task, as the program receives hundreds of submissions each year. But on top of that, the program has been historically underfunded. The new chemicals

program is currently operating with less than 50% of the resources it needs to carry out the program. As a result, career staff have been working in a very high-stress environment for a very long time.

Every year, the federal government conducts an Employee Viewpoint Survey to assess staff morale and other aspects of their jobs. Across the board, OCSPP's 2021 scores show improvement from 2020, and in most instances, the scores are at their highest levels ever. That being said, the data highlight areas for significant improvement even though we have made some meaningful progress in the past year. For example, there is a continued sentiment expressed that the workload in OCSPP is not reasonable – which is, of course, true, given the resource challenges we've been facing for the past 6 years with new TSCA.

7. Do you agree that there are enough resources already allotted to the TSCA program to hire more than two full-time health assessors without additional appropriations?

RESPONSE:

Before the enactment of the FY 22 appropriations, EPA had the authority to hire additional human health assessors. However, the broader TSCA program has been consistently under-funded since the 2016 amendments. As such, the Agency still currently lacks the resources with which to implement the program as Congress intended and has struggled to allocate these resources to address competing statutory responsibilities and deadlines for both new and existing chemicals.

The FY 2022 appropriations, which was passed in March 2022, provided some additional resources. There are currently 25 hiring actions underway across the Office, including seven in the New Chemicals Division. However, the hiring process takes time. Positions must be advertised, qualified candidates must be identified, panels are customarily convened to conduct interviews, selections must be made, offers must be formalized, conveyed and accepted, and security background checks must be completed – all before a new employee can be onboarded to begin orientation and training. In addition to the two permanent human health assessors, we now have five human health assessors onboarded on temporary assignments for the next 3-4 months for a total of seven employees working to perform human health risk assessments. We anticipate having a total of nine human health assessors with a mixture of permanent and temporary details by end of the year, and, by Spring 2023, we will hopefully have 11 full time permanent human health assessors.

Even under the FY2022 appropriations, EPA still estimates that we have less than 50% of the resources we need to carry out the program as Congress intended. The President's Budget Request for FY2023 requests an increase of $64 million and 201 additional full-time employees to support the TSCA program. Those additional resources, together with establishing and collecting fees that reflect the full cost of EPA's TSCA work are critical to ensuring the success of the TSCA program.

8. I appreciate your commitment made during the hearing to utilize a tiered approach to classifying and prioritizing OCSPP's plans to address PFAS chemicals. I understand that that your Office is already in the process of establishing this tiered approach. Can you please elaborate further on how this process is being undertaken and some of the main challenges this effort has faced thus far?

RESPONSE:

In June 2022, the Agency issued the first in a series of test orders under TSCA to require companies to conduct and submit testing on PFAS. The order employs a tiered screening and testing process, as TSCA requires, under which the results of screening-level tests or assessments of available information inform the decision as to whether one or more additional tests are necessary. The results of all the first-tier testing are required to be submitted to EPA within 400 days of the effective date of the order and will inform the decision as to whether additional tests are necessary. This effort is part of our National PFAS Testing Strategy to help identify PFAS data needs and require testing to fill those gaps, which was announced in 2021 in tandem with EPA's Strategic Roadmap to confront PFAS contamination nationwide.

Not all PFAS are the same, and EPA expects that different PFAS will present differing levels of concern. For example, a PFAS that does not dissolve in water would not be expected to pose a risk of exposures from drinking water. And some PFAS have been shown to cause health effects at much lower concentrations than others. Given that there are thousands of chemicals that are considered PFAS, EPA recognizes that assessing PFAS one at a time will make it impossible to understand or address the risks these substances may pose to human health and the environment.

Building off Congress' direction in the 2020 National Defense Authorization Act (NDAA) to develop a process for prioritizing which PFAS or categories of PFAS should be subject to additional research efforts based on potential for human exposure to, toxicity of, and other available information, the National PFAS Testing Strategy employs a category-based approach. Specifically, using published scientific methods, EPA assigned 6,504 PFAS into smaller categories based on similarities in structure and physical-chemical properties. Of these categories, EPA identified 24 that lack toxicity data to inform EPA's understanding of the potential human health effects and contain PFAS with at least one identifiable manufacturer to whom EPA could issue a test order. Rather than seeking data about each of the thousands of individual PFAS, which would require extensive resources in terms of time, costs, and animals, the Strategy aims to prioritize categories that are data-poor when it comes to the potential health effects for earlier action, and to identify a single representative substance(s) for each chemical category where categories have been constructed to span the landscape of PFAS of interest. More details on the National PFAS Testing Strategy are available on EPA's website: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/national-pfas-testing-strategy.

9. In order to manage the EPA's workload, as well as to facilitate more effective risk communication, does the EPA intend to use a more easily understandable approach to

classifying the varying hazard profiles of PFAS substances, for example by assigning labels such as "high-concern," "low-concern," or "no-concern"?

RESPONSE:

The purpose of the National PFAS Testing Strategy is to identify and fill gaps in the Agency's understanding of thousands of PFAS chemicals, most of which have limited or no toxicity data. This information could further inform the Agency's future research, monitoring, and regulatory efforts on PFAS. EPA recognizes that not all PFAS are the same, and that some PFAS will likely present differing levels of concern than others. EPA does not expect to assign each PFAS a label such as "high-concern", "low-concern," etc. as part of this effort at this time. For many PFAS, the data do not exist to do so, which is the significant gap the testing strategy aims to address. The Agency agrees that we cannot achieve our mission without effectively communicating with communities, individuals, businesses, the media, and Tribal, state, and local partners about the known and potential health risks associated with these chemicals. When EPA communicates risk, it is the Agency's goal to provide meaningful, understandable, and actionable information to many audiences.

10. The National Defense Authorization Act for Fiscal Year 2020 amended section 8(a) of TSCA to authorize the EPA to require reporting by manufacturers of the chemical substance the EPA has defined as PFAS:

    "Not later than January 1, 2023, the Administrator shall promulgate a rule in accordance with this subsection requiring each person who has **manufactured a chemical substance that is a perfluoroalkyl or polyfluoroalkyl substance** in any year since January 1, 2011, to submit to the Administrator a report that includes, for each year since January, 2011, the information described in subparagraphs (A) through (G) of paragraph (2)." **[emphasis added]**

    In the EPA's proposed rule implementing this NDAA provision, the preamble states:

    "[A]rticles containing PFAS…are included in the scope of reportable chemical substances."

    How do the Office's proposed regulations implementing section 8 of TSCA define "article" and "chemical substance"?

RESPONSE:

TSCA does not define "article," but EPA has defined "article" for purposes of Section 8(a) reporting rules in 40 CFR 704.3. The term "article" means:

"a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no

commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design."

The term "chemical substance" is defined in Section 3(2) of TSCA as follows:

"(A) Except as provided in subparagraph (B), the term "chemical substance" means any organic or inorganic substance of a particular molecular identity, including—
(i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and
(ii) any element or uncombined radical.
(B) Such term does not include—
(i) any mixture,
(ii) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.]) when manufactured, processed, or distributed in commerce for use as a pesticide,
(iii) tobacco or any tobacco product,
(iv) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 [42 U.S.C. 2011 et seq.] and regulations issued under such Act),
(v) any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1986 [26 U.S.C. 4181] (determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any other provision of such Code) and any component of such an article (limited to shot shells, cartridges, and components of shot shells and cartridges), and
(vi) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

11. Do these definitions establish a distinction between "article" and "chemical substance"?

RESPONSE:

A chemical substance can be part of an article.

12. Do you believe section 7351 of the 2020 NDAA authorizes the EPA to require reporting by manufacturers of articles containing PFAS? If so, how many entities does the EPA envision would be subject to these new reporting requirements?

RESPONSE:

The National Defense Authorization Act for Fiscal Year 2020 (Pub. L. 116-92, section 7351) amended TSCA section 8(a) in December 2019, adding section 8(a)(7), titled PFAS Data. TSCA section 8(a)(7) requires EPA to promulgate a rule "requiring each person who has manufactured

a chemical substance that is a [PFAS] in any year since January 1, 2011" to report information described in TSCA section 8(a)(2)(A) through (G). TSCA section 3(9) defines "manufacture" to include import of a chemical substance into the customs territory of the United States. Therefore, EPA proposed to apply the requirements in the TSCA 8(a)(7) reporting rule to those who import articles containing PFAS. EPA estimated 234 respondents would report under the one-time data call associated with the proposed rule. However, this number does not include the importers of articles containing PFAS, which EPA has sought more data on and is continuing to analyze. Following publication of the proposed rule, EPA convened a Small Business Advocacy Review (SBAR) Panel. We plan to publish the Initial Regulatory Flexibility Analysis and request comment and will carefully consider all feedback received during these processes as we work to finalize the rule.

13. The EPA itself recognized the difficulty in identifying the cost implications for importers of articles containing PFAS in its proposed section 8(a) rule. Does OCSPP still hold the view that it is difficult for importers of articles containing PFAS to have knowledge of the presence of a covered substance in a particular article? If so, what challenges does this pose to implementing the reporting requirements contained within the EPA's proposed section 8(a) rule?

RESPONSE:

EPA proposed that manufacturers (including importers) will report information to the extent that the information is known to or reasonably ascertainable by the manufacturer. The proposed rule at 40 CFR 705.3 would define "Known to or reasonably ascertainable by" to include "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know." This reporting standard would require reporting entities to evaluate their current level of knowledge of their manufactured products (including imports), as well as evaluate whether there is additional information that a reasonable person, similarly situated, would be expected to know, possess, or control. This standard carries with it an exercise of due diligence. EPA acknowledged in the proposed rule that it is possible that an importer of articles containing PFAS may not have knowledge that they have imported PFAS. However, such entities – after they have conducted their due diligence – would not be required to report under the rule but should nonetheless document their activities to support any claims they might need to make related to due diligence.

As noted previously, following the proposed rule, EPA convened an SBAR Panel to hear directly from small entities on the anticipated impact of the proposed rule on their organizations, and to get feedback regarding recommended paths forward to finalize a rulemaking that would minimize the burden of compliance on small entities while still achieving the objectives of TSCA section 8(a)(7). EPA also heard from public commenters, including articles importers, regarding specific implementation concerns. EPA plans to publish the Initial Regulatory Flexibility Analysis and request comment and will carefully consider all feedback received during these processes as we work to finalize the rule.

14. Industry has indicated that manufacturers subject to the proposed section 8(a) reporting requirements are unlikely to have much of the required data for years prior to 2016. Obtaining these data will require significant financial resources and time. Is the EPA able to quantify the economic burden associated with the significant expansion in the scope of reporting requirements for manufacturers of PFAS substances? What will be the regulatory purpose of these data?

RESPONSE:

Congress, in the National Defense Authorization Act for Fiscal Year 2020 (Pub. L. No. 116-92 § 7351), specifically directed EPA to promulgate a rule "requiring each person who has manufactured a chemical substance that is a [PFAS] in any year since January 1, 2011" to report certain information to the Agency. The proposed rule is consistent with this charge. We plan to publish the Initial Regulatory Flexibility Analysis addressing this question and request comment. The Agency would benefit from collecting the requested information on PFAS-containing articles (including articles containing PFAS as part of surface coatings) because the information would improve the Agency's knowledge of various products which may contain PFAS, their categories of use, production volumes, and exposure data. Such data are not currently known to EPA.

15. Can the EPA feasibly regulate or conduct enforcement actions related to evaluating all articles containing PFAS? How would this expansive mission affect personnel and financial resources you testify are already scarce?

RESPONSE:

As noted previously, following the proposed rule, EPA convened an SBAR Panel to hear directly from small entities on the anticipated impact of the proposed rule on their organizations, and to get feedback regarding recommended paths forward to finalize a rulemaking that would minimize the burden of compliance on small entities while still achieving the objectives of TSCA section 8(a)(7). EPA also heard from public commenters, including articles importers, regarding specific implementation concerns. EPA is considering all comments and information received as we work to finalize the rule.

16. In your response to my question during the hearing regarding OCSPP's modeling assumption that personal protective equipment (PPE) is not being worn by workers, you justified this decision based, in part, on the EPA's inability to confirm whether self-employed workers are adhering to the Occupational Safety and Health Administration's (OSHA) PPE requirements. Did Congress intend for TSCA to be a risk-based or hazard-based statute?

RESPONSE:

The "unreasonable risk" standard for TSCA risk evaluations is purely risk-based. In amending TSCA in 2016, Congress told EPA to determine – through a TSCA risk evaluation – whether a

chemical presents an "unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors," including unreasonable risk to potentially exposed or susceptible subpopulations, which may include workers. 15 U.S.C. 2605(b)(4)(A).

17. What is the difference between hazard- and risk-based approaches for chemical evaluations?

RESPONSE:

A hazard-based approach would consider only the chemical's hazards (i.e., potential adverse effects associated with exposure), whereas a risk-based approach looks at both hazard and exposure to determine risk (i.e., the chance of harmful effects to human health or to ecological systems resulting from exposure to an environmental stressor).

18. Please provide a justification as to how the "whole chemical" approach is an appropriate interpretation of a risk-based statute.

RESPONSE:

The "whole chemical" approach, as applied in several recently revised risk determinations for some of the first 10 chemical risk evaluations under TSCA, is an approach that looks at both hazards and exposures from the chemical substance as a whole, as well as other risk-related factors, to determine whether that chemical substance presents an unreasonable risk under its conditions of use, consistent with the language in TSCA section 6(b)(4)(A). In revising the risk determinations, nothing has changed with respect to the underlying analysis or the risk-based manner in which those evaluations were carried out.

19. What is the risk-based standard that is being applied in the PPE example? If it is not risk-based, why not?

RESPONSE:

As described in an announcement on June 30, 2021, EPA intends to remove the assumptions regarding the use of personal protective equipment (PPE) in making the unreasonable risk determinations under TSCA section 6. The risk-based standard under TSCA remains the same – the Agency is looking at the hazards from and exposures to a chemical to determine whether that chemical substance presents an unreasonable risk. The Agency is just no longer simply assuming that workers always appropriately wear PPE. OSHA rules don't apply to all employers. Many of OSHA's chemical-specific rules date back to the 1970s, and even OSHA has acknowledged that these are "outdated and inadequate for ensuring protection of worker health." See https://www.osha.gov/annotated-pels. And on top of that, respiratory and eye and face protection safety violations are almost always on OSHA's annual top 10 list of most frequent safety violations. See https://www.osha.gov/top10citedstandards. That said, the Agency is also aware

that many companies comply with and even go beyond what OSHA requires. The Agency's upcoming risk management rules will level the playing field for all companies by striving for consistency with OSHA rules and industry best practices whenever possible and ensure that all workers are protected against unreasonable risk no matter where they live or who employs them.

20. Does the EPA's apparent justification that the safety of self-employed workers cannot be guaranteed through OSHA standards imply that the EPA will need to levy enforcement actions against self-employed workers? If so, how will the EPA ensure that self-employed workers are adhering to TSCA? What scale of personnel and funding would that enforcement require?

RESPONSE:

The point emphasized in testimony is that OSHA requirements do not necessarily protect all workers, and that, as a factual matter, the requirements do not even apply to self-employed workers or State and local public-sector workers not covered by state plans. There are currently no regulatory requirements under TSCA that apply specifically to self-employed workers; as indicated previously, EPA intends for its future risk management actions to be reasonable and appropriately tailored while also including requirements to the extent necessary to address the identified unreasonable risk, as required by TSCA section 6(a).

21. Does the EPA intend to send enforcement inspectors to individual homes based on their purchasing history of covered chemical substances?

RESPONSE:

There are currently no regulatory requirements under TSCA that apply specifically to self-employed workers, and there are no final risk management rules on the first 10 chemical substances that underwent TSCA risk evaluations. As indicated previously, EPA intends for its future risk management actions to be reasonable and appropriately tailored while also including requirements to the extent necessary to address the identified unreasonable risk, as required by TSCA section 6(a).

22. What existing chemicals indicated as "high-priority" for a risk evaluation under TSCA are available to the average self-employed worker?

RESPONSE:

While large-scale manufacturing settings are where industrial chemical activities are typically thought to occur, smaller commercial settings may use chemical substances that may be considered "industrial chemicals." Such commercial operations include, but are not limited to, machine shops, metal fabricators, auto-repair shops, furniture manufacturing, or construction. Activities that may use industrial chemicals may be done by small businesses, self-employed

individuals, or DIY consumers. Many of the first 10 chemicals subject to TSCA risk evaluations are readily available to the general public. For example, methylene chloride, perchloroethylene, and trichloroethylene could be found in local home improvement stores, in various cleaning products, and on shelves in craft stores. There are numerous examples of individuals – as either commercial contractors or consumers – who were exposed to these dangerous chemicals and suffered illness or death.

23. Please provide any quantitative data comparing the rate of exposure to a high-priority existing chemical for self-employed workers compared to workers employed in conventional manufacturing and industrial facilities with existing industrial hygiene requirements in place.

RESPONSE:

EPA does not have such data. Worker exposures to chemicals are assessed on a chemical-by-chemical basis, and EPA's risk evaluations characterize risk to workers both with and without use of PPE. Supporting data becomes part of the risk evaluation and/or is made available in the public docket for the risk evaluation.

24. Following the EPA's release of Phase 1 of the asbestos risk management proposal earlier this year, public water utilities raised significant concerns about the availability of chlorine if a two-year phasedown on imported asbestos is required.

    According to the American Water Works Association and the Association of Metropolitan Water Agencies, the average cost for each ton of chlorine delivered to water systems has increased by over 160 percent over the last 18 months. Multiple large systems have experienced 300 to 600 percent increases in the unit cost of chlorine over an 18-month period, with one system paying $7000 per ton of chlorine. Are you aware of the concerns from the public water utility sector on the already rising prices of chlorine?

RESPONSE:

Yes. We have learned from several water systems that the cost of chlorine and derivative products (e.g., sodium hypochlorite, ferric chloride, polyaluminum chloride, etc.) has increased substantially, at percentages consistent with those reported by the American Water Works Association and Association of Metropolitan Water Agencies. Furthermore, we have heard directly from the suppliers that sell these products to water systems that the suppliers are incurring increases in the cost of these products, and that they will pass these increased costs on to their customers (including water systems).

25. Do you agree that higher prices paid for chlorine are ultimately borne by ratepayers?

RESPONSE:

Increased expenditures for chemical supplies ultimately will be borne by the communities serviced by the water systems. However, the rates for water services charged to customers may be controlled by a governing body (e.g., local governments, water boards, etc.), and the allowable rates are not always sufficient to cover operating costs, in which case a water system may borrow funds to cover these additional costs.

26. Given these concerns, is the EPA considering exempting chlor-alkali facilities for chlorine production serving public water utilities from the two-year phasedown?

RESPONSE:

I have personally met with a number of industry stakeholders who described some very practical implementation concerns, and I can assure you we will be taking their feedback and other public comments very seriously and will factor those in as the Agency moves to finalize the rule.

27. If not, what is the EPA going to do to address these issues, since chlorine and other disinfectants are critical elements in providing clean water as well as meeting the EPA's regulatory mandates on water systems?

RESPONSE:

EPA cares a great deal about protecting the integrity of the nation's drinking water supply, and we have no intention of creating unnecessary supply chain concerns where they can be avoided. As indicated previously, EPA is aware of concerns and is currently reviewing public comments to determine next steps for the rule.

28. The European Union provided 26 years for the phasedown of asbestos diaphragms in chlorine production. Canada provided an 11-year window. Why did the EPA only give facilities two years under its proposed risk management rule for chrysotile asbestos when other countries had vastly different phasedown timelines?

RESPONSE:

EPA consulted with several companies in the chlor-alkali industry and companies that process and use chrysotile asbestos-containing sheet gaskets in chemical production as part of developing the proposed rule. EPA noted in the proposed rule that it was possible that the required changes could take longer than expected to implement for some, and also considered a longer, 5-year phasedown as one of the regulatory option alternatives. Since then, the Agency has heard from a number of industry stakeholders regarding implementation concerns with the proposed phasedown period. EPA will be closely considering their feedback and other public comments as the Agency moves to finalize the rule.

29. Section 1441 of the Safe Drinking Water Act offers public water systems their only recourse in the event they are not able to access adequate supplies of disinfectants. If the asbestos rule were finalized and up to one-third of US chlorine capacity were affected, would the EPA expect to see an increase of applications from public water systems under section 1441?

RESPONSE:

In the case of a significant decrease in availability of chlorine and its derivatives, and if water systems are unable to secure these chemicals from other suppliers, EPA would expect to receive applications for a certification of need under the authorities of section 1441 of the Safe Drinking Water Act (SDWA 1441). This is based on experience during 2021 when there was a temporary decrease in production of chlorine due to equipment problems and extreme weather events. EPA received 28 applications for a certification of need under SDWA 1441 between June 2021 and April 2022, the majority of which dealt with chlorine or its derivative products. EPA was able to successfully resolve these supply issues by working directly with water systems and chemical suppliers. The Agency is keenly aware of the supply chain and other concerns raised by public commenters, and we will carefully consider that information as we finalize the rule.

30. How, and with what resources, would the EPA respond to these petitions meant to provide relief from a crisis that the Agency itself created?

RESPONSE:

EPA's Office of Water and Office of Chemical Safety and Pollution Prevention continue to coordinate closely on any potential chlorine manufacturing supply chain issues. EPA has staff and resources to support responding to SDWA 1441 applications, though these resource levels are established based on historic utilization of SDWA 1441. EPA also has undertaken a robust array of actions to prepare the water sector to respond to chemical supply issues, including an Incident Action Checklist, a supply chain resilience guide, direct technical assistance to individual water systems, an online water treatment chemical suppliers and manufacturer locator tool, and workshops with the water, chemical and critical manufacturing sectors.

The Department of Commerce (DOC) also has an important role in this process as the entity that issues orders to suppliers. EPA does not have information to comment on the resources that DOC has available to support these activities.

31. Do you expect the EPA and the Department of Commerce to have the means to sufficiently provide decontamination chemicals to public water systems under section 1441 in the event of a nationwide chlorine shortage?

RESPONSE:

Under the authorities of section 1441 of the Safe Drinking Water Act, EPA can issue a certification of need, which authorizes the Department of Commerce (DOC) to issue compulsory orders to a supplier for water treatment chemicals that are otherwise not reasonably available to the water system applicant. SDWA 1441 requires each water system experiencing a shortage to submit its own application, and the orders issued by DOC are issued to specific suppliers on behalf of the specific applicant. Because the SDWA requires this one-by-one process, these authorities may not be the most efficient means of resolving a large-scale shortage that could result in a large number of applications exceeding EPA's current processing capabilities. Furthermore, these authorities are effective only to the extent that there is sufficient availability of water treatment chemicals to meet the needs of water systems.

32. How does the EPA intend to respond to petitions under section 1441 of the Safe Drinking Water Act?

RESPONSE:

In 2021, EPA established a process to respond to and process applications submitted under section 1441 of the Safe Drinking Water Act and posted this information on our website. EPA would follow this established process for any new applications submitted and received.

33. Does the Agency currently have a chlorine stockpile for emergencies or some other mechanism to expand supply in the market rapidly?

RESPONSE:

No, the Agency does not keep a stockpile of chlorine. As described previously, if public water systems experience a shortage or supply chain issues for water treatment chemicals and other critical supplies, EPA first encourages those systems to work with their current suppliers or identify other potential suppliers in their region, consult their primacy agency or permitting authority, and to reach out to existing mutual aid networks for additional relief.

34. Do you agree that the chlorine market is characterized by both a captive market and a merchant market, and that the majority of chlorine supplied to public water systems comes through the merchant market?

RESPONSE:

Chloralkali facilities that produce chlorine for captive use generally lack the logistics infrastructure to move chlorine into the merchant market.

35. If this is the case, how does the EPA intend to address shortages in the merchant market for chlorine to respond to section 1441 petitions if the Agency cannot import or pull from the captive market to make up for shortages?

RESPONSE:

EPA would process SDWA 1441 applications using the procedure noted in the response to question 32. Additionally, EPA would provide direct technical assistance to water systems in need in an attempt to identify manufacturers or suppliers that may have chlorine that could be sold to water systems.

36. In a memo addressed to your staff, you reiterated your commitment to conducting a "robust exchange of scientific views, with differing scientific opinions." Given this commitment, how would you intend to address situations in which a comp[l]eted risk evaluation relies on exposure assumptions that, after the public comment period concludes, have been proven to be inaccurate by data adhering to TSCA's best available science criteria?

RESPONSE:

I am committed to upholding and advancing the principles of scientific integrity throughout OCSPP's work. Healthy discussion of differing scientific opinions ultimately improves the quality of the science in OCSPP's work. Separately, the public comment periods associated with various stages of the TSCA process (e.g., prioritization candidate identification, proposed priority designation, draft risk evaluation scope, draft risk evaluation, etc.), along with scientific peer review, all provide important opportunities to hear from our stakeholders, academics, and the public, to hear feedback on our assumptions and analyses, and to receive additional relevant data that may be used to inform our decisions.

Because our TSCA risk evaluations are based on reasonably available information, it is important that stakeholders engage with EPA during this process and share relevant information that may impact the evaluation. Once a risk evaluation has been finalized and where unreasonable risk has been determined, the law directs the Agency to proceed to rulemaking to eliminate that risk under section 6(a). During the risk management phase, real world exposure and other information that is reasonably available to the Agency can continue to inform the regulatory decision-making. Where new information becomes available after the TSCA process is complete, EPA has the authority under TSCA to re-prioritize the chemical for evaluation.

37. After stating that you anticipate missing every single TSCA statutory deadline, why did you direct resources from the statutorily authorized TSCA program to non-statutory programs such as Safer Choice and IRIS?

RESPONSE:

The IRIS program is implemented by EPA's Office of Research and Development, is not part of the OCSPP or TSCA budget, and no such resource direction has occurred.

Congress specifically directed EPA to budget for Safer Choice in the FY2022 omnibus appropriation, stating: "the Committees support the Safer Choice program and direct that the program be funded and operated consistent with prior years." The Safer Choice Program has the support of a near-universal group of stakeholders [see Enclosure B - June 2021 letter.] The OCSPP reorganization implemented by the previous Administration eliminated the Safer Choice Branch. In April 2021, consistent with Congress' direction, EPA reestablished Safer Choice as a stand-alone branch within OPPT using existing resources already dedicated to Safer Choice work and did not divert any TSCA budget resources to the efforts. The branch currently has nine FTE.

38. Can you please clarify if it is the EPA's intention under the proposed chrysotile asbestos risk management rulemaking to require the removal and replacement of every existing asbestos gasket within two years?

RESPONSE:

EPA proposed to prohibit the manufacturing, processing, distribution in commerce, and commercial use of asbestos-containing gaskets, including the commercial use of existing asbestos-containing gaskets. Under the proposed rule, this prohibition would take effect two years after the effective date of the final rule for sheet gaskets in chemical production, and 180 days after the effective date of the final rule for other gaskets. EPA did not, however, intend for this rule to force removal of significant numbers of asbestos gaskets before the end of their useful life. In fact, EPA recognizes that there could be unintended consequences of doing so in terms of increased exposures and risks during the removal and subsequent disposal. EPA is reviewing the feedback received during the public comment period from stakeholders on the proposed rule and will consider, based on that feedback, potential improvements to clarify, and amend as necessary, the scope of the rule's requirements.

39. Has the EPA noticed a reduction in new chemical submissions over the past six months even as economic activity has approached pre-pandemic levels? Why do you think this reduction in submissions is occurring?

RESPONSE:

The number of new chemical notices and applications that EPA receives for review is entirely dependent on industry submitters. There are months with higher numbers of submissions, and months with lower numbers. Because of this, a six-month period is not enough to draw accurate conclusions on trends, and EPA has not conducted a formal or detailed analysis of submission trends. That said, EPA has observed decline in the annual number of PMN submissions from FY 2016 – FY 2020. The greatest drop occurred in FY 2019, which generally corresponds to the effective date of the TSCA fees rule increasing the fees associated with new chemical submissions. In FY 2019, for the first time, EPA also began to receive more exemption

applications than pre-manufacture notices. Submission rates for exemption applications have continued this trend, now generally making up 50-60% of total submissions received each year. In FY 2021, EPA received an increase in the total number of submissions over FY 2020 numbers (i.e., 511 in FY 2021 as compared to 441 in FY 2020). And for FY 2022, the Agency again received slightly more submissions than in FY 2021 (i.e., 520 in FY 2022).

40. Does the EPA intend to continue to use a chronological approach to addressing the backlog of new chemical submissions? In other words, does the EPA intend to act on the earliest submissions before turning to ones received later? If this is not your intended approach, please explain why and what your approach will be.

RESPONSE:

The new chemicals program does not apply a purely first-in-first-out approach. Every new chemical submission is different, and some may take considerably more or less time to review than others. Moreover, the program has historically operated in an iterative fashion, working closely with submitters throughout the process, allowing companies to submit additional information that may be useful in refining the risk assessment, implementing industry requests to voluntarily suspend review periods when companies want/need more time to review or assemble information. In cases where EPA does receive amended submissions or new information during the review period, EPA may need to "re-run" all or parts of its risk analysis. Intake, review and inclusion of any new information takes time and will necessarily delay final completion of that particular case review. Where companies have amended their original submission – in some cases multiple times over a period of months or even years– EPA informs those companies that their submission will be added to the queue and may have to wait for EPA to complete risk assessments for other submissions. In other words, late amendments are sometimes added to the end of the line for review as they are received, not 'put to the front of the line' just because the assessment was originally submitted and/or previously initiated at an earlier date.

Additionally, EPA recently announced a broad outreach effort to describe and discuss with stakeholders how the Agency evaluates certain data provided for new chemicals submissions (e.g., engineering) and common issues that cause EPA to have to reconduct risk assessments ("rework") for these submissions. The goal of this effort is to reduce rework of initial risk assessments for new chemicals submissions that is caused by submitters supplementing incomplete initial new chemicals review submissions. Rework of assessments has resulted in significant delays in EPA's review of these chemicals and stretched already limited resources. Both EPA and stakeholders share an interest in reducing process inefficiencies while also ensuring a protective review of new chemical risks. More information on this effort is available on EPA's website: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-new-chemical-engineering.

41. Do you believe that a draft IRIS assessment can be used to inform a TSCA chemical evaluation?

RESPONSE:

Yes. Risk assessment involves (1) hazard identification, (2) dose-response assessment, (3) exposure assessment, and (4) risk characterization, which integrate dose-response and exposure information. IRIS assessments only provide chronic hazard and dose-response information that are then used by other Agency programs, including OCSPP. TSCA risk evaluations are developed specifically to determine whether a chemical substance presents unreasonable risk and to include all four aspects of risk assessment. Information used to support an IRIS assessment—whether draft or final—is information that must be considered in developing a draft TSCA risk evaluation in light of the statutory and regulatory requirement to consider reasonably available information and to base decisions on the best available science. The TSCA risk evaluation process ensures that our analyses are made available for public comment and peer review as appropriate, based on the weight of the scientific evidence, and consistent with the best available science.

42. Would an IRIS assessment ever be used in place of a TSCA risk evaluation?

RESPONSE:

No. IRIS assessments are not risk assessments or risk evaluations. Risk assessment involves (1) hazard identification, (2) dose-response assessment, (3) exposure assessment, and (4) risk characterization, which integrate dose-response and exposure information. IRIS assessments only provide chronic hazard and dose-response information that are then used by other Agency programs, including OCSPP. TSCA risk evaluations are developed specifically to determine whether a chemical substance presents unreasonable risk and to include all four aspects of risk assessment. Under TSCA, we must look at, for example, the acute hazards to workers and consumers, the way people could be exposed to the chemical in the real world, and the potential for environmental risk – all components that are not part of IRIS assessments. As such, TSCA risk evaluations must consider and apply a broader suite of scientific information than that assessed under the IRIS program. Thus, IRIS assessments could inform a TSCA risk evaluation, but could not replace it.

43. Section 26(k)(5) of TSCA requires the EPA to issue guidance "to assist interested persons in developing and submitting draft risk evaluations which shall be considered by the Administrator." EPA first issued this guidance in June 2017.

    Following the hearing, the EPA committed to a new approach with regards to TSCA's new chemicals program. That approach entails an improved effort by the EPA to conduct stakeholder outreach in order to better communicate the type of data the Agency expects to receive in a new chemical submission. With this in mind, does the EPA intend to update the section 26(k)(5) guidance in accordance with the Agency's new approach to stakeholder outreach within new chemicals program?

RESPONSE:

The guidance you are referring to under TSCA section 26(l)(5) is specifically guidance for developing and submitting a draft risk evaluation on an existing chemical. EPA does not conduct "risk evaluations" on new chemical substances under TSCA section 6(b). Rather, TSCA requires that EPA review and make an affirmative determination on all new chemical notices pursuant to TSCA section 5(a)(3), prior to those chemicals entering the market. EPA does not intend to update the section 26(l)(5) guidance at this time.

As noted previously, we have recently announced a broad outreach effort to describe and discuss with stakeholders how the Agency evaluates certain data (i.e., engineering) provided for new chemicals submissions and common issues that cause EPA to have to re-do risk assessments for these submissions. The goal of this effort is to reduce rework of initial risk assessments for new chemicals submissions, furthering shared goals of new chemical reviews that are both high quality and timely. More information is available here: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-new-chemical-engineering.

In addition, EPA has separately published a document titled "Points to Consider When Preparing TSCA New Chemical Notifications" – available on EPA's website: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/points-consider-when-preparing-tsca. This document provides general guidance relating to new chemical notices; preparation of Pre-manufacture Notices, Significant New Use Notices, and Exemption notices; EPA scientific approaches; and best practices. Further guidance on how to prepare new chemical notices is also available on EPA's website: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-pre-manufacture-notice-epa#avoid. EPA may consider updating or supplementing this document in the future to support its outreach and communication efforts in the new chemicals program.

44. If you intend to update this guidance required by section 26(k)(5), will you commit to working with industry to better communicate the type of data that should be submitted within an industry-conducted risk evaluation in order to facilitate more efficient reviews?

RESPONSE:

As noted above, EPA is not planning to update the TSCA section 26(l)(5) guidance at this time. However, we are absolutely committed to doing a better job at communicating the type of data that would be most beneficial in completing both reviews in the New Chemicals Program and risk evaluations in the Existing Chemicals Program. To that end, EPA has launched an outreach effort to describe and discuss with stakeholders how the Agency evaluates certain data provided for new chemicals submissions and common issues that cause EPA to redo or "rework" risk assessments. We also published the analysis supporting identification of these common issues, which included review of 94 cases where companies provided additional engineering information during the new chemical review period, available here: https://www.epa.gov/system/files/documents/2022-

07/TSCA%20New%20Chemical%20Engineering%20Initiative%2C%20Analysis%20Methodology%20and%20Results.pdf.

The first in a series of webinars on this topic occurred on July 27, 2022, and drew close to 300 participants. A second webinar occurred on October 18, 2022 with over 500 participants, focusing on EPA's considerations in evaluating qualitative claims or quantitative data, especially when they deviate from model defaults such as those used in the Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER) and its considerations for evaluating information about sites not controlled by the submitter.

Senator Inhofe:

1. Dr. Freedhoff, on June 15, 2022 the EPA announced revised interim drinking water health advisories for PFOA, PFOS, GenX chemicals and PFBS. The new health advisories for several of these chemicals are at near-zero levels that are, in certain circumstances, below detection. How does the EPA expect to measure contamination to the levels set forth in the health advisories and do tools exist that will enable detection at these new levels?

RESPONSE:

Based on current methods, the interim health advisory levels for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS) that EPA released on June 15, 2022, are below the level of both detection (determining whether or not a substance is present) and quantitation (the ability to reliably determine how much of a substance is present). This means that it is possible for PFOA or PFOS to be present in drinking water at levels that exceed health advisories even if testing indicates no level of these chemicals. Based on current methods, the final health advisory levels for GenX chemicals and PFBS are above both the detection and quantitation levels, and therefore can be reliably measured using specified analytical methods in appropriate laboratory settings. EPA continues to conduct research and monitor advances in testing technology, methods, and techniques that may improve our ability to measure PFAS at lower levels.

a. Did the Science Advisory Board review the interim health advisory values for PFAS before EPA issued them?

RESPONSE:

Consistent with EPA's mission and responsibility to protect public health, EPA issued interim health advisories for PFOA and PFOS to help inform the public of new scientific information on these chemicals' health effects.

EPA continues to conduct extensive evaluations of human epidemiological and experimental animal study data to support the development of a National Primary Drinking Water Regulation for PFOA and PFOS. In November 2021, EPA released draft updated health effects analyses for PFOA and PFOS; these analyses are undergoing Science Advisory Board (SAB) review. EPA

evaluated over 400 peer-reviewed studies published since 2016 and used new approaches, tools, and models to identify and evaluate the information. Based on the new data and draft analyses, the levels at which negative health effects could occur are much lower than previously understood when EPA issued the 2016 Health Advisories for PFOA and PFOS (70 ppt) – including near zero for certain health effects.

In light of this new information, including peer-reviewed scientific studies, EPA also announced in November 2021 that the agency would move quickly to update the 2016 Health Advisories for PFOA and PFOS to reflect the new science and draft EPA analyses. To deliver on this commitment, EPA issued interim updated health advisories based on the draft 2021 analyses that are undergoing review by the SAB. The interim health advisories replace the 2016 final health advisories for PFOA and PFOS. EPA is working hard to review and respond to the SAB's August 2022 final report as the agency moves forward to develop Maximum Contaminant Level Goals (MCLGs) to support the development of a National Primary Drinking Water Regulation for PFOA and PFOS. At that time, EPA may update or remove the interim health advisories for PFOA and PFOS based on the best available science. Because the available health effects data indicate a number of different adverse effects resulting from exposure to very low levels of PFOA or PFOS, the health-based water values (health advisories and MCLGs) are likely to remain below the detection limit.

b. If not, why didn't you wait for a review by the Agency's science experts?

RESPONSE:

See response to (a) above.

2. The EPA has committed to issuing maximum contaminant levels (MCLs) under the Safe Drinking Water Act for the above listed chemicals in the near future. Was what prompted the EPA to issue the new health advisories prior to the MCLs statutory or policy based?

RESPONSE:

Consistent with EPA's mission and responsibility to protect public health, EPA issued interim health advisories for PFOA and PFOS to help inform the public of new scientific information on these chemicals' health effects. The Safe Drinking Water Act (SDWA) authorizes EPA to issue health advisories for contaminants that are not subject to a National Primary Drinking Water Regulation (NPDWR) (42 U.S.C. §300g-1(b)(1)(F)).

A health advisory provides information on a contaminant that can cause negative human health effects and is known or anticipated to occur in drinking water. EPA's health advisories are non-enforceable and non-regulatory. They provide technical information to drinking water system operators, as well as federal, state, Tribal, and local officials, on the health effects, analytical methods, and treatment technologies associated with drinking water contaminants. This health effects information includes the concentrations of such drinking water contaminants (the health

advisory "levels" or "values") at which adverse health effects are not anticipated to occur over specific exposure durations, such as one-day, 10-days or a lifetime.

a. Do you expect those MCLs to be different from the interim health advisory levels?

RESPONSE:

EPA is currently developing the proposed National Primary Drinking Water Regulations (NPDWRs) for PFAS. As part of an NPDWR, EPA establishes MCLGs, which are the level of a contaminant in drinking water below which there is no known or expected risk to health. MCLGs are health-based goals that allow for a margin of safety, and they are non-enforceable. Because the available health effects data indicate a number of different adverse effects resulting from exposure to very low levels of PFOA or PFOS, the health-based water values (health advisories and MCLGs) for these PFAS are likely to remain below our ability to monitor for and detect PFOA and PFOS in finished drinking water.

As part of the NPDWR, EPA will also set an enforceable limit in the form of an MCL or a Treatment Technique. An MCL is the highest level of a contaminant that is allowed in drinking water. MCLs are set as close to MCLGs as feasible using the best available treatment technology, considering feasibility, and taking cost into consideration. MCLs are enforceable standards. As EPA is currently in the deliberative process for developing NPDWRs, we cannot speculate on potential values for MCLs or treatment technique requirements at this time. Consistent with EPA's PFAS Strategic Roadmap, the Agency plans to release a proposed NPDWR by the end of 2022 for public comment.

b. Do you expect they will be higher or lower, and if so, why?

RESPONSE:

See response to 2(a) above.

3. The strong implication in the new health advisories is that drinking water is safe only at the proscribed levels. Does EPA expect water providers to bear the cost of abatement?

RESPONSE:

Health Advisories are informational and not enforceable. They do not require any action on the part of the water provider. However, for utilities and communities that choose to take action, EPA has announced $1 billion in fiscal year 2022 grant funding through the Bipartisan Infrastructure Law Emerging Contaminants in Small or Disadvantaged Communities Grant Program. This is the first of $5 billion in grant funding through the Bipartisan Infrastructure Law (BIL) that can be used to reduce PFAS in drinking water in underserved communities, and the

BIL provides a total of $10 billion to address PFAS or other emerging contaminants in water. Communities can also use funding through the general and BIL supplemental State Revolving Funds, totaling over $23 billion over the next 5 years, to address emerging contaminants in water. More information is available in EPA's March 2022 Bipartisan Infrastructure Law SRF Memorandum, available at https://www.epa.gov/dwsrf/bipartisan-infrastructure-law-srf-memorandum.

4. The American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs) are considered by most Industrial Hygienists to be the "gold standard" for exposure guidelines. OSHA, in their Permissible Exposure Limit (PEL) Annotated Tables references ACGIH TLVs as one of the three alternative occupational exposure limits to their PELs.
    a. Are you aware that the EPA proposed Existing Chemical Exposure Limits (ECELs) are significantly lower than the ACGIH TLVs? If so, why are the EPA's proposed ECELs so much lower than the established TLV's?

RESPONSE:

Yes, we are aware that EPA's proposed ECELs are significantly lower than the TLVs developed by ACGIH. We appreciate the work done by ACGIH guiding industrial hygienists to contribute to the overall improvement in worker protection.

There are several reasons why ACGIH TLVs may differ from ECELs. Because many TLVs are several decades old, they may not fully capture either the complete database considered in risk evaluations or more recent advances in modeling and scientific interpretation of toxicological data. ECELs, which EPA considers to represent the best available science, are derived from information in the risk evaluation, which is the result of a rigorous systematic review process that includes an investigation of the entirety of the reasonably available current literature in order to identify all relevant adverse health effects. Additionally, by using the information from the risk evaluation, ECELs incorporate advanced modeling and peer-reviewed methodologies for determining exposure levels below which unreasonable risk to health would no longer be presented.

5. Pursuant to Section 6(b) of the OSH Act, OSHA must adhere to procedures and considerations in rulemaking, which includes technological and economic feasibility. Technological feasibility evaluates what is achievable using work practice or engineering controls that are commonly known and readily available. Economic feasibility evaluates whether the standard threatens the existence or the competitive stability of an industry. The EPA ECEL memorandum for Perchloroethylene states that "OSHA's Permissible Exposure Limit (PEL) must undergo both risk assessment and feasibility assessment analyses before selecting a level that will substantially reduce risk under the Occupational Safety and Health Act." Does this imply that EPA does not have to comply with similar constraints?

RESPONSE:

EPA's mandate under TSCA section 6(b) is to evaluate existing chemicals against a purely risk-based standard, identifying whether there are unreasonable risks of injury to health or the environment without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA, under the conditions of use. The Agency must then eliminate any unreasonable risk through regulatory requirements or restrictions outlined in TSCA Section 6(a). In imposing restrictions to eliminate unreasonable risks, TSCA section 6(c)(2) further directs EPA to consider other factors such as reasonably ascertainable economic consequences of the rule and whether technically and economically feasible alternatives that benefit health or the environment compared to a use proposed to be prohibited or restricted will be reasonably available as a substitute. Those considerations help EPA select the best regulatory option among those that effectively eliminate the unreasonable risk, and the Agency takes the obligation to consider these factors seriously.

TSCA section 6(g) provides authority for EPA to issue time-limited exemptions to risk management regulatory requirements in a few instances, including but not limited to instances when the use is a critical or essential use for which no technically or economically feasible safer alternative is available when taking into account hazard and exposure, and instances where compliance with a risk management requirement for a specific condition of use would significantly disrupt the national economy, national security, or critical infrastructure. However, these provisions do not otherwise limit EPA's authority under TSCA to identify an unreasonable risk in risk evaluations, and the requirement to then eliminate the unreasonable risks in a subsequent risk management rule.

Specifically, in the case of the ECELs, EPA has identified the concentration at which individuals would be unlikely to suffer adverse effects if exposed for a working lifetime. This is a risk-based calculation derived from the risk evaluation, incorporating advanced modeling and peer-reviewed methodologies, including accounting for exposures to potentially exposed and susceptible subpopulations, as required by TSCA. In risk management, EPA plans to consider the implementation practicalities to meet an ECEL for relevant conditions of use and will present the analysis regarding the economic consequences of the proposed regulatory requirements, including any requirements to meet an ECEL.

a. If not, ACGIH also does not consider economic or technical feasibility and yet the EPA ECELs are considerably lower than ACGIH TLVs. How does the EPA account for this discrepancy?

RESPONSE:

There are several reasons why ACGIH TLVs may differ from ECELs. Because many TLVs are several decades old, they may not fully capture either the complete database considered in risk evaluations or more recent advances in modeling and scientific interpretation of toxicological data. ECELs, which EPA considers to represent the best available science, are derived from information in the risk evaluation, which is the result of a rigorous systematic review process that

includes an investigation of the entirety of the reasonably available current literature in order to identify all relevant adverse health effects. Additionally, by using the information from the risk evaluation, ECELs incorporate advanced modeling and peer-reviewed methodologies for determining exposure levels below which unreasonable risk to health would no longer be presented.

6. The Environmental Protection Agency (EPA) must develop risk determinations for each chemical's condition of use by deciding if that chemical presents an unreasonable risk to humans or the environment based on the inherent toxicity and likely exposure. Do you believe the Toxic Substances Control Act reform intended for every chemical substance the EPA reviews to be found to present an unreasonable risk?

RESPONSE:

TSCA directs EPA to "conduct risk evaluations…to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." 15 U.S.C. 2605(b)(4)(A). I don't believe Congress expected that EPA would find "unreasonable risk" for every one of the tens of thousands of chemicals in commerce. Neither the law nor our regulations pre-judge the outcome of the risk evaluation process. We expect to follow the law and follow the science in implementing our responsibilities under the statute.

a. How will EPA ensure that real world exposure data from the workplace will be used in lieu of overly conservative default assumptions that may inaccurately characterize the workplace?

RESPONSE:

Where real world exposure data exists and is made available to the Agency, we do consider that information during the risk evaluation process. There are numerous opportunities during the TSCA process for submission of data to inform EPA's efforts, and we strongly encourage companies and other stakeholders to share relevant information that they may have, as early in the process as possible. We are also committed to doing a better job at characterizing our risk findings. We know, for example, that many companies go above and beyond what they are required to do to protect their workers. In addressing unreasonable risks identified in TSCA risk evaluations, we plan to strive for consistency with OSHA rules and industry best practices wherever possible, leveling the playing field for all companies, while still ensuring that all workers are protected against unreasonable risk no matter where they live or who employs them.

7. In your proposed risk management rule for asbestos, can you please clarify for me if it was EPA's intent to force the removal and replacement of every asbestos gasket within two years?

RESPONSE:

EPA proposed to prohibit the manufacturing, processing, distribution in commerce, and commercial use of asbestos-containing gaskets, including the commercial use of existing asbestos-containing gaskets. Under the proposed rule, this prohibition would take effect two years after the effective date of the final rule for sheet gaskets in chemical production, and 180 days after the effective date of the final rule for other gaskets. EPA did not, however, intend for this rule to force removal of significant numbers of asbestos gaskets before the end of their useful life. In fact, EPA recognizes that there could be unintended consequences of doing so in terms of increased exposures and risks during the removal and subsequent disposal. EPA is reviewing the feedback received during the public comment period from stakeholders on the proposed rule and will consider, based on that feedback, potential improvements to clarify, and amend as necessary, the scope of the rule's requirements.

Position Title	Grade Or Level
OPPT Immediate Office	
DIR,OFC OF POLLUTION PREVNTION & TOXCS	00
DEPUTY DIRECTOR FOR MGMT, OPPT	00
DEPUTY DIRECTOR FOR PROGRAMS, OPPT	00
SENIOR SCIENCE ADVISOR	00
ENVIRONMENTAL PROTECTION SPECIALIST	15
PROGRAM & PROJ MGMT IMPROVEMENT OFCR	15
ENVIRONMENTAL PROTECTION SPECIALIST	14
PROGRAM ANALYST	13
Existing Chemicals Risk Assessment Division	
Immediate Office	
DIR EXISTING CHEM RISK ASSESSMENT DIV	00
SUPVY PHYSICAL SCIENTIST	15
BIOLOGIST	15
TECHNICAL WRITER AND EDITOR	13
Risk Assessment Branch 1	
SUPVY CHEMIST	15
LEAD PHYSICAL SCIENTIST	14
LEAD BIOLOGIST	14
BIOLOGIST	14
TOXICOLOGIST	14
BIOLOGIST	13
BIOLOGIST	13
CHEMICAL ENGINEER	13
CHEMICAL ENGINEER	13
PHYSICAL SCIENTIST	13
PHYSICAL SCIENTIST	13
ENVIRONMENTAL ENGINEER	13
TOXICOLOGIST	13
Risk Assessment Branch 2	
SUPERVISORY TOXICOLOGIST	15
LEAD BIOLOGIST	14
LEAD BIOLOGIST	14
BIOLOGIST	14
EPIDEMOLOGIST	14
BIOLOGIST	13
BIOLOGIST	13
CHEMICAL ENGINEER	13
ENVIRONMENTAL ENGINEER	13
ENVIRONMENTAL ENGINEER	13
TOXICOLOGIST	13
TOXICOLOGIST	13
CHEMICAL ENGINEER	12
PHYSICAL SCIENTIST	12
Risk Assessment Branch 4	
PHYSICAL SCIENTIST	13

LEAD BIOLOGIST	14
STUDENT TRAINEE (ENV PROTECTION)	05
BIOLOGIST	12
TOXICOLOGIST	14
ENVIRONMENTAL SCIENTIST	14
CHEMICAL ENGINEER	13
LEAD BIOLOGIST	14
SUPERVISORY BIOLOGIST	15
CHEMICAL ENGINEER	13
Risk Assessment Branch 5	
SUPERVISORY TOXICOLOGIST	15
LEAD BIOLOGIST	14
LEAD BIOLOGIST	14
TOXICOLOGIST	14
BIOLOGIST	13
BIOLOGIST	13
EPIDEMIOLOGIST	13
PHYSICAL SCIENTIST	13
BIOLOGIST	12
PHYSICAL SCIENTIST	12
PHYSICAL SCIENTIST	12
BIOLOGIST	11
BIOLOGIST	11
INDUSTRIAL HYGIENIST	11
Risk Assessment Branch 6	
SUPERVISORY BIOLOGIST	15
LEAD TOXICOLOGIST	14
BIOLOGIST	13
BIOLOGIST	13
BIOLOGIST	13
BIOLOGIST	13
BIOLOGIST	13
BIOLOGIST	13
BIOLOGIST	13
CHEMICAL ENGINEER	13
PHYSICAL SCIENTIST	13
PHYSICAL SCIENTIST	13
PHYSICAL SCIENTIST	13
TECHNICAL INFORMATION SPECIALIST	13
TOXICOLOGIST	13
BIOLOGIST	12
ENVIRONMENTAL ENGINEER	12
Existing Chemicals Risk Management Division	
Immediate Office	
SUPV ENVIRONMENTAL PROTECTION SPC	15
ENVIRONMENTAL PROTECTION SPECIALIST	15
ENVIRONMENTAL PROTECTION SPECIALIST	14

Risk Management Branch 1	
SUPVY ENVIRON PROTECTION SPEC	15
LEAD ENVIRONMENTAL PROTECTION SPC	14
LEAD ENVIRONMENTAL PROTECTION SPC	14
ATTORNEY-ADVISER	14
ENVIRONMENTAL PROTECTION SPECIALIST	14
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	12
ENVIRONMENTAL PROTECTION SPECIALIST	12
ENVIRONMENTAL PROTECTION SPECIALIST	11
ENVIRONMENTAL PROTECTION SPECIALIST	09
Risk Management Branch 2	
SUPV ENVIRONMENTAL PROTECTION SPC	15
LEAD ENVIRONMENTAL PROTECTION SPC	14
LEAD ENVIRONMENTAL PROTECTION SPC	14
ENVIRONMENTAL PROTECTION SPECIALIST	14
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	12
ENVIRONMENTAL PROTECTION SPECIALIST	11
ENVIRONMENTAL PROTECTION SPECIALIST	11
Risk Management Branch 3	
SUPVY PHYSICAL SCIENTIST	15
LEAD ENVIRONMENTAL PROTECTION SPC	14
LEAD PHYSICAL SCIENTIST	14
ATTORNEY ADVISOR (GENERAL)	14
ENVIRONMENTAL PROTECTION SPECIALIST	14
BIOLOGIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
PHYSICAL SCIENTIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	12
ENVIRONMENTAL PROTECTION SPECIALIST	11
ENVIRONMENTAL PROTECTION SPECIALIST	11
Economics and Policy Analysis Branch	
SUPERVISORY ECONOMIST	15
LEAD ECONOMIST	14
ECONOMIST	15
ECONOMIST	14
ECONOMIST	14
ECONOMIST	13
ECONOMIST	13

ECONOMIST	13
ECONOMIST	13
ECONOMIST	13
ECONOMIST	13
ECONOMIST	12
ECONOMIST	12
New Chemicals Division	
Immediate Office	
DIRECTOR, NEW CHEMICALS DIVISION	00
ENVIRONMENTAL PROTECTION SPECIALIST	15
TOXICOLOGIST	15
Risk Assessment Branch 1	
SUPERVISORY BIOLOGIST	15
SUPERVISORY TOXICOLOGIST	15
LEAD ENVIRONMENTAL ENGINEER	14
TOXICOLOGIST	14
BIOLOGIST	13
BIOLOGIST	13
BIOLOGIST	13
BIOLOGIST	13
CHEMICAL ENGINEER	13
CHEMICAL ENGINEER	13
TOXICOLOGIST	13
BIOLOGIST	12
BIOLOGIST	12
Risk Assessment Branch 2	
SUPVY PHYSICAL SCIENTIST	15
LEAD BIOLOGIST	14
LEAD PHYSICAL SCIENTIST	14
MICROBIOLOGIST	14
TOXICOLOGIST	14
BIOLOGIST	13
BIOLOGIST	13
CHEMICAL ENGINEER	13
CHEMICAL ENGINEER	13
ENVIRONMENTAL ENGINEER	13
MICROBIOLOGIST	13
MICROBIOLOGIST	13
PHYSICAL SCIENTIST	13
TOXICOLOGIST	13
BIOLOGIST	12
Risk Management Branch 1	
SUPERVISORY BIOLOGIST	15
LEAD ENVIRONMENTAL PROTECTION SPC	14
LEAD ENVIRONMENTAL PROTECTION SPC	14
ENVIRONMENTAL PROTECTION SPECIALIST	15
ENVIRONMENTAL PROTECTION SPECIALIST	14

ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
INDUSTRIAL HYGIENIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	12
Risk Management Branch 2	
SUPVY PHYSICAL SCIENTIST	15
LEAD ENVIRONMENTAL PROTECTION SPC	14
ENVIRONMENTAL PROTECTION SPECIALIST	14
BIOLOGIST	13
BIOLOGIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	12
ENVIRONMENTAL PROTECTION SPECIALIST	12
ENVIRONMENTAL PROTECTION SPECIALIST	12
ENVIRONMENTAL PROTECTION SPECIALIST	09
Industrial Chemistry Branch	
SUPVY CHEMIST	15
LEAD CHEMIST	14
LEAD CHEMIST	14
CHEMIST	14
CHEMIST	13
CHEMIST	13
CHEMIST	13
CHEMIST	13
CHEMIST	13
CHEMIST	13
CHEMIST	13
LIFE SCIENTIST	13
PHYSICAL SCIENTIST	13
Data Gathering and Analysis Division	
Immediate Office	
DIR, DATA GATHERING AND ANALYSIS DIV	00
SUPERVISORY BIOLOGIST	15
BIOLOGIST	15
MANAGEMENT ANALYST	15
Data Collections Branch	
SUPERVISORY BIOLOGIST	15
LEAD BIOLOGIST	14
LEAD PHYSICAL SCIENTIST	14
CHEMIST	15

CHEMICAL ENGINEER	14
ENVIRONMENTAL PROTECTION SPECIALIST	13
PROGRAM ANALYST	13
CHEMIST	12
BIOLOGIST	11
ENVIRONMENTAL PROTECTION SPECIALIST	09
Data Analysis and Dissemination Branch	
SUPERVISORY LIFE SCIENTIST	15
LEAD ENVIRONMENTAL PROTECTION SPC	14
CHEMICAL ENGINEER	14
ENVIRONMENTAL PROTECTION SPECIALIST	14
ENVIRONMENTAL PROTECTION SPECIALIST	14
BIOLOGIST	13
BIOLOGIST	13
CHEMIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
PROGRAM ANALYST	13
BIOLOGIST	12
ENVIRONMENTAL PROTECTION SPECIALIST	12
Prioritization and Informatics Branch 1	
SUPVY CHEMIST	15
LEAD BIOLOGIST	14
CHEMIST	14
BIOLOGIST	13
BIOLOGIST	13
BIOLOGIST	13
BIOLOGIST	13
BIOLOGIST	13
BIOLOGIST	13
CHEMICAL ENGINEER	13
EPIDEMOLOGIST	13
EPIDEMIOLOGIST	13
CHEMIST	11
Prioritization and Informatics Branch 2	
SUPVY PHYSICAL SCIENTIST	15
LEAD BIOLOGIST	14
LEAD TOXICOLOGIST	14
BIOLOGIST	13
BIOLOGIST	13
BIOLOGIST	13
CHEMIST	13
CHEMIST	13
CHEMIST	13
BIOLOGIST	12
Project Management and Operations Division	
Immediate Office	

DIR, PROJECT MGMT AND OPERATIONS DIV	00
SUPVY PROGRAM ANALYST	15
PROGRAM SPECIALIST	15
PROGRAM SPECIALIST	15
TSCA Information Management Branch	
SUPV INFO MANAGEMENT SPECIALIST	15
LEAD IT SPEC (PLCYPLN/DATAMGT)	14
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
IT SPEC (CUSTSPT)	13
IT SPECIALIST (SYSADMIN/CUSTSPT)	13
IT SPECIALIST (CUSTSPT/PLCYPLN)	13
PROGRAM ANALYST	13
ENVIRONMENTAL PROTECTION SPECIALIST	11
TSCA CBI Policy and Implementation Branch	
SUPVY INFO MANAGEMENT SPECIALIALIST	15
LEAD ENVIRONMENTAL PROTECTION SPC	14
ATTORNEY-ADVISER	14
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	11
ENVIRONMENTAL PROTECTION SPECIALIST	07
Project and Performance Management Branch	
SUPVY PROJECT MGT SPEC	15
LEAD PROJECT MANAGEMENT SPECIALIST	14
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
IT SPECIALIST (POLICY AND PLANNING)	13
IT SPECIALIST (POLICY AND PLANNING)	13
IT SPECIALIST (POLICY AND PLANNING	13
IT SPECIALIST (POLICY AND PLANNING	12
Stakeholder Engagement Branch	
SUPVY ENVIRON PROTECTION SPEC	15
LEAD ENVIRONMENTAL PROTECTION SPC	14
BIOLOGIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
IT SPEC (INET)	13
ENVIRONMENTAL PROTECTION SPECIALIST	09

June 24, 2021

The Honorable Chellie Pingree
Chairwoman
Subcommittee on Interior, Environment, and Related Agencies
House Committee on Appropriations
Washington, D.C. 20515

The Honorable Jeff Merkley
Chairman
Subcommittee on Interior, Environment, and Related Agencies
Senate Committee on Appropriations
Washington, D.C. 20510

The Honorable David Joyce
Ranking Member
Subcommittee on Interior, Environment, and Related Agencies
House Committee on Appropriations
Washington, D.C. 20515

The Honorable Lisa Murkowski
Ranking Member
Subcommittee on Interior, Environment, and Related Agencies
Senate Committee on Appropriations
Washington, D.C. 20510

RE: US EPA Safer Choice Program

Dear Chairwoman Pingree, Chairman Merkley, Ranking Members Joyce and Murkowksi:

We are writing to express our strong support for the Environmental Protection Agency's (EPA) Safer Choice Program and to encourage you to provide funding at a level that allows the program to be fully staffed and resourced.

In addition, we ask you to include the following report language:

> *The Committee supports the Safer Choice program and directs that the program be funded and operated at least at levels consistent with Fiscal Year 2014, adjusted for inflation.*

There is precedent for including supportive language on Safer Choice in your subcommittees' bill. The joint explanatory statement accompanying Division G of your FY21 bill included the following language:

> *The Committees support the Safer Choice program and direct that the program be funded and operated consistent with prior years.*

Similar language also accompanied the FY20 Senate bill. Despite this clear direction from the committee, over the last four years, resources and leadership have been drained from Safer Choice.

For most of its existence, this unique and valuable program was organized within its own branch, staffed with as many as 13 full-time employees, including a branch chief, toxicologists and chemists. In the last quarter of 2020, EPA announced a reorganization of the Office of Chemical Safety and Pollution Prevention (OCSPP) whereby the Safer Choice branch was dissolved and most staff were reassigned to other areas of OCSPP. As a result, the program is now severely under-resourced with approximately four full-time staff. New leadership at EPA has taken steps to restore the program, but the agency faces resource constraints. We urge you to fully restore the Safer Choice Program – a broadly supported, and impactful recognition program that helps drive a market for safer chemicals and products.

Companies across the value chain utilize the Safer Choice brand to advance their individual safer chemical initiatives – from brand owners to retailers to chemical manufacturers. For example, chemical manufacturers have invested in the difficult task of developing safer chemicals now listed on the Safer

Choice's Safer Chemicals Ingredients List (SCIL). Having chemicals on the SCIL allows these manufacturers to offer best-in-class safer chemicals to the market that carry the robust third-party verification of the EPA. Brand owners and product manufacturers have invested in Safer Choice by undertaking the similarly resource-intensive effort to reformulate products using the SCIL to obtain Safer Choice certification. Major retailers specify the Safer Choice label as a way to verifiably meet corporate goals laid out in public-facing chemicals policies.

The Safer Choice Program also provides value to entities outside of the supply chain. Numerous states and municipalities rely on Safer Choice because it is the only third-party program that requires all ingredients to be screened for hazards instead of simply using a restricted substances list. Several state and local governments specify Safer Choice labeled products in their purchasing contracts as well as point to Safer Choice in public education campaigns and outreach. Non-governmental organizations and consumers find significant value in an authoritative government program that can be trusted to vet safer chemicals and products.

We believe that the Safer Choice Program provides a unique space for product innovation while maintaining high standards for health, safety, and functional use. Safe products that work are increasingly important as consumer awareness and concerns grow about the potential harm that many formulated consumer products can pose to their health and the environment.

The signatories to this letter represent a unique and broad group of chemical manufacturers, brand owners, environmental NGOs, states and municipalities. We respectfully urge you to quickly restore the Safer Choice Branch and its staffing to their previous levels so that they may stabilize the program and serve the constituency they have worked hard to build over the last decade.

Sincerely yours,

ABC Compounding Co., Inc.
Aicello America Corp
Alternative Fuels & Chemicals Coalition
American Cleaning Institute
Amway
BASF Corporation
Belle Aire Creations
Berkley Green
Beyond Benign
Booyah Clean
Breast Cancer Prevention Partners
California Green Business Network
Canberra Corporation
Cascadia Consulting Group
ChemFORWARD
City of San Francisco
City of Santa Monica
Clean Control Corporation
Clorox Company
Cole Hardware
Cradle to Cradle Products Innovation Institute
CRC Industries, Inc.
Defunkify
DeltaGreen Products, Inc.
Diamond Chemical
Earth Friendly Products, ECOS
Ecolab, Inc.
ECOS
Envirocon Technologies Inc (Lemi Shine)
Environmental Biotech International

Environmental Council of the States

Environmental Defense Fund

EPA R7

GOJO Industries, Inc.

Green Chemistry & Commerce Council

Green Life Development, Inc.

GreenBlue

Hartz Mountain Corporation

Henkel

HLF Diversified Inc.

Holloway House, Inc.

Household & Commercial Products Association

IFF

Industrial Chemical Solutions, LLC

inShield Wiper, LLC

ISSA-The Worldwide Association for the Cleaning Industry

Itaconix Corporation

Jelmar, LLC

Lauren Kuby, Tempe City Council

Levi Strauss & Co

Lighthouse for the Blind

McFadden and Associates, LLC

Michigan Sustainable Business Forum

Minnesota Pollution Control Agency

Momar, Incorporated

National Pollution Prevention Roundtable

National Retail Federation

Native Green

OMI Industries, Inc.

Oregon Association of Clean Water Agencies

Oregon Department of Environmental Quality

Osprey Biotechnics

Pollution Prevention Resource Center

Procter & Gamble

PROSOCO

PurposeBuilt Brands

Reckitt Benckiser LLC

Safer Chemicals Healthy Families

San Benito County Integrated Waste Management

Sapient Living LLC

Scientific & Regulatory Consultants, Inc.

Sensitive Home

Sozio Fragrances

Sozio, Inc.

Spartan Chemical Company, Inc.

SSB IP Holdings LLC

State Industrial Products

Stepan

Sunshine Makers, Inc.

Sustainable Works - Green Business Program

The Ashkin Group LLC

The Hate Stains Co.

ToxServices LLC

Vi-Jon, LLC

Vinagreen, LLC

West Michigan Sustainable Business Forum

Wexford Labs, Inc.

Whisk Products, Inc.

Women's Voices for the Earth

Senator CARPER. Thank you again for joining us. Thank you for that testimony.

I will start off and then yield to Senator Capito and Senator Inhofe and others who join us.

You may not be surprised to know that we have heard from many chemical companies that the new chemical review process at EPA has essentially stalled. This goal to complete these reviews under the Lautenberg Act amendments to TSCA, as you know, set about 90 days. With the resources you have, how long is it taking to complete these reviews?

Ms. FREEDHOFF. Thanks very much for that question. The answer is it depends on the chemical, because some are more complicated than others to review. But I would say that for the entirety of the last 6 years, the agency has had typically 200 to 300 new chemical submittals that are waiting for agency action, and our backlog, so to speak, is the same as it has been for just about the last 5 years.

Senator CARPER. If Congress provided the full $64 million boost requested in fiscal year 2023 for our chemical programs, would that enable you and your team to meet this target?

Ms. FREEDHOFF. I think it would sure help a lot. The truth is that the New Chemicals Program is even more challenged than the rest of TSCA. Before the law was changed, EPA only had to do reviews on about 20 percent of new chemicals that came into the agency. After the law was changed, EPA had to do 100 percent.

Not only did the last Administration fail to ask for any more money to complete what is about five times the amount of work, they actually cut the New Chemicals budget by about 15 percent by moving the staff over to work on existing chemical risk evaluations instead. So that is why we are operating with less than 50 percent of what we think we need to review chemicals both quickly and protectively. It is why we only have two human health assessors to review the hundreds of new chemical submittals that come every year, and it is why we will continue to struggle with these new chemical reviews until we are able to get the toxicologists and other health experts that we need on board and trained and ready to do work.

Senator CARPER. All right. Is there anything that the chemical companies can do when they submit their applications that might help the process move more quickly?

Ms. FREEDHOFF. Actually, there is, and I appreciate you asking that question. I think, a lot of times what happens is that companies don't give us all of their data up front, and so they will give us something, say, 30 days in or 60 days in, and then we have to basically restart the clock and redo the risk assessment.

That doesn't just hold up the line for that particular company, it holds up the line for everybody else, because everybody is stuck behind them waiting for their work to be redone with the new information.

One thing that we are actually doing and are getting ready to announce in the coming days is, we actually took a look at the types of data that companies weren't giving us up front and analyzed the reasons for delays in reviewing those companies' new chemical submittals. And we are going to do some pretty aggressive

educational outreach to industry so that they can know what would help us get the work done more quickly.

Senator CARPER. OK. We appreciate your candor with respect to the budget situation facing the TSCA Program. We fully support getting the agency the resources that you need to properly implement this important piece of legislation to protect our communities against the risk from toxic chemicals.

I have two questions, then I am going to yield to Senator Capito. Would you just give us a sense of what EPA will and won't be able to do under TSCA if you do not get the additional money and people requested for fiscal year 2023?

Ms. FREEDHOFF. Absolutely. It is important to remember, before the law was changed, EPA did zero comprehensive risk evaluations under TSCA. After the law was changed, EPA was on the clock to do 10, and then that doubled again to about two dozen now. If we don't get the resources, we will not be able to do even half of those before 2025.

Before the law was changed, EPA did zero comprehensive rules on existing chemicals because of the failed asbestos ban. We are now writing 10 different rules, and without the additional resources that are in the President's budget request, we will only be able to get a handful of those on the books until 2025 or beyond.

With new chemicals, we will continue to occasionally be hindering innovation and preventing the chemicals that are needed to power the Nation, semiconductor, biofuels, battery, and other sectors onto the market as quickly as industry expects and as quickly as the law says.

There are real consequences, not just to people's health because of the delays for protections to be put into place, but there will also be delays for industry for them to get their new chemicals to market.

Senator CARPER. One last question, and then I will yield to Senator Capito. Will the funding and personnel included in the fiscal year 2023 budget take care of the entire program, or is this a down payment that is going to take several years to pay off?

Ms. FREEDHOFF. I think it is like any business. We have had 6 years of budgets that were far too low. It is going to take time to dig out of that hole. I do think that any large, new venture requires a sustained level of resources and requires a sustained level of effort on the agency's part the increase its efficiencies and find ways to work smarter, not harder. We are committed to doing our part of that as well.

Senator CARPER. Thank you so much.

Senator Inhofe.

Senator INHOFE. OK. Michal, first of all, it is nice to see you again. It is kind of funny because we have always gotten along famously in spite of the fact that we disagree probably on more things than we have agreed on, but on the other hand, it has worked very well. I remember, and it was called to our attention a few minutes ago by Senator Carper, that I chaired this Committee back during the time that we were really busy on the thing, and of course, on the Lautenberg bill, another person that we are very fond of and worked very closely with, but we were able, in fact, when we would have our meetings, the Republicans would

have a meeting once a week. They would get around to me at that time. I think you were with Barbara Boxer at that time.

I commented to them, I said, no, from the Committee that actually gets things done, that was us, and we did. In fact, you got along famously with Ryan Jackson, Alex Hergott, Demetri, and all of these people. They really felt a very close relationship with you.

We have some problems, and I have to say this, which will make it a lot easier than repeating it all. I think that Senator Capito, came out, and I agree with the comments that she made and the problems that we are having. I have talked also, as has the Chairman, to areas where we are having problems.

I had questions that I was going to ask you, and I would do it, knowing full well what the answers will be. One was, Dr. Freedhoff, do you agree that delays in the new chemical review process are hampering innovation and will contribute to supply chain constraints and inflationary pressures?

Ms. FREEDHOFF. I do agree that delays in the new chemical review process are delaying the introduction of new chemicals into commerce, but I am not sure I fully understand how a chemical that isn't yet in commerce could be causing supply chain problems. That said, we want to do better, and I am committed to doing what Congress expected us to do, which was to review new chemicals protectively and quickly, and I think we do have to do both of those things. Speed is important, and we want to do better.

Senator INHOFE. Yes. In your opening statement, you commented on your frustration with not being able to get, I think you only got one out of 10 of the list of 10 that were in there. So do you really believe the system that we are using is the best system? There could be a frailty in that system that is causing some of the problems that you talked about that need heavier funding.

A lot of us believe that the EPA has had kind of the hog's end of the funding for a long period of time. I know that you didn't agree with the previous President with what he was trying to accomplish, but on the other hand, there has to be an answer. And right now, I don't know how you can just go to the funding and say that that is where the problem is going to be resolved.

What things, other than just the funding, what could be done better, more efficiently, to crank out more stuff than we are cranking out right now?

Ms. FREEDHOFF. I appreciate you asking the question, because you are absolutely right. It is incumbent on the agency to try to find ways to do things faster and better. We are doing that.

One example in the new chemical space was our biofuels initiative, because we noticed we had several dozen biofuels applications in. And instead of treating them all as entirely new things and giving them to different members of the team, we actually created a dedicated team and streamlined the review of those submittals so that we could get them out more quickly.

Then, we are looking at different sectors as well, where we have a lot of applications for the same types of chemistries coming in, seeing if there are ways we can streamline, write down the process, and then the next risk assessor that sees a chemical like that doesn't have to start from scratch.

We are building up our training, we are investing in the IT, the actual infrastructure of the agency, because one thing that has hindered the new chemicals program for years is basically crumbling information technology that crashes, in some cases, for weeks at a time. Whenever that happens, the new chemical staff can't do any of their work. We are actually investing some money in making sure that those systems are modernized.

We are also trying to standardize our training, write down more of our standard operating procedures in a way that is easy for a new risk assessor to understand, and we are working with the Office of Research and Development to modernize our scientific approach to reviewing these new chemicals.

Senator INHOFE. I had a question that was written down here. It is a complicated question, so I have chosen that to ask you so I can hear your complicated answer. How can you then justify regulations of chemical substances based solely on benefits to carbon dioxide and exhaust particulate matter emissions from the manufacturing of the substance, rather than exposures to the chemical substance itself?

Ms. FREEDHOFF. The law tells us to do risk evaluations to look at whether there is risk to human health or the environment from a chemical substance under the conditions of use. The law doesn't say that it can only be some types of exposures or some types of uses. The law really pushed the agency to look comprehensively at the risk that a chemical substance posed.

Senator INHOFE. OK. Now, what I am going to do, I do want to hear the questions and comments that will be made by Senator Capito. As you might know and you might not know that I am doing the Defense Authorization Bill right now, and that is what I am holding up.

But I just want to hear more about what kind of, and try to analyze myself, knowing the successes that you and I and those of us here at this table have had in the past, so I can try to analyze why we can't do a better job in terms of cranking out more stuff and getting it done. I am concerned what is going to happen to a lot of this stuff. Is it going to go overseas, because there are a lot of unhealthy results and the problems that we are having right now, so I thank you for that.

Senator Capito, I want to hear more of your comments.

Senator CARPER. Senator Capito. Thank you.

Senator CAPITO. Thank you. I am sorry I missed your statement. I had to go over to Commerce, so it is just one of those days, which I am sure you, beyond many people, would understand that.

Obviously, from my statement, it is clear from the data that the new determinations have slowed significantly. What steps are you taking to improve the pace at which these new chemical determinations are issued?

Ms. FREEDHOFF. I appreciate the question. And it is certainly true that our new chemical reviews have been slow for more than 5 years. And we have just about the same number of chemicals that are waiting for EPA approval than has historically been the case over the past several years.

I will note, we also have 15 percent of a smaller staff, because 15 percent of the new chemicals risk assessors were permanently

moved into the existing chemicals risk evaluation division toward the end of the last Administration. So from day one, we actually had less than what both the Obama administration and the Trump administration had for new chemical reviews.

That said, I completely agree that EPA has responsibilities. It is not just about asking Congress for money and continuing to do things the same way, and I 100 percent agree with you. So there are a number of things that we have done already.

One is the biofuels initiative that we rolled out a couple of months ago, where we streamlined the review of those types of chemistries, because we had several dozen different biofuels applications in front of the agency. And we realized that by creating a dedicated team where the same people were always reviewing that type of chemistry, and by streamlining the review of those chemicals, we could get more of them out the door more quickly than if we treated every one like its own new thing over and over again. And we will be expanding that type of initiative into other sectors in the coming weeks and months. We are just trying to sort of narrow our focus there.

I think one thing that we have noticed over the years is that companies often don't give us everything we need to do a risk assessment that they feel reflects the real world conditions.

Senator CAPITO. OK, so let me stop you right there, because isn't that on everybody's plate there? Why are they not giving you what you want? Are you telling them what you want in a timely manner so you can hit these deadlines?

Ms. FREEDHOFF. I think we are realizing that is part of the problem. The problem is us. I think that we are, so we did an analysis of why we have to rework so many risk assessments, and it turns out that what happens is, sometimes, after a couple of months, a company will come and say, oh no, I am not planning on releasing this to water, or oh, I am not making this way, your risk assessment is wrong. We will say, OK, give us the data, but then we kind of have to start over again from scratch and redo the risk assessment, and that causes delays, not just for that company, but for all the companies waiting behind.

What we are about to do is release the results of that analysis that kind of lists and documents the type of information that will help us if we get it on day one, and we are going to do some pretty aggressive and proactive outreach to companies to make sure that they understand what our data needs are. And we are really hoping that that helps us work more quickly as well.

Senator CAPITO. Well, I do know that you have had a lot of outreach to companies and that there is a very open door there, so that is very much appreciated by everybody.

If you have a 15 percent smaller staff over the last year and a half, have you hired into those positions?

Ms. FREEDHOFF. So, the 2022 Appropriations Act gave us a modest number of new hires.

Senator CAPITO. Can you not fill in the 15 percent?

Ms. FREEDHOFF. We have only had that many for a couple of months because I think our spend plan was only approved a couple months ago. So we have done and we are doing an aggressive recruitment strategy. We have either hired or selected or somewhere

in the process about three-quarters of the people that the 2022 Appropriations Law lets us hire.

I want to say to you, because it is true, rebuilding the New Chemical staff is my No. 1 personal priority, and there is not even a close second.

Senator CAPITO. Let me skip to, this is kind of my own personal bugaboo, and I think it is the work from home scenario. So EPA's YouTube channel on April 22nd had a YouTube that said EPA future of work: Tips and tricks, and I have talked to the EPA Administrator about this, returning to work. You said in that, I am so looking forward to meeting as many of you as I can. What does that mean? Have you not met them?

Ms. FREEDHOFF. I hadn't met them in person.

Senator CAPITO. Are they back now?

Ms. FREEDHOFF. Many of them are back. Many of them are teleworking more than they did before. Some have applied to be permanently remote work. I have to say, I think the entire country is reimagining the way its work force is designed following COVID. I think the West Virginia State legislature just wrote a report that sounds much like what EPA has experienced. And I think what they said was that telework has proven to be beneficial and productive as a routine part of conducting the business of the State. It is beneficial.

Senator CAPITO. I am not disputing telework, but if I had an organization that was falling way behind, I think I might be roping people back to the office and saying, look, it is not working this way. I understand it is a capacity thing, and I am not here to beat up on you. I want to help the situation, move it quicker, like you do.

But I did find that, when you have that lack of connection, there is also a lot of stories out there, the lack of connection in work or people doing other things at certain times of the day when you are principally engaged is a problem. But you are right. That is a bigger problem than what is going on in your office.

Ms. FREEDHOFF. I agree with you. It has been great to meet my staff in person. There are intangible benefits associated with in person meetings and walking down the hallway and seeing people. I have really enjoyed it.

Senator CAPITO. Let me ask about PFAS really quickly, because I know you know a lot about this. There are several definitions, I guess, at EPA on PFAS. Do you think a clear and consistent definition would be useful for the EPA?

Ms. FREEDHOFF. Thanks for that question. I do think so. The definition that EPA used in its rule that Congress actually is requiring us to do to collect historic information about the ways PFAS is made and used, that definition was first written by my office in 2006 for purposes of the TSCA New Chemicals Program. We then proposed to use that definition in that rule, and after we proposed it, the OECD, an international organization, proposed a much broader definition.

We are now kind of looking at the public comments that we got on that rule, and we are looking to see what a more robust definition might look like, and whether we should be adding additional PFAS to our original proposal for that rule.

Senator CAPITO. I think uniformity, obviously, is easier, and if you are having issues with meeting deadlines, and having clear roadmaps are always much, much more beneficial. But apparently, Radhika Fox, when she testified before the Committee, said that EPA was not going to be developing a uniform definition.

I have gone over my time, and I see we have some other members here, so I will stop here. Maybe we can get back to this. Go ahead.

Ms. FREEDHOFF. Can I get 30 seconds here?

Senator CAPITO. Sure.

Ms. FREEDHOFF. I think what OECD said was, they created a really broad definition for PFAS and then said that individual regulators might do different things. For example, a definition that would work for the Water Office would properly be focused on PFAS that would be expected to be in water, whereas a definition that worked for the TSCA Office might be one for PFAS that are expected to be manufactured and processed.

I do think there will be some differences, but I think it is important to think about what we all mean when we say that something is or is not a PFAS.

Senator CARPER. I believe we have been joined, by Webex, by Senator Padilla.

Are you there, Alex?

Senator PADILLA. Yes, I am.

Senator CARPER. You are recognized for any questions or comments you have. Go ahead, please. Thanks for joining us.

Senator PADILLA. Thank you, Mr. Chairman. Greetings from the Judiciary Committee. Double duty here.

Dr. Freedhoff, I would like to ask you a question about how the use of supercomputing and computational toxicology could assist your office with the assessment of new chemicals under TSCA. Existing programs, as you know, that address environmental risk and consumer product exposures rely on scientific data, but generating this data can often be slow, costly, and rely on animal testing.

I believe we can improve this by using supercomputers to run models to better predict adverse health effects caused by chemicals and to identify safer chemicals before they are in use in manufacturing. I have been working to advance legislation to create a consortium referred to as "Supersafe" to be comprised of Federal agencies, including EPA, HHS, and DOB, along with State agencies and academic and other research institutions with similar capabilities to supercomputing and machine learning to establish rapid approaches for large scale identification of toxic substances and the development of safer alternatives.

This Supersafe Consortium would develop and validate computational toxicology methods to predict adverse health effects caused by toxic substances and identify the safer chemical alternatives for use before we have widespread chemical pollutions in air, water, land, and consumer products.

With that as the background, Dr. Freedhoff, how would a Supersafe Consortium assist EPA in assessing new chemicals under TSCA, and would such a program be helpful to your efforts to review new chemicals and bolster the use of good science in EPA's decisionmaking?

Ms. FREEDHOFF. Thanks very much for that question. I think the answer is pretty simple. We are excited by any new scientific tool that can speed up our reviews and help us meet our obligation to reduce the use of animal testing under TSCA.

We have recently started a collaborative research program with the Office of Research and Development, and we are making some similar efforts to try to modernize the models and the other scientific tools that we are using for new chemicals. And the project that you are describing, I think, would be a really good complement to that.

Senator PADILLA. That is getting a little technical on you, but that is what happens when you have some scientists and engineers in the Senate and serving on this Committee.

Ms. FREEDHOFF. I hear you.

Senator PADILLA. Just one follow up to the Supersafe Consortium concept. As you know, TSCA also requires that EPA reduce and replace the use of vertebrate animals in the testing of chemical substances to the extent that is practicable and scientifically justified. So can you talk just for a minute on how a Supersafe Consortium and the use of these computational tools and models help EPA meet these TSCA mandates?

Ms. FREEDHOFF. I think it would be a huge help. I think we are working to develop similar models and tools to reduce the use of animals in the TSCA Program, and any additional help we could get through the type of consortia that you are contemplating, I think, would be very appreciated.

Senator PADILLA. OK. Well, thank you very much. I look forward to following up with you on that.

I do have other questions, but they seem to overlap with a question that has been raised by other members of the Committee, so with that, Mr. Chairman, I will yield back.

Senator CARPER. All right. Thanks, Senator Padilla.

I think Senator Markey is next.

I don't know that you have ever met Dr. Freedhoff, but does she look familiar? How many years did you work for her?

[Laughter.]

Senator MARKEY. I think I worked for her for 16 years, and I think you worked for her for 4 years, yes. I think that is how it broke down.

So, one particular area where additional funding and staffing would be very beneficial is tackling biphenyls, or PCBs, which have been linked to cancer, immune effects, and other health harms. Around one-third of all school aged children may be exposed to PCBs through their school environments, with more children likely being exposed through daycare and other facilities, which is why I introduced the Get Toxic Substances Out of Schools Act.

Dr. Freedhoff, would additional budgetary support help your work with States or local educational agencies to better understand and work on the risks that toxic PCBs pose to children?

Ms. FREEDHOFF. Thanks very much for that question. And that is an issue that comes up repeatedly whenever I talk to the regional staff, because they are in the position of hearing from schools, in some cases, where the lighting fixtures are so old that the PCBs are literally dripping out of them and exposing people.

And the schools often lack the technical expertise that they need to be able to address and mitigate the problem. So in the 2023 budget request, we do have a modest amount of money that is designed to augment those efforts in the States.

Senator MARKEY. As Dr. Freedhoff knows, back in 1979, a woman, Annie Anderson, came into my office with her 3 year old boy, Jimmy, who had leukemia. She was in Woburn, Massachusetts, and everyone was ignoring her.

Ultimately, it became a movie, a civil action with John Travolta playing the lawyer, but in fact, it was Annie Anderson and the mothers who were the heroes. That is who the movie should have been about. And they identified the TCE that was ultimately the cause for those cancers in all of those children. Superfund was largely driven by that Woburn and by Love Canal in terms of it going on the books in 1980.

We are still, now, dealing with the funding issues. How are we going to provide for the protections for these devastating cancers so that more children aren't exposed to them? The Trump administration undermined the EPA risk determination of TCE by refusing to look at all the negative health effects on pregnant women and children.

Dr. Freedhoff, how is your office working to protect families from the dangers of TCE?

Ms. FREEDHOFF. I really appreciate you asking me that question, because of all the chemicals that we are writing rules for under TSCA, TCE is the one that feels the most personal to me. And that is because of my work for you. He already told you some of the history of Anne Anderson with her little boy, Jimmy, and I was rereviewing that case, that whole story, a few months ago in preparation for an agency meeting on TCE. And I tell you, I was blown away to realize that Jimmy Anderson would have been just about exactly my age, had he not died when he was 12 years old.

In the four decades since he died, we have managed to regulate TCE under the Clean Air Act; we have managed to regulate it under the Safe Drinking Water Act; we have managed to regulate it under the Superfund Law, but we have yet to regulate its manufacturing use under TSCA. If there is one thing that drives me every day in this job, it is knowing how important it is to get that rule on the books.

Senator MARKEY. Yes. It is absolutely critical, and again, there was always a lot of denial in the chemical industry on that issue.

By the way, it was one of the first Superfund cleanup sites, and now it is called the Jimmy Anderson Transportation Center. It is where we built an incredible, industrial, commercial, and transportation center up there, named after that little boy.

If you could just briefly touch on asbestos. We fought hard in 2016 to have asbestos included in that TSCA rewrite bill, and it was with the great hope that we would be able to see enormous progress made on asbestos, and ultimately, to see it banned. A lot of the countries in the rest of the world have done so.

Can you talk about the progress you are making on that issue, and what additional resources you might need in order to accomplish that goal?

Ms. FREEDHOFF. Absolutely. Thanks very much for that.

Asbestos, symbolically enough, was the very first rule that we proposed that came from the risk evaluations under the new TSCA Program. We did propose a ban on the ongoing uses of chrysotile asbestos. We are taking comments on that proposal now, and we will be looking to finalize it sometime in 2023.

As you might remember, the last Administration chose to exclude other fiber types of asbestos, as well as legacy uses of asbestos, from that risk evaluation. A court found that the agency had improperly excluded those uses and types. So we are doing a second part of the risk evaluation as a result, and that will be done by December 2024.

Senator MARKEY. Thank you so much.

And Mr. Chairman, that issue is personal to me as well. My staff director, Joe Zampitella, his father was the head of the Asbestos Workers in Massachusetts in the 1970s and 1980s. I only had two unions endorse me in my first race, the Asbestos Workers and the Teachers, when I ran for Congress.

Ultimately, Mr. Zampitella passed away in 1986 from asbestos. One of the most powerful images I can ever remember is an entire church filled with asbestos workers, all sitting there, row after row after row after row, because he was the leader of the union, and he had asbestosis, and he had just passed away.

For so many of them, they realized that would be their fate as well, because there had been no protections that had been put on the books.

We just have an obligation to finish this job on asbestos. I thank you, Dr. Freedhoff, so much for all of your great work on that.

Senator CARPER. Senator Markey, thank you so much for joining us.

I think next in line of questioning is Senator Kelly. I believe he is going to be followed by Senator Whitehouse and Senator Sullivan. I think that is the order.

Senator KELLY. Am I up?

Senator CARPER. Senator Kelly, I think you are up. Go ahead.

Senator KELLY. Right, thank you, Mr. Chairman.

Dr. Freedhoff, thank you for being here today. I want to begin by discussing the latest drinking water advisory level for PFAS chemicals, and how that impacts the work done by your office to develop national strategies for PFAS testing and tracking PFAS which are still in use.

As you know, last week, EPA updated the lifetime health advisories for two of the most pervasive PFAS chemicals, PFOA and PFOS from 70 parts per trillion to 4 parts per quadrillion for PFOA and 20 parts per quadrillion for PFOS. These updated guidelines are significant for the more than 20 communities in Arizona which have recorded levels of PFAS at or above these levels.

As I understand it, we don't have testing technology which can detect PFAS in quadrillions yet, meaning many more communities could also be vulnerable, more than the 20 in Arizona.

Dr. Freedhoff, I understand that your office is responsible for developing a national strategy to test for PFAS. How do the new lifetime health advisories affect that work?

Ms. FREEDHOFF. Thanks very much for that question, Senator Kelly.

Our testing strategy is really about the thousands of PFAS that we don't know enough about to write health advisories or regulate in some way, because, as you know, there were thousands that were allowed into commerce or historically made or used in this country. And if we try to study them one by one by one by one, we will never get the answers that we need in order to take action on the ones that need action taken on.

What we did was we divided those thousands of PFAS into categories based on their structure and other chemical properties, looked at the categories for which we had no health information, because that is clearly the most important question, is, what does this type of PFAS do to your body if you are exposed, and we are designing a testing strategy designed to fill in those data gaps.

Our first test order went out a couple weeks ago. It was for a PFAS that is found in firefighting foam and other products. And when we get the data back for that chemical, it will help us understand more about the human health effects of 500 other PFAS that are similar to it.

I think there is not exactly a connection between health advisories and our testing strategy, but our testing strategy is designed to fill in the holes on human health data that exist for so many PFAS.

Senator KELLY. Are you confident you are going to be able to develop the tests necessary to detect in the quadrillions?

Ms. FREEDHOFF. We are not testing that way. What we are doing is we are using our authority under TSCA to tell companies to give us information and data about the chemical. So sometimes it is doing modeling to show us what its effect would be. Other times it might be animal testing, if we need to pursue animal testing. Other times, it is information about whether the chemical dissolves in water and would therefore be likely to be in drinking water.

Senator KELLY. So then, my understanding is, as we test drinking water, we are still going to be testing in the parts per trillion, and the only way we are going to know if somebody is exceeding the lifetime health limit in the quadrillions will be on the data you get from companies that manufacture these chemicals?

Ms. FREEDHOFF. I think it is a slightly different question. I think, sort of taking a step back, I think EPA has historically written a couple hundred different health advisories for drinking water over the years, and for information on these particular ones, I would say that the Office of Water probably has more answers than I have.

I think, maybe one way to think about it is to think about the lead rules. It is generally accepted that there is no safe level of lead, and so the goal for lead in drinking water is zero.

Senator KELLY. Yes, I got you.

Ms. FREEDHOFF. But the rules are what factor in the detection levels, how to detect it, and how to treat it, and how to remove it. I think that is what you will see. That is sort of the difference between a health advisory for PFAS and a rule for PFAS.

Senator KELLY. I got it. I am going to have my office follow up with yours on this to make sure that, because these 20 communities, we know that the level is above what you just set the lifetime health advisory for, so we need to figure out how we are going

to clean up this water. The drought situation we are facing in Arizona right now is so critical that, at some point here, in the near future, some communities are going to be relying on groundwater, and we have to make sure that water is clean. So thank you.

And thank you, Mr. Chairman.

Senator CARPER. Senator Kelly, thank you so much for joining us.

Now, live from the great State of Alaska, Senator Sullivan.

Senator SULLIVAN. Thank you, Mr. Chairman. Thank you very much.

Dr. Freedhoff, I want to just begin by commenting. You have a lot of experience with this Committee, correct?

Ms. FREEDHOFF. Yes.

Senator SULLIVAN. And TSCA?

Ms. FREEDHOFF. Yes.

Senator SULLIVAN. I would like to begin by complimenting the Chairman and the Committee's culture here of getting things done, big things done, big, important pieces of legislation. I have been on this Committee since I first came to the Senate over 7 years ago.

We have our debates, and we have our disagreements, but we manage to actually produce legislation like TSCA. This is the first Committee that Senator Whitehouse and I started our series of Save Our Seas Act legislation, which are very important laws, and the Infrastructure Bill. And there is a lot that has happened in this Committee that I think benefits the country and shows our fellow Americans that the Senate can work in a bipartisan way.

With that, the TSCA Bill was actually one of the first major pieces of legislation that I worked on as a new Senator in 2015, and I know that you were a part of that. I think it was a really good effort. But one thing that I am concerned about now is, I worry that it might be in line to be subject to abuse.

Let me give you a little bit of context. The Biden administration is encouraging agencies that have no legislative mandate to regulate the energy sector, choke off capital to the energy sector, whether it is the Federal Reserve, for goodness' sakes, whether it is the SEC, the Chairman of the SEC put out an 800 page rule all about climate change, and he committed to me during his confirmation process he wasn't going to do that. He is doing it.

Comptroller of the Currency, who was nominated by this President, said she wanted to put oil and gas businesses out of business. The Comptroller of the Currency, what the heck does she have to do with it? So you have this major power grab, and of course, this is contributing to $6 a gallon gas, which is crushing working families in America and Alaska and West Virginia.

I was concerned to read about one of these extreme far left groups that just petitioned the EPA to use TSCA as a way to phase out fossil fuel production, use, and disposal. Now, you and I worked on TSCA together. We all worked on TSCA together. I was involved, but I am pretty darned sure that I would have noticed a provision that somehow gave EPA authority to do something like that.

An article called this group's filing to the EPA a "novel approach" to TSCA. That is a nice way of saying that TSCA did not give the EPA the authority to try to phase out fossil fuel production.

Can you just definitively agree with me on that, saying that, no, TSCA was not focused on that, we are not going to let that bipartisan law be abused in ways that other Federal agencies and the Biden administration are abusing their power to try to shut down American energy, which hurts our national security, hurts working families, drives up gas prices at the pump.

Could you agree with me on that? You helped write this law. You did a great job. This Committee did a great job, but this Committee did not contemplate using TSCA to phase out energy production in America. Do you agree with that?

Ms. FREEDHOFF. I do agree that the purpose of TSCA was not to phase out energy production in America.

Senator SULLIVAN. And will you look at the petition, I forget which radical group filed it, with the discerning statutory authority of the EPA, which was not intended? You helped draft it; we all worked on it together. It was not intended to do that. Novel or not novel, would you agree with me on that as well?

Ms. FREEDHOFF. I think I will just sort of take a step back. First of all, we just received the petition. We haven't reviewed it. We have an obligation to review it, and we have an obligation to respond. So we will do that. I will also say that we do, as an Administration, believe that climate change is an urgent threat, but when we wrote TSCA——

Senator SULLIVAN. But was TSCA really focused on climate change? It wasn't.

Ms. FREEDHOFF. Climate change was not debated when we negotiated TSCA. That is absolutely the case.

Senator SULLIVAN. Correct. I remember.

Ms. FREEDHOFF. What TSCA did say, though, was that for all the chemicals that are in commerce, EPA was supposed to study them all and put regulations in place when EPA found risk.

Senator SULLIVAN. Let me just, I know I am out of time, and I don't want to abuse this, but these kinds of back door regs, particularly when we all worked on it, we know that that is not what TSCA was meant to do. If you have a novel approach, you have the President of the United States quoted recently. He is all over the map, but we want to lower gas prices, we need to have more oil supply right now.

Geez, OK, that is different from what he said as a candidate, but I will take him at face value.

But I think this is a test from this White House. If they accept this petition as another Federal agency overreach to choke off capital to the American energy sector and then have the President say, oh, no, we are trying to help the American energy sector, no one is believing it. And this is going to be another test case.

I hope that you can read the statute with fidelity to what we agreed to here in this Committee in a good bipartisan way, but it wasn't meant to regulate the energy sector. By the way, neither is the SEC statutory authority. That chairman is way over his skis.

This Administration is hurting the energy sector, hurting American families. But I just hope you of all people take a hard look, because you know what this statute was about, and it wasn't about the regulation of the American energy sector. And I hope you reject this petition.

Thank you, Mr. Chairman.

Senator CARPER. You are welcome.

Senator Whitehouse, welcome.

Senator WHITEHOUSE. Thanks very much. I am extremely fond of my colleague, Senator Sullivan, and we work very, very well together on a lot of areas. But I have just got to offer some opposing views regarding some of the stuff that he said.

Senator SULLIVAN. I am shocked, Mr. Chairman. I am shocked. [Laughter.]

Senator WHITEHOUSE. For starters, when he talks about the American energy sector, he is talking about America's fossil fuel sector. If you look at America's energy sector, the Biden administration is working very hard to grow as fast as we can the renewable energy that we need for the future, because climate change is an actual thing, and the transition has to actually happen.

I know that there are a lot of people, and particularly the industry, doesn't want climate change discussed by financial regulators, but for Pete's sake, every major central bank has sent out financial warnings about what climate change is going to do. Freddie Mac has warned of coastal property values crash, cascading through the economy worse than 2008. We have the major corporate folks, most recently Deloitte, coming out with a report talking about a multitrillion-dollar swing between getting it right on climate and getting is wrong on climate.

So the fact that financial regulators are paying attention to this shows nothing more than that they are paying attention. Of course they are paying attention to this.

As for the petition being filed by extreme environmental groups, the guy's name is Henson. He was the top scientist for NASA. NASA got stuff driving around on the surface of Mars. Their scientists are actually pretty good at stuff, and his testimony first came out in this room with a Republican Senator chairing it, John Chafee of Rhode Island, so I take this a little bit personally. And facts have proven his testimony in this room all those years ago extremely, extremely accurate. There is my counterpoint to my friend Dan Sullivan's point.

With respect to TSCA and paying for it, we gave EPA authority to levy fees to target that 25 percent of the program would be covered by industry contributions. What percentage is now covered by user fees?

Ms. FREEDHOFF. Far less than that, actually, Senator. And the fees rule was one of those implementation challenges that I am hoping we can course correct on, because the first fees rule didn't kick in until fiscal year 2019. It actually excluded all of the costs of the first 10 risk evaluations, which was the most expensive thing the agency was working on on TSCA at that time.

As a result, it only collected about 12 or 13 percent of our costs, not the 25 percent that Congress expected and that every stakeholder supported. So in the 2022 Appropriations Bill, Congress directed us to write a fees rule that would reflect the actual cost of implementing TSCA, and that is what we are planning on doing.

Senator WHITEHOUSE. OK. Where are you in that process? Where are you with redoing that?

Ms. FREEDHOFF. We are close to being able to send a supplemental proposed rule to OMB in the next couple of months. There was a proposed rule that went out toward the end of the last Administration, but it exempted the costs of rulemaking, so it needs to be supplemented in order to do what it was intended to do.

Senator WHITEHOUSE. You think it will get to OMB by when?

Ms. FREEDHOFF. I think it will get to OMB sometime this summer or fall, and we are hoping for it to be finalized before fiscal year 2024.

Senator WHITEHOUSE. OK. Good. Well, I have used a good deal of my time.

Senator CARPER. It was time well used. Go ahead.

Senator WHITEHOUSE. With Senator Sullivan, but I would remind the Committee that there are a lot of people who don't seem to take climate change seriously, but for me and for Chairman Carper, who come from coastal States and not very big ones. We are looking at actual projections supported by Federal and State government that are unrebutted that we are going to have multiple feet of sea level rise along our shores. We have got maps that show that people who live on Warwick Neck in Rhode Island are going to be living on Warwick Neck Island soon, that people who live in Bristol are going to be living in Bristol Island soon. We have major thoroughfares that are going to be flooded out, which are also the escape routes from flooding.

We have enormous, enormous risks and challenges ahead of us. We have enormous expenditures, and all you have to do is read the newspaper, whether it is wildfires or droughts or lost water out west or massive flooding. Things have gone haywire in the Earth's operating systems, and we know why. And to pretend that it doesn't have something to do with burning fossil fuels is just simply fictional, magical thinking.

We have to address it, and I hope we will. Thank you.

Senator CARPER. Thank you so much. Thanks so much for joining us, Sheldon.

Senator Capito, I have some more questions. Would you like to go first?

Senator CAPITO. Thank you. I would love that. Thank you.

I just wanted to clarify. I think you addressed this when you talked about how you are going to handle the PFAS issue, but I was wondering, do you intend to utilize a tiered approach? I think you said you would, to classifying PFAS by categorizing and prioritizing them based on different physical properties and hazards. Is that your intention?

Ms. FREEDHOFF. Yes, we are.

Senator CAPITO. OK. And I think that some of the confusion that we hear today is your office's role with PFAS as opposed to the health advisory that came out from the Water Office.

This, to me, having had PFAS in our water systems and shut down our local water systems overnight, the risk assessments and the risk communications are so extremely important. And so I am concerned that when you have one office from the EPA setting an advisory level, what does advisory mean to people? It means that if you are in that area, that it is unsafe, and they are planning to

come out with a safe drinking water level, which is going to be higher than the advisory level.

I know this is not your problem, but it is your problem, because it is a chemical. I don't know, how do you message that to people when you are trying to tell them what is safe and what isn't?

Ms. FREEDHOFF. I think you are absolutely right, that risk communication is important, and as a science based agency, we often speak scientifically and don't do as much work as we should, speaking from my part of the agency, at translating into words that people can really understand and access.

I think though, on the drinking water side, it is not that different from the lead rules, because the maximum contaminant level goal for lead is zero, because it is generally accepted that there is no safe level of lead. The rules do factor in detection limits and treatment techniques and other things that present barriers to actually getting to zero. And I feel like the agency managed that risk communication well, and I have confidence that the agency can also succeed in the PFAS space.

Senator CAPITO. OK. I am concerned, because obviously, what Senator Kelly was getting to is on the health advisory level, we can't measure that low, and so how do you know? You don't.

Let me ask you about the PPE, because I mentioned it in my statement with OSHA, and I think there is some concern that you are drifting into OSHA regulations where making assumptions that people aren't wearing PPE. So a chemical may not be safe in a water, but if they are fully gowned up and have protective equipment, it is safe to be in and around.

Why are you making assumptions that workers are not wearing their PPE? Isn't that OSHA's job, rather than yours? We have already discussed that your deadlines are last, so let us stay in our lane, I guess, is my message.

Ms. FREEDHOFF. I appreciate the question. First of all, the law tells us to look at potentially exposed and susceptible subpopulations, and that clearly has to include workers. While we are in extremely close contact with OSHA and NIOSH and are coordinating with them really well, we can't just assume that OSHA will work for everyone.

There are a few reasons for that. One is that OSHA rules don't apply to everybody. They don't apply to self-employed workers, and they don't apply to public sector workers who live in a State that doesn't have an OSHA approved plan, so that is reason No. 1.

Reason No. 2 is when you actually go on OSHA's website for the chemical specific standards that they write, the very first sentence of that website says that they are outdated and inadequate for protecting worker health, because they were written in the 1970s.

The last reason is, when you look at OSHA's top 10 most frequent safety violations, a list that they put out every single year, every single year, you see respirator, eye, and skin protections safety standards among those top 10 most frequent violations.

We can't just assume that OSHA is enough, and we can't just assume that OSHA is used and followed by everybody. But this is where that risk communication point you just made is so important, because we know that a lot of companies, especially the larger

manufacturers, go beyond what OSHA requires them to do when they are looking out for their workers, and we know that.

I think it is incumbent on the agency to make sure to communicate that when we write our risk evaluations, so that people aren't unduly afraid of an absence of a safety measure that is actually there at their facility where they work.

That is something that we do plan to do. As we move toward risk management, I think what we are striving for is consistency with OSHA rules when OSHA rules are enough, consistency with best industry practices when best industry practices are enough, and to basically level the playing field and make sure that everyone is protected, no matter who they work for or where they live.

Senator CAPITO. I think the goal of that, obviously, is what TSCA is about, but we have other agencies. My concern is to get to your core functions and to meet those obligations that are outlined very specifically in the law, and that you have additional, whether it is OSHA or somebody else, Clean Water, Clean Air, whatever, entities that are tangential to TSCA, important.

I am just concerned about, as the mission creep, or if you take on too much, you are not going to get anything done. I just put that on your table. I appreciate everything, you have been very candid in your answers. I appreciate your service. You are doing a good job. Thank you.

Ms. FREEDHOFF. Thank you.

Senator CARPER. I have a few more questions, if your schedule allows.

When I ran out of time for my question and yielded to Senator Capito, we were talking about resources, which you have been talking about literally all morning. I want to come back to this just for a minute. The question is regarding the fiscal year 2023 budget. And my question is pretty straightforward.

Will the funding and the personnel that are included in the fiscal year 2023 budget take care of the entire challenge of the problems you face in doing your job, or is this a down payment that will take several years?

Ms. FREEDHOFF. I think, in order for the program to work sustainably, it will need a sustainable investment of resources. It will need an updated fees rule, and it will need us to work on modernizing our approaches and streamlining them when we can so that we can make the costs of our work go down using the lessons we have learned over the past 6 years.

Senator CARPER. OK. With respect to work force, I suspect Senator Capito has experienced the same thing, I like to do customer calls in Delaware. A lot of them are to businesses.

Now that we are both back up for business here, we have a lot of folks who want to come and meet with us. Just before I came to this hearing, I had a significant American business that came in and talked about how they are doing and what their challenges are. And they said work force. They just can't find folks with the kind of training, the interest, and the will, the ability to do the jobs that they need to fill.

I hear that all over the country, all over the country. I am sure it is something that you face. Talk a little bit about the expertise that you are looking for to meet your ability to do your job. Talk

about the skills that you are looking for and are maybe find the hardest to fill. Is there anything, is there something that we need to be doing about the hiring process that exists?

We tried; I think we had a situation at the IRS that they took forever to hire people. Some good work has been done and that has been addressed, at least in part, but we need to focus on this. What can we do, what are the needs, the expertise, what are you looking for, and how are you trying to find it? What can we do to help?

Ms. FREEDHOFF. I appreciate the question. It is daunting to think about staffing up so quickly. We are putting together a pretty aggressive recruitment strategy, particularly for New Chemicals, because we don't just want a handful of toxicologists now. We want to build relationships with universities so that we have a steady stream of people that we can draw from to perform that role, because it can be a pretty specialized role.

I also think the Title 42 authority that Congress provided the agency with, which lets us hire a small number of much more senior scientists in a much more streamlined hiring process, is actually going to be really helpful to the agency moving forward. But I agree with you, we will need to really work hard to tell people how exciting an opportunity it is to come and work on a new law that has barely scratched the surface of its potential. I think that will be appealing to a lot of the Nation's younger scientists and engineers.

Senator CARPER. When I talk to people, a lot of times, at some point in our conversation, when they are talking about what they do for a living and their careers and all, and I will ask them, what gives you joy in your work. That is what I ask them, what gives you joy in your work.

A lot of times, what I hear from people, basically, is they like helping people. They like helping people. I think there is a great opportunity for folks who work with you, for you to help people, not just to help make sure that we are looking out for folks and their families on the safety side, but also to make sure that we are providing economic opportunity and job creation on the economy side.

The world has changed a lot since I was graduating from school and going off to be in the Navy in the Vietnam war. But I am convinced that there was a generation of young people coming out of high school, colleges, and so forth these days that want to help people. And if they had some idea that they could do it through an endeavor, really, the endeavor that you are leading, I think they would want to do that.

I would just urge you to find ways to communicate that clearly, maybe. Ask most people in colleges: How would you like to work on TSCA? I haven't a clue. I think there is something to be said for being able to message better.

Is the expertise that you need, is it out there?

Ms. FREEDHOFF. It is out there. It is out there. I think there are people graduating from college every year with amazing education in environmental science and toxicology and ecology. I really do think the work force is there, and I agree with you. The people at EPA are incredibly excited and committed to the mission of the agency, and really do get excited by the opportunity to help people, as you said.

Senator CARPER. Let's talk a little bit about good science, and perhaps a good example is your decision to consider risks of a chemical broadly rather than consider the so called conditions of use. When you assess the risk of a chemical, as I understand it, the conditions of use refer to the processes or protections that companies might use to minimize releases and exposure to the chemical. I believe you would assert that the decision to consider risks broadly is the scientifically sound way to proceed. I may be mistaken there, but I understand the industry feels that good science dictates that you consider conditions of use in these risk evaluations.

Question: Would you help us understand this disagreement over how science should be used to assess chemical risk?

Ms. FREEDHOFF. Absolutely. So, the law does says study the chemical substance over its conditions of use, and the risk evaluations do look at the risk attached to each condition of use. And they analyze that risk, and we are going to continue to do that.

I think where industry is not in full agreement with our approach is they think that when we say that an entire chemical substance poses unreasonable risk, they think that is unfair, because they think that there are some risks and some conditions of use that are not risky at all. There are some conditions of use that are very risky, and there are some conditions of use that are less risky. And they want everyone to know which those are.

We agree with them on that, and we are going to continue to tell people which of the uses are more risky than others and which are the ones that are most likely to be regulated. But I do think that people have the ability to sort of understand the agency's process. It is kind of like Americans know how much junk food is too much. They know how much medicine is too much. They know how much sun is too much, and when it is time to put sunscreen on.

Ultimately, what our risk evaluations are saying to people is how much of a chemical is too much and what are the ways that that chemical is used that are too risky. Then, when we get to rules, what we want is for the public to trust that we have evaluated the risks, that we have properly addressed them, and our rule says to people, this is how this chemical can be used safely.

I think that is on us to communicate properly, and we do plan on doing a better job in this regard and also would absolutely welcome industry's feedback when they think we have missed the mark on the communications front.

Senator CARPER. OK. One of the things that gives me joy is working with my colleagues across the aisle to take on challenging issues and getting input from all directions and all different quarters and being able to enact meaningful legislation, thoughtful legislation. As you will recall, I was so proud of this Committee and the Congress and the Administration at the time for our ability to collaborate with industry and with the folks at EPA in order to enact legislation. Very proud, a high moment from the years that I have been here.

I am just, as we sit here today, 6 years later, to see how that dream, the hope that we had, is not being realized. It is deeply troubling to me. I know it is to my colleagues. This has not been a Committee—this has not been a hearing. It is not our nature to

cast aspersions at you or the folks that you lead and the folks at EPA, but we have got to do better. I like to say, and Senator Capito has heard me say more often than she wants, everything I do, I know I can do better. Everything I do, I know I can do better.

This is a shared responsibility. One member of our staff likes to say, "Teamwork makes the dream work." I think there is a lot of good intention here to get this right. And we need to. A lot of people are counting on us, and we need to get it right.

With that, I want to thank you, Dr. Freedhoff, Michal, thank you for sharing your experience and your expertise with us today. Thank you for all that you did to help make this legislation a law in our country and try to enact it.

There is, surely, no road to success without a full understanding of the challenges that you face in implementing a critical Federal law. This is not easy. This is hard. And the implications couldn't be greater. They include the health of our families, the health of our communities, and include our environment and our ability to tap novel chemistries to hasten our transition to a more stable climate, to obtain medical breakthroughs, and hopefully, someday, a litter free circular economy.

I look forward to much help across the dais, and I think I have heard from our colleagues here that there is a strong interest in doing that, and help throughout the Senate to ensure that you get the resources that you and your colleagues need to succeed and help all of us succeed.

With that, a little bit of housekeeping. I would like to ask unanimous consent to submit for the record materials that relate to today's hearing.

Hearing no objections, so approved.

[The referenced information follows:]

July 8, 2022

Dr. Michal Ilana Freedhoff
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460

Re: EPA's Proposed Rule "Asbestos Part 1: Chrysotile Asbestos; Regulation of Certain Conditions of Use under Section 6(a) of the Toxic Substances Control Act," Docket ID # EPA-HQ-OPPT-2021-0057

Request to Withdraw Or Modify Proposed Restrictions On Diaphragms In The Chlor-Alkali Industry, Sheet Gaskets In Chemical Production, and Other Gaskets Contained In Proposed § 751.X05

Dear Assistant Administrator Freedhoff:

The organizations signing on to this request appreciate the opportunity to comment on the referenced proposal issued by the Environmental Protection Agency.

Chlorine chemistry is an integral part of the goods and products Americans use every day. The computer screen – or paper – on which you are reading this letter was made using products that are derived from chlorine and co-product sodium hydroxide chemistry. The chlor-alkali process, which utilizes chrysotile asbestos safely to manufacture chlorine and sodium hydroxide, or caustic soda, is also used to treat drinking water. In addition to water treatment, chlorine from this same process helps to ensure the safety of consumer goods, medical equipment, medications, and other life-enhancing products. We, the undersigned organizations, urge you to reconsider the need for the U.S. to transition completely away from targeted and safe uses of chrysotile asbestos in the proposed Toxic Substances Control Act (TSCA) Risk Management Rule.[1] An abrupt ban would affect one-third of America's chlorine capacity and impact many industries. It would also affect a large number of chemical manufacturing sites using sheet gaskets across the country that would additionally impact supply of other needed chemistries to downstream users. At a time when the United States is facing inflation and supply chain issues, we respectfully urge the Biden-Harris Administration not to risk severely reducing the ability of Americans to have access to clean drinking water and essential products that rely on chlorine.

Chlorine and sodium hydroxide are critical building block chemicals, and the chlor-alkali sector supports a broad range of essential uses that are key to the U.S. economy. Industry has maintained safe use of asbestos diaphragms for over five decades and this chlorine chemistry technology is important to

[1] Asbestos Part 1: Chrysotile Asbestos; Regulation of Certain Conditions of Use under Section 6(a) of the Toxic Substances Control Act (TSCA). 87 Fed. Reg. 21706 (April 12, 2022).

public health. The interruption to the domestic chlorine market that would result if EPA finalized the current proposal could set in motion a catastrophic chain-reaction for many industries and would negatively impact a large portion of the population. It is important to note that EPA based its risk elimination proposal on an estimated worker subpopulation of 100 highly trained and protected workers in the entire chlor-alkali industry, which numbers in the thousands. EPA made the incorrect assumption that these workers handle asbestos without using personal protective equipment (PPE). It ignored that asbestos use in the chlor-alkali process is heavily regulated by the Occupational Safety and Health Administration (OSHA), which requires the use of PPE, and that the asbestos handling takes place under highly controlled conditions. The chlor-alkali industry has provided substantial evidence in the administrative record during the risk evaluation phase on how it safely uses asbestos diaphragms with appropriate engineering and administrative control measures, and there is no risk posed to the general public or surrounding communities.

According to the Chlorine Institute, 33% of the U.S. chlorine capacity depends on the use of asbestos diaphragms, and therefore, the proposed rule by the EPA for the chlor-alkali sector will have harmful supply chain and economic consequences. The subsequent sections highlight the necessity of chlorine and its byproducts in the following sectors:

Chemical and Basic Materials Production Sector

Many products of the chemical industry depend on chlorine chemistry. A major use of chlorine is that it is used to produce various other chemicals such as propylene oxide, chlorates and organic compounds like carbon tetrachloride and synthetic rubber.

Chlorine is also one of the basic feedstocks used to make durable and versatile materials like polyvinyl chloride (PVC), which is essential to the future drinking water, sewerage, irrigation, and electric vehicle charging infrastructure of the U.S. PVC is also critical to the medical community since it is used in many life-saving products, including many medical devices, such as blood bags, medical tubing, oxygen masks and ventilators. If this Proposal is enacted, that would lead to shortages of these products. This would mean that pipe, conduit, and other products that are key to the successful roll-out of the Infrastructure Investment and Jobs Act (IIJA) would be made with alternatives that are less environmentally friendly than PVC resin that is made in America.

Manufacturing Sector

Not only is chlorine critical as a building block for consumer goods, but the chlor-alkali industry directly employs more than 20,000 Americans and another 245,000 are employed by chlor-alkali-related industries.[2] Chlorine chemistry is used to manufacture processors that power smart phones, digital tablets and computers along with hybrid car batteries.[3] Chlorine chemistry is an integral part of the goods and products Americans use every day. The EPA's economic justification and analysis of the likely costs and benefits of the proposed ban on Chrysotile Asbestos manufacture, importation or use in commerce is cleverly presented in a manner that disguises much of the real economic significance of the matter.

---

[2] Fisher, Dan. Dixon Valve, Chlor-Alkali: State of the Market in 2020. Available at https://www.dixonvalve.com/sites/default/files/Chlor-Alkali-State-of-the-Market-2020_0.pdf

[3] ChemicalSafetyFacts.org, Chlorine, American Chemistry Council, 2022. Available at https://www.chemicalsafetyfacts.org/chlorine/

Energy Sector

Chlorine is an essential component to the energy sector. In both solar and wind energy, chlorine chemistry is used in the manufacturing of solar panel chips and wind turbine blades. In addition, some plastic foam insulations and vinyl windows manufactured that utilize chlorine chemistry increase the efficiency of home heating and air-conditioning systems and reduce greenhouse gas emissions.[4] The current Administration has put forth ambitious greenhouse gas guidelines, which rely on the ability to use low emission refrigerants, and these refrigerants are based in chlorine chemistry. Chlorine is also a component in lightweight materials that are needed to produce lower emission vehicles as well as items that increase household energy efficiency, like spray foam insulation. Many items that are needed to help our country move towards lower carbon intensity are based in the essential chemical chlorine.

Food and Agriculture Sector

The need for chlorine extends far beyond the chemical production and manufacturing sectors of our economy. Chlorine is a building block chemical in the crop protection supply chain. In addition, chlorine-based products are used in commercial food preparation for sanitizing and disinfecting equipment and food contact surfaces, destroying food-borne bacteria and in manufacturing packaging to prevent contamination and keep food fresh.[5] As climate change increasingly strains farm management practices, more and more agricultural producers are moving to some form of irrigation,[6] with a heavy reliance on indoor growing facilities that need PVC pipe to operate.

Healthcare and Public Health

Chlorine has become increasingly important in recent years as we have witnessed the rise of COVID-19. Chlorine is a main component of bleach, disinfectants, medical tools and devices, as well as serving as the foundation for 85% of pharmaceuticals.[7,8] As people mitigate public health risks in a post-COVID world, chlorine is in demand now more than ever.

Water and Wastewater

For over 100 years, drinking water chlorination has been used and is a major factor in preventing cholera and other waterborne diseases.[9] Approximately 98% of public drinking water treatment facilities use some form of chlorine-based disinfectant, according to American Water Works Association. Residual chlorine in drinking water is mandated through the National Primary Drinking Water Regulations. A series of events between March 2021 and June 2021 nearly led to boil water notices in multiple cities due to sudden chlorine production reductions. While drastic measures were taken to avoid boil water notices, these events go to show how any unplanned restrictions of chlorine can immediately generate a supply shortage.

---

[4] ChemicalSafetyFacts.org, Chlorine, American Chemistry Council, 2022. Available at https://www.chemicalsafetyfacts.org/chlorine/
[5] Sustainable Progress, World Chlorine Council, 2017. Available at https://worldchlorine.org/wp-content/uploads/2018/10/WCC_Sustainable-Progress_Version-3-2017.pdf
[6] Irrigation and Water Use, USDA, 2022. Available at https://www.ers.usda.gov/topics/farm-practices-management/irrigation-water-use/
[7] ChemicalSafetyFacts.org, Chlorine, American Chemistry Council 2022. Available at https://www.chemicalsafetyfacts.org/chlorine/
[8] What is Chlorine Used For?, March 2021. Available at https://www.medicinenet.com/what_is_chlorine_used_for/article.htm
[9] Drinking Water Chlorination: A Review of Disinfection Practices and Issues. Available at https://waterandhealth.org/wp-content/uploads/2017/04/dwwp.pdf

Sheet Gaskets and Other Gaskets

In addition to the chlor-alkali industry, asbestos has widespread use in sheet gaskets and other gaskets in chemical plants and refineries as a mechanical seal to prevent leakage from or into objects under compression and other challenging conditions. These gaskets prevent liquids and vapors from being released from joints called flanges in pipes and other equipment. The number of asbestos gaskets remaining in use across industry in chemical plants and refineries is suspected to be in the hundreds of thousands and potentially the millions, as the gaskets are durable can be safely utilized for decades (typically trapped between two pipe flanges) before needing to be replaced.

The chemical plant and refining industry produces energy, essential fuels, pharmaceuticals, sanitizing agents, and other chemicals. Replacing the asbestos gaskets in the short timeframe EPA has suggested would cause plants and refineries to shut down from weeks to years at a time. This is not the time for the nation to shut down essential infrastructure for extended periods of time to remove and replace gaskets in the chemical plant and refining industry, leading to further supply chain disruptions beyond those that the nation is already facing. Premature removal is likely to have a debilitating effect, resulting in shortages of fuels, energy, and other essential chemicals, including sanitizing agents.

***

We encourage EPA to consider the impacts a severe and abrupt reduction in chlorine production would have on the supply chain and the economy as well as the unintended consequences of forcing chemical plants, refineries, power plants and pharmaceutical companies to close for extended periods of time to replace sheet and other gaskets. We urge the Administration to think about these drastic economic and environmental impacts the proposed rule will have on American lives. It is our hope that EPA will work with industry to ensure there is no shortfall in the availability of domestic chlorine, fuel or other critical supplies by recognizing that asbestos in these applications has been and can continue to be used safely. TSCA provides EPA with a variety of risk management tools short of a complete ban on these conditions of use. We urge EPA to re-propose this rule and avoid the disruptive public health, economic, and social consequences that are likely to flow from the agency's proposed approach.

Sincerely,

American Chemistry Council
American Forest & Paper Association
American Fuel and Petrochemicals Manufactures
American Petroleum Institute
Chemical Fabrics & Film Association
Chemical Industry Council of Delaware
Chemical Industry Council of Illinois
Chemistry Council of New Jersey
Council of Producers and Distributors of Agrotechnology
The Chlorine Institute
The Fertilizer Institute

Georgia Chemistry Council
Flexible Packaging Association
Industrial Mineral Association—North America
Louisiana Chemical Association
Manufacture Alabama
Massachusetts Chemistry & Technology Alliance
Michigan Chemistry Council
National Association of Chemical Distributors
New York State Chemistry Council
North American Millers' Association
Ohio Chemistry Technology Council
Pennsylvania Chemical Industry Council
Plastics Industry Association
Pool & Hot Tub Alliance
South Carolina Chemistry Council
Texas Chemistry Council
U.S. Chamber of Commerce
Vinyl Institute
Virginia Chemistry Council
Water Mission
West Virginia Manufacturer Association

Senator CARPER. Senators will be allowed to submit written questions for the record through the close of business on Wednesday, July 6th, 2022. We will compile those questions, send them to our witness, and ask Dr. Freedhoff to reply by Wednesday, July 20th, of this year, if you would.

With that, this hearing is adjourned. Thank you again so much. Thank you.

[Whereupon, at 11:28 a.m., the hearing was adjourned.]

○