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HEARING ON OVERSIGHT OF TOXIC SUBSTANCES CONTROL ACT AMENDMENTS IMPLEMENTATION

HEARING BEFORE THE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS UNITED STATES SENATE

ONE HUNDRED EIGHTEENTH CONGRESS

SECOND SESSION

JANUARY 24, 2024

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COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

ONE HUNDRED EIGHTEENTH CONGRESS
SECOND SESSION

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C O N T E N T S

Page

JANUARY 24, 2024

OPENING STATEMENTS

Carper, Hon. Thomas R., U.S. Senator from the State of Delaware	1
Capito, Hon. Shelley Moore, U.S. Senator from the State of West Virginia	3

WITNESS

Freedhoff, Hon. Michal, Ph.D., Assistant Administrator, U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention	5
Prepared statement	8
Responses to additional questions from:	
Senator Carper	20
Senator Whitehouse	27
Senator Merkley	32
Senator Markey	32
Senator Capito	34
Senator Lummis	48
Senator Ricketts	53
Senator Sullivan	58

ADDITIONAL MATERIAL

Article from E&E: Ellie Borst, EPA goes after plastics with chemicals plan	66
Report on Critical PFAS Substance Uses	80
Letters to Senator Carper and Senator Capito from:	
Alliance for Chemical Distribution and 21 other associations	120
American Coatings Association (ACA)	122
American Chemistry Council (ACC)	127
American Fuel & Petrochemical Manufacturers and American Petroleum Institute	128
American Cleaning Institute	130
Global Clean Energy	131
Solugen, Inc.	133
Univar Solutions	136
Report from American Chemistry Council: Impact of Rising Regulations on Chemical Manufacturing & American Priorities	137

HEARING ON OVERSIGHT OF TOXIC SUBSTANCES CONTROL ACT AMENDMENTS IMPLEMENTATION

WEDNESDAY, JANUARY 24, 2024

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, Merkley, Markey, Fetterman, Cramer, Lummis, Mullin, Ricketts, Boozman.

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

Senator CARPER. Good morning, everyone. I want to start by welcoming our witness, Dr. Michal Freedhoff, the Assistant Administrator for the Office of Chemical Safety and Pollution Prevention. Michal, as most of you know, is no stranger to EPW or to the issues we are going to be discussing today, having worked on this Committee with us for a number of years and also previously for Senator Markey, although he says he worked for her, in both the House and Senate.

In 2016, Michal was one of the lead negotiators of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the first reform to the Toxic Substances Control Act, TSCA, in approximately 40 years. A number of us worked tirelessly alongside our staff and colleagues on and off of this committee to support the bipartisan reforms in the Lautenberg Act. These reforms would help ensure that TSCA worked as Congress intended to protect the health and safety of Americans and our environment, while also allowing for innovation and competition within industry.

The task of protecting the health of our families, communities, and environment, while also continuing to advance chemistry that enriches our lives, is no easy feat. It takes skill and experience to navigate the complexities around the implementation of this law. Through TSCA, Congress has charged the EPA with this demanding responsibility.

Since we last welcomed Dr. Freedhoff before the Committee in 2022, I want to share some of the progress that has occurred in relation to the implementation of TSCA. The first 10 priority chemical reviews that were established in 2016 have been completed.

The Biden Administration has already begun to publish proposed rules for these chemicals, some of which are known carcinogens.

The EPA has also launched several initiatives to prioritize and streamline new chemical reviews for chemicals associated with batteries, with clean energy technologies, and with semiconductors to more quickly deploy investments from the Bipartisan Infrastructure Law and the Inflation Reduction Act, major pieces of which were discussed and debated right here in this room. According to the EPA, since June 2023, the agency has more than doubled the average amount of new chemical reviews that they are able to complete each month. This means EPA is addressing the backlog of chemicals awaiting review, while also reviewing new submissions.

As the members of this committee have often heard me say, everything I do, I know I can do better. The same is true with respect to TSCA. As we gather here today, my hope is that this hearing will offer us an opportunity to reflect on and discuss what is working better and what can be done to further improve the implementation of this critical law.

Let's be clear: there is still more work to be done. The EPA needs adequate support from both Congress and the Administration to meet the expectations set into law by those of us who helped write the Lautenberg Act. As Dr. Freedhoff will highlight in her testimony, the EPA has been tasked with high expectations and a heavy workload, but has not always been equipped with the necessary funding to complete this technical work. Congress needs to ensure that the EPA has the appropriate resources to implement TSCA as intended.

Further, we know that the EPA is updating its fees rule to be able to more effectively collect revenues from chemical manufacturers. This is an important part of the funding equation, and we look forward to hearing more from Dr. Freedhoff about this effort.

Insufficient resources, over the course of multiple fiscal years, have led the agency to miss deadlines and delay decisions. This situation has created grievances from both those in industry pushing to get their chemicals to market and from environmental advocates eager to see harmful chemicals regulated.

As Dr. Freedhoff will relay today, the EPA is implementing a law that is written to the best of their ability. That said, we hope today's discussion will help us determine what further actions the EPA can take, or what additional resources Congress can provide to better support the Lautenberg Act's implementation.

In closing, let me just to reiterate a couple of things. First, I am committed to working together with Senator Capito and all the members of this committee to ensure that we are providing the agency with the resources it needs in Fiscal Year 2024. Second, we will continue to collaborate with the EPA and request transparency in the agency's actions as they work to protect us from harmful toxins while allowing chemistry to usher in a new world of clean energy and lifesaving technologies.

Dr. Freedhoff, we look forward to hearing from you today, and welcome back.

With that, let me turn to 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, Chairman Carper. Thanks for holding the hearing, and Dr. Freedhoff, thank you for being here. Thank you for coming to my office last week. I think we had a very fruitful discussion and very substantive. I appreciate that.

For 3 years, the Biden Administration has been implementing the 2016 TSCA Amendments. Yet the slow pace, and the Chairman talked about this, of new chemical approvals has not improved. The scapegoat of blaming the prior administration is no longer holding water. Three years is long enough to take the reins.

Reviews are regularly blowing past the deadlines by months, but in some cases years. Approving submissions within the deadline is not an aspirational goal, it is a legal obligation for the EPA to ensure that innovation is not stifled by bureaucracy.

Agency timeliness in the chemical space is crucial to maintaining a competitiveness in the global market and also achieving what I believe, a point of bipartisan agreement, expanding key industries and onshoring critical supply chains right here in this Country. Chemical manufacturers in China are more than happy to fill the void of U.S.-based companies that are stuck in regulatory purgatory by the EPA.

The slow pace of new chemical approvals forces continued reliance on older chemistries that may have not just lower performance by higher risk profiles and fewer environmental benefits than newer alternatives. According to a 2022 survey of American chemical manufacturers, 70 percent reported that they have decided to introduce new chemicals and therefore make the requisite investments in job creation outside of the United States. Let me repeat that: they have decided to introduce their new chemicals outside of the United States.

Slower reviews create a negative spiral for the EPA's own work. Slower reviews means fewer submissions, and with fewer submissions, the agency collects fewer fees to implement TSCA.

In addition to the slow pace, a troubling zero-risk approach at the EPA has taken hold of the TSCA program. Since 2021, the number of cases that have received a determination of "not likely to present risk" has dropped by 75 percent. It seems that no volume of data provided by applicants is satisfactory to the EPA to drop its predisposed worst-case assumptions of risk.

Previously, you stated that it is the submitter's responsibility to come in earlier to talk about the data that your assessors require. Those that have heeded that advice have not had positive things to report back. Stakeholders have complained of a lack of responsiveness from the EPA staff, moving of goalposts and presumptions of denial at the start of the process as well as a failure of the EPA to consider data and approvals from regulators in Europe and Asia. In short, they found no benefit from making contact with the EPA early and often.

Your office seems to also have a mission creep where no data can satisfy risk assessments. The EPA is intruding on other agencies like OSHA, Occupational Safety and Health Administration, to which Congress has provided relevant authorities. The zero risk approach undermines the intent of the 2016 Amendments, and

ironically, will hamstring the Biden Administration's ability to realize its own goals.

As an example, in 2023, the EPA selected a company to receive a green chemistry challenge award for developing a new bio-based chemical feedstock that would significantly decarbonize the chemical industry. Meanwhile, when that same chemistry went through the TSCA review process, it received such stringent restrictions that it can no longer be commercialized.

Unfortunately, this is just one of the many examples of the profound disconnect between the new hazard-based interpretation of TSCA and the Biden Administration's so-called onshoring efforts. It is the same disconnect that has the EPA mulling proposed rules to destroy domestic semiconductor manufacturing by effectively prohibiting essential chemistries, despite Congress and the Biden Administration doling out tens of billions of dollars to stand up capacity here. I fear the program is in a worse State now, maybe, than before the Lautenberg Act was passed.

We may not agree on everything, but we can at least agree that the status quo needs to change. It is not lost on me that you didn't receive all the resources that you would like. However, simply throwing more money at the problem while doing nothing to change the underlying structural issues is not a solution, and Congress has made more resources available.

The EPA hired almost 2,000 new employees last year, but somehow the TSCA program struggles to fill vacancies that have been open for years. It is concerning to me to hear, and we talked about this last week, that it has taken 2 years to hire a single person under the Title 42 authority that Congress provided in 2022.

It is also troubling that the Office of Inspector General criticized the OCSPP, Office of Chemical Safety and Pollution Prevention, for its lack of standard operating procedures and outdated guidance to more effectively onboard new staff. If resources are a problem, then why at a time when 70 percent of guidance documents and standard operating procedures for the new chemical programs are out of date is the EPA announcing that it is expanding resources for elective programs without statutory authorization?

Examples like this give me the impression that TSCA's programs resource demands and programmatic workload arbitrarily grow every year, no matter what resources Congress makes available for the policies that we choose to prioritize. During today's hearing, I expect that will once again hear about the need for more resources and we will consider that request as the Chairman mentioned.

More valuable will be learning how you intend to allocate the resources you have and what transparent commitments you are willing to make to improve management of and tangibly accelerate the review process. I shared with you in advance some of the ideas that we have to achieve that goal together, and I hope we can discuss those this morning.

Thank you, Chairman Carper.

Senator CARPER. Thank you so much.

We are now going to turn to our witness. We are pleased to welcome you back to our committee today. Dr. Mihal Freedhoff is the Assistant Administrator of the Office of Chemical Safety and Pollution Prevention at the Environmental Protection Agency. Dr.

Freedhoff has more than 20 years of government experience and service, the majority of which were spent on Capitol Hill, and many of which were spent literally in this building.

She began her congressional service in 1996, as I mentioned earlier, in the office of then-Congressman Ed Markey as a congressional science and engineering fellow, after earning a Ph.D. in physical chemistry at the University of Rochester. With environmental expertise spanning a range of policy areas, her legislative work includes the 2016 reauthorizing of the Toxic Substances Control Act, 2019 legislation to address PFAS contamination, the fuel economy provisions in the 2007 Energy Independence and Security Act, and the law requiring creation of an online data base of potential consumer product safety defects.

Before you begin your testimony, Dr. Freedhoff, I have heard a number of people say to me, I have never met anybody named Mihal. Where does that name come from? For those of you who are steeped in the scripture, you may remember the story of David and Bathsheba. They had a son who sadly died, and he ended up having other wives, one of whom was named Mihal. Mihal became the mother of a guy named Jedidiah. Jedidiah became King Solomon, one of the wisest men who ever lived. This is a new generation of Mihal. She has quite a history in her lineage, and we welcome you warmly back to the committee where you spent so many years.

Please proceed. Thank you.

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

Ms. FREEDHOFF. Good morning, Chairman Carper, Ranking Member Capito, and other members of the committee. Thank you for the invitation to testify about the Toxic Substances Control Act, or TSCA. It is always a pleasure to come back to EPW.

When I was last here, I described how years of underfunding had delayed our work to put essential protections in place for communities across our Country, and delayed our ability to review the new chemistries needed to power our economy. While those problems have not entirely been solved, and will not be at current funding levels, I am proud to say we have come a long way.

The promise of the new law was for EPA to evaluate tens of thousands of existing chemicals left unreviewed under the old law and to write rules to protect people. We are finally starting to make good on that promise. We proposed rules for five dangerous chemicals that would collectively protect 1 million workers and 15 million consumers. We feel a strong sense of urgency to get these and another four rules we have yet to propose across the finish line.

I can also assure you that I have personally met with companies who think our proposals miss the mark for some uses. We are taking their input seriously and will be making some needed adjustments along the way.

We are also working on our risk evaluations. We have released two drafts and expect to finalize seven this year.

Last month, we announced the next five chemicals we expect to evaluate, including vinyl chloride, a cancer-causing chemical that was one of the examples used by the Nixon Administration when they first came to Congress and asked Congress to write the original TSCA. Before we even named those chemicals for the very first time, we also asked a very wide range of stakeholders for their input and their data so that we can get a jump start on those evaluations and come closer to meeting our deadlines.

We are expanding our scientific toolbox for risk evaluations with approaches that focus on the most concerning exposures, efforts to improve our understanding of occupational safety practices, and ways to account for exposures to the most vulnerable populations. These changes will help ensure that the people who need chemical safety protections get them and get them faster.

EPA also plays an important role in ensuring the safety of new chemicals. If the 2016 requirements that EPA formally evaluate the risks of all new chemicals before they were allowed into commerce had been the law all along, our people's pollution story, for example, might have had a very different ending. I know there are continuing concerns that we are not moving fast enough to get new chemistries to market, and I know there is more we can do. I refuse to accept that we have to choose between safety and speed.

With the budget increase, we hired 14 new chemical staff with 7 more hires in the works which were much-needed reinforcements for a staff that had been stretched razor-thin. We have standardized our review approaches for some of the approaches used in batteries and semiconductors. We have developed a framework for new PFAS which will ensure their continued availability for sectors like the semiconductor industry.

We have prioritized the review of the new chemicals we need to support the Biden-Harris Administration's domestic manufacturing initiatives, and now review those in a third of the time compared to other sectors. By any objective standard, these efforts are working.

In Fiscal Year 2023, we completed 70 percent more risk assessments compared to Fiscal year 2022. Since June, we have more than doubled the monthly average number of completed risk assessments as compared to the year before. We have cleared out about 50 percent of the older backlogged cases.

The truth is, we are not able to achieve all that TSCA was expected to. The problem is clear: TSCA is underfunded. It is the conclusion of EPA's analysis, the Inspector General, and GAO.

The solution is equally clear. We do not need to change the law. We need funding to implement the law we have.

Full funding would mean 25 new hires to review new chemicals. It would mean we could modernize our IT more quickly, modernize our procedures and science more quickly, do more industry outreach and come closer to meeting that 90-day deadline for reviewing new chemicals.

Full funding would allow us to hire 75 new people to finish our risk evaluations and rules more quickly, which means that the protections workers and communities have been waiting for decades will also come more quickly.

No matter what our budget is, you have our assurance that we are going to continue to build the foundation for a chemical safety program that can deliver both the protections and the regulatory certainty that Congress envisioned in 2016.

Industry and environmental organizations all know that our door is always open, and I hope you will not hesitate to ask for additional briefings, calls, or answers to your questions. If a visit to companies or communities in your home State would help, we will do our best to make it happen. We all want the law to work as Congress intended, and I am fully committed to doing whatever it takes to get there.

Thank you again, and I look forward to your questions.
[The prepared statement of Ms. Freedhoff follows:]

**TESTIMONY OF MICHAL FREEDHOFF
ASSISTANT ADMINISTRATOR FOR CHEMICAL SAFETY AND POLLUTION
PREVENTION
U.S. ENVIRONMENTAL PROTECTION AGENCY**

**BEFORE THE
SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS**

January 24, 2024

Good morning, Chairman Carper, Ranking Member Capito, and other Members of the Committee. Thank you for inviting me back to testify on EPA's implementation of the Toxic Substances Control Act, or TSCA.

I last testified before this Committee a year and a half ago on TSCA's sixth anniversary. At that time, I described the impacts of the years of significant underfunding of the new law— which had delayed our work to review existing chemicals, put essential protections in place for communities across our country, and enable new chemistries to power our economy and to keep America on the leading edge of technological innovation in industries like semiconductor manufacturing, battery production for electric vehicles, and clean energy. While that problem hasn't been entirely solved, thanks to an increase in our Fiscal Year 2023 budget and a lot of hard work from our dedicated staff, I am proud to say that we have come a long way – even though I know more work must still be done.

Today, I will share some updates on our TSCA implementation efforts, including the impressive progress we have made in the prioritization, evaluation and management of existing chemicals, and the review and management of new chemicals. But I would also like to spend some time on what we have not been able to do under current funding levels and what we would be able to do with our full FY 2024 budget request. Although we are focused on building an efficient and sustainable scientific and regulatory infrastructure for this still young law, in order for the TSCA program to work as Congress and the American public expect and deserve, we simply must have more resources.

I will start with existing chemicals. As many of you who authored or supported the 2016 legislation already know, there were tens of thousands of existing chemicals on the market at the time Congress passed the original TSCA, and all of them were effectively left unreviewed and unmanaged in that 1976 law. Although EPA tried to use the authority it did have, litigation on EPA's asbestos ban ultimately rendered the 1976 law even less able to address the way chemicals are made and used in order to avoid the creation of future Superfund sites or contaminated drinking water. In 2016, Congress provided EPA with both the authority and the requirement to systematically prioritize and evaluate existing chemicals, and to write rules to safeguard the public and vulnerable communities against risks. This was the promise of the new law, and we're just now starting to make good on it.

We have already proposed rules for asbestos, methylene chloride, trichloroethylene, perchloroethylene, and carbon tetrachloride, and expect four more proposals in the coming months. It is hard for me to overstate the importance of these actions. Collectively, these five proposals would protect over 1 million workers and over 15 million consumers from chemicals known to cause cancer and other adverse health conditions. We have known for decades that many of these chemicals are dangerous. I know that I, and everyone at EPA, feels a strong sense of urgency to finish the job and get these important protections in place for communities across the country – which we expect to do later this year. While we have missed the statutory deadlines for all of the first 10 chemical rules, with some increased staff we have been working to improve the efficiency of both our intra- and inter-Agency processes, and I believe we will meet the statutory requirement that we issue a final rule within a year of issuing the proposal for at least some of these chemicals as a result.

At the same time, we also realized that there was more EPA could have done as those first chemicals were undergoing risk evaluation during the previous Administration to proactively engage with the companies who make and use those chemicals to ensure we had a realistic understanding of the safety measures they already take. I can confidently say that EPA's Office of Chemical Safety and Pollution Prevention

(OCSPP) is doing far more to engage with industry and federal Agency users of the chemicals we are prioritizing, reviewing, and regulating than ever before, and our final rules and future risk evaluations will see the fruits of those efforts realized. I personally met with companies that think we have missed the mark on some of our proposed rules when it comes to the way they make and use these chemicals, and I can assure you that we are taking their input seriously and will be making some needed adjustments along the way.

We are also continuing to advance existing chemicals through the prioritization and risk evaluation pipeline. Only one of the risk evaluations for the more than 30 existing chemicals that have finished or are currently in the risk evaluation process was completed within the statutory deadline. In November 2021, EPA's Office of Inspector General identified TSCA risk evaluations as a "Top Management Challenge," estimating that we would need to increase our capacity by 140 percent in order to meet deadlines for just the 24 risk evaluations we had ongoing at that time. While the additional resources from the FY 2022 and FY 2023 budgets have helped to an extent, we also think there are additional opportunities to make our risk evaluations more focused and efficient.

As a necessary first step, we have been working to get our initial evaluations back on track. For example, we issued a draft supplement to the 1,4 dioxane risk evaluation – a chemical that can cause liver toxicity and cancer – to follow our science advisory committee's recommendations to consider the air and water exposure pathways that were previously excluded because of the previous Administration's policy not to consider them. We have been steadily working towards issuing the second part of our asbestos evaluation that will consider risks from legacy uses and additional fiber types that were also previously excluded – both contributors to exposure to this cancer-causing chemical. Likewise, we are pushing forward on evaluations for the next high-priority substances and manufacturer-requested risk evaluations. We published a draft risk evaluation for TCEP – a flame retardant linked to neurological effects, reproductive effects, developmental effects, kidney effects, and cancer – last month and expect to release additional

draft and final risk evaluations this coming year for two phthalates, a chlorinated solvent, and formaldehyde. To ensure the Agency follows the science and the law in future risk evaluations, we proposed a rule updating the procedural framework for conducting TSCA risk evaluations, incorporating advice from our scientific advisory committee and lessons we learned along the way – a rule we hope to finalize later this Spring.

Just over a month ago, we announced five more candidates for prioritization for risk evaluation, including vinyl chloride – a chemical known to cause cancer, and the same one involved in the recent East Palestine, Ohio train disaster and of concern to communities near where it is made and used, like the Gulf Coast. The Nixon Administration actually exemplified this chemical, and the cancer risks it posed to workers, when it asked Congress to write the original TSCA in the early 1970s.

Moving forward, we are aiming to shift to a five-chemical-per-year risk evaluation prioritization process – an approach we think will help EPA, and really all stakeholders, better manage the workload and make the entire multi-year review and regulatory process more sustainable. Before we even start the prioritization process, we are taking stock of available data on potential candidate chemicals to help inform selection decisions, talking to other parts of EPA, industry and environmental stakeholders, Tribal communities, state and local governments, and other federal agencies, in order to get their views on potential candidates, facilitating timely use of our data gathering authorities, and opening opportunities for more engagement with industry to better understand uses or sectors.

We are also trying to further focus our risk evaluations. Not every use of a chemical warrants the same level of analysis. Our risk evaluations will reflect a fit-for-purpose approach, diving deeper into the exposures that merit the most attention because they are likely to pose the most risk, while providing more qualitative descriptions of uses that we do not think are likely to contribute to the unreasonable risk posed by the chemical. Together, these changes will help us achieve the clear statutory deadlines in the

law, while also staying true to our mission to protect human health and the environment, including vulnerable populations.

We are also working to advance our scientific tools and approaches to ensure we are using the best available science in all of our work products. For example, we released a framework in February 2023 for considering the cumulative risks of multiple chemicals under TSCA and an approach for applying those principles to the phthalate chemicals currently undergoing risk evaluation. We are also continuing to refine our approaches for exposure analyses, including consideration of aggregate exposures across multiple uses or pathways, as well as improving exposure assessment processes for workers. In fact, we hosted two workshops in 2023 that included a range of stakeholders including industry, representatives from the public health and environmental community, academia, and other interested federal agencies. To date, these have been focused on the identification of ways to improve exposure assessment for workers and how we identify occupational exposure scenarios using a variety of data sources. A third workshop focused on exposure data and modeling is being scheduled for late spring of this year.

I would also like to touch on our efforts in the new chemicals program. EPA plays an important gatekeeper role in ensuring the safety of new chemicals before they enter commerce. Robust, upfront safety reviews of these chemicals can prevent legacy contamination issues like we have seen with flame retardants or PFAS—chemicals linked to cancer and reproductive harms and that are nearly ubiquitous today. The program also plays a critical role in getting new and innovative chemistries to market. We recognize there are continuing concerns that we are not moving fast enough, and I know there is more we can improve upon – but I refuse to accept that we have to choose between safety and speed. While we have made good progress towards more timely and efficient new chemical reviews, our resource shortfalls have ultimately prevented us from implementing some of these improvements as quickly as we'd like.

The 2016 amendments to TSCA brought about a dramatic increase in EPA's workload, especially for new chemicals. Previously, EPA only made formal risk determinations for around 20 percent of new chemicals submittals. The remaining 80 percent went into commerce automatically, when the 90-day review period the old law provided for EPA to complete its work expired. The new law requires EPA to conduct assessments and make formal safety findings for 100 percent of new chemicals *before* they can enter commerce. Despite these significant new responsibilities, the program's budget stayed essentially flat for the first six years of the new law. EPA has struggled since 2016 with the new law's requirements to ensure new chemicals can be used safely *and* can quickly enter commerce. We prioritized the resources needed by the new chemicals program when we received budget increases in FY 2022 and FY 2023, but we will continue to struggle for as long as our budget continues to be insufficient.

That said, we have taken a number of key actions to improve the program – and I believe we can and must do more. First, with the FY 2023 budget increase, we were actually able to hire more people to tackle the increased workload. Last time I testified, we had just 2 human health assessors to review the hundreds of submissions that come into the new chemicals program each year. Now, we have a dozen. Since the end of FY 2022, we have increased staff in the New Chemicals Program by a total of 14, with two additional hires about to join us and five additional recruitments in process – some much-needed reinforcements for a staff that has been stretched razor thin.

And we're putting those resources to good use:

- We proposed an update to our procedural regulations aimed at ensuring better quality upfront submissions – which means faster reviews;
- We created a standardized review approach for mixed metal oxides, which are used for batteries, electric vehicles, semiconductors, and renewable energy generation;

- We developed a framework for reviewing and managing new PFAS, which will ensure the continued availability of these chemistries for sectors like the semiconductor industry that plan to use them in ways that will not result in environmental releases, while generally expecting to prohibit new PFAS from being used in a way that will result in releases or exposures, like in cleaners or furniture polish;
- We are working collaboratively with the semiconductor sector to ensure a predictable regulatory approach for chemistries they rely on like photo-acid generators, while additional testing is ongoing, and hope to expand the collaboration in the coming months;
- We developed a broad industry outreach campaign to reduce late submission of key engineering-related information that often results in the need for EPA to re-work its assessments and longer review times;
- With more people, we have been able to do more and faster quality assurance reviews and identify areas for improvement, and to assemble problem solving teams to tackle longstanding science and science policy issues that can hold up the finalization of assessments;
- We recently issued a decision framework related to identifying eye irritation or corrosion hazards that will help ensure a consistent and transparent approach to this issue and reduce animal testing. This decision framework will be considered for every new chemical submission going forward;
- Later this month, we are holding an expert workshop to discuss science issues related to chemicals used in the fragrance industry, for which there are roughly 21 submissions in our queue; and
- We continue to improve the reliability of our IT systems to avoid significant disruptions to our reviews, like the outage that paralyzed the program for two weeks in 2022.

All of these efforts are designed to shore up our processes to ensure new chemicals are safe before they can enter commerce, make our reviews more consistent and more efficient, and build the scientific and

regulatory infrastructure that was simply not tended to in the early years of the new law. And these efforts are working.

The program has undeniably gotten more efficient. But you do not have to take my word for it – the proof is in the numbers that we post each month on our redesigned statistics webpage. In FY 2023, we completed risk assessments for 270 notices and 202 exemption applications – 472 in total. That is compared to 280 in FY 2022 – a nearly 70 percent increase. With respect to the backlog of notices and exemption applications submitted in FY2022 or earlier, we have closed out 219 cases or 48 percent of the total. The program also made big gains in scientific throughput. Starting in June of last year, we are more than doubling the monthly average number of risk assessments completed from the previous year. As a direct result of our hiring efforts, we have sustained those increases and, over the last six months, have averaged about 42 risk assessments completed each month.

We are going to continue to do our best with the resources we have, and – given the foundational steps we have taken to advance the program – I think you can expect these numbers will only get better with time.

Despite all the positive improvements we have made in the TSCA program and the progress we have been able to achieve, the truth is we are not yet able fully achieve Congress' intent under the law. We know that our stakeholders on all sides are frustrated. We have a responsibility to do better. But there is a clear problem: the TSCA program is underfunded. It is the overwhelming conclusion of EPA's own internal workforce analysis, multiple reports by EPA's Office of the Inspector General, and the Government Accountability Office. The program cannot fulfill the direction provided by Congress without the necessary resources.

And the solution is equally clear. We do not need a new law. We need funding to implement the one we have.

The enacted budget for the TSCA program in FY 2023 was \$82.8 million. In the President's FY 2024 budget request, we have asked for a nearly \$48 million increase – \$130.7 million total.

Full funding for the TSCA New Chemicals Program would mean hiring 25 new employees to support the review process. It would allow continued investment in stabilizing and modernizing the EPA's IT platforms and infrastructure for managing case workflows, reducing or eliminating system downtime. It would allow more focused review and development of standard operating procedures and science policies to support consistency and efficiency in program implementation. It would mean more time for staff training. It would result in the development of new science through a fully funded collaborative research program with EPA's Office of Research and Development. It would enable staff to increase engagement with stakeholders to improve models and assumptions that feed into our risk assessments. It would enable quicker progress towards the elimination of the backlog and review of new submissions within 90 days.

Likewise, full funding for the TSCA Existing Chemicals Program would make a significant and positive difference. We could hire around 75 additional people to support the TSCA existing chemicals work – prioritization, risk evaluation and risk management - from start to finish. We could staff three additional risk assessment branches consisting of interdisciplinary scientists and engineers dedicated to more timely completion of risk evaluations, which means that the protections workers and communities have been waiting for decades will also come more quickly. We could staff an additional branch of rule writers to complete the necessary TSCA rulemakings within the aggressive statutory deadlines. We could staff a new branch dedicated to implementing TSCA existing chemicals rules and regulatory programs, including experts in engineering and industrial hygiene who could focus on engagement with impacted industries to ensure our rules are implementable and reflect modern industrial and technology practices. Full funding would enable us to build a robust data management infrastructure to effectively and

efficiently manage receipt, tracking, and integration of information received from data gathering efforts for use in TSCA risk evaluation and risk management.

Full funding for the program would also help us better tackle the problems of emerging contaminants like per- and polyfluoroalkyl substances, or PFAS. These “forever chemicals” are an urgent public health and environmental threat that are linked to a number of negative health outcomes, and we have been taking a whole-of-agency approach to addressing the issue under EPA’s PFAS Strategic Roadmap. Over the last year, my office has taken numerous actions to address PFAS chemical safety—including finalizing rules for PFAS reporting, announcing a framework for reviewing new PFAS, proposing to eliminate exemptions for new PFAS and to restrict certain legacy PFAS, and issuing test orders to better understand categories of PFAS.

Understanding where and how PFAS are used is key to ensuring protections for people and the environment, and to advancing the science on PFAS used in commerce. In October of last year, to carry out a provision authored by this Committee, we finalized a reporting rule under TSCA to collect the largest-ever dataset of PFAS manufactured in the United States. We also finalized a rule that will improve communities’ right to know by eliminating an exemption that allowed facilities to avoid reporting PFAS information to the Toxics Release Inventory (TRI) when those chemicals are used in small concentrations and continue to add additional PFAS to the list of chemicals subject to TRI reporting. And we have continued to advance efforts under the National PFAS Testing Strategy to require development of new information representative of categories of PFAS, releasing our second and third orders on PFAS used to make plastics and GenX chemicals. We’re anticipating more orders in the year which will help accelerate research and innovation and amplify the effectiveness of regulatory and policy solutions to restrict and remediate PFAS.

We have also made significant progress last year in establishing policies that ensure the safety of new PFAS before they enter commerce. In May of last year, we proposed a rule to eliminate eligibility for exemptions that had allowed some PFAS to go through an abbreviated analysis – and would instead require that all new PFAS undergo a full safety review. And in June, we announced a framework for evaluating new PFAS and new uses of existing PFAS, to ensure they do not pose risks to people’s health and the environment before new PFAS are approved for use. We recognize in this framework that PFAS can be used responsibly in many products and critical industries, like semiconductor manufacturing. Our approach to managing risks distinguishes uses that could result in environmental releases—and those with expected human exposures—from those that will not, and will require upfront testing for many PFAS. And earlier this month, we finalized a rule that prevents companies from starting or resuming the manufacture or processing of more than 300 PFAS that have not been made or used for many years without a complete EPA review and risk determination.

Ultimately, our ability to effectively implement these important efforts to address PFAS – and to take further actions to protect public health as we learn more about PFAS or other emerging contaminants – is contingent on sufficient funding for the program.

No matter what the budget scenario looks like ahead, you have my assurance that we’re going to continue to push for even more progress on both new and existing chemicals. We are going to continue to put in place the foundation for a chemical safety program that can deliver both the promised health and environmental protections and the regulatory certainty that Congress envisioned in 2016.

We have already demonstrated that more resources yield demonstrably better and faster results. But the takeaway is that we cannot get all the way there without sufficient funding. We certainly cannot continue to do more and more with less – though we will continue to try to find efficiencies and invest in solutions to make the program more sustainable over the long term.

Finally, I want to emphasize that industry, state and local governments, and environmental and community organizations all know that our door is always open and will remain so. While we have also had regular engagements with Congress on various issues, I hope you and your staffs also will not hesitate to ask for additional briefings, calls, meetings, or answers to your questions. If an EPA visit to companies or communities in your home state would help bring more clarity to the issues in front of us, we will do our best to make it happen. We all want this law to work as Congress intended, and I am fully committed to doing whatever it takes to get there.

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

Senate Committee on Environment and Public Works
Hearing on “Oversight of the Toxic Substances Control Act Amendments Implementation”
January 24, 2024
Questions for the Record for The Honorable Michal Freedhoff, Ph.D.

Chairman Carper:

1. You have shared with the Committee that hiring additional staff is a top priority for the new chemicals program and that you have been able to do some hiring. What progress has the new chemicals program made as a result of increased staff capacity?

EPA RESPONSE: EPA was able to hire more than 20 new people in the new chemicals program since the end of Fiscal Year 2022. Together with our efforts to improve training and streamline reviews, the program has realized a nearly 70 percent increase in the number of reviews completed in FY 2023 as compared to FY 2022. Since March of last year, the program has more than doubled the number of reviews completed per month – from around 20 risk assessments per month to around 40 – and have generally sustained that increase over the last year. This improved progress tracks closely with EPA’s ability to hire new staff in late FY 2022 and the approximately 6 months it takes to train them. Between October 2022 and July 2024, the program closed 60 percent of the older backlogged cases. The program has also prioritized the review of new chemicals in the semiconductor, EV battery, biotechnology, and HFC sectors—as well as other key sectors important to growing all the new jobs from the Biden Administration’s domestic manufacturing initiatives—and we now review these new chemicals in a third of the time compared to other sectors. EPA would note, however, that cuts to the operating budget in FY 2024 have constrained our ability to accelerate this progress, and inhibited some of our ongoing efforts. For example, the program has had to pause hiring new staff. Without more staff support, we can only maintain the current pace of reviews and activities. EPA also won’t be able to restart the Sustainable Futures program as planned this year; or work as quickly to develop new approach methods and update our scientific models and tools.

- a. Are there additional barriers beyond funding that have hindered your ability to meet your staffing needs?

EPA RESPONSE: For the new chemicals program, the 2016 TSCA reforms essentially quintupled our workload overnight without a commensurate increase in resources. Although increased levels in funding are necessary to hire the scientists and staff needed to run the program as Congress intended, it is also imperative that those levels are sustained over the long term to provide stability to program operations. Additionally, EPA would note that even after new staff are hired, which takes some months in and of itself, it takes additional time – often 3-6 months – for the employees to be trained after onboarding to effectively perform their responsibilities.

2. Congress has heard concerns from various industry stakeholders regarding the EPA’s practice of making a determination on a chemical as a whole. Industry is concerned that

this is overly restrictive and could hamper uses of a chemical that do not present an unreasonable risk. Please explain why the EPA believes it is important to make one risk determination on a chemical and how this approach protects public health and the environment.

EPA RESPONSE: EPA believes a single risk determination on the chemical substance reflects a plain reading of the statutory text and structure, is consistent with Congressional intent, and best executes on the goals of the chemical risk evaluation provisions. EPA recognizes that TSCA also requires consideration of the chemical's conditions of use (i.e., the intended, known and reasonably foreseen circumstances under which the chemical is manufactured, processed, distributed in commerce, used or disposed of). Often there may be different exposure scenarios presented by different conditions of use, and such scenarios are reflected in the risk evaluation's exposure assessment. However, the plain language of the law requires EPA to determine whether the chemical substance, rather than individual conditions of use, present an unreasonable risk. Considering chemical exposures based on isolated uses does not reflect the reality that a person or population may be exposed to the same chemical from multiple uses or pathways. Although a specific use might not present an unreasonable risk on its own, it may nonetheless significantly contribute to an unreasonable risk when considered together with other uses of the chemical (e.g., when considering it in an aggregate exposure scenario). Considering the risk from the entire chemical substance – as opposed to individual uses – ensures that the Agency's risk determinations are based on the best available science, and positions EPA to deliver the protections for health and the environment that Congress intended.

- a. Congress continues to hear that this approach will lead to entire bans on chemicals. Is this a fair concern?

EPA RESPONSE: A single risk determination on the chemical substance will not increase regulatory burden or result in bans on every condition of use for that chemical. The risk determination (e.g., EPA has determined under TSCA section 5 that a new chemical may present or presents unreasonable risk, or determined under TSCA section 6 that an existing chemical presents an unreasonable risk) does not, by itself, dictate how EPA will regulate conditions of use to address the unreasonable risk during the risk management phase. It also does not alone dictate how particular industry sectors will be regulated. EPA's statutory authority to regulate chemicals under TSCA sections 5 and 6 is available, respectively, "to the extent necessary to protect against [unreasonable risk]" and "to the extent necessary so that the chemical substance or mixture no longer presents [unreasonable] risk." (15 U.S.C. §§ 2604(e)–(f), 2605(a)). EPA determines the extent of necessary regulation in this context by considering the entirety of the pre-manufacture notice review under section 5 or the risk evaluation under section 6 – not just the risk determination. For every chemical, EPA will—using the best available science and based on the weight of scientific evidence—conduct a hazard assessment, an exposure assessment based on the chemical's conditions of use, characterize the risks, and then determine whether

those risks are unreasonable or may be unreasonable under TSCA as well as the nature and extent of regulation appropriate to specific conditions of use.

EPA recognizes the concerns and the desire for more certainty on future regulatory actions and clear risk communications as part of each risk determination. EPA fully intends to identify which conditions of use or exposure pathways are significant contributors to risk, and has already begun to do so. While not necessarily a perfect indicator of how EPA will ultimately regulate to address unreasonable risks, this should give industry stakeholders improved insight and more certainty about which uses are most likely to be covered in future regulations. The Agency is further committed to clearly communicating the Agency's analysis of particular uses and to refraining from making unqualified statements about the risk associated with the chemical substance that could generate the type of confusion that some industry stakeholders are concerned about.

3. Protecting workers from exposure to harmful chemicals is of the utmost importance. Please share some additional details about how you and your staff are working to address risks to workers and how those efforts align with the EPA's responsibilities under TSCA.

EPA RESPONSE: TSCA requires EPA to consider risks to “potentially exposed and susceptible subpopulations” in risk evaluations – and that very clearly includes workers. EPA and the Occupational Safety and Health Administration (OSHA) meet regularly and are closely coordinating efforts to ensure protections for workers are consistent, to the extent possible given the differences between the agencies’ statutory requirements. EPA is also no longer assuming – as part of TSCA risk evaluations – that all workers will be covered by OSHA, or that existing OSHA protections are always sufficient to meet the risk-based standard under TSCA. For example, many workplaces are not subject to OSHA requirements at all. OSHA lacks direct jurisdiction over state and local government workers, and does not cover self-employed workers, military personnel, and uniquely military equipment, systems, and operations, and workers whose occupational safety and health hazards are regulated by another Federal agency (for example, the Mine Safety and Health Administration, the Department of Energy, or the Coast Guard). Further, for many chemicals, OSHA has not established a chemical-specific requirement, like a permissible exposure limit. Even where OSHA has established such a limit, many of OSHA’s chemical specific standards were developed around 50 years ago in the 1970s. OSHA’s own website states that many of their standards are “outdated and inadequate for ensuring protection of worker health.”¹ Part of EPA’s mandate under TSCA in applying the best available science – and more broadly, to ensure the protection of human health and the environment – is to check to see what scientific developments may have occurred since any existing applicable standard was established and determine how those might impact EPA’s analysis of hazards, exposures and conditions of use with respect to the chemical under evaluation. Moreover, exposure and potential risks to workers are reasonable to foresee in cases where there is a failure of an employer to control workers’ exposure, for example by

¹ Permissible Exposure Limits – Annotated Tables. <https://www.osha.gov/annotated-pels>. Accessed February 2024.

substitution with a safer chemical or through use of engineering controls and/or PPE; or failure to ensure controls and PPE function adequately and are used and maintained correctly.

EPA's approach of not assuming PPE use for purposes of the risk determination ensures thorough consideration of risks to workers and ensures that all workers are protected no matter where they live or who employs them.

4. Almost one year ago, a train carrying vinyl chloride derailed in East Palestine, Ohio, contaminating the air, water, and soil in the surrounding communities in Ohio and Pennsylvania. The communities still face lingering health impacts following the derailment. Shortly afterward, the EPW Committee held an oversight hearing to hear about the EPA's authorities to clean up those toxic chemicals. EPA recently announced that vinyl chloride would undergo the prioritization process through TSCA. Please share the importance of EPA accurately evaluating the risks of chemicals, such as vinyl chloride.

- a. How is your team working to make sure all risk evaluations adequately reduce the risks of chemicals that threaten public health?

EPA RESPONSE: Under this administration, EPA has implemented policy changes that more closely adhere to the letter and intent of the 2016 TSCA amendments. EPA broadened the scope of risk evaluations to ensure that the Agency is assessing potential risks of chemical exposure via air and water, as the law expected EPA to do. EPA removed assumptions that had kept the Agency from fully characterizing workplace risks so we can perform the holistic and comprehensive risk evaluations that are the foundation for protective and robust risk management regulations.

- b. What is the EPA's timeline for making a final prioritization determination for vinyl chloride?

EPA RESPONSE: EPA began the prioritization process for vinyl chloride in December 2023. This process is statutorily required to take no less than 9 months and no more than 12 months. EPA intends to make a final prioritization determination before the end of the calendar year.

5. The EPA recently proposed a strong risk management rule for trichloroethylene (TCE) that will protect public health and the environment by banning the use of this toxic chemical. TCE is classified as a known carcinogen and is linked to neurological damage and birth defects. How important is this ban to families and communities across the country?

- a. Would you share your view of the strength of the science behind the ban?

EPA RESPONSE: This proposed rule is an important and meaningful step towards protecting families and communities across the country from dangerous

chemicals. TCE's hazards are well established. EPA's 2020 Risk Evaluation for TCE, which was peer reviewed by the TSCA Science Advisory Committee on Chemicals (SACC), considered the hazards associated with exposure to TCE and determined that TCE presents an unreasonable risk of injury to health due to the significant adverse health effects associated with exposure to TCE. While some of the risks of adverse effects from TCE exposure are experienced following acute single exposures, other risks are incurred following long-term repeated exposures. Risk of non-cancer effects, specifically fetal cardiac defects and autoimmunity following chronic exposure, are the most sensitive adverse effects. In addition, risks of other significant adverse outcomes associated with TCE exposure include non-cancer effects (liver toxicity, kidney toxicity, neurotoxicity, immunosuppression, reproductive toxicity, and developmental toxicity), as well as cancer effects (liver, kidney, and non-Hodgkin lymphoma). EPA is proposing requirements so that TCE would no longer present unreasonable risk to human health.

6. The EPA's website states that prior to the 2016 amendments to TSCA, the EPA issued risk determinations for approximately 20% of new chemical submissions. Prior to the Lautenberg Act, what was required of the EPA for new chemical reviews?

EPA RESPONSE: Prior to the 2016 amendments, EPA had no affirmative requirement to make a determination regarding the risks associated with every new chemical. There was no provision at the time for EPA to determine that a new chemical or significant new use was unlikely to present unreasonable risk. While manufacturers were subject to the same notice requirements under TSCA section 5 (i.e., submittal of a pre-manufacture notice prior to initiating manufacture for a new chemical substance), EPA had discretion to decide whether to issue a risk determination regarding a specific new chemical or significant new use and take any actions under the law. Where the 90-day review period ended and EPA had not taken action, the submitter could commence manufacture of the new chemical. Using this discretion, EPA issued risk determinations for only approximately 20 percent of new chemical submissions. In 80 percent of cases, EPA "dropped" the chemical from further review and allowed it to go to market.

- a. How did the codification of the Lautenberg Act alter the process for new chemical reviews?

EPA RESPONSE: The 2016 TSCA amendments changed the process for new chemical reviews in several ways, including a requirement that EPA (1) evaluate all nonexempt new chemical substances under their "intended, known and reasonably foreseen" conditions of use, and (2) make a risk determination before those substances can enter the market, including those new chemicals or uses that are unlikely to present unreasonable risk. These new requirements created an approximate 5-fold increase in workload for the Agency. EPA has developed new policy and procedural frameworks to meet the new mandates of TSCA – all while continuing to process both the older submissions in the queue and additional new incoming submissions.

7. A 2022 EPA analysis highlighted that when New Chemical Submissions come into the EPA, they are sometimes incomplete. This results in a back and forth between the EPA and industry, further delaying chemical reviews. What percentage of new chemical applications are submitted to EPA with 100% of the information needed to complete the new chemical review process?

EPA RESPONSE: In virtually all TSCA section 5 notices, certain data elements are left unreported, which may indicate that such information is not known to or reasonably ascertainable by the submitter. EPA has observed approximately 30 percent of all new chemical submissions have additional information submitted after the initial submission, which results in EPA rework (and thus delays for companies). Further, each of those individual cases might be reworked anywhere from one to five times. Although the time required to conduct the rework can vary substantially across different cases, the example from the 2022 analysis found that re-submissions and rework increased the new chemical case review time by 5-7 months. In June 2024, EPA began to track and publish instances of rework on its statistics webpage and will continue to update those numbers moving forward.

- a. What is the EPA doing to stop the repeated “rework” of new chemical determinations when companies submit data late or at the end of the chemical review process to ensure that the agency can do its work in a timely manner?

EPA RESPONSE: TSCA section 5 submitters sometimes provide additional information to EPA to supplement their initial submission well after EPA has already begun a risk assessment of the new chemical substance. The additional information often relates to environmental release and/or occupational exposure assessment of the new chemical substance (i.e., engineering information). Between July 2022 and February 2023, EPA conducted a broad outreach effort to reduce the need to rework risk assessments due to industry submitters providing engineering-related information late in the review process. EPA held three webinars with approximately 300 attendees each to help educate submitters about how to reduce rework. As a result, the quality of engineering information in submissions has improved. The webinar materials are now publicly available on EPA’s website and can be a future resource to submitters who are new to the program or need a refresher. In addition, EPA is working to finalize updates to its procedural regulations for new chemical reviews. As part of the proposed updates, EPA proposed to include more detailed data requirements for incoming submissions. These amendments, if finalized, would add detail to the existing data requirements that are necessary for EPA to perform refined, quantitative risk assessments. The details would reflect the kinds of information that submitters often provide to EPA during the review process rather than upfront, even when such information has potentially been known to or reasonably ascertainable by the submitter all along, and, as such, would also be expected to help EPA to complete its assessments in a more timely manner.

In addition, EPA has implemented a new internal “engineering checklist” step that occurs early in the review process that should help make things run smoother. This step allows us to better identify potential issues at the beginning of the process, allowing early engagement and resolution with the submitter before any unnecessary work (and subsequent rework) has been completed.

EPA would also like to restart and revamp its “Sustainable Future” training program – something the Agency used to offer to better educate new chemical submitters. This training was focused on helping attendees better understand the steps of the process and the use of predictive models and tools in more detail. EPA would walk attendees through each of the New Chemical Program’s predictive tools and models, provide attendees free copies of the software, and do hands-on exercises for most of the models over the course of multiple days. However, this effort necessitates increased resources. The Sustainable Future program has not run since 2017, and would require additional resources to restart. For example, much of the material is outdated due to advancements in models and tools and in light of the changes to the program in the 2016 TSCA amendments. In addition, contract support would be necessary to implement the program from a logistical standpoint. In light of the cuts to EPA’s FY 2024 budget, however, there is not sufficient FTE and extramural funding to support moving forward on Sustainable Futures training this year. EPA is considering future FTE and resource needs to accomplish this goal.

8. One of the key reforms to TSCA was about access to information and greater transparency between the EPA, industry, and the public. How is the EPA ensuring that communities and stakeholders have access to timely information?

EPA RESPONSE: EPA is committed to greater transparency under TSCA, and to meeting our statutory and regulatory obligations for making information publicly available. Generally, EPA communicates TSCA information in the *Federal Register*, the public docket, ChemView (a TSCA web application) and our Agency webpages. The Agency updated or is in the process of updating our procedural regulations for new chemicals reviews, existing chemical risk evaluations, and for reviewing claims of confidential business information – all with a goal of increasing transparency and ensuring the public can have timely access to information. EPA is also working to automate our data and document publishing processes related to additional TSCA section 5 submissions, TSCA section 8(e) submissions and test data submissions in ChemView, and continues to regularly update the TSCA inventory by moving chemical identities that are no longer confidential from the CBI portion of the Inventory to the public portion of the Inventory – nearly 1,000 chemicals in the last several years. For existing chemicals, in addition to the numerous opportunities for review and comment on milestone steps throughout the entire process (e.g., prioritization candidate selection, proposed priority designation, risk evaluation draft scope, draft risk evaluation, proposed risk management rule, etc.), EPA is augmenting its stakeholder outreach and engagement to ensure the Agency has a thorough understanding of the potential exposures and risks from chemicals undergoing TSCA review.

9. Cumulative risk assessment is proven to be more representative of real-world risks than considering a chemical individually and will, consequently, allow for more robust risk management to protect vulnerable populations.
 - a. For which chemicals other than phthalates is the EPA currently conducting or intending to conduct a cumulative risk assessment under TSCA?

EPA RESPONSE: EPA is not currently conducting cumulative assessments on other chemicals aside from the phthalates, but may consider doing so in the future where the best available science may indicate that the development of a cumulative risk assessment is appropriate to ensure that risk to human health and the environment is adequately characterized, and consistent with TSCA's statutory deadlines and available resources.

- b. Does the EPA intend to conduct cumulative risk assessments in its risk evaluation process?

EPA RESPONSE: In the amendments to the risk evaluation procedural rule (89 Fed. Reg. 37028, May 3, 2024), EPA described the Agency's plans with respect to conducting cumulative risk assessments. TSCA gives the Agency the authority to consider the combined risk from multiple chemical substances or a category of chemical substances. EPA recognizes that for some chemical substances undergoing risk evaluation, the best available science may indicate that the development of a cumulative risk assessment is appropriate to ensure that risk to human health and the environment is adequately characterized. As EPA continues to prioritize and evaluate chemicals under TSCA, the public will continue to have ample opportunity to weigh in on the Agency's expected approaches and supporting science – including approaches related to cumulative risk assessments. EPA's ability to expand upon its current risk evaluation approaches and activities is necessarily dependent on the operating budget for the TSCA program.

Senator Whitehouse:

1. The EPA still has not established Effluent Limitation Guidelines (ELGs) for the industrial categories known to discharge PFAS. What are the public health and environmental risks if these ELGs on PFAS are delayed?

EPA RESPONSE: EPA's rulemaking efforts to develop Clean Water Act Effluent Limitations Guidelines for industry sectors that discharge PFAS are led by EPA's Office of Water. EPA is developing rules under the ELG program to limit PFAS discharges to waterways from PFAS manufacturers, metal finishers, and landfills. For more information, EPA's Office of Congressional and Intergovernmental Relations can arrange an update for your office.

2. How does EPA plan to balance the need for expedient PFAS risk evaluations while still ensuring safe and equitable decisions?

EPA RESPONSE: PFAS – because of their widespread use and persistence in the environment – are found in the blood of people and animals all over the world. They are also in water, air and soil at locations across the globe. Scientific studies have shown that exposure to some PFAS are linked to harmful effects in humans and animals. Because this group of chemicals is so large and because many of the chemicals are not well-characterized, it is challenging to assess risks and take appropriate steps to protect people and environment for the entire class. EPA recognized that solving the problem was going to take increased and sustained leadership from every level of government – Federal, Tribal, state, and local. In April 2021, EPA Administrator Michael Regan established the EPA Council on PFAS and charged it to develop a bold, strategic, whole-of-EPA strategy to protect public health and the environment from the impacts of PFAS. As part of implementing the PFAS Strategic Roadmap, developed by the EPA Council on PFAS, EPA has taken a number of significant actions on PFAS over the last several years.

In the TSCA New Chemicals Program, EPA plays an important gatekeeper role in ensuring that risks from new chemicals – including those chemicals not yet in commerce – are addressed before they’re allowed to enter the market. Because EPA continues to get premanufacture notices for new PFAS through the new chemicals program, the Agency published a framework outlining our expected approach for reviewing and managing those new PFAS. The approach in the framework first involves a consideration of whether the new chemical is likely to be persistent, bioaccumulative and toxic or “PBT.” Where it is a PBT – which EPA thinks will most often be the case – the Agency will generally pursue a qualitative assessment based on EPA’s longstanding approach to assessing PBT chemicals. The approach also reflects some expectations for data and testing to ensure that EPA has an adequate understanding of the chemical’s properties and characteristics in order to make informed decisions as to where more information might be needed. EPA expects to allow new PFAS to be manufactured and used only when exposures and releases can be sufficiently controlled or avoided.

Some PFAS will not result in worker, general population or consumer exposure and are not expected to result in releases to the environment, such as PFAS used in a closed system. In such a negligible exposure and environmental release scenario, if EPA can ensure that the PFAS can be disposed of properly and no consumer exposure is expected, EPA generally expects to allow the PFAS or the new use of a PFAS to enter commerce after receiving basic information, such as physical-chemical property data, about the substance. If this initial data cause concern, then EPA would require additional testing and risk mitigation before moving forward.

For PFAS that are expected to lead to exposure and environmental releases, and absent a critical or national security need for the substance that necessitates limited and restricted manufacture while testing is ongoing, EPA generally expects that the substance would not be allowed to enter commerce before extensive testing is conducted

on physical/chemical properties, toxicity, and fate. For example, use of PFAS in spray-applied stain guards inherently involve releases to the environment. If the test results cause concern, then EPA could require additional testing and risk mitigation before moving forward or could prevent the substance from being manufactured at all.

PFAS continues to play a role in critical industry sectors like semiconductor manufacturing and PFAS use may be necessary to support a critical need. This framework helps strike the balance between our requirement under the law to protect human health and the environment, while supporting and fostering innovation in the chemical sector.

3. Although the 2016 TSCA Act directs EPA to replace or reduce animal testing, EPA has since removed several target dates to end mammal studies by 2035.

- a. Why were these target dates removed?

EPA RESPONSE: EPA remains committed to phasing out animal testing. While the goal dates in the original work plan may have been intended to spur focus and action, those dates were not derived using the input of the Agency's scientific experts, and became the primary focus of discussion within the scientific and stakeholder communities as opposed to what actions or path the Agency should take to reduce the use of animals while still remaining fully protective of human health and the environment. Since the 2016 amendments to TSCA, EPA has continued to make considerable progress in developing and implementing NAMs, however, there are still scientific challenges and information gaps that limit a complete reliance on NAMs for Agency decisions in a manner that fulfills EPA's mission of protecting human health and the environment. EPA will continue leading the development of the science and policies necessary to reduce its reliance on vertebrate animal testing, while ensuring that the Agency has the robust, relevant, and scientifically supportable information it needs to protect our health and our environment.

- b. What is EPA doing to make sure non-animal approaches are a priority for TSCA testing?

EPA RESPONSE: Consistent with the Biden-Harris Administration's focus on the use of the best available science to inform decisions, and on the importance of scientific integrity, EPA intends to proactively continue to reduce the use of animals to test and evaluate chemicals by supporting the development of new scientific methods. The development of new science will be led by Agency career scientists, and the timing of development, demonstration, and adoption of new methods will proceed according to scientific considerations. EPA is already prioritizing ongoing efforts to develop and use NAMs to test chemicals for health effects. For example, EPA considers NAMs and existing non-animal data when prescribing tests under TSCA section 4, including some recent test orders for PFAS chemicals.

In 2022, EPA launched a new effort, called the New Chemicals Collaborative Research Program, to modernize the process and bring innovative science to the review of new chemicals before they can enter the marketplace. Through this effort, EPA is conducting a multi-year collaborative research program with stakeholders focused on approaches for performing risk assessments on new chemical substances under TSCA. This collaborative research program is developing new NAMs and models. However, this program has, for two years in a row, been funded at only a fraction of what was requested from Congress.

In 2024, EPA also hosted scientific expert meetings on both chemicals used in the fragrance sector and PFAS where the development and application of NAMs and predictive models were discussed in detail.

Additionally, EPA created the NAMs Work Plan to prioritize Agency efforts and resources toward activities that aim to reduce the use of vertebrate animal testing while continuing to protect human health and the environment. The original EPA NAMs Work Plan was released in June 2020 and laid out the Agency's objectives and strategies. As part of the NAMs Work Plan, EPA will develop a framework to establish scientific confidence based on the quality, reliability and relevance of NAMs. EPA will also facilitate joint development of NAMs by EPA scientists and regulators as part of a regular 4-year collaborative research planning cycle. Finally, EPA expects to regularly update a centralized portal for releasing EPA-related NAM information to ensure transparency and accountability. EPA is also committed to soliciting comment and feedback associated with its deliverables, including public feedback and scientific peer review where appropriate, as well as to the development of training courses, workshops, and conferences for stakeholders on the development and application of NAMs.

- c. How much animal testing has been used per year since 2016 to assess the safety of chemicals under TSCA?

EPA RESPONSE: With respect to the TSCA New Chemicals Program, it is important to note that there are no specific testing requirements for a submission. The type and quantity of available test data the Agency receives is determined by the new chemical submitter. One of the key milestones in EPA's 2021 New Approach Methods Work Plan is the development of metrics (https://www.epa.gov/system/files/documents/2021-11/nams-work-plan_11_15_21_508-tagged.pdf). As part this effort, EPA OPPT has conducted an analysis of the available test information submitted for TSCA section 5 notices (pre-manufacture and significant new uses) and exemptions to establish a baseline of vertebrate animal use in the New Chemicals Program after the 2016 TSCA amendments. From FY 2017 through FY 2023 the approximate number of vertebrate animals used in test information received by EPA OPPT ranged from 18,000 – 35,000 and averaged 27,000 per year.

EPA has not been tracking use of NAMs for TSCA actions on existing chemicals in a similar manner. However, as described above, consideration of NAMs and existing non-animal data is a priority for EPA when prescribing any new test requirements under TSCA section 4 for existing chemicals.

- d. To what extent are new alternative methods replacing animal tests used to assess TSCA chemicals.

EPA RESPONSE: TSCA section 4(h) specifically requires that EPA reduce and replace the use of vertebrate animals in the testing of chemical substances, to the extent practicable and scientifically justified. TSCA also required EPA to develop a strategic plan to promote the development and implementation of alternative test methods and strategies to reduce, refine or replace vertebrate testing and provide information of equivalent or better scientific quality and relevance for assessing risks of injury to health or the environment from chemical substances.

In the New Chemicals Program, EPA has used non-animal methods such as read across, use of analogs, and quantitative structure activity relationships in nearly every risk assessment. This means that EPA is using new approach methods in hundreds of assessments every year. Select NAMs data were counted during the analysis of the available test information submitted for TSCA section 5 notices and exemptions. From FY 2017 through FY 2023 the approximate number of in vitro studies submitted to EPA's New Chemicals Program totaled 744 studies ranging from 45 to 131 studies per fiscal year.

EPA is continuing to make progress in the development and implementation of NAMs. For example, in January 2024, EPA announced a new framework for identifying eye irritation and corrosion hazards for new chemicals reviewed under TSCA. With this new framework, EPA will place increased weight on data from non-animal test methods that are more reproducible and provide results more relevant to humans. The New Chemicals Program regularly receives NAMs data for TSCA section 5 submission to assess eye and skin irritation and skin sensitization as replacements to the traditional tests which utilize rabbits, rats, and guinea pigs.

For existing chemicals, testing may be required under TSCA section 4, which requires EPA to use a tiered approach for testing. EPA considers NAMs and existing non-animal data when prescribing tests under TSCA section 4. Under EPA's National PFAS Testing Strategy, EPA employs a category-based approach to testing so that representative test substances can be used to inform the effects of other PFAS within the same category of the representative PFAS. Implementing these tiered and category approaches to testing has significantly decreased the potential amount of vertebrate testing to be conducted and/or number of vertebrates to be used under the program.

Senator Merkley

1. Dr. Freedhoff, for years, EPA approved new PFAS chemicals and chemistries through various exemptions in lieu of a full safety review. Last summer, the Office of Chemical Safety and Pollution Prevention (OCSPP) proposed ending the use of exemptions for PFAS chemicals. If that proposal is finalized, EPA will no longer exempt new PFAS chemicals from full safety reviews going forward.

What are OCSPP's plans to address those PFAS already approved for use under an exemption? If so, when? If not, why not?

EPA RESPONSE: EPA has the authority to revoke previously granted low volume exemptions (LVEs) for PFAS, in accordance with the existing regulations at 40 CFR 723.50(h)(2), on a case-by-case basis. Revocation actions would be resource intensive, and EPA's ability to take on additional work in this space is dependent on the program's operating budget. In the meantime, EPA continues to work cooperatively with companies who wish to voluntarily withdraw previously granted LVEs for PFAS. As of August 2024, 58 LVEs have been withdrawn through EPA's PFAS Low Volume Exemption Stewardship Program.

2. Dr. Freedhoff, now that EPA's Office of Land and Emergency Management is close to releasing the final Risk Management Program rule relating to chemical accidents at facilities, does your program plan to use this data on chemical accidents in risk evaluations as you consider the likely exposures, including peak exposures, for fence-line communities?

EPA RESPONSE: As required under TSCA, EPA will consider all reasonably available information during the TSCA risk evaluation process. Where the reasonably available information demonstrates that certain exposures associated with a spill or leak are known or reasonably foreseen to occur during a condition of use that is part of a risk evaluation (e.g., regular or predictable exposures from equipment leaks as part of the manufacturing process), EPA would expect to include that exposure within the scope of the risk evaluation. However, a future one-time accident involving the chemical substance that could be caused by an atypical one-time set of circumstances would generally not be assessed as part of a risk evaluation. EPA generally does not expect to include within the scope of the risk evaluation exposures from releases of a chemical substance that are unsubstantiated, speculative, or otherwise not likely to occur.

Senator Markey:

1. How is your office fulfilling its obligations to frontline communities to fully consider exposures and risk?

EPA RESPONSE: TSCA requires EPA to evaluate risk to "potentially exposed or susceptible subpopulations" identified as relevant to the risk evaluation by the Administrator, which the law defines as "a group of individuals within the general population identified by the EPA who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from

exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.” (15 U.S.C. § 2602(12)). Although TSCA does not further define “greater susceptibility” or “greater exposure,” greater susceptibility could include increased risk of experiencing an adverse effect due to one’s lifestyle or a pre-existing condition or circumstance, and that “greater exposure” could include fence-line communities (e.g., those communities in close proximity to facilities releasing chemicals to air, or those living near effluent releases to water).

EPA has been making a number of significant improvements to its TSCA risk evaluations and process to ensure a comprehensive review of a chemical’s risks, including risks to potentially exposed and susceptible subpopulations. EPA’s more thorough consideration of these vulnerable communities in risk evaluations will also better position the Agency to design appropriate risk management approaches to address identified unreasonable risk, including risks disproportionately borne by communities living on or near the fence-line.

2. Your office has conducted effective engagement with and outreach to small businesses. Is there a person or team within your office similarly dedicated to or tasked with ensuring community advocacy and engagement?

EPA RESPONSE: In addition to many efforts to engage communities and public stakeholders through the typical public notice and comment process, webinars, public meetings, and other communications (listservs, press releases, social media, etc.), EPA has an entire branch within the Office of Pollution Prevention and Toxic’s Project Management and Operations Divisions dedicated to partner and stakeholder engagement. EPA meets with stakeholders and community advocates regularly. Our ability to conduct more outreach and engagement with communities and other stakeholders is necessarily tied to the availability of resources to support the program, and the reduction in the program’s FY 2024 budget will impact our ability to expand efforts in this area.

- a. One way EPA can support community advocacy and engagement is by ensuring that the voices of impacted communities are part of the decision-making process through holding public meetings and by taking public comments. In what ways do EPA staff ensure community participation throughout all stages of the rulemaking process?

EPA RESPONSE: There are numerous opportunities for public participation throughout the entire TSCA process (i.e., prioritization candidate selection, proposed priority designation, risk evaluation draft scope, draft risk evaluation, proposed risk management rule, etc.). EPA meets with community groups regularly, as an opportunity for groups to voice their concerns and help shape the decision-making process. EPA staff have traveled on several occasions to local communities to see and hear directly from those most impacted. EPA is also augmenting its stakeholder outreach and engagement to ensure the Agency has a thorough understanding of the potential exposures and risks from chemicals undergoing TSCA review. For example, in advance of EPA’s identification of the most recent set of chemicals to undergo prioritization, EPA met with numerous stakeholders including environmental organizations, labor

organizations, state and local governments, and Tribes to discuss the prioritization process and presented a list of 15 chemical substances that EPA was considering for prioritization. EPA took feedback from these discussions into consideration when selecting this set of five chemicals for prioritization. However, as described above, the reduction in the program's FY 2024 budget will impact our ability to accelerate and expand these efforts (e.g., travel for in-person meetings and site visits will likely be limited).

3. One of the key reforms to TSCA was about access to information. How does your office ensure that communities and stakeholders have access to timely information?

EPA RESPONSE: EPA is committed to greater transparency under TSCA, and to meeting our statutory and regulatory obligations for making information publicly available. Generally, EPA communicates TSCA information in the *Federal Register*, the public docket, ChemView (a TSCA web application) and our Agency webpages. The Agency updated or is in the process of updating our procedural regulations for new chemicals reviews, existing chemical risk evaluations, and for reviewing claims of confidential business information – all with a goal of increasing transparency and ensuring the public can have timely access to information. EPA is also working to automate our data and document publishing processes related to additional TSCA section 5 submissions, TSCA section 8(e) submissions and test data submissions in ChemView and continue to regularly update the TSCA inventory by moving chemical identities that are no longer confidential from the CBI portion of the Inventory to the public portion of the Inventory – nearly 1000 chemicals in the last several years. For existing chemicals, and in addition to the numerous opportunities for review and comment on milestone steps throughout the entire process (i.e., prioritization candidate selection, proposed priority designation, risk evaluation draft scope, draft risk evaluation, proposed risk management rule, etc.). EPA is augmenting its stakeholder outreach and engagement to ensure the Agency has a thorough understanding of the potential exposures and risks from chemicals undergoing TSCA review.

Ranking Member Capito:

1. How long after March 2022 did it take the Office of Chemical Safety and Pollution Prevention (OCSPP) to present a compliant Title 42 handbook to the Office of Personnel Management for approval?
2. Do you believe more could have been done by the Biden Administration to expedite the use of this hiring authority by your Office?

EPA RESPONSE: OCSPP needed to complete a 4-step process before it could begin using the Title 42 authority authorized by Congress in March 2022. These steps included: 1) receiving concurrence from the Office of Personnel Management (OPM) to use the Title 42 authority; 2) drafting and receiving approval for OCSPP's Title 42 handbook and standard operating procedures; 3) revising the EPA Order that oversees the use of the Title 42 authority within the Agency; and 4) completing a revision to the delegation of authority to allow OCSPP managers to implement the Title 42 authority.

In March 2022, soon after authorization by Congress, OCSPP began drafting its Title 42 handbook and standard operating procedures, and simultaneously began drafting revisions to the delegation of authority and EPA Order. The Administrator signed the delegation of authority in October 2022. The Administrator signed the revised EPA Order in November 2022.

With these steps completed, EPA began informal consultation with OPM in November 2022, which included sending OPM drafts of the handbook, and then formal consultation with OPM that concluded in March 2023.

In January 2024, EPA completed the final step in the process when the Office of Mission Support issued its approval for OCSPP's Title 42 handbook and standard operating procedures.

3. Section 26(a) of the TSCA (15 U.S.C § 2625(a)) authorizes other federal agencies – upon the EPA's request – to provide "services, personnel, and facilities to assist in the administration of TSCA." As of my staff's latest conversation with the Government Accountability Office, there was no indication that the OCSSP considered using TSCA section 26(a) in its workforce planning. Why?

EPA RESPONSE: In the enacted budget for FY 2023, EPA received an increase of 65 full-time equivalents (FTEs) to support its implementation of TSCA. In response to that increase, the Agency's workforce planning for TSCA has focused on hiring those employees as directed by Congress. As of July 30, 2024, EPA has made 55 of those hires. These efforts represent meaningful progress to use the authorities at its disposal to enhance and align EPA's TSCA workforce, which necessarily includes highly specialized technical and scientific experts in a range of disciplines. Prior to the enacted budget for FY 2023, EPA also made significant efforts to leverage its own internal resources and expertise by bringing scientists and other staff in other EPA offices (e.g., EPA's Office of Research and Development) to OCSPP on detail assignments to support TSCA implementation. With respect to use of TSCA section 26(a) authority as described in your question, EPA would note that any such interagency agreement would likely involve an agreement by EPA to pay for or reimburse the other Agency for their services, personnel or facilities. As such, and in light of the program's budget situation, such an agreement would not help resolve the broader issue regarding lack of sufficient funding to implement the program. The enacted budget for FY 2024 includes a significant reduction in TSCA resources that will negatively impact EPA's ability to implement TSCA as envisioned by Congress. In this context, EPA will continue to use its TSCA authority as appropriate to implement TSCA.

4. For new chemicals – I am aware of only one instance where the EPA concluded a substance was not likely to present a risk after identifying a hazard. Is the EPA employing a hazard-based standard that precludes mitigating risk for compliance?

EPA RESPONSE: Since the 2016 TSCA amendments, and as of August 1, 2024, EPA has allowed 760 new chemicals and significant new uses of existing chemicals to

commercialize without restriction, meaning that EPA made 760 determinations that a chemical substance was “not likely” to present an unreasonable risk. See EPA’s statistics webpage for new chemical reviews here: <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review>. As required under the law, EPA considers both hazard and exposure (i.e., a risk-based standard) in assessing the risk from new chemicals.

5. Please provide the data justification the EPA used to support the claim made in your testimony that there has been a 50-percent decrease in the PMN backlog.

EPA RESPONSE: As noted in my testimony, “...we have cleared out about 50 percent of the older backlogged cases.” The “older backlogged cases” in this statement refers to the approximately 454 exemption applications and premanufacture notices that were submitted in FY 2022 or prior years, and not yet completed. Between October 2022 and August 2024, EPA has now closed out 62 percent (282 of 454) of those backlogged cases.

6. On May 26, 2023, the EPA issued a proposed rule entitled “Updates to New Chemicals Regulations under the Toxic Substances Control Act.” The rule would make perfluoroalkyl and polyfluoroalkyl substances (PFAS) categorically ineligible for low volume exemptions (LVEs) and low release and exposure exemptions (LoREXs). What risk-based standard is the EPA applying in this decision?

EPA RESPONSE: TSCA section 5(h)(4) provides the standard for exempting new chemical substances from the typical pre-manufacture notice review process and requires EPA to determine that a chemical “will not present an unreasonable risk of injury to health or the environment.” Due to the scientific complexities associated with assessing PFAS and the lack of data on most PFAS with regards to toxicity and exposure to human health and the environment, EPA expects in most cases to be unable to determine pursuant to TSCA section 5(h)(4) that a PFAS “will not present an unreasonable risk” under the conditions of use within the 30-day review period provided for LVE and LoREX notices. While the current state of science and EPA’s understanding of PFAS has motivated the proposal to make all PFAS ineligible for the LVE and LoREX exemptions, these proposed amendments are not based on hazard, exposure, or risk. This proposed action would be a procedural action based on the Agency’s experience administering TSCA and reviewing LVEs for PFAS, and the expectation that EPA will need the full 90-day review for new PFAS that is standard for most new chemicals. Such reviews are conducted in a risk-based manner and in accordance with EPA’s “Framework for TSCA New Chemicals Review of PFAS Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs).”

7. In your responses to the June 2022 hearing’s questions for the record – you stated, “not all PFAS are the same, and EPA expects that different PFAS will present differing levels of concern.” Similarly, during the June 2022 hearing you responded “yes, we are” to a question on whether the EPA intends to utilize a tiered approach to classifying, categorizing, and prioritizing PFAS based on different physical properties and hazards. Does the EPA still recognize that not all PFAS are the same and will present differing levels of risk?

EPA RESPONSE: Yes.

8. If so, why is the EPA is applying a one-size-fits-all approach to the proposed decision to make PFAS categorically ineligible for LVEs and LOREXs?

EPA RESPONSE: EPA would not characterize its approach to PFAS and exemption eligibility in the proposed rule as “one-size-fits-all.” Instead, the proposed rule reflects the reality that TSCA’s section 5(h)(4) standard is not a good fit for PFAS. PFAS are a broad category of chemical substances, and EPA agrees that the assessment and management of these substances should generally be done on a case-by-case basis or as groups of substances with common toxicological properties, exposures, or uses. Furthermore, any assessment of PFAS should be done in line with the scientific standards, weight of scientific evidence, and consider any reasonably available information as outlined in section 26 of TSCA. Reviews of new PFAS are conducted in a risk-based manner and in accordance with EPA’s “Framework for TSCA New Chemicals Review of PFAS Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs).”

As described in response to Question 6 above, the proposal to make PFAS ineligible for LVEs and LOREXs is not based on an assessment of all or any PFAS and does not reflect a determination of risk for all or any PFAS. This action is a procedural action based on the Agency’s experience administering TSCA and reviewing LVEs for PFAS, and the expectation that EPA will need the standard, full 90-day review for reviewing this complex set of chemistries.

9. Will you commit to applying a risk-based standard to regulate a given PFAS compound?

EPA RESPONSE: Yes, and the law requires it. For example, where EPA determines that a new PFAS may present an unreasonable risk under TSCA section 5(a)(3)(B)(ii), the law requires that EPA issue an order under TSCA section 5(e) to impose restrictions on PFAS “to the extent necessary to protect against 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.”

10. During the January 2024 hearing, you testified: “[I]f the PFAS is going to be used in a sophisticated industrial environment, like the semiconductor industry has, workers are protected, environmental releases are controlled, there will be a path through the New Chemicals program for PFAS like that.” Does this statement indicate that your office has reconsidered its LVE and LOREX decisions for PFAS under the New Chemical Procedural Rule?

EPA RESPONSE: No. The path referenced here is through the typical/standard pre-manufacture notice review process, rather than the exemption processes for LVEs and LOREXs.

11. Did your office conduct interagency consultations with executive membership of the Department of Commerce and the Department of Defense prior to issuing the proposed LVE and LOREX changes for PFAS on May 26, 2023?

EPA RESPONSE: EPA followed the process for interagency review of regulatory actions pursuant to Executive Order 12866 and this proposed rule was not subject to interagency review. The final rule is, however, subject to and currently undergoing interagency review.

That said, I have met with representatives of the U.S. Department of Commerce's CHIPS program, as has the Division Director of the New Chemicals Program, to answer clarifying questions about EPA's New Chemicals PFAS Framework and the May 2023 proposed rule, as they relate to the semiconductor industry. By aligning the regulatory text with the 2016 amendments to TSCA's new chemicals review provisions and improving the efficiency of EPA's review processes, the proposed rule would also provide clarity for semiconductor manufacturers when they submit new chemicals for evaluation, allowing them to move through the regulatory process more efficiently and help to foster innovation.

Further, I—and others at EPA—meet regularly with officials at the U.S. Department of Defense to discuss TSCA actions and other issues of concern, including those that relate to continued access to PFAS. EPA held a specific meeting on January 23, 2024, to provide a briefing on the proposed amendments to the new chemicals procedural regulations and the PFAS Framework. Mitigation of potential impacts on national security are accounted for in EPA's existing chemical regulations, and the importance of mitigating such potential impacts is acknowledged in EPA's policies for new chemicals. For example, within the New Chemicals PFAS Framework document, EPA explicitly acknowledges that there may be case-specific circumstances where the use of a new PFAS or new use of an existing PFAS may be needed by a Federal agency to meet its mission or is required to meet a critical need. EPA may allow some limited manufacture of a PFAS while testing such PFAS is ongoing if appropriate risk management measures can be applied so that the limited manufacture would not present unreasonable risk.

12. Please provide all communications with the Department of Commerce and Department of Defense related to the May 26, 2023 proposed New Chemical Procedural Rule?

EPA RESPONSE: The final rule is currently undergoing interagency review. EPA recognizes the importance of Congress's interests in obtaining information necessary to perform its legitimate legislative and oversight functions, and the Agency is committed to cooperating with Committee staff to provide non-privileged information the Committee needs, and to engaging in the accommodation process.

13. After the 2016 amendments, how does the EPA interpret the relationship between new chemical reviews, the TSCA inventory, and prioritizing existing chemical evaluations?

EPA RESPONSE: The 2016 amendments comprehensively amended TSCA, including provisions related to new chemical reviews, the TSCA inventory, and prioritization and evaluation of existing chemicals. The changes to new chemical reviews – including the requirement to make an affirmative determination of risk in every case – reinforce the program’s role as a gatekeeper to ensure the safety of new chemicals before they are allowed to enter commerce. Requirements for new chemicals (i.e., those not yet on the TSCA inventory) are distinct from the requirements to prioritize and evaluate existing chemicals (i.e., those already on the TSCA inventory and in U.S. commerce). The 2016 amendments required a reset of the TSCA inventory (completed through implementation of a reporting rule) to help distinguish between existing chemicals on the inventory that are still actively manufactured or processed (i.e., “active” chemicals) and those that are not (i.e., “inactive” chemicals). When TSCA was originally signed into law in 1976, the more than 60,000 existing chemicals in commerce at that time were “grandfathered” in with no requirement for EPA to review or manage risks. That fundamentally changed in 2016. EPA is now required to systematically prioritize existing chemicals for review, conduct risk evaluations on chemicals designated as “high-priority substances” and, where unreasonable risk is identified, promulgate regulatory restrictions to eliminate such risks – all within statutory deadlines. These and other provisions of the law work together to increase the American people’s confidence in the safety of new and existing chemical substances in commerce.

14. Does the EPA intend to prioritize more low-priority substances for review in the next calendar year? If so, why? If not, why not?

EPA RESPONSE: EPA would like to, yes, and the Agency is actively talking about what it would take to do that. Ultimately, however, EPA’s ability to take on discretionary activities is budget-dependent. Given the cuts to the program’s budget in FY 2024, additional low-priority designations do not seem likely this calendar year.

15. During negotiations over the 2016 Amendments to TSCA, did the EPA ever provide technical assistance to Congress objecting to the continued use of a 90-day deadline for new chemical review decisions?

EPA RESPONSE: No.

16. How are the proposed revisions to the definition of “applicable review period” consistent with congressional intent that there be a 90-day review period for new chemical submissions?

EPA RESPONSE: Under TSCA section 5(i)(3), the “applicable review period” means 90 days from the date EPA receives a notice under TSCA section 5(a)(1), or up to 180 days from that date if EPA extends the applicable review period according to the provisions in TSCA section 5(c). As part of the proposed amendments to the new chemicals procedural rule, EPA proposed to replace the terms “notice period,” “notification period,” “statutory review period,” and “notice review period” with the term “applicable review period” throughout 40 CFR part 720 to be consistent with the new terminology in TSCA section 5 added by the 2016 amendments. EPA also proposed

to add a definition for “applicable review period” to 40 CFR 720.3, which EPA would define as “the period starting on the date EPA receives a complete notice under section 5(a)(1) of the Act and ending 90 days after that date or on such date as is provided for in sections 5(b)(1) or 5(c) of the Act.” As such, when EPA receives a notice under TSCA section 5(a)(1) that contains errors or is otherwise determined to be incomplete, the applicable review period would not begin until such deficiencies are corrected. These changes are both consistent with the Congressional intent, and necessary for the efficient implementation of the program.

17. If the EPA proposes a Workplace Chemical Protection Program (WCPP) utilizing an existing chemical exposure limit (ECEL) that is considered protective of public health and the environment, what justification does the EPA use to propose more additional stringent regulatory control, such as outright bans, that go beyond “the extent necessary” requirement to address unreasonable risk (for example, the EPA has utilized this approach in its recent risk management proposals for methylene chloride, perchloroethylene, and trichloroethylene)?

EPA RESPONSE: EPA agrees that successful implementation of a workplace chemical protection program can in some cases address the unreasonable risk to workers identified in a risk evaluation, including certain conditions of use for methylene chloride and PCE, when EPA has confidence that the typical workplaces associated with those conditions of use can successfully implement a workplace chemical protection program. In those instances EPA would not ban such use. However, in some cases EPA has determined, based on the full record, that typical workplaces will not be able to successfully implement a WCPP because of the nature of the workplace or the nature of work activities. In those instances, a use prohibition may be the appropriate mechanism for addressing the unreasonable risk to the extent necessary. As discussed in the preamble to the proposed rules for those chemicals, EPA determined that the WCPP would be challenging to implement for some uses in some environments. These include work that takes place in the field, such as on-site paint removal or the use of adhesives at construction sites, where it would be more difficult to establish regulated areas and conduct exposure monitoring. In other cases, the donning of respirators would create challenges for work activities in small, enclosed spaces or for work activities that require a high range of motion and may further present communication problems, vision problems, worker fatigue, and reduced work efficiency. EPA also considered the reasonably available information on exposure levels, the limitations of respirators, and the significant hazards presented by the chemical (for example, methylene chloride is acutely toxic when inhaled and there have been numerous workplace fatalities caused by methylene chloride exposure).

To the extent that EPA receives information during the public comment period for a proposed rule demonstrating that successful implementation of the WCPP for a particular condition of use (or subset of a condition of use) is possible without undue reliance on respiratory protection, EPA will take that into account in developing the final rule. TSCA does not require or permit EPA to regulate all workplaces via implementation of a WCPP when EPA lacks evidence and/or confidence that a WCPP can be successfully implemented for certain conditions of use or subsets of conditions of

use. Failure by any entity to adequately implement the WCPP would subject workers to the same unreasonable risks that a TSCA section 6(a) rule is designed to address.

Moreover, if EPA were to regulate all workplaces via implementation of a WCPP, it could present significant and widespread implementation difficulties across multiple industry sectors, leading to high non-compliance rates that would undermine the health-protectiveness of the rule. For example, EPA is aware that there remains ongoing non-trivial levels of noncompliance with the existing OSHA Methylene Chloride Standard.² Given this background, and the fact that EPA's ECEL is lower than OSHA's PEL, it is not reasonable to assume that, if EPA were to apply the WCPP to all uses, entities with ongoing difficulty implementing a WCPP would cease use of methylene chloride because they are unable to comply with the WCPP. Rather, EPA expects that those entities would instead continue attempting (albeit unsuccessfully) to implement such protections, leaving the unreasonable risk unmitigated. Accordingly, EPA's rule would fail to ensure that methylene chloride no longer presents an unreasonable risk to health, as required by TSCA section 6(a). Conversely, where EPA has information demonstrating that companies can meet the WCPP reliably, there is a record basis upon which EPA can determine that the condition of use can continue under the WCPP without contributing to the unreasonable risk posed by methylene chloride. In the case of methylene chloride, of the over 40 occupational uses assessed, EPA determined that 13 could continue under the WCPP, including use in the manufacture of other chemicals, as a processing aid in the manufacture of separators electric vehicle batteries, and in plastic manufacturing.

In other cases, such as for trichloroethylene, given that the magnitude of risk is so high, and that the extremely high level of PPE would be an ineffective long-term way of addressing that risk along with information provided by the public, EPA has significant uncertainty that any measures short of prohibition would be sufficient to address the unreasonable risk. The extremely low level of the ECEL, while fully addressing unreasonable risk, will be infeasible for industry to meet due to the need for a combination of engineering, administrative controls, and full-face, self-contained, air-supplied respirators. As such, EPA's proposed risk management rule for TCE reflects its proposed conclusion that the only way to protect human health consistently, reliably, and continually from unreasonable risk would be to prohibit the chemical.

18. Section 9(c) of the TSCA states: "In exercising any authority under this Act, the Administrator shall not, for purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970, be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health." Please explain how the EPA is not contradicting the plain language of the statute when issuing ECELS in risk evaluations and management plans.

² Hoang, Ahn, Fagan, Kathleen, Cannon, Dawn L., et al. Assessment of Methylene Chloride-Related Fatalities in the United States, 1980-2018. JAMA Internal Medicine. American Medical Association. Chicago, Illinois. April 19, 2021. 181(6): 797-805.

EPA RESPONSE: The purpose and effect of TSCA section 9(c) is to ensure that the exercise of TSCA authority does not preempt or limit OSHA's authority to regulate working conditions in the same space. In other words, it effectively negates a provision in the OSH Act that would otherwise limit the OSH Act's applicability. Section 4(b)(1) of the Occupational Safety and Health Act of 1970 states, "Nothing in this Act shall apply to working conditions of employees with respect to which other Federal agencies, and state agencies acting under section 274 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2021), exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health." Pursuant to TSCA section 9(c), EPA's exercise of its statutory authority under TSCA to protect against unreasonable risk in the occupational setting does not impact OSHA's ability to exercise its own statutory authority under the OSH Act.

TSCA and the OSH Act have different legal standards and operate independently in the worker space. For example, TSCA section 6(a) directs EPA to regulate where it determines the manufacture, processing, distribution in commerce, use or disposal of a chemical substance presents an unreasonable risk, including an unreasonable risk to a potentially exposed or susceptible subpopulation, which is defined to explicitly include workers. So where unreasonable risks associated with TSCA chemicals in the worker space exist, the Agency has to address them. That said, the Agency is routinely communicating and coordinating with OSHA as EPA develops the TSCA rules. Where existing OSHA requirements will address the unreasonable risk, EPA may adopt those requirements and codify them for workers who are not covered by OSH Act, such as self-employed workers and state and local employees not covered by a state plan. Where OSHA requirements are not sufficient, for example, where the TSCA inhalation exposure limit is more stringent than OSHA's, EPA will continue to work with OSHA to ensure that provisions relevant to our shared jurisdiction are compatible with OSHA's approaches to the extent possible while still requiring the EPA exposure limit in order to meet our legal standard.

19. As your Office develops risk evaluations and management final rules, how often does your staff consult with, and consider input from, state programs with delegated authority under the Occupational Safety and Health Act?

EPA RESPONSE: As noted above, EPA has biweekly meetings with OSHA on its risk evaluation and risk management activities, and this engagement has on occasion included the OSHA office responsible for liaison efforts with state administered OSHA programs. This is certainly an area where the Agency can, and will, consider expanding engagement directly with state occupational safety and health programs (in coordination with OSHA). In addition, as part of EPA's risk management rules, EPA conducts numerous consultations with myriad stakeholders, including a formal federalism consultation under Executive Order 13132 to consider input from state and local officials. Generally, those consultations involve the Environmental Council of the States, which represents the state environmental commissioners.

20. Are existing Threshold Limit Values (TLVs) used to inform ECELs promulgated by the EPA?

EPA RESPONSE: As EPA develops its risk management rules, it considers other occupational exposure values such as TLVs in evaluating feasibility of an exposure value that informs the establishment of the regulatory ECEL. Other occupational exposure values, when they exist, are informative for risk management because they also give an understanding of what facilities may already be doing and what additional incremental changes might be necessary to meet an ECEL and timeframes to do so.

21. On June 20, 2023, the EPA proposed significant new use rules (SNURs) for 18 chemicals that were made from plastic waste-based feedstocks. Please clarify if the SNURs were intended to regulate either (1) the plastic feedstocks used at the frontend of the pyrolysis process or (2) the pyrolysis oil end products?

EPA RESPONSE: SNURs impose notice requirements for any entity intending to manufacture or process a chemical substance for a “significant new use.” In the June 20, 2023 rule referenced here, EPA proposed to identify as a “significant new use” the manufacturing of the 18 chemical substances using feedstocks, e.g., pyrolysis products derived from plastic waste, that contain any amount of certain chemicals like heavy metals, dioxins, phthalates, PFAS, PBDEs, and others. If finalized as proposed, the SNURs would ensure that the 18 chemicals are not manufactured with pyrolysis products that contain these impurities absent notice to EPA and further opportunity for review. As proposed, the SNURs would not impose any requirements on the use of plastic waste in the pyrolysis process.

22. When issuing the June 20, 2023, SNURs, did your Office intend to make landfilling or incineration the only viable end-of-life cycle management practices for difficult-to-recycle plastics?

EPA RESPONSE: No. TSCA SNURs are notice requirements and do not impose any regulatory restrictions. The June 20, 2023 proposed SNUR did not propose to impose any specific disposal requirements.

23. The proposed “National Strategy to Prevent Plastic Pollution” makes clear that addressing plastic waste is a priority for the Biden Administration. However, some stakeholders argue that the June 20, 2023 SNURs have significantly impeded the development of the domestic chemical recycling industry. Does the EPA acknowledge there is a potential conflict between the goals of the “National Strategy to Prevent Plastic Pollution” and the impacts on the chemical recycling market stemming from the June 20, 2023 SNURs?

EPA RESPONSE: Addressing plastic waste is a priority of the Biden-Harris Administration, as exemplified by the National Strategy to Prevent Plastic Pollution, and EPA does not believe the June 20, 2023 proposed SNURs are in conflict with this goal. The June 20, 2023 proposed SNURs would apply only to 18 new chemicals – all for similar fuel-related uses – and simply require prior notice to EPA if any of those 18 chemicals will be manufactured using feedstocks that contain named impurities described above. EPA also does not view the SNUR as a significant impediment to the development of the domestic chemical recycling industry.

24. TSCA allows the EPA to set *de minimis* levels to screen potential substances that appear as an impurity from regulation. Has the EPA considered utilizing *de minimis* thresholds with regards to impurities detected in plastic feedstocks for chemical recycling?

EPA RESPONSE: For chemicals that EPA has determined present unreasonable risk to human health or the environment, EPA is open to considering all possible risk management approaches including the establishment of *de minimis* thresholds, where appropriate. TSCA requires that any risk management approach taken by EPA following a risk evaluation must ensure that the chemical substance or mixture no longer presents unreasonable risk, and, as such, will necessarily be a case-by-case, chemical-specific analysis.

25. Can you commit to providing *de minimis* thresholds for all future risk evaluation and management rules?

EPA RESPONSE: EPA can commit to considering *de minimis* approaches in risk management rules, where appropriate, as described above. For example, in the recent methylene chloride risk management rule, EPA finalized a *de minimis* regulatory threshold for formulations below which regulatory requirements do not apply. However, *de minimis* thresholds might not always be needed, for example, if EPA's risk management rule does not prohibit any use of a chemical. In the context of risk evaluations, however, EPA lacks discretion under the law to exclude conditions of use from consideration within the scope of a risk evaluation. In other words, where EPA determines that a chemical is used or present in small quantities or concentrations (i.e., levels that might otherwise be considered "*de minimis*"), such known use/presence is squarely a condition of use under TSCA that generally must be considered in the risk evaluation. As described in the proposed update to EPA's procedural framework for conducting TSCA risk evaluations, EPA has discretion to appropriately tailor the level of analysis for particular uses in a fit-for-purpose manner.

26. If not, please explain why the EPA will not utilize the discretionary authority the TSCA provides to establish *de minimis* thresholds in determining what substances are subject to regulation.

EPA RESPONSE: As described previously, EPA will establish *de minimis* thresholds in the context of risk management rulemakings, following a risk evaluation, where appropriate and consistent with the statutory requirement in TSCA to eliminate unreasonable risk.

27. At what stage in the risk evaluation process does the EPA engage with executive membership of other regulatory authorities?

EPA RESPONSE: Beginning in this Administration, EPA has prioritized regular engagement at the staff level with other Federal agencies on TSCA actions throughout the entire process, beginning even before prioritization of a chemical for risk evaluation. Engagement and collaboration with Federal partners helps ensure EPA has

timely access to information to support a comprehensive understanding of, for example, a chemical substance's conditions of use and their importance to national security or critical infrastructure, the hazard and exposure potential of that chemical, and existing safety measures Federal agencies already have in place for their uses. For each chemical substance, EPA expects to typically engage during at least four stages with interested Federal agencies and departments: first, before EPA begins the prioritization process for the substance; second, during the 9-12 month prioritization process; third, during the development of the draft risk evaluation; and fourth, after the draft risk evaluation has been released for public comment. At each engagement, in addition to receiving any information about the substance Federal agencies wish to share, EPA would typically share scientific and other information about its progress on the risk evaluation, including any information it has developed related to Federal agency uses of the substance.

Engagement with the heads of other Federal regulatory agencies may also be warranted in the context of referring identified unreasonable risks under TSCA to another Federal agency pursuant to TSCA section 9. While those discussions may begin to occur during the risk evaluation process (e.g., after the issuance of a draft risk evaluation), any referral under TSCA section 9 would occur after the finalization of the risk evaluation and after EPA has determined that the chemical substance presents an unreasonable risk.

28. Does the EPA consider a study to be "best available science" if the study results subsequently cannot be reproduced?

EPA RESPONSE: TSCA section 26(h) provides EPA with statutory considerations to help guide the identification and application of the "best available science" in TSCA actions, including:

- (1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;
- (2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;
- (3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;
- (4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and
- (5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.

The reproducibility of a particular study may be relevant to several of these statutory considerations (e.g., the extent of independent verification of the information). Although not determinative, such a characteristic would certainly inform EPA's conclusions. Not

every study will be reproducible (e.g., multi-year/decade epidemiological study), and such a study may nonetheless be considered the best available science.

29. On December 26, 2023, the EPA indicated it intends to rely upon the IRIS assessment for formaldehyde to inform upcoming risk evaluations. However, reputable scientific entities both internally at the EPA (e.g., the Office of Air and Radiation and the Office of Pesticide Programs) and externally (e.g., the National Academy of Sciences, Engineering, and Medicine [NASEM]) have criticized the IRIS formaldehyde assessment for not constituting “best available science.” Considering these criticisms, how has the Agency concluded that the formaldehyde IRIS assessment is “best available science”?

EPA RESPONSE: EPA/OCSP released the draft TSCA Risk Evaluation for Formaldehyde in March 2024 for public comment and peer review. This risk evaluation does rely on the IRIS assessment for chronic inhalation exposure hazard endpoints. The OCSP staff worked closely with the IRIS program to ensure that the information used was the most current with the developments of the IRIS assessment in light of the 2023 NASEM peer review.

The TSCA draft evaluation also relies on recommendations from recent peer reviews of controlled human exposure studies by the Human Studies Review Board (HSRB) to inform acute inhalation and dermal exposure hazard endpoints in the re-evaluation of the registered pesticidal uses of formaldehyde under the Federal Insecticide, Fungicide, and Rodenticide Act.

Specifically, HSRB recommended that “EPA conduct a more coordinated approach with other entities (e.g., National Academies of Sciences, Engineering, and Medicine (NASEM), TSCA Science Advisory Committee on Chemicals (SACC)) regarding advice in establishing [points of departure] PODs for formaldehyde as well as reviewing recommendations from these and other entities on formaldehyde exposure. To further this recommendation, the HSRB recommends that EPA share this HSRB report with the NASEM and TSCA SACC, and that EPA consults with other state and Federal agencies working on formaldehyde guidance/regulations, as appropriate.” In March 2024, OCSP issued draft SACC peer review questions for public comment in the formaldehyde SACC peer review docket (EPA-HQ-OPPT-2023-0613). Several of these questions ask the reviewers of the TSCA risk evaluation to review the strengths and uncertainties of OPPT’s application of the values in the draft IRIS assessment. OCSP will consider the TSCA SACC peer review in conjunction with the NASEM and HSRB reviews. EPA recognizes that these peer reviews may not all reach a consensus. As per EPA’s Scientific Integrity Policy, differing views and opinions on scientific and technical matters are viewed as a legitimate and necessary part of the scientific process.

30. Were any of the NASEM’s criticisms over the formaldehyde IRIS assessment used to inform the EPA’s proposed revisions to the regulatory definitions of “best available science” and “weight of scientific evidence”?

EPA RESPONSE: No. TSCA requires EPA to use the best available science in TSCA risk evaluations and to make decisions based on the weight of scientific evidence.

EPA/OCSPPP recently finalized the revised Procedures for Risk Evaluations under TSCA which amended the previous rule to exclude specific definitions to “best available science” and “weight of scientific evidence.” Regulatory definitions of either of these terms do not modify the underlying statutory requirement for EPA to uphold the standards in its decision-making on chemicals under TSCA. For both TSCA risk evaluations and IRIS assessments, the best available science and weight of evidence are specific to the individual chemical assessment, just as the recommendations from the NASEM are specific to the formaldehyde assessment.

31. On multiple occasions, the NASEM and even the EPA’s own Human Services Review Board have criticized the EPA’s approach to systematic review to determine “best available science.” How has the EPA taken these criticisms into account when proposing to revise the definitions of “best available science” and “weight of scientific evidence” in its October 18, 2023, proposed rule?

EPA RESPONSE: The criticisms cited in the two reports are specific to the studies/assessments that were presented for peer review for these two peer review bodies. TSCA requires EPA to use the best available science in TSCA risk evaluations and make decisions based on the weight of scientific evidence. Regulatory definitions for either of these terms do not modify this existing statutory requirement to uphold these standards when making decisions on chemicals under TSCA.

The best available science and weight of evidence are specific to the chemical assessment in question. Definitions for either of these two terms would not alter the approaches taken to upholding the best available science or basing decisions on weight of evidence. Further, because peer review can help ensure that the Agency is upholding these requirements, EPA expects to strongly consider any peer review recommendations to further strengthen our science products.

NASEM also reviewed EPA’s 2018 Application of Systematic Review in TSCA Risk Evaluations, and, in their 2021 study report, offered recommendations to improve EPA’s systematic review process. In response to these recommendations, as well as comments received from the TSCA SACC and the public during the review of the first ten risk evaluations, EPA/OCSPPP significantly updated the TSCA systematic review process and developed a systematic review protocol. The draft TSCA Systematic Review Protocol replaced the Application of Systematic Review in TSCA Risk Evaluations. Consistent with these recommendations, EPA’s proposed changes to the “weight of scientific evidence” definition in the October 18, 2023 proposed rule ensure that the concepts and principles of systematic review and weight of scientific evidence are used in the evaluation of existing chemicals and are appropriately considered separately.

32. If, under a weight of evidence approach, a study was not utilized to inform an IRIS assessment, does that automatically preclude that study from being utilized in a TSCA risk evaluation? Why or why not?

EPA RESPONSE: No. EPA's IRIS Program develops human health hazard identification and dose-response assessments of potential health effects from exposure to environmental contaminants. An IRIS assessment is typically a chronic hazard assessment. TSCA requires a comprehensive risk evaluation that includes chronic toxicity and acute hazards and exposure assessments under the conditions of use of a chemical. As such, the type and number of studies and information used to support TSCA risk evaluations will necessarily be broader than those used to inform IRIS assessments. If IRIS has not considered a study based on weight of evidence, that does not mean it will not be considered in a TSCA risk evaluation. Additionally, TSCA requires EPA to make decisions consistent with the best available science. While the approaches taken to inform IRIS assessments will be informative to that analysis, it may not be determinative in every case.

33. If a preponderance of reputable scientific or regulatory entities arrives at a less conservative value than an EPA risk evaluation, how can the EPA maintain that the *outcome of its risk evaluation constitutes "best available science"*?

EPA RESPONSE: TSCA section 26(h) requires that EPA use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science. EPA is further required to document its use of the "best available science" as part of TSCA risk evaluations. Scientific information or values from other reputable scientific or regulatory entities would be part of the reasonably available information that EPA must consider in carrying out TSCA risk evaluations consistent with the "best available science."

Senator Lummis:

1. Under the Lautenberg Amendments, TSCA requires EPA to make a determination as to the "unreasonable risk" of injury to health or the environment of a new chemical. What are the factors that EPA uses to make this determination?

EPA RESPONSE: When a risk is identified as part of the review of a new chemical, EPA considers a variety of factors in determining whether or not the risk is "unreasonable." These factors include but are not limited to the potential adverse effect (e.g., severity and/or reversibility) of the substance and/or its degradation products, and the nature of the potential exposures (e.g., duration, magnitude, population, etc.) under the conditions of use. As described in EPA's procedural regulations for conducting risk evaluations on existing chemicals, the term "unreasonable risk" is not defined in the law or in EPA's regulations. Instead, a determination of whether or not a risk is unreasonable is made on a case-by-case, chemical-specific basis.

2. How does the agency help applicants address a finding of "unreasonable risk" during the application review process?

EPA RESPONSE: Where EPA identifies “unreasonable risk” as part of a determination that a new chemical substance “may present unreasonable risk” under TSCA section 5(a)(3)(B)(ii), EPA issues an order including requirements to mitigate the unreasonable risk – typically through a process of engagement with and the consent of the submitter. TSCA section 5(a)(3)(B) authorizes EPA to act via an order, and such orders are typically consent orders agreed to by EPA and the submitter. Prior to issuance of the order, the EPA program manager will generally discuss the contemplated terms with the submitter and reach agreement on any necessary restrictions or limitations. Both EPA and the submitter would then sign the order.

3. What avenues exist to address scientific disagreements between submitters and the EPA if there is a disputed finding of “unreasonable risk?”

EPA RESPONSE: For every new chemical submission, an EPA program manager is assigned to each submission early within the review process and is the submitter’s main point of contact. Submitters can (and do) reach out to the assigned program manager regarding status of a review, to provide amended or supplemental information, and to share any disagreements. EPA has found that the best avenue for avoiding disagreements is for the submitter to provide more robust/thorough information in its initial submission, which EPA has been strongly encouraging in various settings, such as in the proposed updates to the procedural regulations for new chemical reviews and in outreach/training related to engineering assessments and reducing rework. Sometimes, for example, submitters raise objections to an assumption or input used in the risk assessment, and endeavor to provide EPA with more or different information that demonstrates lower exposures and can potentially influence the Agency’s risk conclusions. Where this happens late in the review process, that may result in EPA having to rework substantial portions of its assessment and can slow review times. While EPA works closely with submitters to resolve disagreements and/or to provide additional explanation for the Agency’s position, ultimately the law reserves the determination as to whether a chemical presents unreasonable risk to health or the environment to EPA alone.

4. If the agency asks an applicant to provide additional information to support a finding of no “unreasonable risk,” how long, on average, does it take the EPA to update a risk assessment with the new data provided?

EPA RESPONSE: The specific amount of time is highly variable, and EPA has not historically tracked the amount of time taken to rework PMN assessments as a result of amended submissions or following receipt of supplemental information. In 2022, EPA did an analysis that found re-submissions and rework can increase the new chemical case review time by 5-7 months. In June 2024, EPA began to track and publish instances of rework on its statistics webpage and will continue to update those numbers moving forward.

5. How can EPA ensure that the additional data requested is not burdensome on applicants?

EPA RESPONSE: EPA has conducted a significant amount of outreach and training to help submitters better understand the submission process and the types of information that can inform EPA's assessment, which should result in more robust upfront submissions and reduce the overall need for EPA to ask for additional data. In turn, these efforts should also decrease the likelihood or frequency of pauses or Agency rework during new chemical reviews, making the process overall more efficient and less burdensome for submitters. For example, EPA proposed updates to the regulations that govern new chemical reviews to help prevent delays caused by submitters not understanding the information or level of detail needed. The Agency also conducted a broad outreach effort to reduce the need to rework risk assessments due to industry submitters providing engineering-related information late in the review process. EPA held three webinars with approximately 300 attendees each to help educate submitters about how to reduce rework. This outreach will ensure better quality submissions up front in the future and thus improve efficiency. In addition, EPA has announced an internal "engineering checklist" step to ensure that potential issues with a submission are identified and resolved at the beginning of the process, saving time and potential frustration for all. EPA also published a "Points to Consider" document to aid submitters in preparing pre-manufacture notices for submission, and regularly participates in events or workshops (e.g., recent Global Chem PMN Workshop, etc.) to provide submitters with additional practical tips. Finally, the program recently launched the New Chemicals Division reference library to provide an online collection of public guidance documents, compliance advisories, templates, manuals and more to enable the regulated community to more easily locate and access these helpful resources.

6. How does EPA distinguish between intended vs. unintended uses of a chemical when making a determination of "unreasonable risk" during the review process?

EPA RESPONSE: In reviewing new chemical notices, TSCA requires EPA to assess the chemical substance "under the conditions of use," defined in the law 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." For purposes of new chemical reviews, EPA generally considers the intended conditions of use to be the circumstances of manufacture, processing, distribution in commerce, use, or disposal as stated in the section 5 submission (i.e., those intended by the submitter). While EPA does not distinguish "unintended" uses, the Agency is required to consider known and reasonably foreseen uses, as discussed above. Such uses might include other circumstances not intended by the submitter but otherwise known to be occurring (e.g., uses for which the chemical is already being manufactured in the United States pursuant to an exemption under TSCA section 5(h)), or those that are reasonably foreseen to occur in EPA's professional judgment.

7. Please provide a list of specific factors considered by the agency in assessing the intended vs. unintended uses of a chemical.

EPA RESPONSE: See response to Question 6 above. In reviewing new chemical notices, TSCA requires EPA to assess the chemical substance “under the conditions of use,” defined in the law 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.” Unintended uses may be assessed when they are “known” or “reasonably foreseen” circumstances of manufacture, processing, distribution in commerce, use or disposal.

8. Please provide a copy of any official guidance used by the agency to make a determination of intended vs. unintended uses of a chemical.

EPA RESPONSE: Not applicable. See responses to Question 6 and 7 above.

9. How does the Agency assess the reasonably foreseeable uses of a chemical?

EPA RESPONSE: The law requires EPA to consider the new chemical’s conditions of use (i.e., the circumstances under which the new chemical is intended, known and reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of) as part of every assessment, and for such consideration to inform the Agency’s determination under TSCA section 5(a)(3). The Agency’s approach for identifying/determining the “reasonably foreseen” uses of a chemical is described in response to Question 10 below.

10. Please provide a list of specific factors considered by the agency to determine the reasonably foreseeable uses of a chemical.

EPA RESPONSE: EPA expects that the identification of “reasonably foreseen” conditions of use will be made on a fact-specific, case-by-case basis. EPA will apply its professional judgment and experience when considering factors such as evidence of current use of the new chemical substance outside the United States, information about known or intended uses of chemical substances that are structurally analogous to the new chemical substance, and conditions of use identified in an initial PMN submission that the submitter omits in a revised PMN. The sources EPA uses to identify reasonably foreseen conditions of use include searches of internal confidential EPA PMN databases (containing use information on analogue chemicals), other U.S. government public sources, the National Library of Medicine’s Hazardous Substances Data Bank (HSDB), the Chemical Abstract Service STN Platform, REACH Dossiers, technical encyclopedias (e.g., Kirk-Othmer and Ullmann), and Internet searches.

11. Please provide a copy of any official guidance used by the agency to determine the reasonably foreseen uses of a chemical.

EPA RESPONSE: The identification of “reasonably foreseen” conditions of use will necessarily be made on a fact-specific, case-by-case basis. In 2019, EPA published an updated document titled “TSCA New Chemical Determinations: A Working Approach for Making Determinations under TSCA Section 5” that provides some discussion on

the identification of reasonably foreseen uses of a chemical, available on EPA's website at: https://www.epa.gov/sites/default/files/2021-04/documents/new_chems_working_approach_-_12.20.19_final_with_disclaimer.pdf.

12. How does the EPA incorporate findings from other relevant federal entities, such as the Occupational Safety and Health Administration (OSHA) and the Consumer Product Safety Commission (CPSC), when assessing worker safety?

EPA RESPONSE: EPA strongly values its relationship with other Federal agencies such as OSHA and CPSC, and coordinates with them regularly on a wide variety of actions under TSCA. In the context of new chemical reviews under TSCA – and because the chemicals are “new” and generally not yet in U.S. commerce – there are generally not findings from OSHA or CPSC related to worker safety with respect to such chemicals.

13. When performing chemical reviews under the TSCA program, does EPA ever disregard or override findings from other federal bodies, such as OSHA or the CPSC?

EPA RESPONSE: No. Relevant findings from other Federal agencies and other reasonably available information would absolutely be considered in the context of new and existing chemical reviews. EPA does not disregard relevant information.

14. Will the EPA commit to not being overly prescriptive with restrictions in the form of SNURs when findings from agencies beyond EPA, such as OSHA or CPSC, support the safe use of a chemical?

EPA RESPONSE: EPA is not overly prescriptive when carrying out its statutory mandate to address unreasonable risks to human health and the environment. As described earlier, “findings” from other Federal agencies are not likely to be available for new chemicals, which are generally not yet in U.S. commerce when EPA is conducting its review. Regarding SNURs, EPA would note that SNURs are notice requirements rather than regulatory restrictions. Additionally, where unreasonable risks are identified and managed as part of the new chemical review process, TSCA section 5(f)(4) requires EPA to consider following that action with issuance of a SNUR that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the order. Doing so helps to put the submitter on a level playing field with all future manufacturers and processors of that new chemical.

15. Do you believe the EPA should be required to use risk information from its own existing databases on chemical profiles to aid and expedite the new chemical review process?

EPA RESPONSE: As required at TSCA section 26(k), EPA reviews new chemicals based on reasonably available information as the law requires, which is information that EPA possesses or can reasonably generate, obtain, and synthesize for use considering the deadlines for completing the assessment. In the context of new chemical

reviews, in addition to information included in the incoming pre-manufacture notice, the reasonably available information regularly includes information from both EPA internal sources such as EPA's CompTox dashboard, IRIS assessments, data received pursuant to TSCA section 8(e), and external sources like JChem.

16. If it is EPA's position not to use risk information from the agency's existing databases on chemical profiles to aid and expedite the new chemical review process, please explain why not.

EPA RESPONSE: No, that is not EPA's position. See response number 15 above.

Senator Ricketts:

1. Does the Office of Continuous Improvement still exist at the EPA?

EPA RESPONSE: EPA's Office of Continuous Improvement (OCI) is located within the Office of the Chief Financial Officer, and coordinates agency-wide implementation of the continuous improvement program and Lean Management System. Information about OCI is available at: <https://www.epa.gov/aboutepa/about-office-continuous-improvement-oci>.

2. Does the New Chemicals Program still utilize the Lean Program?

EPA RESPONSE: Lean management tools were previously applied to achieve greater efficiencies in the new chemicals review process, and those process improvements continue to be a part of current implementation of the program. Additionally, EPA continuously works to identify ways to streamline our processes, enhance our programs and services, and better manage our employee and financial resources. For example, EPA proposed updates to the procedural regulations for new chemicals to align them with amended TSCA, increase transparency and speed up review time by helping submitters to better understand the information and level of detail needed. EPA also conducted a broad outreach effort to reduce the need to rework risk assessments due to industry submitters providing engineering-related information late in the review process, including three webinars with approximately 300 attendees each. The program has implemented a standardized and efficient process to assess risk and apply mitigation measures for new chemicals with applications in batteries, electric vehicles, semiconductors and renewable energy generation. And the Agency continues work under the multi-year New Chemicals Collaborative Research Program to bring innovative science to, modernize, and enhance the transparency of new chemical reviews. Finally, EPA has implemented a new internal "engineering checklist" step that occurs early in the review process to better identify potential issues at the beginning of the process, allowing early engagement and resolution with the submitter before any unnecessary work (and subsequent rework) has been completed.

3. In August 2020, EPA excluded composite wood products from the Final Scope of its upcoming Risk Evaluation for Formaldehyde given a recent rulemaking on emissions

from those products finalized in December 2016. However, EPA has recently indicated it has flipped that position and will include composite wood products and related finished goods in the Risk Evaluation. EPA has data showing that the finishing process for furniture reduces formaldehyde emissions, from already EPA compliant levels, by 50-90%. Why did EPA reverse its scoping document decision without any public notice or comment?”

EPA RESPONSE: EPA stated in the 2020 Final Scope that the Agency had determined that three types of composite wood products (hardwood plywood, particleboard, and medium density fiberboard [including thin-medium density fiberboard]), and laminated products currently regulated under the Formaldehyde Emission Standards for Composite Wood Products final rule (40 CFR part 770, promulgated under TSCA Title VI), would not be included in the scope of the risk evaluation.

However, EPA no longer interprets the law to provide discretion to exclude exposure pathways that are addressed under other EPA-administered statutes or regulatory programs from the scope of TSCA risk evaluations. This change was announced in June 2021 (<https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations>). As a result, all composite wood products, including those regulated under TSCA Title VI, are included in the draft formaldehyde risk evaluation. EPA determined that excluding TSCA Title VI regulated composite wood products from the formaldehyde risk evaluation would reduce the comprehensiveness of the risk evaluation and introduce complexities and uncertainties due to the regulated vs. non-regulated materials that may be present in a finished good in indoor environment. However, the Agency also recognizes that allocating exposures due to emissions from finished goods in indoor environments might be difficult because the monitoring data available for the evaluation does not necessarily reflect information after the implementation of TSCA Title VI.

In October of 2023, EPA did meet with several of the main stakeholders including American Home Furnishings Alliance, Composite Panel Association, Decorative Hardwoods Association, and the International Wood Products Association to provide notice of this change in scope of the formaldehyde risk evaluation. EPA released its draft risk evaluation for formaldehyde on March 15, 2024. All stakeholders had the opportunity to comment by May 14, 2024, on the draft risk evaluation for formaldehyde, available in the docket here: <https://www.regulations.gov/docket/EPA-HQ-OPPT-2023-0613>. In the Agency’s preliminary risk determination, EPA found that the conditions of use related to exposure in residences from wood articles does not contribute to the unreasonable risk of formaldehyde.

4. Dr. Freedhoff, a Significant New Use Rule (SNUR) can impose additional record-keeping requirements on a company that chooses to use that chemical, creating a financial deterrent and perversely incentivizing the continued use of older chemicals.
 - a. Does the agency acknowledge that having a SNUR placed on a new chemical application could put companies at a market disadvantage?

EPA RESPONSE: EPA is aware of concerns raised by some companies that chemicals covered by a SNUR are less desirable to their downstream customers. However, EPA would note that SNURs are notice requirements rather than regulatory restrictions. Additionally, where unreasonable risks are identified and managed as part of the new chemical review process, TSCA section 5(f)(4) requires EPA to consider following that action with issuance of a SNUR that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the order. Doing so helps to put the submitter on a level playing field with all future manufacturers and processors of that new chemical.

- b. How much, on average, does attaching a SNUR to a PMN slow down the overall timeline for new chemical reviews? Please provide specific examples of chemicals that did and did not receive SNURs and the timeline for review.

EPA RESPONSE: Where EPA determines that issuance of a SNUR for a particular chemical is appropriate, the development of such a proposed rule occurs *after* the conclusion of the PMN review. As such, SNURs do not slow down the overall timeline for the review of the new chemical at all.

In the prior Administration, SNURs were often proposed *during* the PMN review period and then used to potentially narrow the scope of EPA's review by determining that uses for which further notice was required were not likely to present unreasonable risk because these uses would be evaluated by EPA, who would take appropriate action to prevent unreasonable risk. This practice could sometimes slow EPA's timeline for determination. That is no longer the Agency's practice.

- c. Using EPA data, please provide the number of Premanufacture Notices (PMNs) that have received SNURs annually between 2017 and 2020?

EPA RESPONSE: The table below shows the number of chemical substances for which final SNURs were issued annually between 2017-2020:

Calendar Year	Number of Chemical Substances
2017	64
2018	66
2019	325
2020	160

- d. Using EPA data, please provide the number of PMNs that have received SNURs annually between 2021-present?

EPA RESPONSE: The table below shows the number of chemical substances for which final SNURs were issued annually between 2021-present:

Calendar Year	Number of Chemical Substances
2021	211
2022	83
2023	84
2024	0 (as of 08/01/24)

As of August 2024, EPA has proposed SNURs for 128 chemical substances in calendar year 2024. EPA is in the process of finalizing SNURs for 251 substances, including those 128. Additionally, EPA plans to propose SNURs covering an additional 253 substances.

- e. What was the average number of SNURs placed on new chemical applications annually between 2006-2016?

EPA RESPONSE: To clarify, SNURs do not apply to the application (i.e., premanufacture notice) itself, but rather are proposed after the conclusion of the review and establish notice requirements that apply to potential future manufacturers of the new chemical substance. On average, EPA issued SNURs for 80-90 chemical substances annually between 2006-2016. Prior to 2016, EPA generally only completed full assessments on around 20 percent of cases. As a result, at least 80 percent of cases would not have been considered for a SNUR. Following the 2016 amendments, the law requires EPA to conduct a full assessment and make a determination on 100 percent of cases. Where an order is issued under TSCA section 5(e), EPA must consider following the order with a SNUR.

- f. Please explain the disconnect between agency policy and practice when it comes to promoting green chemistry and recognizing the importance of approving safer chemical alternatives, yet placing greater restrictions on chemical use through SNURs.

EPA RESPONSE: EPA supports innovation in the chemical sector and is committed to continuing to improve the efficiency of its TSCA new chemical review processes to help bring new chemistries safely into commerce. EPA's mandate under TSCA section 5 is to determine whether a new chemical presents an unreasonable risk – without consideration of costs or other non-risk factors – and to ensure appropriate protections are in place to address any unreasonable risks before that chemical can enter the marketplace. Those protections often come in the form of orders under TSCA section 5(e) that apply certain requirements or restrictions to the new chemical submitter. The law requires EPA to consider following these orders with a SNUR (or to publish a statement explaining the reasoning for not) to ensure that – absent further EPA review –

all other future manufacturers of that chemical are held to same standard as the original submitter.

- g. If the EPA is not placing restrictions that limit marketability on older chemicals, how can EPA level the playing field for new chemicals that may be less hazardous than existing chemicals, but do not quite meet the “no unreasonable risk” criteria used for assessments under the New Chemicals Program?

EPA RESPONSE: One of the significant improvements to TSCA under the 2016 amendments was the new requirement for EPA to systematically prioritize and evaluate existing chemicals, and to manage identified risks – all within new statutory deadlines designed to drive forward progress on the backlog of existing chemicals reviews.

That said, EPA disagrees with the assumption or premise that review and regulation of a new chemical substance – even one that is perhaps comparatively less hazardous than another existing chemical – creates an imbalance in the playing field or limits marketability. A new chemical that has been reviewed through the TSCA new chemicals program brings certainty for that chemistry for both the regulated community and the general public. For example, a new chemical that is subject to a consent order and/or SNUR means that EPA has effectively reviewed the chemical and applied the necessary risk mitigation measures to eliminate unreasonable risk to human health or the environment. This can be viewed as a ‘clean bill of health’ of sorts and could be marketed in a favorable way by the manufacturer. Downstream purchasers may desire the certainty associated with a chemical that has already been through the process over an older chemistry that could be prioritized/evaluated/regulated by EPA in the future. Likewise, the public should have greater confidence in the safety of new chemicals that have been reviewed by EPA, and where appropriate protective controls are in place.

- h. How can EPA help industry adjust to the reality that SNURs limit the growth of new, often safer, chemicals?

EPA RESPONSE: See the response to question 4.g, above. Additionally, EPA can do more to educate stakeholders on the benefits of SNURs and, as described above, help explain how chemicals that have been through the TSCA New Chemicals program could be marketed as potentially safer than older existing chemicals that were grandfathered onto the Inventory without an EPA assessment. Resources allowing, EPA also hopes to make reporting (e.g., reporting under the Chemical Data Reporting (CDR) rule, TSCA section 12(b), etc.) and recordkeeping requirements associated with chemicals regulated by SNURs less burdensome by upgrading its older electronic reporting tools and conducting more outreach.

Senator Sullivan:

1. EPA announced it is proposing “Significant New Use Rules” (SNUR) under TSCA, blocking 18 chemistries that could be used to develop transportation fuels from plastic waste feedstock. The ambiguity of the proposal as drafted has completely frozen this new market and a new opportunity to reduce plastic waste. Without the SNUR, the market has the potential to divert over 12 million metric tons of used, recoverable plastics from landfills each year, not to mention creating billions of dollars in economic output and thousands of jobs for skilled workers. Additionally, one-quarter of the plastic in our waste stream can’t be recycled by anything other than advanced recycling. One of the problems with the EPA rule is that it regulates the feedstocks going into the recycling unit — in other words, the used plastic — instead of the product coming out of the recycling unit – pyrolysis oil leading to other things like fuels. Can you please clarify what EPA means to do by proposing this SNUR?

EPA RESPONSE: The SNUR, as proposed, would require notice to EPA if a company intends to manufacture any of the 18 chemistries using feedstock containing any of the impurities listed in the SNUR. The proposed SNUR would not apply requirements for plastic waste coming into a plastics recycling unit. Rather, the proposed SNUR requirement would require notice and possibly further EPA review if the pyrolysis oil coming out of the recycling unit (or other feedstock) that is then used to manufacture the 18 chemical substances contains the listed impurities. EPA expects to provide additional clarification in the final SNUR on this point.

2. How is the EPA taking account of the special concerns of Alaska, including Alaska Natives, in assessments of chemicals under TSCA, particularly PBTs?

EPA RESPONSE: One of the important changes to TSCA in the 2016 amendments was a new, explicit requirement that EPA consider risks to potentially exposed or susceptible subpopulations (i.e., individuals who, due to either greater susceptibility or greater exposure, are at greater risk of adverse health effects from chemicals than the rest of the general population) in all new and existing chemical risk assessments. Those experiencing “greater exposure” could include individuals or communities experiencing higher levels of exposure to a chemical substance due to unique exposure pathways that differ from those of the general population, like Tribal communities where reliance on subsistence fishing results in increased chemical exposure via ingestion.

EPA continues to make significant improvements to its TSCA risk evaluations and process to ensure a comprehensive review of a chemical’s risks, including risks to potentially exposed and susceptible subpopulations. Specific considerations for Tribal communities were included, for example, in EPA’s risk evaluation for TCEP, the first of the high priority substances prioritized in 2019 for which EPA released a draft risk evaluation. EPA’s more thorough consideration of these vulnerable communities in risk evaluations will also better position the Agency to design appropriate risk management approaches to address identified unreasonable risk, including risks disproportionately borne by certain groups like Alaska Natives.

3. There have been rising concerns about plastic pollution in the Arctic. What is EPA doing through its work on the new international treaty on plastics related to the Arctic?

EPA RESPONSE: The Administration supports strong, universal obligations to address plastic pollution as part of the intergovernmental negotiating committee (INC) process underway to develop a global instrument on plastic pollution. In addition, the Administration works across the Federal family to implement the National Strategy for the Arctic Region which reflects commitments on plastic pollution and solid waste management in remote Arctic communities.

Senator CARPER. Thanks so much for your testimony and for being with us today. You have been consistent in your testimony to this committee that EPA has not had adequate resources needed to fully implement the Lautenberg Act. I think most of us will agree that funding for the program can come from two different sources, as we know, user fees generated by EPA and annual appropriations provided by us, and Fiscal Year 2023 received some additional resources from Congress, as you know, though while still short of the President's request.

The EPA is also working to improve its ability to collect user fees.

Would you give us a sense of what the EPA was able to do with the increased funding in Fiscal Year 2023? I know you have touched on this to some extent, but I think it deserves some additional attention. What more would the EPA be able to do if the agency received additional funding through both annual appropriations and more effective user fee collection?

Ms. FREEDHOFF. Thanks very much for that question, Senator Carper. We have really prioritized hiring with that additional pay increase, or funding increase, and have especially focused our efforts on the New Chemicals Division, because we really do agree that that was the area that was most under resourced as a result of the new law, which basically changed what our past practice had been, which was reviewing 20 percent of new chemicals before they go into commerce to doing 100 percent of new chemicals before they go into commerce. Five times the amount of work, and for 6 years, zero extra dollars with which to do it.

In addition to prioritizing hiring and getting people in the door and trained as quickly as possible, we have also really tried to standardize our approaches for chemistries that we know industry comes in with a lot of applications for. For example, we have been working to create a standardized and streamlined review process for the chemicals that are needed by the battery sector. We have a years-long collaboration with the semiconductor sector, and that has resulted in a regulatory path forward for dozens of the photoacid generators that they need to do their work. I personally met with them a couple of weeks ago and we talked about expanding that collaboration in the future.

We have really tried to work smarter, not harder, which is something Senator Markey often says, and are going to continue to do so with the funding that we have. If we got more, we would be able to modernize those standard operating procedures more quickly. We would be able to modernize our science policies more quickly. We would be able to create efficient approaches for classes of chemistries more quickly, and of course, we would also be able to write rules more quickly and do risk evaluations more quickly, which would move through the tens of thousands of chemicals that were left unreviewed under the old law more quickly as well.

Senator CARPER. All right, thank you.

Before I turn to Senator Capito for her questions, I have one more I want to ask. In 2018, the previous Administration, you will recall, promulgated a user fee rule that was based on faulty data, which has limited the EPA's ability to collect user fees as intended by those of us who worked to pass the Lautenberg Act.

The Biden Administration has been working to update this data and revise the rule. Would you please explain to us where the previous rule went wrong, and how the Biden rule is proposing to correct it? Also, when do you anticipate the new rule will be finalized?

Ms. FREEDHOFF. Sure, thanks for that question, Senator Carper. The Congress expected the EPA would write a fees rule, and collect 25 percent of our authorized TSCA costs from fees. The first fees rule didn't collect any fees until Fiscal Year 2019, and it exempted the cost of the first 10 risk evaluations from being subject to fees at all. Those were by far the most expensive thing that the agency was working on in those first 4 years of the law.

As a result, we only collected a couple of million dollars a year, \$2 million to \$5 million a year in the first couple of years under the new law. Moreover, to calculate the 25 percent baseline, the previous administration used the cost of the old TSCA before it was revised to expand EPA's authority. As a result, overall, that first fees rule collected less than half of the 25 percent of authorized TSCA costs that Congress expected it to collect.

We have done things differently. We have tried to heed congressional direction to reflect the accurate costs of implementing the law in our proposed fees rule. I think that rule is in the final stages of review at OMB, and I expect it to be finalized in the coming weeks.

Senator CARPER. Good, thanks. Senator Capito?

Senator CAPITO. Thank you. I mentioned the document that we had shared earlier, last week, and you all came back with some responses to that on ways that we could improve the system. I wanted to get your initial reaction on any of these you think would help the most, maybe prioritize one, two, or something of that nature.

Ms. FREEDHOFF. Sure. Thanks again for the constructive meeting we had, Senator Capito. I always appreciate the way you and your staff work with the agency since I have been there, and of course on the Hill as well, when I was here. I thought your list had a lot of really good ideas in it and I think there is a few I feel we can commit to, as long as our budget is not cut.

First, there was a program called the Sustainable Futures Initiative that existed before the law was changed. The purpose of that program was for EPA to help industry write better new chemical submissions, do training, technical assistance, and that sort of thing.

Assuming our budget is not cut, we would like to hire someone who is entire job it will be to revamp the Sustainable Futures Initiative, and build on the outreach industry that we have been doing over the past few years, to help them help us, really, in reviewing new chemicals.

Another thing that your list said, that sometimes we use models instead of industry submitted data, and there was sort of an interest in getting more transparency from us on why we might choose to do that if we have actual industry data. We think that is a great idea and are absolutely able to commit to that.

Senator CAPITO. I am going to stop you there, because I will have an additional, on the resource issue, because this keeps coming up. The budget has gone up, and I mentioned in my opening statement the interest in Title 42, which used to be the universal title that

does everything, but it gave you an opportunity to get some highly specialized individuals.

You have had this ability for 2 years and have not used it. It is hard for me to square, I need more resources, when we gave, as a Congress, you an ability to really specialize here and it hasn't been used. What kind of assurances are more resources going to solve this issue?

Ms. FREEDHOFF. I totally appreciate the question. We are actually really excited about that authority, although it seems that we have not used it.

Senator CAPITO. You and only one other entity has that ability.

Ms. FREEDHOFF. It took us more than a year to kind of do the administrative things we needed to do, both within the agency and with OPM to get the all clear to actually use the authority. We have not had the clearance to use it for two full years.

We do want to use it, and I think the very first place we would use it is in the New Chemicals program. Having a senior scientist who can really help us modernize those processes would be great.

I will also say, though, that those hires cost more money.

Senator CAPITO. Right.

Ms. FREEDHOFF. When we are balancing, can we have three risk assessors, or one senior scientist, we are not quite comfortable yet to put our money on the senior scientist. We are getting there.

Senator CAPITO. Well, I would hope that authority, since it is so unusual, and I think could be impactful, just on the face of it having a senior scientist and then having younger, newer hires coming in would have a mutual benefit there as well.

Let me ask you, one of the suggestions was sort of a mid-review meeting, a mid-stage meeting between engineering team members and submitters. You were pretty negative about that when we talked earlier last week. I do think, and I think some of the stakeholders feel that if they can see where they are before they get into the engineering phases and other more technical phases of the assessments, so they could make the adjustments mid-stage instead of waiting toward the end, what would your response be to something like that? Seems to me that would benefit both sides of the submission.

Ms. FREEDHOFF. I did take that back to my staff. They do feel like it could have the unintended consequence of slowing not just that application down, but other people's applications down as well. We did have two other ideas that we think get to the same problem that you are raising.

First is, we encourage companies to come in and have presubmittal meetings with us. We do not always have engineers in those meetings, and we could. I think that would be one way for companies to sort of get a reality check on what information they might want to include in their package before they even send their package to the agency.

The second thing we are able to do now that we have some more staff is actually create a second queue, a different line for those applications that are almost at the end of the process, but something in the engineering changes and they need a little rework before they can get it over the finish line.

Senator CAPITO. Right.

Ms. FREEDHOFF. We actually want to create a dedicated, a tiger team of people whose job it will be to get those applications over the finish line more quickly. We actually think that might be a faster way of getting at the problem.

Senator CAPITO. Yes, I think that makes a lot of sense. One thing I would say is, in talking with submitters ourselves about this mid-evaluation meeting, I think their opinion sort of anecdotally would be, if I can get more clarity, more procedural clarity mid-way through the process, I will take a longer process. In the end, it ends up being longer anyway.

I would just put that on your plate with everything else. Thank you, Mr. Chairman.

Senator CARPER. Thank you very much.

Senator BOOZMAN, you are next. Welcome, and good morning.

Senator BOOZMAN. Thank you, Mr. Chairman.

Thank you for being here, we appreciate your many years of service in lots of different ways.

Section 9 of TSCA requires EPA to consult and coordinate with other Federal agencies on its TSCA activities for existing chemical reviews, to maximize enforcement and reduce duplication. Long-standing executive orders also require interagency reviews of significant EPA actions.

I guess the question is, why hasn't EPA sought feedback from other agencies like USDA, FDA, the Small Business Administration, Department of Defense on its soon-to-be-released draft of the TSCA risk evaluation of formaldehyde?

Ms. FREEDHOFF. Thanks very much for the question, Senator. We actually engage more across the executive branch than I think had previously been done. We have an interagency TSCA group that includes membership of DOD, the Ag Department, FDA. It meets almost monthly, every month or two, I think. We do talk to them in a very proactive way about the work that we expect to be coming up. We talk to them about the chemicals that we have just put onto the TSCA process before those chemicals were named to the public.

We are actually doing a lot of very proactive engagement with the rest of the Federal family. We will certainly be doing that when it comes time to release our draft formaldehyde risk assessment as well.

Senator BOOZMAN. I understand the problem of being underfunded. Also, I do think there is a lot of stove piping. We should be working more interagency. Here is what the Small Business Administration said in their file comments last month on your risk evaluation framework rule. "EPA should commit to a robust interagency process for a review of the draft and final risk evaluations." Unfortunately, neither the preamble nor the current EPA practice reflect the commitment to interagency collaboration. EPA's risk evaluations "create a significant risk that the resulting risk management regulations will impose unnecessary and duplicative burdens on small businesses with minimal public benefits." "It is not good use of EPA's resources to duplicate the effort and expertise of these other Federal offices."

Ms. FREEDHOFF. I think we greatly value the input from other Federal agencies that we get during the risk evaluation process and the risk management process, which does go through formal

interagency review. We have been proactively reaching out to the agencies that we know use some of the chemicals that we are looking at to make sure that we account for critical uses and needs that they might continue to have.

I think those conversations are going very well. I have personally been involved in many of them. We do take that responsibility to talk to the other agencies extremely seriously.

Senator BOOZMAN. I have the opportunity to serve also as Ranking Member on the Agriculture Committee. Formaldehyde is something that many users use there to keep us safe and keep our food supply safe, keep it affordable. Farmers use formaldehyde to reduce virus infectivity in pigs, as a barn disinfectant, protect against African swine fever. Egg producers rely on formaldehyde during incubation to help protect hatchling eggs against bacteria like salmonella. Animal feed, again, the list goes on and on.

Is it true that the EPA is considering an existing chemical exposure level for formaldehyde which is lower than the levels of formaldehyde humans exhale as much as 16 times below exposure levels set in European jurisdictions?

Ms. FREEDHOFF. First of all, let me just say that we have a great relationship with your staff on the Senate Ag Committee, same with Senator Stabenow's staff. We view that relationship as extremely constructive and collaborative. I would also note that the pesticidal uses of formaldehyde are not subject to TSCA.

Getting to your question about the exposure limits, we have not calculated a level like that for formaldehyde yet. It is something that we do at the end of our draft risk evaluation process. We have not published one.

I can commit to you that if the risk evaluation, which by law is not supposed to consider costs and other non-risk factors like the ones you are raising, if we end up with a level like that in the draft risk evaluation, it can not be measured because it is below background, we will say right in the draft risk evaluation that it will not be the thing that we would propose to do in our rule. We are not going to propose something that can not be met, if that is the way it turns out in our risk evaluation.

Senator BOOZMAN. I would hope not. Thank you.

Senator CARPER. Senator Boozman, good to see you. Thanks so much.

Senator Mullin, how are you?

Senator MULLIN. Good, thank you. Good to see you.

Ma'am, thank you for being here. This committee has been focused on plastics for quite some time. As I always like to say, almost a war on plastic. I want to be very careful as we are moving forward that the EPA is actually working with industry, not just working with activists and knowing where we are headed.

I do have some concerns, because last month the EPA announced five more chemicals for prioritization underneath TSCA, all of which use plastics, the chemicals that they are using all goes toward plastics, including vinyl chloride, which is a chemical used for PVC piping. Obviously, that is something I am very familiar with, and it raises alarms, because we use PVC piping in almost all your homes now, either through your drainage or your water, most of our drinking water is delivered through PVC piping.

When we start looking at eliminating, there's a lot of questions that say, OK, what are you going to do then? Obviously, what are you going to replace it with?

You were quoted recently in a press release, you chose to quote a partisan, what I would consider very partisan, radical, anti-plastic activist and president of Beyond Plastic named Judith, I will leave her last name out of it. The article, Chairman, that I would like to enter into the record from E&E News, December 14th, a quote that Dr. Freedhoff credited, that meeting with Judith is making a real difference as we move forward to make these decision.

Senator CARPER. Without objection.

[The referenced information follows:]

E&E

EPA goes after plastics with chemicals plan

By Ellie Borst | 12/14/2023 01:44 PM EST



EPA announced chemical review plans that focus on chemicals used in plastics. AFP via Getty Images

EPA announced it is prioritizing risk evaluations for five chemicals primarily used to make plastics, signaling a growing and concerted effort to crack down on plastics.

Wednesday's announcement marks the start of a 12-month process that EPA said will likely result in each chemical's designation as a "high priority" substance under the Toxic Substances Control Act. With that designation, regulators can then launch the intensive, 3 ½-year review process that could lead to the agency banning or restricting uses of the chemical if deemed unsafe.

Each of the five chemicals has already been tied to an increased risk of causing cancer. The review process will help EPA determine if specific uses — like vinyl chloride in PVC pipes, plastic packaging or other consumer products — pose health risks.

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“This is the very beginning of the process, the part where we study the chemical before we come to conclusions about what the chemical may or may not be,” said Michal Freedhoff, assistant administrator for the Office of Chemical Safety and Pollution Prevention.

“The Biden-Harris administration certainly does recognize that plastic pollution is a problem,” she continued, adding, “Part of the problem is how you make and use the chemicals in the first place ... and certainly as we looked at the many chemicals that we could choose, the question of what they’re used for was one of the questions that we asked ourselves.”

The following five chemicals will be prioritized for risk evaluation:

- Acetaldehyde, a chemical mainly used to make other chemicals, adhesives or petrochemicals, the building blocks of plastics. EPA regulates it as a probable human carcinogen, and it has also been linked to respiratory problems.
- Acrylonitrile, a chemical primarily used to make paints, plastics or petrochemicals. EPA regulates it as a probable human carcinogen, and it has been linked to lung, skin and nervous system damage.
- Benzenamine, a chemical mainly used in manufacturing dyes, resins, petrochemicals or plastics. EPA regulates it as a probable human carcinogen that can have adverse effects on blood, fetal development and reproduction.
- 4,4'-Methylenebis(2-chloroaniline), or MBOCA, is a chemical used to make rubber and other plastics. EPA regulates it as a probable human carcinogen that has been tied to cell damage and other health risks, especially when infants and children are exposed.
- Vinyl chloride, a widely used chemical primarily used to make PVC pipes or other plastics. EPA has regulated it as a known human carcinogen since 1996, but its adverse health risks have been well-known since the 1970s. Other adverse health effects linked to exposure include liver, lungs and kidney damage, along with skin and eye irritation.

‘One of the most important chemical review processes ever’

The announcement is a monumental victory for advocates like Judith Enck, a former Obama-era EPA regional administrator and founder of Beyond Plastics.

"Most vinyl chloride is used to make polyvinyl chloride (PVC) plastic, which poses significant health and environmental problems that have been known for over 50 years," Enck said in a statement. "This is one of the most important chemical review processes ever undertaken by the EPA."

Vinyl chloride made headlines earlier this year after a train derailed in East Palestine, Ohio, causing the spill of multiple toxic chemicals and eventual burn of vinyl chloride. Despite EPA's repeated assurances that all chemicals were detected below levels of concern, residents and emergency responders have reported unusual illnesses.

Beyond Plastics has since collected more than 30,000 signatures on a petition demanding EPA ban vinyl chloride.

But vinyl chloride's woes trace back way before the catastrophic train derailment.

"Vinyl chloride was actually one of the examples" that was used to get the original TSCA passed in 1976, Freedhoff said.

That recent history coupled with meeting with Enck and other advocates "did make a real difference ... thinking about both the recent history and the longer-ago history as we move forward to make this decision," Freedhoff added

Advocates have been sounding the alarm on the many harmful chemicals used in plastics for years. The concerns recently reached a global stage, as a number of "high ambition" nations fight to include a list of chemicals used in plastics that should be banned in an international treaty to address plastic pollution.

Efforts to rein in plastics, as well as the chemicals used to make plastics, have faced fierce opposition from industry groups.

If designated as "high priority," which is likely, the five chemicals will be added to a backlog of more than 30 chemicals awaiting an evaluation, risk determination or final rule.

Major amendments made to TSCA in 2016 requires EPA to continue adding more existing chemicals to the list as other chemicals reach different milestones throughout the process, but the agency has not designated any additional substances since 2019, when it added 20 all at once.

Swamped with the new responsibilities and lacking resources, EPA took the four-year lapse to catch up on those risk evaluations. Progress is being made, Freedhoff said, but challenges still remain.

A group of House Republicans and industry groups such as the American Chemistry Council have recently voiced frustrations about the agency using the risk evaluation and determination process to initiate quick bans that disrupt critical manufacturing operations and are not based on science.

Freedhoff disagreed. “I don’t think we’re using the prohibition option lightly or quickly,” she said. “What we’re really doing is following the science, following the law, not doing so with an ideological preference to ban things, but also recognizing that for some of the uses of some of the chemicals, we don’t really see a safe way for those uses to continue.”

ACC did not respond to requests for comment by publication time.

Senator MULLIN. Thank you. My question, ma'am, is when you go on a victory lap with activists and include their quote directly under your press release, how do manufacturers, contractors, that work in industry have any confidence that this is not just some activist move driven by and prejudged before it even comes out?

Ms. FREEDHOFF. Thanks for the question. I think that any of the stakeholders who work on TSCA, whether they are companies, whether they are families who have lost family members because of exposures to chemicals, environmental organizations, labor organizations, other Federal agencies, there is not any of them who would say that they feel like me or my staff are not accessible to them, do not listen to them, and are not doing——

Senator MULLIN. Being accessible is different.

Ms. FREEDHOFF. And are not attempting to fairly implement the law.

Senator MULLIN. I think being accessible is not the question here. When you quote an activist in your paper, when you are releasing information that you are going after plastics and you are quoting the president of an activist group that is, you know, Beyond Plastics, and you didn't quote any industries in there. When you got a movement toward that to begin with, being accessible does not mean you are listening, does not mean you are taking the industry into account or what is the next step for the industry.

A lot of people listen in Washington, DC. They already had their mind made up where they are headed. When you quote someone like that, it would obviously send shockwaves to the industry saying that your mind is already made up before you even made this decision that you are looking into it.

I am asking, how can they be confident that you are actually taking them into consideration?

Ms. FREEDHOFF. First of all, I would say we met with the industry to tell them what our short list of chemicals was before we met with any, with that particular organization. Second of all——

Senator MULLIN. Why would you choose to name and to quote her?

Ms. FREEDHOFF. I think there is an undeniable interest in a large part of the community in taking a look at the chemicals that are used to make plastic. Vinyl chloride was actually the example used by the Nixon Administration in the 1970's for why Congress should write a Toxic Substances Control Act in the first place.

I assure you, we have a multi-year scientific process that precedes any regulatory decisions. We have not even started that process. We are committed to being there——

Senator MULLIN. When you say multi-year, what are you talking about? Like so before your decision is coming out on anything, you are going to spend years studying this?

Ms. FREEDHOFF. Correct.

Senator MULLIN. What does that look like?

Ms. FREEDHOFF. In the next year, what we are trying to do is work with Federal agencies, industry, other organizations to get data and really sort of get ahead of our risk evaluation process so we can meet our deadlines. After this year passes, the law gives us three to three and a half years to actually finish the draft risk evaluation.

There will be multiple public comment periods as well as a peer review of the draft risk evaluation during that time. Really, an enormous number of opportunities for companies to provide their perspective and give us their data. It is only after that that we would move to proposing a rule for vinyl chloride. I can assure you with full confidence that nobody at the agency has made up any, has any idea of what that rule would look like. We have only just started.

Senator MULLIN. Thank you. Thank you, Mr. Chairman.

Senator CARPER. Thanks for those questions. We have been joined by Senator Markey. While he prepares to ask some questions, I do not think this was Richard Nixon, but one of my favorite quotes is, people may not believe what we say; they will believe what we do. I think that is something for us all to keep in mind.

Senator Markey, welcome.

Senator MARKEY. Thank you.

Senator CARPER. You must have a sense of déjà vu here.

Senator MARKEY. Eleanor Roosevelt said, "I do not see the things which have been done, but only those things which remain to be done," which I think fully reflects the philosophy of our witness here today. There is more work to be done.

First of all, thank you to Dr. Freedhoff for decades of work, including in my office to protect the public from dangerous chemicals. As you know, I have fought for decades on behalf of the families in Woburn, Massachusetts. In Woburn, there was a boy named Jimmy Anderson. He was like any other kid from Woburn, except that at 3 years old he was diagnosed with a rare form of leukemia.

The kids in his neighborhood were like kids anywhere around Boston, except that they were also being diagnosed with this rare form of leukemia at an alarming rate in his neighborhood. Because of their exposure to trichloroethylene, or TCE, these children fell sick and died, deaths that may have been prevented if we had laws in place that allowed us to ban the use of these chemicals to begin with. Finally, last October, you led the EPA in proposing to ban the use of TCE, an incredible accomplishment.

That story became the book, *A Civil Action*, and then the movie, *A Civil Action*, about those families. It was nominated for an Oscar. Dr. Freedhoff, did the 2016 TSCA Amendments make it finally possible to take action against TCE?

Dr. FREEDHOFF. Thanks, Senator. The answer is unequivocally yes. I learned about the Anderson family from you, but it wasn't until I started working on the TCE rule at EPA that I realized that Jimmy would have been exactly my age if he hadn't died as a kid. He might have been sending his kids off to college, he might have had a life like mine.

It is not just his family. On the way to meet you that day, when we announced the proposed rule, I phoned two other parents who lost children and let them know that we were finally going to be addressing the risks of TCE because Congress had finally given the authority to EPA to do that.

Senator MARKEY. We were able to get it designated as a Superfund site, to get it cleaned up. It is now the Jimmy Anderson Transportation Center, named after that boy who Anne Anderson had brought into my office when he was 9 years old, asking for

help. We didn't even have a law at that time, we didn't have a Superfund law.

Senator Mullin asked about the listing of vinyl chloride and what it means for companies. That is a fair question and I am glad Dr. Freedhoff noted those companies are part of this process. I want to raise another group of stakeholders here. Next week will mark 1 year since the toxic train derailment and chemical fire devastated East Palestine, Ohio and the surrounding community. Vinyl chloride was the main chemical being transported on that Norfolk Southern train, more than 887,000 pounds. I was glad to see EPA's recent announcement that vinyl chloride is under consideration to be a high priority chemical for regulation under TSCA.

Dr. Freedhoff, would an eventual ban or use restriction on vinyl chloride help protect communities like East Palestine from hazards ranging from work exposure to disastrous explosions?

Ms. FREEDHOFF. Thanks, Senator. As I was saying to Senator Mullin, our risk evaluation and our rule on vinyl chloride has to go through very rigorous scientific process. The reason why the Nixon Administration used vinyl chloride as one of the three examples of why Congress had to write the Toxic Substances Control Act was because they knew even then that it caused liver cancer to workers.

I am sure that occupational safety practices are vastly different now than they were in the 1970's. The truth is that the original 1976 law that was supposed to ensure the safety of existing chemicals never really lived up to that promise. What the Nixon Administration said to Congress at the time, it is a great quote, so I hope you do not mind if I read it.

Senator MARKEY. Please.

Ms. FREEDHOFF. This is what they said. "We should no longer be limited to repairing the damage after it has been done nor should we continue to allow the entire population or the entire environment to be used as a laboratory." That was what the Nixon Administration said when they asked Congress to write the original law.

The original law failed to protect people against existing chemicals. The 2016 law that you and so many members of this committee worked on has the potential, and I think we will be able to see it realized, not just with TCE and vinyl chloride, but with many of the other chemicals that are long overdue for a look.

Senator MARKEY. It is not a ban on the transportation of it, it is whether or not it should be manufactured at all, because it is too dangerous.

Ms. FREEDHOFF. Or whether it should be manufactured and used in a way different than it currently is.

Senator MARKEY. Yes. Thank you, Mr. Chairman.

Senator CARPER. Thank you, Senator Markey. Senator Cramer, welcome.

Senator CRAMER. Thank you, Mr. Chairman, and thank you to the Assistant Administrator for being here.

Thank you for the response letter to me and several of my colleagues of both the House and the Senate regarding chlorpyrifos and the Eighth Circuit's vacating of their final rulemaking.

For the benefit of the dozens of people watching this online somewhere, the farmers in the prairies and throughout the Country, I

want to ask you to drill down a little bit on some of the specifics in response. Specifically, is the EPA beginning the process of restoring, or how are you restoring those tolerances? I will give you all of them up front and then you can just elaborate.

To include like, timelines, if you have some specific timelines, what has been done? I would also just add on behalf of several constituents, they feel like the EPA has been fairly, well, not very specific. Some of the statements since the vacating of the rulemaking have not provided very much clarity.

What I want to give you the opportunity to do over the next 4 minutes is provide that clarity for them, drill down a little bit on the specifics, the timelines, the tolerances that will be restored, and what-not, if you could, please.

Ms. FREEDHOFF. Happy to do that, Senator. I actually met with a bunch of the brewer groups yesterday on this question. They told us about some of the confusion that some of the State regulators have, and we are following up on that. We did try to reach out to everyone in advance of our December statement, but we will clearly need to do a better job and talk to more people.

First of all, what the Eighth Circuit did was it vacated EPA's rule that took away the permission to use chlorpyrifos on food crops. That decision has already happened, and all of those permissions to use chlorpyrifos on food are back in effect.

EPA has to write basically a technical correction to the Code of Federal Regulations. I think that is happening next week, but it is already in effect.

I think the next thing that we are doing, and the timeline on this I can not be quite as specific about, is the Eighth Circuit decision as well as a 2020 document that the agency put out on chlorpyrifos really focused on 11 uses of chlorpyrifos that had high benefits. What we are working to do is talk to the companies that make the pesticide in order to incorporate some additional mitigations that were talked about in the 2020 decision, as well as some of the Endangered Species Act work that we need to do in order to comply with that law.

I know those conversations are well underway. Since it is a conversation with external parties, I can not be more specific about when we will be finished.

Senator CRAMER. The whole thing is about 2 months old. You touched on the confusion that seemed to permeate the early statements. All I would say, wrapping up, Mr. Chairman and Madam Assistant Administrator, just be as clear as you can be. This is very, while we are heading into, hard as it is to believe in North Dakota today, we are heading toward spring, and the new seasons and all of that. Everybody from the manufacturers, the suppliers, the users themselves, the producers themselves, that seek this clarity, it is critical to get it done in a timely fashion. I appreciate your attempt.

Ms. FREEDHOFF. Absolutely, and if you get questions and people are still confused, just send them to us. Our staff want to be clear, also. It actually helps us when people come straight to us and ask us the questions.

Senator CRAMER. I appreciate that. Thank you very much.
Thank you, Mr. Chairman.

Senator CARPER. Senator Merkley, if you are ready, you are next in line, and then Senator Ricketts.

Senator MERKLEY. Thank you, Mr. Chairman, and welcome, good to have you.

OMB is currently reviewing its Asbestos Part 1 rule for chrysotile asbestos. Can you give us a sense of a date when the final rule will be available?

Ms. FREEDHOFF. Thanks very much for that, Senator. As you know, it is our first Section 6 rule that went through the new process. It is not an accident that it was the first one, because of the symbolic significance of the failed asbestos ban from the 1980's, and the fact that asbestos continues to kill tens of thousands of people every year.

It is at OMB, I think the 90-day period ends maybe in, I think it ends in early March. It is hard to predict, though, since it is not in our control, whether it will hit the early March timeline or not. I know we are in very active conversations with our agency partners and are really eager to unveil that final rule.

Senator MERKLEY. Well, it takes continuous advocacy, because things go to OMB and just disappear. It is like a, what the hell happened to it. Keep pressing, and keep us posted on that.

This rule only affects one form of asbestos. There are seven other types of asbestos fibers. Does EPA have a plan to address the additional asbestiform varieties?

Ms. FREEDHOFF. Yes. We are in the middle of Asbestos Part 2. As you might remember, when the last administration chose to only study chrysotile because that form is the only form used in ongoing uses, there was an adverse court decision that caused the agency to have to split that risk evaluation and rule into two. We are working on the second part of asbestos, which includes the other forms and includes legacy uses, and it includes reasonably available information on its presence in talc.

We expect to both release a draft and final risk evaluation for Part 2 in this calendar year.

Senator MERKLEY. OK. Thank you. I am glad to hear that.

One concern that we have heard about is in the peer review process. EPA released peer review comments, and one reviewer wrote that, "The members of this panel who are reviewing this document have been told, 'we are not to talk to one another. We have been told there will be no conference calls with one another. We have been told there will be no face to face meetings.' This is entirely inconsistent with the history of EPA's Science Advisory Panels."

I have concerns about that point. I have heard EPA saying, well, we are not going to let people talk to each other because we do not have enough funding, and we are not going to have conference calls if we do not have enough funding.

A lot comes from people actually sharing their comments with each other. Is this an accurate description of what is going on? why is this a good process?

Ms. FREEDHOFF. Thanks very much for that question. First of all, let me just say that we think the scientific advice that we get from our peer review committee is invaluable. We really do listen to what they say and take their input seriously.

I think it is also a pretty standard process though to do peer review, to do letter peer reviews of scientific documents. One of the reasons why we moved to doing that for Asbestos Part 2 is because a lot of the science, the exposure models and other information that we are using for Part 2, we had already had peer reviewed when we went through the Part 1 risk evaluation.

We also felt that moving to a letter peer review in this case would also really help us finish that Part 2 risk evaluation more quickly.

I do not want you to come away thinking that we are abandoning the peer review process. We are absolutely not. I think we did choose for the first time to try a different approach for this one, and part of the reason for that was our sense of urgency in completing that risk evaluation.

Senator MERKLEY. Mr. Chairman, I think this is something we need to take a further look at. The idea that scientists are being told they can not talk to each other, even Zoom meetings, in person, I do not think you get the best result having individual people told they are in silos and have to operate without the process of consultation. I am not sold. Count me skeptical.

Ms. FREEDHOFF. I appreciate it. Thank you.

Senator MERKLEY. My final question, actually I am out of time.

Senator CARPER. Just make it a brief one.

Senator MERKLEY. OK. In terms of PFAS, it is not a short question, so I may have to submit it to the record or just followup with you.

Senator CARPER. If we can do that, that would be good.

Senator MERKLEY. OK, that is what I will do. Thank you.

Senator CARPER. Thanks very much.

Senator RICKETTS. Good morning.

Senator RICKETTS. Good morning, and thank you, Chairman Carper, and Ranking Member Capito, for holding this hearing today. Dr. Freedhoff, thank you for joining us.

I have a few examples behind me of chemicals that have undergone the TSCA process which are critical for global food production. Formaldehyde is necessary for livestock production, to prevent disease. While you all may know that Nebraska is the Beef State, something you may not know is that we are also the global leader in irrigation system production such as what you see here, a center pivot, actually about 80 percent of all the world's center pivots are made in Nebraska.

Vinyl chloride is critical for the irrigation tubing, hoses, and drip lines. Both ethylene oxide and acetaldehyde are used in the production of crop protection tools, protecting our food supply from insects and disease. These examples really exemplify the importance of predictable and reliable permittance of chemicals.

As Governor of Nebraska, I implemented Lean Six Sigma for our State agencies to improve our processes. My understanding is the Trump Administration established an Office of Continuous Improvement at the EPA to implement the Lean program at the EPA. We talked about this a little bit yesterday, Dr. Freedhoff.

I am just looking for a simple yes or no on these. Does the New Chemicals program still utilize the Lean program?

Ms. FREEDHOFF. No, but we do seek to continuously improve through many of the same approaches that are in Lean Six Sigma.

Senator RICKETTS. Does the Office of Continuous Improvement still exist at the EPA?

Ms. FREEDHOFF. That I am not sure about. I know there are agency-wide conversations about ways to improve our processes and when one part of EPA comes up with something, it is actually shared throughout the agency.

Senator RICKETTS. Well, there are clearly other process improvement methodologies besides Lean Six Sigma. If you could followup with me on the Office of Continuous Improvement, if that still exists at EPA.

Ms. FREEDHOFF. Sure.

Senator RICKETTS. Also, we have heard that one of the problems holding up PMNs, Project Management Networks, are changes to the staff contacts throughout the process. If a new project manager is assigned to a PMN, will you commit to us that that project manager will then notify the submitter within a week to let them know there has been a change?

Ms. FREEDHOFF. I think that is an incredibly reasonable idea. We would be happy to do that. I think that would improve transparency for everybody.

Senator RICKETTS. Great, thank you very much, Dr. Freedhoff.

The EPA issues existing chemical exposure limits, in other words, regulating chemicals throughout the workplace exposures. However, they are multiple times more stringent than the rest of the world. These limits are based on information from EPA's Integrated Risk Information System, or IRIS program, which is not congressionally authorized and is a hazards based program.

This is not consistent with the agency's statutory mandate to complete risk-based chemical reviews using the best available science, not to mention that OSHA already is completing the work on this through some of their enforcement permissible exposure limits. In addition, the American Conference of Governmental Industrial Hygienists established exposure limits far above EPA's ECHOs, Extension for Community Healthcare Outcomes. These values are regularly updated following industry standardization practices.

For many of the chemicals under EPA review, including asbestos, methylene chloride, perchloroethylene, carbon tetrachloride, and trichloroethylene—

Senator CARPER. Could you say that again?

[Laughter.]

Senator RICKETTS. I thought I did about as good as I could the first time through.

The ECHOs have come out after the proposed and final risk evaluation, some with proposed risk management rules which left stakeholders with no real opportunity to comment on these levels.

This is a significant problem that is compounded by the fact that these numbers are extremely low, often below the level of detection, and much lower than regulatory numbers in the rest of the world, as we kind of mentioned.

Setting levels below the level of detection is a de facto ban on these chemicals. For clarification, when you set a final regulatory

ECHO for industrial uses, does that mean there is a level at which no unreasonable risk exists?

Ms. FREEDHOFF. I think what we are saying for some of those levels is that the proposed exposure levels that came out address the unreasonable risk that was identified in the risk evaluation. It is important to understand that the risk evaluations are prohibited by law from considering costs and other non-risk factors, like the point you made about them being unimplementable.

I think as we move through the regulatory process following the risk evaluations, we are engaging pretty actively with industry to make sure that we really understand what their occupational safety practices can achieve. I think you will see some shifts in our approaches between proposed and final rules for some of the chemicals.

Senator RICKETTS. OK, thanks. If I understand what you are saying, and correct me if I am wrong, the process has been set up, and the rule has been established and the law has been passed actually to make it so that you recommend some of the risk levels below detection level because you are not allowed to consider other factors? Is that accurate?

Ms. FREEDHOFF. Not quite. In the risk evaluations, we are not supposed to be considering costs or other non-risk factors. When we write rules, we 100 percent consider those things. I think in an exchange I had earlier with Senator Boozman, I believe it was, going forward, if we get a draft risk evaluation that leans to a masked outcome that the draft proposed occupational safety limit is below background levels for that chemical, we will see very clearly in the draft risk evaluation that that number will not be the basis of our rule.

Senator RICKETTS. OK, so it is not a de facto ban in that case, then?

Ms. FREEDHOFF. No.

Senator RICKETTS. OK, thank you very much, Dr. Freedhoff, I appreciate your explaining that to me. Thanks.

Senator CARPER. Senator Ricketts, thank you for those questions.

I think Senator Fetterman is trying to get here to join us. Do we expect any other Republican colleagues to join us? Senator Lummis, OK, good.

I want to return to the issue of new chemical review for a minute or two. As you know, our committee has consistently heard concerns from stakeholders about the pace of new chemical reviews. Specifically, the chemical industry believes that EPA is moving too slowly, whereas others are concerned that EPA is not being thorough enough.

Dr. Freedhoff, your office has taken some innovative approaches to improve the pace of new chemical reviews. We talked about some of that already. Would you please elaborate on some of those approaches and specifically, what has worked well, and how have those approaches allowed EPA to review these new chemicals faster, while also being more thorough? Where might there still be room for improvement? In the spirit of everything that we do, we know we can do better. Go ahead.

Ms. FREEDHOFF. Thanks for that question, Senator Carper. I think we have talked about new chemicals a little bit in this hear-

ing, and I really do think there is still upside in what the agency can deliver. I think we have already demonstrated some, but I think we can continue to do more.

It used to be when EPA didn't know enough about a new chemical before the 2016 amendments were passed, that chemical went right into commerce without a formal EPA review. As a result, there are a whole bunch of types of chemistries that EPA never really had to write anything down about. One of the things we have tried to do is work to write down the science policy that would allow us to standardize and streamline the review for chemicals that we see a lot.

One example, mixed metal oxides, which are used by the battery sector in particular. We had companies tell us that they expected to send us dozens of those every year as we move to increased electric vehicle production in this Country. We decided we really needed to get ahead of that and worked on our science policy and risk assessment approach for that class of chemistry.

We are doing that with other sectors, too. The fragrance sector has a couple dozen PMNs that have been stuck at the agency because of science questions like that. While I do not think we can do the exact same thing for the fragrance sector as we did for the battery sector, we are convening a scientific workshop with them and other stakeholders next week, I believe, to try to work to figure out what the answers to those questions are, so that we can move those PMNs along also.

Really it is a class work smarter, not harder, modernize our approaches, be strategic about where we focus our resources and try to increasingly improve both our speed and our protectiveness.

Senator CARPER. Let me ask one more question, then we will turn to Senator Lummis. There are differences of opinion, as you know, about the amount of money that you need to run the programs in your agency. The House has proposed further cuts to the TSCA program in its Fiscal Year 2024 appropriations bill. Can you give us a sense of how you will prioritize your work if this is enacted? What will have to be sacrificed?

Ms. FREEDHOFF. Thanks for that question. It is important to remember, before the law was changed, EPA did zero comprehensive risk evaluations. Of the 30 chemicals that have gone through the process, we have met the statutory deadline for only one of them.

Before the law was changed, we wrote zero comprehensive rules to protect people against some of the most dangerous chemicals that have ever been made or used in this Country. Now we are in the middle of working on 10 of those. We have missed the statutory deadlines for those as well.

We have talked about our consistent struggle, since the new law was enacted, to meet Congress' expectation that new chemicals would be reviewed protectively within 90 days.

The House budget would take us back to the budget of the old law that didn't do any of the things that the new law has told the agency to do. What it means is that the workers and communities who have been waiting for decades to get the protections they need will have to wait longer. What it also means is that the new chemistries that are needed to reshore the domestic manufacturing of everything from semiconductors to biotechnology to refrigerants to

comply with the EMAC, Environmental Management Assistance Compact, to all of these other chemistries, they will need to wait a little bit longer, too. We simply will not have the resources to do what Congress expected us to do.

Senator CARPER. All right. I think that is an important point for us to keep in mind as we go through the appropriations process in the days to come.

Senator Lummis, we are glad to see you. Welcome aboard.

Senator LUMMIS. I am delighted to see you too, Mr. Chairman. Thank you very much for holding this hearing, and thank you, Ranking Member Capito.

My questions at least are going to start with PFAS. As you know, there is an ongoing debate over the definition of PFAS as it applies to a range of Federal regulatory regimes. I am concerned that there is no current consistent agreed-upon definition for these chemistries being used across Government agencies.

While some PFAS chemistries may need urgent regulations to keep our communities safe, I am concerned that EPA is needlessly restricting critical PFAS chemistries essential for American manufacturing. I am not the only one that is concerned.

Mr. Chairman, I would like to ask unanimous consent to enter into the record a report from the Department of Defense on critical applications of PFAS substances.

Senator CARPER. Without objection, so ordered.

[The referenced information follows:]

Report on Critical Per- and Polyfluoroalkyl Substance Uses

**Pursuant to Section 347 of the James M. Inhofe National Defense Authorization Act for
Fiscal Year 2023 (Public Law 117-263)**



August 2023

Office of the Assistant Secretary of Defense for Energy,
Installations, and Environment

Office of the Assistant Secretary of Defense for Industrial
Base Policy

The estimated cost of this report or study for the Department of Defense is approximately \$83,000 in Fiscal Year 2023. This includes \$47,900 in expenses and \$45,100 in DoD labor.
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Table of Contents

Acronyms	iii
I. Introduction	1
II. Definitions	2
II.1 Per- and Polyfluoroalkyl Substances	2
II.2 Critical to the National Security	3
II.3 Sectors Considered	4
III. Data Collection Methodology	4
III.1 CMRMP Data Call	5
III.2 Additional Industry Engagement	5
III.3 OASD(IBP) Industry Sector Data Collection Process	5
IV. Results	5
IV.1 Kinetic Capabilities	5
IV.2 Energy Storage and Batteries	6
IV.3 Microelectronics and Semiconductors	7
IV.4 Castings and Forgings and Strategic and Critical Minerals	8
IV.5 Additional Mission Critical PFAS Uses	9
IV.5.1 Refrigeration and Air Conditioning, Cooling, and Electronics Thermal Control	10
IV.5.2 Fire Suppression in Naval Vessels, Aircraft and Ground Combat Vehicles	10
IV.5.3 Aqueous Film Forming Foam	11
IV.5.4 Lines, Hoses, O-Rings, Seals and Gaskets, Tapes, and Cables and Connectors	11
IV.5.5 Electronic/Dielectric Fluids	12
IV.5.6 Advanced Oils, Greases, Fluids, and Lubricants	12
IV.5.7 Precision Cleaning Fluids	12
IV.5.8 Degreasing/Cleaning Fluids	13
IV.5.9 Adhesives	13
IV.5.10 Insulation and Foam Blowing	13
IV.5.11 Resins for Specialty Materials	13
IV.5.12 Specialty Filters and Membranes	14
IV.5.13 Fabrics, Fabric Liners, and Fabric Barriers	14
IV.5.14 Customized Applications	14

V. Conclusions	14
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Figure

Figure: Overview of PFAS Groups (refined from OECD 2021)	3
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Appendix

Appendix: Summary of Known Mission Critical PFAS Uses	A-1
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Acronyms

AFFF	Aqueous film forming foam
AIM Act	American Innovation and Manufacturing Act of 2020
CMRMP	Chemical and Material Risk Management Program
DoD	Department of Defense
ECTFE	Ethylenechlorotrifluoroethylene
EPA	U.S. Environmental Protection Agency
EU	European Union
F3	Fluorine-free foam
FY	Fiscal Year
HFCs	Hydrofluorocarbons
HFOs	Hydrofluoroolefins
Li-ion	Lithium-ion
MCMEU	Mission-critical military end use
MilDep	Military Department
NDAA	National Defense Authorization Act
NDT	Non-destructive testing
OASD(IBP)	Office of the Assistant Secretary of Defense for Industrial Base Policy
ODASD(E&ER)	Office of the Deputy Assistant Secretary of Defense for Environment and Energy Resilience
OECD	Organisation for Economic Co-operation and Development
PA&T	Policy, Analysis, & Transition
PFA	Perfluoroalkoxy alkanes
PFAA	Perfluoroalkyl acid
PFAS	Per- and polyfluoroalkyl substances
polyFAA	Polyfluoroalkyl acid
PTFE	Polytetrafluoroethylene
PVDF	Polyvinylidene fluoride
SOTA	State-of-the-Art
SOTP	State-of-the-Practice
U.S.	United States
USS	United States Ship
UV	Ultraviolet

I. Introduction

Section 347(a) of the James M. Inhofe National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2023 (Public Law 117-263) directs the Secretary of Defense, in consultation with the Defense Critical Supply Chain Task Force (i.e., the Office of the Assistant Secretary of Defense for Industrial Base Policy (OASD(IBP))) and the Chemical and Material Risk Management Program (CMRMP) of the Office of the Assistant Secretary of Defense for Energy, Installations, and Environment (OASD(EI&E)), to submit to the Committees on Armed Services of the House of Representatives and the Senate a report outlining the uses of per- and polyfluoroalkyl substances (PFAS) that are critical to the national security of the United States. This report focuses on critical uses in the sectors outlined in the February 2022 Department of Defense (DoD) report titled *Securing Defense-Critical Supply Chains* and sectors of strategic importance for domestic production and investment to build supply chain resilience.

PFAS are common chemicals used across DoD. Most weapons platforms incorporate PFAS, and PFAS are found throughout the defense industrial base in roles supporting mission critical component production and supply. PFAS uses may be direct, where a PFAS is a constituent in a consumable item or is incorporated into an article (e.g., end item), or indirect, where a PFAS is used to formulate another chemical or is part of a manufacturing process. These uses and processes are necessary to the production of key components of the defense industrial base, such as microelectronic chips and lithium-ion (Li-ion) batteries.

PFAS are chemically quite stable, and many are water and oil repellent, heat resistant, and/or stain resistant, often leading to non-stick surfaces on various materials. Examples of applications of PFAS are in plastics, o-rings, gaskets, lubricants, coolants, and fabrics. DoD is reliant on the critically important chemical and physical properties of PFAS to provide required performance for the technologies and consumable items and articles which enable military readiness and sustainment. Losing access to PFAS due to overly broad regulations or severe market contractions would greatly impact national security and DoD's ability to fulfill its mission, and impact domestic defense industrial base manufacturing and supply.

This report provides details on what is currently known about direct and indirect mission critical PFAS uses that could impact mission readiness if the substances are no longer available. It also highlights the challenges and costs related to finding and qualifying equal or improved performing alternatives to existing PFAS materials in sectors of strategic importance to DoD. It is important to note that the information contained in this report is limited to what was available at the time of its drafting. As such, the information presented represents a fraction of the mission critical PFAS uses due to a lack of knowledge of the complete chemical composition in consumables and articles (e.g., end items)¹. In addition, there is significant uncertainty regarding

¹ A consumable is defined as "an item of supply or an individual item (except explosive ordnance and major end items of equipment) that is normally expended or used up beyond recovery in the use for which it is designed or

the presence of PFAS in products that make up a complex value chain. A more complete understanding of PFAS essential uses would require an extensive and complex evaluation of the market, a gap analysis of current requirements for manufacturer-provided product information, and illumination of the value chain of products.

II. Definitions

For purposes of this report, the terms used within section 347(a) of the NDAA for FY 2023 are defined in the following sub-sections.

II.1 Per- and Polyfluoroalkyl Substances

There is currently no consensus definition of PFAS as a chemical class.² Congress did not define PFAS within section 347(a) of the NDAA for FY 2023 for purposes of this report.³ While there is no consensus definition, regulators in the European Union (EU) and the United States have proposed, but not yet adopted, different chemical-structure-based (rather than hazard- or risk-based) definitions. In anticipation of the most stringent future regulatory actions, DoD used the definition put forward by the Organisation for Economic Co-operation and Development (OECD) in its 2021 report, *Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance*,⁴ for collecting data and developing this report. OECD states “The term ‘PFASs’ is a broad, general, non-specific term, which does not inform whether a compound is harmful or not, but only communicates that the compounds under this term share the same trait for having a fully fluorinated methyl or methylene carbon moiety.” OECD cautions that this definition should not be used in deciding how to group and manage PFAS in regulatory actions; however, future PFAS legal and regulatory frameworks may disregard the OECD caution and seek to restrict the use of PFAS based on chemical structure.

intended. An end item is the “final combination of end products, component parts, or materials that is ready for its intended use, e.g., ship, tank, mobile machine shop, or aircraft.” *DoD Supply Chain Terms and Definitions* (February 21, 2023). https://www.acq.osd.mil/log/LOG_SD/policy_vault.html/DoD_Supply_Chain_Terms_and_Definitions.pdf.

² *Per- and Polyfluoroalkyl Substances (PFAS) Report: A Report by the Joint Subcommittee on Environment, Innovation, and Public Health*, Per- and Polyfluoroalkyl Substances Strategy Team of the National Science and Technology Council, March 2023.

³ Congress previously defined PFAS in the NDAA for FY 2021 for purposes of establishing the interagency working group to coordinate federal activities related to PFAS research and development. Section 332(g)(1) defines PFAS broadly as (A) man-made chemicals of which all of the carbon atoms are fully fluorinated carbon atoms; and (B) man-made chemicals containing a mix of fully fluorinated carbon atoms, partially fluorinated carbon atoms, and nonfluorinated carbon atoms. William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, Pub. L. 116-283 (2021).

⁴ “PFASs are defined as fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), i.e., with a few noted exceptions, any chemical with at least a perfluorinated methyl group (–CF₃) or a perfluorinated methylene group (–CF₂–) is a PFAS.” OECD, *Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance* (Series on Risk Management No. 61), July 9, 2021. [https://one.oecd.org/document/ENV/CBC/MONO\(2021\)25/En/pdf](https://one.oecd.org/document/ENV/CBC/MONO(2021)25/En/pdf).

The figure below provides an overview of the PFAS groups based on the OECD definition. This very broad definition encompasses more than 38,000 individual PFAS chemicals.⁵ DoD uses are represented in each major category of PFAS (i.e., perfluoroalkyl acids (PFAAs) and polyfluoroalkyl acids (polyFAAs)), PFAA precursors, and other PFAS (e.g., fluoropolymers, fluoroelastomers).

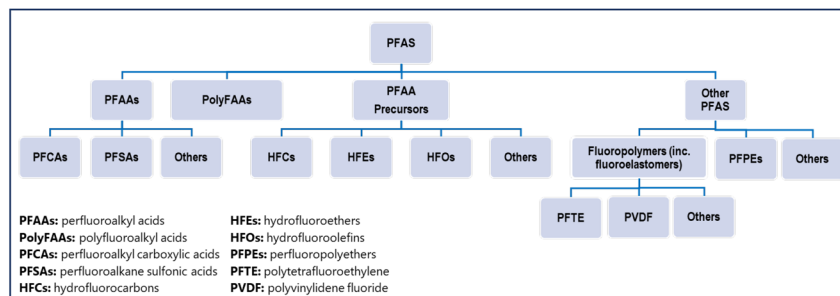


Figure: Overview of PFAS Groups (refined from OECD 2021)

II.2 Critical to the National Security

Congress did not define “critical to the national security of the United States” within section 347(a) of the NDAA for FY 2023. The term “mission-critical military end use (MCMEU),” however, is defined in regulations promulgated by the U.S. Environmental Protection Agency (EPA) under the American Innovation and Manufacturing Act of 2020 (AIM Act).⁶ The AIM Act addresses the phasedown of production and consumption of hydrofluorocarbons (HFCs) (e.g., regulated substances). MCMEUs are “[t]hose uses of regulated substances by an agency of the Federal Government responsible for national defense that have a direct impact on mission capability, as determined by the U.S. Department of Defense, including, but not limited to uses necessary for development, testing, production, training, operation, and maintenance of Armed Forces vessels, aircraft, space systems, ground vehicles, amphibious vehicles, deployable/expeditionary support equipment, munitions, and command and control systems.”⁷

The MCMEU definition focuses on *regulated substances*. As with HFCs, PFAS are undergoing increased regulation. But in addition to regulation, market forces can directly impact mission capability by limiting DoD’s ability to source and use PFAS and PFAS-containing

⁵ Williams, et al. 2022. Assembly and Curation of Lists of Per- and Polyfluoroalkyl Substances (PFAS) to Support Environmental Science Research. *Front. Environ. Sci.* 10:850019. doi:10.3389/fenvs.2022.850019.

⁶ 42 U.S. Code 7675.

⁷ See 40 Code of Federal Regulations 84.3, “Phasedown of Hydrofluorocarbons” (October 5, 2021).

products. The most recent example is 3M's decision to phase out production of PFAS and PFAS-containing products by 2025.⁸

For purposes of data collection and report development, DoD used the MCMEU definition with the recognition that both market forces and increased regulation can have a direct impact on mission capability.

II.3 Sectors Considered

Section 347(a) of the NDAA for FY 2023 directs DoD to focus this report on critical PFAS uses in the four focus areas identified in DoD's February 2022 report *Securing Defense-Critical Supply Chains*.⁹ The four focus areas—kinetic capabilities, energy storage and batteries, microelectronics, and castings and forgings—have critical supply chain vulnerabilities posing the most pressing threats to national security. In addition, this report focuses on semiconductors—a sector of strategic importance for domestic production and investment to build supply chain resilience—and strategic and critical minerals. These areas are described as:

- **Kinetic capabilities:** Current missiles systems and advanced and developing missile capabilities, including hypersonic weapons technology, as well as directed energy weapons.
- **Energy storage and batteries:** High-capacity batteries, with a particular focus on lithium batteries.
- **Microelectronics and semiconductors:** State-of-the-Practice (SOTP) and legacy microelectronics, State-of-the-Art (SOTA) microelectronics, and semiconductors.
- **Castings and forgings:** Metals or composites developed into key parts and manufacturing tools through high-intensity processes.
- **Strategic and critical minerals:** Minerals to supply U.S. military, industrial, and essential civilian national emergency needs, with emphasis on those that are not produced in sufficient quantities in the United States.

III. Data Collection Methodology

Data collection efforts for this report were led by the CMRMP of the ODASD(E&ER) and the OASD(IBP) and included engagement with the DoD Components and Military Departments (MilDeps), industry, and industry associations.

⁸ "3M to Exit PFAS Manufacturing by the End of 2025" (December 20, 2022). <https://news.3m.com/2022-12-20-3M-to-Exit-PFAS-Manufacturing-by-the-End-of-2025>.

⁹ Securing Defense-Critical Supply Chains: An Action Plan Developed in Response to President Biden's Executive Order 14017 (February 2022). <https://media.defense.gov/2022/Feb/24/2002944158/-1/-1/1/DOD-EO-14017-REPORT-SECURING-DEFENSE-CRITICAL-SUPPLY-CHAINS.PDF>.

III.1 CMRMP Data Call

In March 2023, the CMRMP asked the DoD Components and MilDeps to provide information about its critical uses of PFAS, to include use of neat PFAS, use of PFAS-containing products, the functionality provided by the PFAS, specific uses and applications, and availability of alternatives (if known).

III.2 Additional Industry Engagement

The CMRMP held engagement sessions with various industries and industry associations to obtain information about the PFAS and PFAS-enabled products that they (or their member industries) manufacture and how DoD uses those products. The CMRMP shared this information with the DoD Components and MilDeps to inform their data collection efforts.

III.3 OASD(IBP) Industry Sector Data Collection Process

The Kinetic Capabilities Team at Policy, Analysis, & Transition (PA&T), OASD(IBP), engaged with PA&T Industry Sector leads and their industry partners to identify PFAS uses that are critical to U.S. national security. These sectors include Kinetic Capabilities, Energy Storage and Batteries, Microelectronics and Semiconductors, Castings and Forgings, and Strategic and Critical Materials. The Sector leads identified PFAS uses in industry, operation, manufacturing, processes, components, parts, and materials. They also discussed how and where losing access to PFAS could have significant mission readiness impacts and what they could do or are doing to mitigate those impacts.

IV. Results

DoD's known critical uses of PFAS are summarized in the following sub-sections, organized by focus area, and in the Appendix. The complexities in dissecting the defense industrial base value chain and supply chain dependencies, in addition to the lack of transparency in chemical and material content data, prevented the CMRMP from gathering comprehensive data on all critical PFAS uses.

Critical PFAS uses were identified in almost every major weapon system category including but not limited to fixed wing aircraft (trainers, fighters, bombers, transports, refuelers, ground support, unmanned, and associated support equipment); rotary wing aircraft (attack, transports, heavy lifts, search-and-rescue, and associated support equipment); surface ships (combat, destroyers, aircraft carriers, cutters, landing crafts); submarines; missiles (air-to-air, ground-to-air, air-to-ground, ballistic); torpedo systems; radar systems; and battle tanks, assault vehicles, and infantry carriers.

IV.1 Kinetic Capabilities

Kinetic capabilities represent a direct use of PFAS, as PFAS are found in a variety of applications across the DoD munitions portfolio. About a dozen fluoropolymers, including

fluoroelastomers, are ingredients in polymer bonded explosives, pyrotechnics, and propellant components used in munitions, decoy flares, and chaff. They serve as high temperature resistant binders and resins. These uses, which represent some of the few purely military PFAS applications, include:

- Unique binder materials specifically developed for use in the energetic portion of conventional and strategic weapons platforms.
- Fluoroelastomers, such as Viton™, used as a binder in explosive and booster charge formulations integrated into many DoD munitions.
- Fluoropolymers, such as Teflon™, used in pyrotechnics and as a material used in the manufacture of munitions for a variety of missile systems.

PFAS are used in a variety of applications during energetics processing and testing. Currently, non-PFAS alternatives do not exist for most of these applications, and the likelihood of developing alternatives for these uses is estimated to range from moderate to almost impossible. If available, alternatives require multi-year processes and cost program offices millions of dollars to requalify every missile system that used the material, even if products are similar.

IV.2 Energy Storage and Batteries

Impacts to national security from PFAS applications in energy storage and battery applications are indirect. Manufacturers use fluoropolymers (e.g., polytetrafluoroethylene (PTFE)) and polyFAAs in multiple subcomponents in modern Li-ion batteries. They serve as heat transfer materials or insulation and provide weather resistance and ultraviolet (UV) light resistant functionalities to final components. Military applications rely on Li-ion battery technologies that are largely innovated in the civilian sector. Manufacturers use PFAS in the electrolyte solutions, cathode binders, and separator coatings; and, to a lesser extent, PFAS are found in casing materials and gaskets due to their deterioration resistance properties.

PFAS materials also play an important role in battery manufacturing. Filters and other components of manufacturing equipment are essential to battery production. The battery industry's ability to make products for a broad range of commercial and military applications would be greatly impacted if PFAS were no longer available for use in these components. The significant time and money needed to identify and qualify alternatives as replacements would cause ripple effects throughout the economy as consumers and users absorb the additional cost.

Fully eliminating PFAS from energy storage in the U.S. economy would likely take more than 10 years. Energy storage is a broad issue for U.S. industrial competitiveness as well as an important part of Federal initiatives around combating climate change. DoD is not the primary consumer of batteries in the United States, but battery supply chain issues would impact the ability to produce missiles and field military vehicles that increasingly rely on batteries.

IV.3 Microelectronics and Semiconductors

The semiconductor industry produces the chips that drive modern electronic devices. The microelectronics packaging and assembly industry integrates these chips into the electronic products used every day across the defense enterprise. In the semiconductor industry, fluoropolymers, fluoroelastomers, polyFAAs, and other fluorochemicals are used in a number of applications and at every stage of semiconductor fabrication. These uses include etching materials (photoresists), etching coolants, masks in photolithography processes, packaging materials that provide heat dissipation for the chip, and cleaning gases at various stages in the microchip production process. Examples of specific PFAS in the semiconductor industry include polyvinylidene fluoride (PVDF; a fluoropolymer), ethylenechlorotrifluoroethylene (ECTFE; a fluoropolymer), FKM/FFKM (fluoroelastomers), and perfluoroalkoxy alkanes (PFAs).

One significant use of PFAS in semiconductor manufacturing is during the photolithography process, where the patterns that define the microchip circuitry are developed onto bare silicon surfaces. Manufacturers use photolithography specialty formulations containing fluorinated compounds in various steps of this process to ensure final chip quality and reduce the probability of defects. PFAS are ideal for these purposes due to their low surface tension and compatibility with other chemicals. The PFAS materials used in these processes are typically no longer present in the finished product, except in some specific applications, such as imaging chips used in cameras, displays, and some medical devices.

Similar to the energy storage industry, PFAS are essential for semiconductor manufacturing equipment and factory infrastructure. The exceptional combination of heat and chemical resistance and chemical inertness allows fluoropolymers to be used both in equipment components (e.g., tubing, gaskets, containers, filters) and lubrication (e.g., various oils and greases). These same properties are also needed to ensure the functioning of the surrounding infrastructure.

In wider microelectronics applications, PFAS remain key industrial materials in applications that integrate microchips into electronic products, such as printed circuit boards. PTFE and PFA base laminate materials are currently used in many radio frequency (RF) and microwave circuits, as they provide unique properties related to isolating RF and microwave signals. Identifying and qualifying potential replacement materials will require significant time, particularly for use in fielded systems. There currently are no available drop-in replacement materials for a PTFE designed printed board. Lack of access to PTFE laminate will necessitate the redesign and requalification of the printed board, the assembly, and potentially the system.

Several PFAS-containing vapor phase soldering and flux removal products are used in the manufacture of printed circuit boards. Vapor phase soldering is used primarily for printed board assembly when there is a high thermal mass, in combination with advanced technologies such as fine-pitch features, or when there are temperature sensitive components used. Alternative materials are not currently identified and would need to be evaluated for performance

and safety. New equipment may be required to implement new vapor phase soldering liquids. PTFE cable jackets are used in printed circuit board and other electronic systems in connectors and wire. PTFE has unique properties as a wire insulator including fire, smoke, and chemical resistance to mitigate the risk of wire exposure in harsh environments. PTFE can withstand 450°C and is used widely in products that have been developed to meet MilSpec applications. Manufacturers also use fluoropolymers as electronics sealants and encapsulants to protect microelectronic components from degradation due to environmental, chemical, or UV-light exposure. Vapor degreasing solvents, used in a variety of cleaning processes during microelectronics production, contain hydrofluorocarbons (HFCs) and hydrofluoroolefins (HFOs), which, in many cases and in the broadest sense, are defined as PFAS. These materials impart fire suppression properties to the degreasing solvent, creating safer manufacturing environments for workers.

Currently, no alternatives to PFAS have been identified that can provide the functional properties required for photolithography or some applications in semiconductor manufacturing equipment. Even if alternative chemicals and technologies were discovered today, due to the extremely complex qualification process throughout the value chain, it would take another 15 years to deploy them in high-volume manufacturing. Therefore, continued access to PFAS is a prerequisite for high-volume and advanced semiconductors. Lack of continued access to PFAS could lead to an inability to produce and supply semiconductor manufacturing technology.

Replacing most PFAS uses in semiconductor fabrication would require industry-wide re-tooling and other process innovations, at a minimum. Some might be achievable within 10 years, but many would not. As stated above, there are some PFAS uses for which no alternatives are known. For these uses, it may be necessary to invent novel chemistries and processes. Replacing PFAS in semiconductor fabrication could be a 25-year effort and may not succeed in all respects if alternatives cannot be identified or qualified at the microchip level.

Consideration must also be given to the resultant impact on DoD programs. It is highly probable that manufacturers would need to change semiconductor manufacturing processes to accommodate PFAS replacements. This change has the potential to result in the costly requalification of specific components. For example, radiation hardened microelectronics applications typically mandate requalification if a manufacturer substantively alters the fabrication process, which can easily exceed \$10 million; many programs lack intrinsic funding for requalification.

IV.4 Castings and Forgings and Strategic and Critical Minerals

Specialty fluorochemical gases and fluids are used for advanced metalworking, casting, and fabrication due to the temperature and wear resistance functionalities they provide. These gases and fluids are used in the production of advanced metal parts throughout U.S. industry, including military-specific parts. Requiring a move to PFAS-free alternatives in under 10 years may make construction using certain alloys impossible and require returning to previous methods

of construction leading to lower performance, shorter life, and higher weight of constructed parts.

In both the casting and forging and strategic and critical minerals industries, loss of access to PFAS is an indirect threat to national security and a potential source of significant disruption to supply chains vital to the DoD mission. These industries depend on PFAS in products used during normal business operations. A product used as a liquid cold spray in castings and forgings or coolant in drilling operations for critical minerals may contain PFAS, but the product user would not know that PFAS are present until the product is discontinued. Both industries are at risk of losing critical capabilities with little warning, as there are limited requirements for companies to provide composition information for the materials used to create the products they sell to DoD or on the commercial market. The risk for these industries is particularly high, even if the probability is low, because there may be no warning for critical product obsolescence and no ability to develop and qualify alternatives in a timely fashion.

PFAS are also contained in mold release chemicals and release films typically used in composite manufacturing processes. Loss of access of PFAS would impact the commercial composites manufacturing industry and, indirectly, the DoD who is reliant on the commercial industry for applications.

Mold release chemicals are applied to mold hardware to prevent the composites from strongly adhering to the mold hardware during cure. The mold release chemicals typically contain PFAS chemicals or a PTFE polymer spray. Peel plies are used to prevent attachment of vacuum bag materials and other disposable molding materials to the composite part and to impart a textured surface to the molded component to improve adhesion in secondary bonding or painting. Peel plies are typically made of non-PFAS polymers, such as polyamides and polyesters; however, to prevent adhesion of the composite to the peel ply, PFAS modification (most commonly) or silicone modification is done to the fabric. Additionally, if high cure temperatures are required, PTFE and PVDF peel plies are typically used. Polymer release films are similar to peel plies but are generally used with composite resins that need to release gasses during cure. Many of these release films are polyethylene, polypropylene, or other polyolefins and work well for many applications; however, certain applications (typically higher temperature curing systems) require use of fluoropolymers, such as PTFE, PVDF, and others. Pre-preg release film is used to keep individual layers of pre-pregs (e.g., fabrics that are pre-impregnated with a fully curable, mixed resin system during manufacture) separated from each other within the rolls of materials that are prepared and transported for use in composites manufacturing facilities. Fluoropolymer release films are generally used to ensure the releasability of the release film during composite layup. Silicones are also useable for this application but are generally not used because of the low rigidity of silicone films.

IV.5 Additional Mission Critical PFAS Uses

Mission critical PFAS uses extend beyond the five industries discussed to this point. DoD identified a range of additional critical uses for which the potential risk of supply chain

disruption would undercut not only mission readiness but the U.S. economy. These uses are discussed in more detail in the following sub-sections.

IV.5.1 Refrigeration and Air Conditioning, Cooling, and Electronics Thermal Control

Most refrigerants used in civil and military cooling and refrigeration applications can be classified as PFAS. Many next-generation refrigerant alternatives adopted by U.S. industry (and U.S. households) between now and the end of 2025 are also PFAS. Under the AIM Act and EPA technology transition regulations, the U.S. economy is in the process of switching from one set of PFAS-classified refrigerants (e.g., HFCs) to a new generation of refrigerants (e.g., HFOs), which are also, in the broadest definitions, considered to be PFAS. Known non-PFAS alternatives (e.g., hydrocarbon or ammonia alternatives) pose flammability, toxicity, or high-pressure concerns. The same PFAS that are used in quantities of several hundred million pounds per year throughout the U.S. economy for cooling applications are used in much smaller quantities (i.e., a fraction of one percent) for military cooling and military thermal control of all kinds.

IV.5.2 Fire Suppression in Naval Vessels, Aircraft and Ground Combat Vehicles

Fluorochemical specialty gases are used in “clean agent” fire suppression in naval vessels, aircraft, and ground combat vehicles. Most known clean agent, low-corrosion, low-weight, low-toxicity alternatives will likely be classified as PFAS, broadly defined.

Since the advent of regulations against halogenated agents, Naval vessels commonly utilize an HFC clean agent in compartments subject to flammable/combustible liquid fuel fires such as engine modules and hazardous material storage spaces. For new U.S. Naval ship designs, the Navy continues to move to alternate fire suppression technologies (e.g., water mist) where suitable, however limited use of HFC remains for those spaces where the alternatives are not appropriate. For existing ship HFC uses, there is no “drop-in” replacement for these HFC agents.

Well over 10 million pounds of PFAS fire suppressants are installed in civil aircraft engine, cargo compartment, and lavatory fire suppression systems, and in hand-held aircraft fire extinguishers, worldwide. This includes halons (which meet PFAS definitions but are frequently excluded from draft PFAS regulations because they are separately covered by ozone depleting substance regulations) and all currently implemented aviation replacements for halons. In 2022, Working Paper 96 presented at the 41st Assembly of the International Civil Aviation Organization recommended considering PFAS use in aircraft fire suppression an essential use in prospective PFAS regulations to maintain progress in replacing halons.¹⁰

¹⁰ International Civil Aviation Organization (ICAO), Working Paper 96: Aircraft Halon Replacement, A41-WP/96, 28 July 2022. https://www.icao.int/Meetings/a41/Documents/WP/wp_096_en.pdf.

IV.5.3 Aqueous Film Forming Foam

Mission critical ocean-going vessels employed by DoD and the Military Services continue to use aqueous film forming foam (AFFF) containing PFAS for combating Class B (flammable/combustible liquid) fuel spill fires. U.S. Navy ships are required to use AFFF qualified to MIL-PRF-24385. MIL-PRF-24385 qualified AFFF provides the capability to rapidly control and extinguish shipboard fires. AFFF is critical for fire emergencies on flight decks where aircraft movement, fueling, launch/recovery, and weapons loading occur, and substantial risk exists for loss of aircraft, ship, and life if a fire is not rapidly controlled and extinguished.

Past flight deck fires, such as those that occurred on the United States Ship (USS) FORRESTAL, USS ENTERPRISE, and USS NIMITZ, all demonstrate the potential for such catastrophic events to occur. The risk of devastating loss of life and warfighting capability in incidents such as these, and the more recent fire emergency which resulted in the loss of the USS BONHOMME RICHARD, necessitates the use of the most effective firefighting agents available.

Beyond the potential for the immediate loss of life and impacts to operational capability that can result from an uncontrolled fire on a warship, the defense industrial base has limitations with respect to repairing or delivering replacement national security assets, including ordnance, aircraft, and ships. It could take a decade or longer to replace large amphibious assault ships and aircraft carriers.

Currently available fluorine-free foams (F3s) have significant limitations compared to AFFF that preclude their use on DoD ocean-going vessels, including the U.S. Navy fleet. Those limitations include reduced firefighting performance; chemical and physical properties that make them unsuitable for use with existing ship firefighting foam storage and delivery systems; and cross-agent compatibility issues. There are currently no equivalent, fully performing firefighting alternatives to AFFF for shipboard use.

DoD continues to sponsor research and development for F3 technologies to address these limitations, with the goal that continued technology improvements will support efforts toward a future path for use on ships. To date, DoD has invested approximately \$45.8M since 2017 toward the development and qualification of F3 technologies.

Until such time that a capable F3 alternative is found, the safety and survivability of naval ships and crew from shipboard fires depends on the continued availability of MilSpec AFFF products and their PFAS-containing constituents, which were formulated, tested, qualified, and implemented in order to save lives and military assets.

IV.5.4 Lines, Hoses, O-Rings, Seals and Gaskets, Tapes, and Cables and Connectors

Dozens of different fluoropolymers (e.g., PVDF, ECTFE, PTFE) and fluoroelastomers (e.g., FKM/FFKM) are critical to modern UV-resistant, ozone-resistant, weather-resistant,

temperature-resistant, high pressure-resistant, chemical-resistant “rubberized” fuel lines. They are also key materials in hoses, tubing, hydraulic system lines, O-rings, seals and gaskets, tapes, and cables and connectors widely used in civil and military aircraft, space systems, vehicles, weapon systems, utility systems, and other applications. Alternatives are not as resistant to embrittlement and break-down and have a much shorter useful life, leading to more frequent part replacement, which is not feasible for space or satellite uses.

IV.5.5 Electronic/Dielectric Fluids

Fluorochemicals are found in electronic and dielectric fluids that are used in civil and military radars and high-power electronics and electrical system/utility system components because of their dielectric and heat transfer properties. Industry and DoD have repeatedly investigated alternatives for these applications. Known alternatives have high global warming potential (e.g., sulfur hexafluoride) or may pose health/environmental risks (e.g., the polychlorinated biphenyls banned by the U.S. Toxic Substances Control Act and the Stockholm Convention on Persistent Organic Pollutants). Examples of PFAS-containing electronic/dielectric fluids used by DoD include 3M™ Fluorinert™ Electronic Liquids FC-40, FC-72, FC-770, and FC-3283.

IV.5.6 Advanced Oils, Greases, Fluids, and Lubricants

PFAS are used in many advanced turbine engine oils, greases, fluids, and lubricants due to their wear- and heat-resistant properties. These uses are common throughout the most demanding applications in the U.S. civil transportation, industrial, and space sectors. Analogous PFAS-containing oils, lubricants, and fluids are used in military critical ground, sea, air, and space applications. Previous generations of oils, fluids, and lubricants approached, but did not equal, the performance of PFAS additives that have become more prevalent in high performance oils, greases, fluids, and lubricants over the past 20 years.

Castrol Braycote 640AC is an example of a PFAS-containing grease, designed to be oxidizer and propellant compatible for use in aerospace vehicles, spacecraft, rocket and aircraft engines, and associated ground support equipment, oxygen equipment, and transport equipment. Braycote 640AC is typically used to lubricate threaded fasteners, connectors, valves, gaskets, elastomers, and bearings. Perfluorinated greases, in general, exhibit excellent shelf lives due to their intrinsic inertness.

Two additional examples of PFAS-containing greases used by DoD (and original equipment manufacturers and the maintenance, repair, and overhaul industry) are NYCO GREASE GN25013 and NYCO GREASE GN617. PTFE is used as a thickener in both products and perfluoropolyether is used as the base stock for GN617.

IV.5.7 Precision Cleaning Fluids

Fluorochemicals are used in precision cleaning applications, including the cleaning of sensitive oxygen systems in civil and military aerospace.

IV.5.8 Degreasing/Cleaning Fluids

The MilDeps reported the use of PFAS-containing degreasing/cleaning products and contact cleaners (e.g., 3M™ Novec™ Engineering Fluids, 3M™ Novec™ Contact Cleaners, 3M™ Novec™ Contact Cleaner/Lubricant) in vapor degreasing and flux removal.

The Army reported the use of FCC2 Enhanced Fiber Connector Cleaner and Preparation Fluid, which contains butane, 1,1,1,2,2,3,3,4,4-nonafluoro-4-methoxy, for cleaning fiber optic connectors in secure link manager assemblies and primary modem assemblies.

The MilDeps reported the use of fluorinated non-destructive testing (NDT) solvent cleaner/remover for precleaning before NDT and for removing excess surface penetrant from an inspection area before applying developer during liquid penetrant testing.

The MilDeps also reported that PFAS-containing degreasers are used to effectively remove grease, oil, tar, and other substances from military equipment to increase its operating efficiency. These degreasers leave no residue, have no flash or fire point, and serve as an alternative to legacy solvents (e.g., n-propyl bromide, trichloroethylene, tetrachloroethylene).

IV.5.9 Adhesives

The MilDeps reported the use of the following adhesives, which contain PFAS: 3M™ Super Foam Fast Spray Adhesive 74-Orange, 3M™ Hi-Strength Spray Adhesive 90 (aerosol), and 3M Scotch-Weld Epoxy Adhesive DP420 Off-White, Part A.

IV.5.10 Insulation and Foam Blowing

Fluorochemicals are components of insulation and foam blowing products used in civil and military aircraft and space vehicles/rocket motors.

IV.5.11 Resins for Specialty Materials

Fluoropolymers are used in resins for specialty high-temperature or weather-/UV-resistant composites due to their temperature-, pressure-, wear-, and chemical-resistance properties. Fluoropolymers are also used in high cleanable, high weathering and chemical resistant coatings for military assets. Many aircraft topcoats contain fluoropolymer resins due to their UV and chemical resistance properties. PFAS are not actually in the coatings themselves but are used in fluoropolymer resin manufacturing.

Moving to alternatives in under 10 years may require a return to previous methods of parts construction which produced shorter life and higher weight composites with lower performance characteristics.

IV.5.12 Specialty Filters and Membranes

Fluoropolymers are used in specialty filters and membranes (e.g., aviation filters) due to their temperature-, pressure-, and wear-resistance properties. PFAS are also found in several air filtering masks and air filtering respirators used by DoD.

IV.5.13 Fabrics, Fabric Liners, and Fabric Barriers

A variety of textiles used in uniform clothing and footwear items, tents, and duffle bags are treated with PFAS to repel water and oils while providing durability to laundering, UV light exposure, and temperature cycling. The main PFAS used on textiles are fluoropolymers, such as PTFE and short chain PFAS, known as C6 or C4 chemistries. PFAS can be incorporated as an additive mixed into individual fibers or sprayed as a coating onto finished fabrics during manufacturing or after sale and are present in/on textiles in two forms: a non-polymerized compound that can be washed out or evaporated or as a molecule integrated into a fluorine free polymer network via covalent bonds. The MilDeps reported the use of PFAS in chemical, biological, radiological, and nuclear protective equipment (the Uniform Integrated Protection Ensemble Family of Systems) and in a number of uses within health care communities.

Coretech, the biological protective fabric lining used on the Joint Biological Agent Decontamination System, includes a barrier layer for biological protection during the decontamination of aircraft. The barrier layer contains PFAS.

IV.5.14 Customized Applications

Customized applications like gyroscope suspension fluids and analytic gases and fluids for thermometric and other sensors use specialty fluorochemicals because of their pressure-resistant, wear-resistant, and temperature control properties. These applications require very small quantities of specialty PFAS and are particularly susceptible to disruptions in PFAS supply chains due to challenges in attracting manufacturers to develop low-volume commodities.

V. Conclusions

This report summarizes known direct and indirect uses of PFAS that are critical to the national security of the United States, but it is not comprehensive. Also highlighted are the challenges and costs related to finding and qualifying alternatives to existing PFAS materials in sectors of strategic importance to DoD. The information contained in this report is limited to what was available at the time of its drafting. As such, the information presented represents a fraction of the mission critical PFAS uses due to a lack of transparency in the chemical composition in consumables and articles. In addition, there is significant uncertainty regarding the presence of PFAS in products that make up a complex value chain. A more complete understanding of PFAS essential uses would require an extensive and complex evaluation of the market, a gap analysis of current requirements for manufacturer-provided product information, and illumination of the value chain of products.

PFAS are critical to DoD mission success and readiness and to many national sectors of critical infrastructure, including information technology, critical manufacturing, health care, renewable energy, and transportation. DoD relies on an innovative, diverse U.S. industrial economy. Most of the structurally defined PFAS are *critical to the national security of the United States*, not because they are used exclusively in military applications (although a few are) but because of the civil-military commonality and the potentially broad civilian impact. This report provides details on what is currently known about direct and indirect mission critical PFAS uses that could impact mission readiness if the substances are no longer available.

Emerging environmental regulations focused on PFAS are broad, unpredictable, lack the specificity of individual PFAS risk relative to their use, and in certain cases will have unintended impacts on market dynamics and the supply chain, resulting in the loss of access to mission critical uses of PFAS. These market responses will impact many sectors of U.S. critical infrastructure, including but not limited to the defense industrial base. Collectively, international and U.S. regulatory actions to manage PFAS' environmental impacts and identify and eliminate PFAS from the market, and the resulting market changes, pose risks to DoD operations and the defense industrial base supply chain. In addition, impacts to the global PFAS supply chain will present risks to the DoD Foreign Military Sales program and to North Atlantic Treaty Organization interoperability.

The Department will continue to oversee coordinated lines of effort to expeditiously identify essential uses of PFAS, prioritize actions according to vulnerabilities to national security, and address mission readiness associated with the potential loss of access to PFAS. Actions include:

- Implementing DoD PFAS policy directing the DoD Components and MilDeps to determine the PFAS content in DoD weapon systems, to the extent feasible, and enabling continued access to mission critical uses, while encouraging safe use by DoD personnel and adoption of PFAS-free alternatives.
- Engaging with industry to identify PFAS content in other materials commonly used within the DoD to assess potential obsolescence risks and potential PFAS alternatives.
- Engaging with industry and federal agencies during routine meetings to assess obsolescence risks, mission criticality, and potential PFAS alternatives.
- Investing in research, development, and qualification efforts required to demonstrate conformance with Military Standards or Specifications.
- Collaborating across the Federal Government to develop a long-term research plan for the most challenging applications where it will take a decade or more to find viable replacements.
- Investing in research to support advanced manufacturing approaches by improving purification, deconstruction technologies, scale-up of sustainable materials design and manufacturing, and circularity for the most critical and irreplaceable PFAS.

Concurrent with efforts to identify essential uses of PFAS, the Department is phasing out non-essential and non-critical PFAS uses in accordance with NDAA requirements where there is no mission impact (e.g., in food packaging, cookware, furniture, personal protective firefighting equipment). Additionally, per the 2023 U.S. Government Accountability Office (GAO) recommendations,¹¹ the Department is developing an approach to implement the April 2023 prohibition for military exchange resale procurements. The Department is also updating DoD Instruction 4105.72, *Procurement of Sustainable Goods and Services*, to include procedures specifically targeted to implementing the provisions of Executive Order 14057, *Catalyzing Clean Energy Industries and Jobs Through Federal Sustainability*, with respect to limiting the procurement of items containing PFAS.

Eliminating PFAS from non-essential uses is an important step toward addressing public concerns and protecting human health and the environment. Mission critical PFAS uses provide significant benefits to the framework of U.S. critical infrastructure, and national and economic security. DoD will consider future policy actions to manage non-essential and essential PFAS uses and will implement these actions with the intent of protecting human health and the environment while ensuring no adverse impacts to U.S. critical infrastructure and national security.

If future PFAS legal and regulatory frameworks ignore the OECD caution on the use of its PFAS definition and seek to broadly restrict the use of PFAS based on chemical structure, there could be extensive economic, industrial competitiveness, and quality-of-life impacts to U.S. society. The PFAS universe is structurally and physiochemically diverse and subgroups of PFAS may be more or less stable, persistent, and/or bioaccumulative compared to well-studied PFAS such as perfluorooctane sulfonate and perfluorooctanoic acid.¹² Congress and the Federal regulatory agencies should avoid taking a broad, purely “structural” approach to restricting or banning PFAS. It is critical that future laws and regulations consider and balance the range of environmental and health risks associated with different individual PFAS, their essentiality to the U.S. economy and society, and the availability of viable alternatives.

¹¹ U.S. Government Accountability Office (GAO). Persistent Chemicals: Actions Needed to Improve DoD’s Ability to Prevent the Procurement of Items Containing PFAS. GAO-23-105982. April 2023.

¹² EPA Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS) (Public Review Draft), EPA-822-P-23-003 (March 2023).

Appendix: Summary of Known Mission Critical PFAS Uses

PFAS	Application	Functionality	Availability of Alternatives	Time Frame / Cost to Develop and Qualify Alternatives*
Kinetic Capabilities				
Fluoropolymers (e.g., Teflon™)	Ingredients in binders and resins used in PBX, pyrotechnics, and propellant components that are used in a variety of applications across the DoD munitions portfolio.	High temperature resistance	NA*	NA
Fluoroelastomers (e.g., Viton™)				
PFAS	Used in energetic slurry processing.	Enables high levels of mixing between key energetic components.	NA	NA
Fluorinated performance fluids (e.g., 3M™ Fluorinert™ fluids)	Enable energetics laboratory research. Are critical for developing and transitioning new energetic materials.	NA	NA	NA
Energy Storage and Batteries				
Fluoropolymers (e.g., polytetrafluoroethylene (PTFE))	Multiple subcomponents in modern Li-ion batteries: electrolyte solutions, cathode binders, separator coatings, casing materials, and gaskets.	Serve as heat transfer material or insulation. Provide weather-resistance, UV light-resistance, and deterioration-resistance properties.	NA	Fully eliminating PFAS from energy storage in the U.S. economy would likely take 10+ years.
Polyfluoroalkyl acids (PolyFAAs)				
PFAS	Battery manufacturing: filters and other components essential to production.	NA	Possibly available	Time and cost to identify and qualify alternatives would be significant and have ripple effects throughout the economy.
Microelectronics and Semiconductors				
Fluoropolymers	Semiconductor fabrication: etching materials and masks in photolithography processes; cleaning gases.			
Fluoroelastomers		Dielectric, heat transfer, and insulation functionalities.	Currently no alternatives to PFAS for photolithography.	NA
PolyFAAs				
Other PFAS				

Report on Critical Per- and Polyfluoroalkyl Substance Uses

A-1

Appendix: Summary of Known Mission Critical PFAS Uses

PFAS	Application	Functionality	Availability of Alternatives	Time Frame / Cost to Develop and Qualify Alternatives*
Fluoropolymers	Semiconductor manufacturing equipment and factory infrastructure: equipment components (e.g., tubing, gaskets, containers, filters) and lubrication (various oils and greases).	Heat and chemical resistance, and chemical inertness.	Currently no alternatives for some applications in semiconductor manufacturing equipment. Replacing most PFAS uses in semiconductor fabrication would require industry-wide re-tooling and other process innovations. Some might be achievable within 10 years, but many would not.	Development of alternatives for some uses may require the invention of novel chemistries and processes. Due to the extremely complex qualification process, it would take another 15 years to deploy alternatives, once developed, in high-volume manufacturing. Replacing PFAS in semiconductor fabrication could be a 25-year effort and may not succeed in all respects if alternatives cannot be identified or qualified at the microchip level. Replacing PFAS has the potential to initiate costly requalification of specific components. Example: microelectronics applications typically mandate requalification if a manufacturer substantively alters the fabrication process, which can easily exceed \$10 million.

Appendix: Summary of Known Mission Critical PFAS Uses

PFAS	Application	Functionality	Availability of Alternatives	Time Frame / Cost to Develop and Qualify Alternatives*
PTFE	Microelectronics applications: base laminate materials used in many RF and microwave circuits.	Provide unique properties related to isolating RF and microwave signals. Used in radar, antenna, guidance systems, 5&G infrastructure, and other network/transmission applications.	There is no drop in alternative material. Any material replacement for fielded systems would require redesign of the printed board and potentially the electronic system to account for material property differences. Fielded systems that have been redesigned may require requalification.	Developing and or identifying suitable alternative materials and qualifying them could be a forward-looking action for all future DoD systems. This however does not address sustainment of existing systems. There will continue to be a need to have PTFE laminate materials available for system sustainment until all systems currently designed with PTFE are retired.
PFAS	Manufacture of printed circuit boards (PCBs); vapor phase solder and flux remover products.	Vapor phase soldering process is used for PCB assemblies with high thermal mass, fine-pitch structures, and temperature-sensitive components to minimize risk to materials, structures and components. The material stability and flame retardant qualities are well suited for the enclosed high temperature operation of the process.	It is unknown if there are suitable materials that can be used, however it is likely that current equipment may need to be replaced or modified to accommodate the replacement materials.	Developing and evaluating new materials could take 5 years or more. Equipment replacement would add time and have a cost impact.
PTFE	PCBs; cable jackets used in PCB connectors.	Used because it has excellent fire, smoke, and chemical resistance. Wide temperature range -200 to 260C constant use and up to 450C for peak exposure.	It is unknown if there are suitable replacement materials for all of the applications for PTFE wire jacket material. PTFE is higher cost than some other wire jacket materials. When it is selected for use there are typically no other suitable replacement materials.	Qualification of alternatives will be both costly and time consuming. Many materials will require new UL or other certification body approval before they can be implemented. Many current products are MilSpec certified.

Appendix: Summary of Known Mission Critical PFAS Uses

PFAS	Application	Functionality	Availability of Alternatives	Time Frame / Cost to Develop and Qualify Alternatives*
Castings and Forgings and Strategic and Critical Minerals				
Specialty fluorochemical gases and fluids	Advanced metalworking, casting, and fabrication processes used in the production of advanced metal parts throughout U.S. industry, including military-specific parts.	Temperature and wear resistance.	NA	Moving to alternatives in under 10 years may require returning to previous construction methods and may make construction using certain alloys impossible.
PTFE, PVDF, other PFAS	Mold release chemicals and release films typically used in composite manufacturing processes.	Prevent composites from strongly adhering to mold hardware.	NA	NA
Refrigeration and Air Conditioning, Cooling, Electronics Thermal Control				
HFOs	Next-generation refrigerant alternatives (to HFCs) used in civil and military cooling and thermal control applications.	NA	Known non-PFAS alternatives (e.g., hydrocarbon or ammonia alternatives) pose flammability, toxicity, or high-pressure concerns.	NA
Fire Suppression in Aircraft and Ground Combat Vehicles				
Fluorochemical specialty gases	"Clean agent" fire suppression in aircraft and ground combat vehicles.	NA	Most known clean agent, low-corrosion, low-weight, low-toxicity alternatives will likely be classified as PFAS, broadly defined.	NA
Aqueous Film Forming Foam (AFFF)				
PFAS	AFFF use to combat Class B (flammable/combustible liquid) fuel spill fires on mission critical ocean-going vessels employed by DoD and the Military Services.	MIL-PRF-24385 qualified AFFF provides the capability to rapidly control and extinguish shipboard fires.	Current F3s have significant limitations compared to AFFF that preclude their use on DoD ocean-going vessels, including the U.S. Navy fleet.	NA

Appendix: Summary of Known Mission Critical PFAS Uses

PFAS	Application	Functionality	Availability of Alternatives	Time Frame / Cost to Develop and Qualify Alternatives*
Lines, Hoses, O-Rings, Seals and Gaskets, Tapes, and Cables and Connectors				
Fluoropolymers (e.g., PVDF, ECTFE, PTFE)	Critical to modern "rubberized" fuel lines. Key materials in hoses, tubing, hydraulic system lines, O-rings, seals and gaskets, tapes, and cables and connectors widely used in civil and military aircraft, space systems, vehicles, weapon systems, utility systems, and other applications.	Functionalities include UV-resistance, ozone-resistance, weather-resistance, high temperature-resistance, high pressure-resistance, and chemical resistance.	Alternatives are not as resistant to embrittlement and break-down and have a much shorter useful life, leading to more frequent part replacement, which is not feasible for space or satellite uses.	NA
Fluorelastomers (e.g., FKM/FFKM)				
Electronic/Dielectric Fluids				
Fluorochemicals	Used in electronic and dielectric fluids used in civil and military radars, high-power electronics, and electrical system/utility system components.	Provide dielectric and heat transfer properties.	Industry and DoD have repeatedly investigated alternatives in these applications. Known alternatives have high global warming potential (e.g., sulfur hexafluoride) or may pose health/environmental risks (e.g., the polychlorinated biphenyls).	NA
Advanced Oils, Greases, Fluids, and Lubricants				
PFAS	Used in many advanced turbine engine oils, greases, fluids, and lubricants common throughout the U.S. civil transportation, industrial, and space sectors. Analogous oils, lubricants, and fluids are used in military critical ground, sea, air, and space applications.	Wear- and heat-resistant properties. Perfluorinated greases exhibit excellent shelf lives due to their intrinsic inertness.	Previous generations of oils, fluids, and lubricants approached, but did not equal, the performance of PFAS additives that have become more prevalent in high performance oils, greases, fluids, and lubricants over the past 20 years.	NA

Appendix: Summary of Known Mission Critical PFAS Uses

PFAS	Application	Functionality	Availability of Alternatives	Time Frame / Cost to Develop and Qualify Alternatives*
Precision Cleaning Fluids				
Fluorochemicals	Precision cleaning applications such as cleaning of sensitive oxygen systems in civil and military aerospace.	NA	NA	NA
Degreasing / Cleaning Fluids				
PFAS	Degreasing/ cleaning products and contact cleaners used in vapor degreasing and flux removal.	NA	NA	NA
	Non-destructive testing solvent cleaner/remover used for precleaning and for removing excess surface penetrant before applying developer during liquid penetrant testing.	NA	NA	NA
	Degreasers used to effectively remove grease, oil, tar, and other substances from military equipment to increase its operating efficiency.	Leaves no residue, has no flash or fire point, and serves as an alternative to chlorinated solvent-based cleaners (e.g., 1,1,1-trichloroethane).	NA	NA
	Connector cleaner and preparation fluid used for cleaning fiber optic connectors in secure link manager assemblies and primary modem assemblies.	NA	NA	NA
Insulation and Foam Blowing				
Fluorochemicals	Components of insulation and foam blowing products used in civil and military aircraft and space vehicles/rocket motors.	NA	NA	NA

Report on Critical Per- and Polyfluoroalkyl Substance Uses

A-6

Appendix: Summary of Known Mission Critical PFAS Uses

PFAS	Application	Functionality	Availability of Alternatives	Time Frame / Cost to Develop and Qualify Alternatives*
Resins for Specialty Composites				
Fluoropolymers	Resins for specialty high-temperature or weather-/UV-resistant composites.	Temperature-, pressure-, wear-, and chemical-resistance properties.	NA	Moving to alternatives in under 10 years may require a return to previous methods of parts construction and an acceptance of lower performance, shorter life, and higher weight composites.
Specialty Filters and Membranes				
Fluoropolymers	Used in specialty filters and membranes (e.g., aviation filters); and in air filtering masks and air filtering respirators used by DoD.	Temperature-, pressure-, and wear-resistance properties.	NA	NA
PFAS				
Fabrics, Fabric Liners, Fabric Barriers				
PFAS	- Fabrics used in a variety of uniform clothing and footwear items, tents, and duffle bags. - Reported use in chemical, biological, radiological, and nuclear protective equipment. - Used in the biological protective fabric lining used in the Joint Biological Agent Decontamination System.	Water and oil repellency.	NA	NA
Customized Applications				
Specialty fluorochemicals	Used in customized applications like gyroscope suspension fluids and analytic gases and fluids for thermometric and other sensors.	Pressure-resistant, wear-resistant, and temperature control properties.	NA	NA

* NA = no information provided through data collection efforts.

Report on Critical Per- and Polyfluoroalkyl Substance Uses

A-7

Senator LUMMIS. Thank you.

Now, I want to quote from the Department of Defense report. It says, "Losing access to PFAS due to overly broad regulations or severe market contractions would greatly impact national security and DOD's ability to fulfill its mission and impact domestic industrial manufacturing and supply."

The report raises concerns about regulatory risks to our Nation's national security and industrial base and overall economy on page 15. After all, as the report reminds us, the DOD is reliant on the commercial industry for its applications.

As the report cautions, there is no consensus on PFAS definitions. A simple grouping together of over 38,000 specific individual chemicals does not inform whether a compound is harmful or not.

First question. Are you aware of the 2023 DOD report regarding PFAS?

Ms. FREEDHOFF. Yes, Senator, I am aware of it.

Senator LUMMIS. OK. Does the EPA intend to establish an expedited review process for PFAS with less concerning hazardous profiles, or for those used in limited volumes but critical to technological innovation?

Ms. FREEDHOFF. Yes, actually my office has already developed a framework just like that. What it basically says is if the PFAS is going to be used in a sophisticated industrial environment, like the semiconductor industry has, workers are protected, environmental releases are controlled, there will be a path through the New Chemicals program for PFAS like that. We agree that while PFAS have unquestionably contaminated a large number of places in the United States, we also think that if the new chemicals provisions of the 2016 law had been in place all along and EPA had been charged with making sure that the new chemicals were being used responsibly, we would have a lot less PFAS pollution in the Country than we do now.

Senator LUMMIS. Have you met with DOD to try to go through with them which of those PFAS chemistries they believe are pivotal to national security, as they mentioned in the report, and those that are not?

Ms. FREEDHOFF. I met with DOD myself a number of times, not just on PFAS but on other chemicals that are going through the TSCA process. We are very committed to continuing to work with them to make sure that our work in the Chemicals Office does not undermine military readiness or remove their access to things they need to keep us safe.

Senator LUMMIS. Can you help us by returning to this committee a list of these 38,000 chemicals that DOD feels that they need to have access to without undue restriction, and those that you feel are appropriate for higher scrutiny?

Ms. FREEDHOFF. I am not sure how I would go about that list without knowing exactly what DOD needs. I can also say that there are more than two options under TSCA. It is not use it without restriction or ban it. There is also, use it responsibly. I think that is what we are striving for when it comes to critical uses of chemistries, not just PFAS, but some of the others that we are looking at as well.

Senator LUMMIS. OK. What might that look like?

Ms. FREEDHOFF. It could just be, do not dispose of it in sources of drinking water. It could be, make sure that when your workers are handling it, they are protected, either with PPE, Personal Protective Equipment, or with engineering controls that prevent exposures to them during key tasks. It is a whole range of things. I do not think the choice is ban them all or continue as we have for the past decades in ways that clearly harmed human health and the environment.

Senator LUMMIS. As you know, we are sometimes demanding that we onshore products that we have offshored. Then we want to restrict them from onshore manufacturing to the point that we can not onshore them.

We are sort of giving with one hand and taking with the other. I think this is an area, chemistry, where there needs to be some very careful consideration, working with industry, working with Department of Defense to make sure that we are finding the sweet spot.

I thank you for your testimony. Mr. Chairman, I yield back.

Senator CARPER. Thank you for those questions.

Next, we are going to recognize Senator Merkley again, if we are not joined by anyone else. Senator Capito will be after Senator Merkley.

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

As long as we are on PFAS, EPA finalized a rule in September of last year that requires reporting for manufacturers to share data about the chemical identity, the uses, the volumes made and processes, so on and so forth.

Dr. Freedhoff, when will that data collected by EPA be available to the public?

Ms. FREEDHOFF. I know that it is due for different reporters at different times. I think we are expecting to get it next fall, to start getting it next fall. I know we will be working to make as much of it public as we can.

Senator MERKLEY. Does that mean it is not clear that the public will have access to that data?

Ms. FREEDHOFF. The law requires us to protect confidential business information, so if we get something into the agency that is marked that way, we will have to take some time to review it and make sure that we can get it into a form that the public can see.

The entire point of that data collection effort, which was something that this committee actually wrote the law directing us to do, was to make sure that data was available and useful to everyone who might want to see it, including members of the public.

Senator MERKLEY. Yes, I hope that that information, which will help inform the PFAS debate extensively, is available to help inform the debate. Thank you, and the understanding of the challenge.

I want to turn to plastics-to-fuel. Pyrolysis is being advocated by many to be able to essentially use heat to return plastics down to a State where it is essentially once again fuel. The EPA has studied, well, what happens if you have that in a marine setting, what happens if you have that in an airport, a jet setting?

EPA's model produced a lot of concern, a lot of articles written about the high level of toxicity really was exceeding the standards

that we normally have, producing cancer in one in 10,000 as opposed to the standard of one in 1 million, the one in four cancer risk from a lifetime of exposure.

Then I think EPA has said, oh, well, that is scary. Let's just set this whole model aside, and then approve the chemicals. How does setting a whole model aside and just approving the chemicals serve the scientific process and the whole goal of TSCA to evaluate chemicals with deliberate scientific analysis?

Ms. FREEDHOFF. You said a lot in that question, Senator. First of all, the original chemicals that took the plastics and turned them into fuels were approved in 2015 and 2019. What we looked at was taking what companies wanted to do, which was take small amounts of those chemicals, mix them with traditionally drilled fuels, put them in a refinery, and come out with something that looked for all intents and purposes exactly like normal jet fuel or normal marine fuel.

I think our staff was quite convinced that the safety profile of the resultant fuels was going to look exactly the same as what you would get if you just drilled for oil and put the oil through a refinery. That said, I do think that when our exposure model spit out numbers like that, we should have done a better job at reality checking ourselves.

When we did that after the fact, we learned that it was sort of clear that those exposure models are exceedingly conservative. They basically assume that 100 percent of the fuel burns in one location and the same person stands there and breathes 100 percent of the exhaust fumes from the plane in at one time.

That is clearly not a real world scenario, not a real world risk. It was on us to explain it better, and we are learning a lot from that experience.

Senator MERKLEY. Or to go back and say, we think our assessment model was flawed, and now we are going to get a more realistic assessment model and actually use an assessment model rather than just throwing it aside and ignoring it.

Ms. FREEDHOFF. I think what we learned, normally when we make these, when we do not have actual exposure information, which is often the case for a new chemical, we just assume that the worst case scenario is some set percentage of it gets into the environment, or some set percentage of it exposes workers. That model fundamentally fails when the end product is a fuel that is supposed to be burned.

I agree with you; we should not be doing it that way for transportation fuel.

Senator MERKLEY. I do think the reason it is raising concerns is that the plastics themselves have huge numbers of contaminant chemicals. The pyrolysis process vents off a lot of stuff, and often, we have made an emphasis on environmental justice in this community, in communities that are poor, in communities that are primarily Black and Brown communities.

Then those same contaminants survive and are in the fuel when it is burned. Therefore, our evolving understanding of this potential pathway, which could involve fuels that are not just a slight amount added to some other fuel, but burned in the whole as folks

try to get a more circular economy. These are significant concerns that should not be ignored in this process.

Ms. FREEDHOFF. I agree with you. I think we know a lot more about those potential impurities now than we did in 2015 and 2019 when those original chemicals were approved. I think our policy going forward, including for these particular fuels, is to make sure that there are not impurities like that, if companies are going to move forward with a process that creates those fuels.

Senator MERKLEY. Thank you.

Senator CARPER. All right, thanks, Senator Merkley.

Senator Capito?

Senator CAPITO. Thank you, Mr. Chairman.

I am going to kind of go back on a few things that have been alluded to in some of the questions. It seems there has been a question of EPA's interpretation of what is reasonably foreseen. Is it reasonable to foresee that somebody would drink bleach? Of course not. None of us are going to drink bleach. Well, I wouldn't say none of us.

These speculative, unintended uses of chemicals are being used to justify overly stringent restrictions. Do you believe that every potential use of a chemical, including the intentional misuses, are reasonably foreseeable or a reason to restrict?

Ms. FREEDHOFF. No, I do not.

Senator CAPITO. Well, good. I believe what we are hearing too is that sometimes your office will continue to assume non-compliance on OSHA standards. Senator Ricketts kind of alluded to the OSHA issue. I, in my opening statement, talked about a mission creep here.

What is your relationship in terms of, how do you put the bright line between where you are and where OSHA is? It sounds like you have more than enough on your plate. I am not sure you want to go into what OSHA is doing as well.

Ms. FREEDHOFF. TSCA says that we have to consider the risks to potentially exposed and susceptible subpopulations. That term is explicitly defined to include workers.

Senator CAPITO. It includes what?

Ms. FREEDHOFF. It includes workers. Explicitly by law it includes workers. OSHA wrote most of its chemical-specific rules in the 1970's. When you go on their website, the very first sentence that you read is that their standards are outdated and inadequate for the protection of worker health. That is what OSHA says about its own chemical safety worker rules.

The other thing is that OSHA rules do not cover everybody. They do not cover self-employed workers and they do not cover public sector workers that are not subject to a State OSHA plan. Even if the OSHA rules weren't outdated and inadequate for the protection of worker health, we would still need to recognize that some of the workers that the TSCA risk evaluation uses cover wouldn't be subject to them in the first place.

What I do think we are trying to do is work extremely closely with both OSHA and NIOSH, National Institute for Occupational Safety and Health. We are trying to align what we write in our final rules to be as consistent as possible with what their practices and approaches are for things like monitoring and detection. I also

think we are working really closely with industry, because in many cases, industry has gone way beyond those 1970 standards when it comes to protecting their workers, because those standards are outdated, and those sophisticated companies know it.

We are also trying to align with the best industry practices that we are made aware of as well, as we make sure that our final rules are implementable.

Senator CAPITO. Well, I mean, I guess my interpretation of that would be, there is laxness in, or inadequacy in a particular different part of the Department of Labor, is obviously where OSHA is. I just think with what we have kind of uncovered and agree where some of the issues are, staying in the lane would probably be helpful.

Let me ask you another thing to clarify. I said this in my opening statement, and I want to make sure we are in agreement here, where I said that companies are opting to go offshore to create chemicals and that your applications for new chemicals are down, therefore your user fees, we are getting to the resource thing, the user fees, the amount of people paying use fees is going down.

Is that an accurate statement from your viewpoint?

Ms. FREEDHOFF. I do not think so. I think it was accurate for a couple of years after the enactment of the 2016 law. We have actually seen new chemical submittals kind of come back up to what they have been historically in the last couple of years.

Senator CAPITO. Well, we need to follow that, because I think that is an important issue in terms of being able to move forward.

Another suggestion, question, is, there is an ability, because you are talking about being resource constrained, there is an ability for you under the Intergovernmental Personnel Act to be able to access other Federal employees at no cost to your agency for specialized things. We see this in endangered species, Fish and Wildlife, we see them borrow from other agencies when they have a large request. I have seen that in my own home State.

Is this something that you have considered to fill in the gaps that you say you have?

Ms. FREEDHOFF. Actually, we have already done that. Under the Fiscal Year 2022 budget, which gave us a really small increase in resources, and wasn't enacted until March 2022. That was sort of more than a year of this Administration with a flat budget. We actually did borrow some staff from other parts of the agency, specifically for New Chemicals, because of the dire situation that New Chemicals was in.

I think it is one of those things, though, that most Federal agencies, including EPA, have resource issues and have workload issues. Other parts of the agency also have laws that they have to implement.

There is not an infinite capacity for us to be able to do that. We have done it in a temporary basis with New Chemicals.

Senator CAPITO. OK, so I think we have a lot of agreement. We will keep working on the list that we put forward.

I do not want the hearing to end, to have any kind of misunderstanding that questions or accountability issues means that any of us, certainly me in particular, would want to sacrifice any kind of safety issues around a chemical use for speed. We do have certain

deadlines in the law. You were probably around when TSCA was written, and those were established to be reasonable deadlines at the time. There is a reasonable expectation that those can be met.

I think, while I expressed to you last week the frustration I have as a member, I think probably all of us, does not matter what side of the aisle you are, it may matter what administration it is, it is always, I just need more money, if I had more money, I would solve every single problem. Sometimes, we have to be more efficient, we have to be more innovative, we have to be more, use the authorities, like Title 42 that we have to be able to move forward for more specialized investigations, listen more to the stakeholders.

All these kinds of things I think we can make improvement on, understanding that the resource issues—but you have gotten more resources, and certainly EPA, 2,000 more people. I mean, could the Administrator reprioritize? This is an important area.

Another thing, then I will get off my high horse here, is if we look at chemicals, I think the assumption is sometimes, well, you just want more chemicals that are going to be more hazardous and more flammable, and everybody thinks it is always the bad part of chemistry.

The good part of chemistry is getting held up, too. The chemistries that would take our old chemistries off the shelf and make improvements, have better health outcomes, maybe even be more efficient, maybe even be more economical to use and certainly can be made here, they are getting held up at the same time.

We will just continue to monitor this. I appreciate your frankness, and thank you for coming.

Senator CARPER. Senator Markey, if you are ready to go again for another round, I will recognize you. Otherwise we will go to Senator Whitehouse.

Senator MARKEY. I would love to hear his questions.

Senator CARPER. Senator Whitehouse?

Senator WHITEHOUSE. Thank you, Senator Markey. Thank you very much for being back here again on one of our favorite topics and one where I think we did some very good bipartisan work. I think of Senator Inhofe, who was not always somebody that I agreed with, and our good work together on this issue.

I would like to ask you about the process involved. As you recall, as you know, we set up a process for the industry to make application to go through the TSCA process. What I hear we have seen is a lot of industry revisions of the application.

Could you tell me first of all, is that true? How often is that happening? Are there multiple revisions sometimes, not just one but a cascade of cumulative revisions? What effect have those revisions had on the ability of EPA to meet the schedule and proceed to the conclusion of the process?

Ms. FREEDHOFF. Thanks very much for that question, Senator. You are right, sometimes companies do come in toward the end and give us new information that we wish they would have given us at the very beginning. That causes us to have to rework, redo parts of the risk assessment, and that does not just delay their chemical, it delays everybody else who is waiting behind them in line.

I think some of that is a reflection of the still pre-1990 law, companies do not necessarily know what we need to know to review their

chemicals quickly. One of the things that we have really tried to do is outreach to industry, do webinars, do trainings, really kind of tell them from the beginning, this is what we really need to review your chemical as quickly as possible.

Some of those efforts are working. I think we could do more, and I think industry could do more to get a complete application in front of the agency in the first place. I think it would have benefit to everybody.

Senator WHITEHOUSE. Is the source of these revisions just confusion? Or do you think there is also some motivation to delay?

Ms. FREEDHOFF. I do not think there is motivation to delay on the New Chemical side. I think what happens is they didn't write down in their application that they were going to dispose of the chemicals properly, and then when we do our risk assessment, we assume they are going to release it to water. Then they see that, and they say, oh, we weren't going to do that, and we say, well, you should have told us that from the start. It is a lot of those kinds of changes. I do not think they are intentional. I think they are a little bit a lack of experience, a little bit of a failure to realize that the more they give us, the better it is for them.

Senator WHITEHOUSE. Okay. You think the kinks in the process have now been worked through pretty well?

Ms. FREEDHOFF. I think it is a work in progress. I think we have made a lot of improvements, but it is important to note that before the 2016 law, we only did formal safety reviews on about 20 percent of new chemicals. Now we have to do them on 100 percent, and for the first 6 years of the law, we got zero extra dollars.

The agency was sort of hamstrung for a good, long time. Now that we have gotten a modest increase in our budget, we are working to build in some of those efficiencies without losing the protectiveness of what we are supposed to be doing.

Senator WHITEHOUSE. How many employees does EPA have? Thirteen thousand?

Ms. FREEDHOFF. Ish, yes. In the New Chemicals Division, we were able to hire 14 new people with the Fiscal Year 2023 budget increase, with a handful more that are still in the works. We are not at 15,000 people in the New Chemicals Division.

Senator WHITEHOUSE. I get that. When I worked in the Department of Justice, and there was an urgent matter, they would detail people from the field to headquarters to work on it, just as they have done with the January 6th prosecutions. I hope that EPA is at least considering borrowing from the regional offices and putting people in detail for significant projects like this, where the immediate staff are not sufficient to meet the new need.

Ms. FREEDHOFF. We have done some detailing, and will continue to do that. I do think some of the expertise we need is pretty specialized. There just are not that many toxicologists around who know how to study exposures.

Another thing we have done is we have dedicated a person in the Toxics Office to really revamp our recruitment process, and really go places to advertise the jobs that we have that we have not previously gone. Now we are getting a lot of qualified applicants for those jobs, which is great. It hasn't always been the case.

Senator WHITEHOUSE. Well, thank you. It is great to see progress in this area.

Thank you very much, Chairman.

Senator CARPER. Thank you, Senator Whitehouse.

Senator FETTERMAN, welcome. You are recognized. Good to see you.

Senator FETTERMAN. First, I just have to acknowledge your recent happy birthday, Mr. Chairman. Sixty-three, was it?

[Laughter.]

Senator CARPER. God bless you.

[Laughter.]

Senator FETTERMAN. Thank you.

I live across the street from a steel mill, actually the largest steel mill in my State, one of the remaining ones left. I have some really personal experience of myself and my family of the impact of the industrial sector and what that can have on the surrounding community.

I do not believe that we have to choose between keeping good union jobs and also be averse to a clean, safe environment. Do you agree, how you are seeing the dynamic play out, how you lead the EPA's work regulating toxic substances?

Ms. FREEDHOFF. Yes, Senator, I do. As we talked about last week, I really do not believe you have to choose between good paying jobs and having clean air to breathe and clean water to drink.

One thing that we have been doing is working really hard with the sectors that are trying to bring good jobs into this Country to make sure that we are approving their chemicals more quickly, or as quickly as we can. For example, we have prioritized the chemicals that are needed by the semiconductor sector, by the battery sector, by the biotechnology sector, and put those to the front of the line whenever we can. Now we approve those in about a third of the time as compared to other sectors.

We do think that you can use chemicals responsibly, keep your workers safe, keep communities safe and do well as a company.

Senator FETTERMAN. The EPA, are you familiar with the history, who established the EPA?

Ms. FREEDHOFF. President Nixon.

Senator FETTERMAN. Nixon, well, he was a Republican, right?

Ms. FREEDHOFF. He was.

Senator FETTERMAN. That is right, he was, oh my gosh. Actually the fact that the EPA was funded by a Republican, and now it is really a shame that sometimes that has drifted away from us, and that gets weaponized here, where two things can be true at the same time, that we need to maintain and protect good union jobs that sustain the community and families, but also, we know a clean environment is pretty useful. I think it is useful all the time. I think both can happen together. I would like to remind everybody that a lot of important environmental things were done under leadership of a Republican administration.

Now moving on, of course we are all familiar with the Norfolk Southern train derailment in Ohio. That is very close to my State's border. It released more than 100,000 gallons of vinyl chloride into our community, as I am sure you know. Last month, the EPA announced that the vinyl chloride would be prioritized for considering

under the Toxic Substances Control Act. We are still looking at years of that evaluation to be finished, and a safety protocol to be recommended. Why does this process take so long?

Ms. FREEDHOFF. Thanks very much for that question, Senator. Ironically, it was the Nixon Administration also that led Congress to write the Toxic Substances Control Act. They actually used vinyl chloride as one of three examples for why that law was needed back in 1971. They basically said, when they asked Congress, this is what they said: "We should no longer be limited to repairing the damage after it has been done, nor should we continue to allow the entire population or the entire environment to be used as a laboratory." That was the Nixon Administration's reason for why Congress had to write TSCA in the first place.

When Congress rewrote that 1976 law, it was because it wasn't effective. It was because when EPA tried to ban asbestos, a chemical that has killed tens of thousands of people every year for decades, EPA's ban was overturned in court and it rendered the original law unable to be used. When Congress came together and wrote the 2016 law, it defined fairly prescriptively the process by which EPA was supposed to review those thousands of chemicals, including vinyl chloride, that hadn't been evaluated before.

The timelines in the law are very clear. We need to spend a year with two public comment periods before we can start work on vinyl chloride. Once we do start work on vinyl chloride, the law says we have three to three and a half years to finish our work and really and really comprehensively assess all the risks. After that, it is a year to propose a rule and a year after that to finalize a rule.

It is a long process. The idea was, instead of doing little, we will regulate this use here and that use there, the idea behind the law was, we really want to comprehensively study all the ways in which a chemical is made and used, and write a comprehensive rule using that best available science in order to give the public confidence that the chemical can continue to be used safely for the uses that we think can continue.

Senator FETTERMAN. Mr. Chairman, thank you, and thank you.

Senator CARPER. Senator Fetterman, thank you for those questions. Senator Lummis, you are recognized again, and a vote is underway. I think we are about 10 minutes into our first vote of a couple of votes. Senator Lummis, then Senator Markey.

Senator LUMMIS. Thank you, Mr. Chairman. I do appreciate the perspective of the gentleman from Pennsylvania. I too live next to a refinery and have benefited personally from the existence of the RCRA law, without which we would have had no remediation of significant migration of hydrocarbons into the creek where our cattle drink. This is a bipartisan subject, this is not partisan. Reasonableness becomes the issue.

I want to return to the ECHOs Draft Rules. I have heard from experts in industry who say there is no realistic way to implement some of the draft rules on ECHOs. My question here is, when you hear from industry that there is no realistic way to implement a draft rule, will any of the proposed changes be adopted between the proposal and the final rule?

Ms. FREEDHOFF. I do think we are working quite closely with industry to understand what might be needed by way of adjustments

to make those more implementable. I will say that for a number of our chemicals, the data we have shows industry is already either meeting our proposed levels or pretty close to it.

They will change between proposed and final sometimes. Sometimes it might be more time to come into compliance, sometimes the numbers themselves might change. I think when we propose a rule and look for public comment on it, we are serious about reviewing those comments and making adjustments whenever we think they are needed.

Senator LUMMIS. Question about existing chemicals that were never peer-reviewed. It is my understanding that EPA's worker exposure levels for existing chemicals were not peer-reviewed. Can you commit to ensure there will be peer review and public comment on these values going forward?

Ms. FREEDHOFF. Just to elaborate a little bit, the last administration wrote the risk evaluations. I think they were in such a rush to get them done that they didn't really think a few steps ahead for how they were going to do the worker protection, how they were going to address the worker protection risks that they found. That is why those exposure limits came out after the risk evaluations came out.

I will say, all of the data that went into deriving those limits was peer reviewed. That said, I also know that industry really wants to see them earlier in the process, really wants to see them go through the peer review process, and I think that is entirely reasonable. That is what we have started to do and will continue to do going forward.

Senator LUMMIS. Thank you. Question about hazard based review of a new chemical. Can you explain to me what factors are considered in a hazardous based review of a new chemical, and how that differs from the standard applied to older chemicals under TSCA?

Ms. FREEDHOFF. Sure. I think with existing chemicals, we have a lot of data. Sometimes we have data, like in Woburn, Massachusetts, where we know that exposure to TCE caused a cancer cluster. We have information about what that chemical did to people that were exposed to it.

With new chemicals we do not have that usually. What we have sometimes are tests that the company has put together, sometimes using non-animal testing to show what the new chemical's expected hazard might look like. Sometimes what we do is we look at the structure of the new chemical and compare it to something that do know something about, and infer what we can from reading across what we know about an old chemical to what we can expect to happen from the new.

It is a variety of techniques, but with new chemicals they are by definition new, there is less information about them.

Senator LUMMIS. I appreciate that.

Mr. Chairman, I want to just return for 1 second to the PFAS discussion, and just remind you that DOD's report kind of sets off some alarm bells about the importance of working closely with DOD. His debate over the definition of PFAS is going to be extremely important to them. Just to implore you to work closely with Department of Defense on these definitions, and to try to

make sure that we are not compromising our national security or our defense posture by a regulatory regime that is so rigid that it provides no escape valve.

Thank you. Thanks for being here. I yield back.

Senator CARPER. Thanks for your focus on PFAS and permanent chemicals. It is much needed and much appreciated.

We have been advised by the cloakroom that we are almost 20 minutes into our first vote. Senator Markey, I am going to recognize you but not for a real long time. Thank you.

Senator MARKEY. I appreciate it. I was willing to wait a good long time, in my Chevron deference to Senator Whitehouse to go first, not understanding all of the implications of that decision in terms of other people who would be asking questions.

[Laughter.]

Senator MARKEY. I thank you for that.

The Trump Administration violated TSCA by ignoring fence line communities in its chemical exposure and risk analysis. What is a fence line community? Well, I guess I grew up in a fence line community, because I lived three blocks from the Malden River, and my mother told me when I was 10, whatever you do, Eddie, do not swim in the Malden River, because it was black, with a kind of pre-Jimi Hendrix purple haze over it, because of the coal companies, the chemical companies, all of the polluting companies right along the Malden River.

Just do not swim in that river. There were no fences in that era. Now the company has put up a fence. One hundred feet later at the homes of the kinds who were playing, and then it goes out for two or three miles.

There was an underestimation of the harms and it undervalued the lives of environmental justice communities living near polluting facilities. The Biden Administration made the right call by changing that harmful policy of the Trump Administration by actually look at the risks that dangerous chemicals pose to fence line communities, people who live right up next to the facilities.

Dr. Freedhoff, when done as required by TSCA, do fence line analyses help EPA better protect vulnerable communities by more fully accounting for how those communities get exposed to dangerous chemicals?

Ms. FREEDHOFF. Thanks very much, Senator, and absolutely. I toured a number of those communities and visited with them in Houston. It was just unbelievable to be standing in the middle of a playground and seeing 10 smokestacks literally on the other side of the road. Unquestionably there are some communities that are more exposed to more chemicals than others.

Unquestionably, even though TSCA requires us to look at one chemical at a time, the fact is that you sometimes breathe more than one chemical at a time and you sometimes drink water that has more than one chemical in it as well.

What we have been doing is trying to create the scientific tool box, so to speak, that will let us really understand those risks, the risks from more than one chemical, the risks from exposure through both the air and the water to the same chemical, and the different risks that some communities have compared to others.

Senator MARKEY. Thank you for that. There was like a cloud over my ward growing up. In fact, there was a union leader in my office last week, and we were talking about the Lewis Candy Company where I worked making gum drops and jelly beans when I was 16, right on the Malden River.

He said, oh, yes, everyone knew there was like a huge black cloud over that building, which we didn't even think about, because that is just the way it was along the Malden River, just this big cloud which today would be something that obviously families would be concerned about young people being exposed to.

Dr. Freedhoff, what would you say to those who say that TSCA is not an integral part of the EPA's ability to use science to keep the United States and workers clean and healthy? What would be your message to them?

Ms. FREEDHOFF. There are people who say that TSCA is not supposed to be for protecting workers who might be exposed to chemicals inside facilities. There are people who say that TSCA should not be about protecting people in communities who breathe or are exposed to chemicals from breathing air or drinking water.

I kind of struggle to understand what TSCA is about, if it is not supposed to be about protecting the people who work with chemicals, and it is not supposed to be about the people who are exposed to those chemicals in their homes and communities. I think very clearly that is what it is about. It is important for us to be writing rules that are implementable and do not prevent the reshoring of jobs in this Country.

I really do not think you have to choose between jobs and safety. We can do both things, and I think we have to.

Senator MARKEY. I agree with you. I was a worker in one of those facilities. Absolutely, it is historic work that you are doing, and clearly within the full intent, the penumbra of what the law intended. It is to protect people from these dangerous chemicals and you are doing an historically great job in accomplishing that goal.

Thank you, and thank you, Mr. Chairman.

Senator CARPER. Thank you, Senator Markey, very, very much.

Dr. Freedhoff, is there anything you have not been asked, you have been asked a lot of questions here today, but anything you might like to have an opportunity to just very, very briefly highlight before we close?

Ms. FREEDHOFF. Honestly, all I would say is that I really value the bipartisan engagement on EPW. It was integral to getting the law passed in the first place. EPW was really the center of all of those years of work to get the law over the finish line. I really do welcome and appreciate the ideas, all the constructive engagement, and all of the collaboration as we work to implement the pridian law.

Senator CARPER. My colleagues have heard me say over and over again, bipartisan solutions are lasting solutions. It took a hard-fought, difficult struggle to get us to where we actually could enact and sign TSCA into law. Our thanks to you and all the staff folks who helped us in those days to get the ball into the end zone.

My dad used to say, some of the hardest things to do are some of the things that are most worth doing. Passing TSCA was a hard

thing to do. It is not enough for us to just say, we are going to pass this bill, and that is that. We have a responsibility to make sure it is being implemented in the spirit it was intended.

We need to make sure that folks who are needed to help run these programs are well chosen and they do a good job. We have to make sure that funding is provided. In this case here, we have two major sources of funding, one is EPA has the opportunities in those fees, and we have the obligation to provide reasonable appropriations to make sure they are being well utilized.

I want to comment you. I have talked to several of our colleagues who said that you have taken time to come and meet with them and talk with them and their staffs. I urge our witnesses to do more of that. I think it pays great benefits. President Biden likes to say, all politics is personal, all diplomacy is personal. It always has been, and it continues to be that.

The last thing I would say, there is a shared responsibility in terms of oversight. We have a responsibility, and the House has that responsibility, and we need to work in a spirit of collaboration and cooperation with them and the administration and other interested parties.

Not forgetting the football playoff season, a guy who pulls for the Eagles pretty regularly, I am a great Andy Reid fan. He used to coach for the Eagles. As he used to say, it is not time to spike the football, and it is not time to spike the football on this front either.

Thank you for joining us today. Thanks even more for your service to our Nation, and our thanks to your family for sharing you with us for all these years. We appreciate your dedication and your insight into some of the challenges that EPA is facing in the implementation of this legislation. I believe both you and the members of the committee are committed to addressing TSCA implementation challenges. We also have a shared interest in both protecting people from exposure to harmful chemicals, and preserve our Nation's ability to compete and bring innovative chemicals into the market.

I am an optimist by nature, and I am optimistic that we can work together to continue to make progress. With the right kind of leadership here on this side of the dais and on your side, I think we can continue to make progress.

Before we adjourn, a little bit of housekeeping. I want to thank our staffs, your staff, and also the staffs of our committee for a lot of work that went into the preparation of this hearing. I just want to say a special thanks to everyone, and Senator Capito.

Senators will be allowed to submit written questions for the record until the close of business on Wednesday, February 7th, which is about 2 weeks from today. We will compile those questions, we will send them to our witnesses who are going to be asked to respond by Wednesday, February 21st.

With that, it is a wrap. This hearing is adjourned. Thank you so much.

[Whereupon, at 11:52 a.m., the hearing was adjourned.]

November 20, 2023

The Honorable Tom Carper
Chair
Committee on Environment and Public Works
United States Senate
410 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Shelley Moore Capito
Ranking Member
Committee on Environment and Public Works
United States Senate
410 Dirksen Senate Office Building
Washington, DC 20510

Dear Chair Carper and Ranking Member Capito,

The undersigned associations, all of whom are members of the American Alliance for Innovation (AAI), urge the Committee to hold a hearing to examine the Environmental Protection Agency's (EPA) chemicals management policies, in particular its implementation of the 2016 Frank R. Lautenberg Chemical Safety for the 21st Century Act, which reformed the Toxic Substances Control Act (TSCA).

AAI is a coalition of more than 150 trade associations representing a broad spectrum of U.S. businesses and industries across manufacturing and supply chain. AAI members work to promote sound domestic chemical management policy that puts science first, promotes innovation, and supports supply chain resiliency. For the U.S. to remain a global leader in innovation, it is imperative we get America's chemical management policies right.

AAI members were key supporters of the overwhelmingly bipartisan 2016 Lautenberg Amendments. Unfortunately, six years since passage of the TSCA amendments, EPA has shifted course, implementing policy changes that run counter to the bipartisan compromise that made TSCA modernization possible.

Continued congressional oversight is critical to ensuring effective implementation of TSCA. Since the Committee's last oversight hearing on TSCA in June of 2022, there has been a significant amount of regulatory activity. The undersigned AAI members would appreciate the opportunity to work with the Committee to hold another productive hearing.

Thank you for your continued attention to the challenges surrounding TSCA implementation and other EPA chemical management policies.

Sincerely,

Alliance for Chemical Distribution
American Chemistry Council
American Cleaning Institute
American Composites Manufacturers Association
American Forest & Paper Association
American Fuel & Petrochemical Manufacturers

American Petroleum Institute
Consumer Technology Association
Essential Minerals Association
Fragrance Creators Association
Household & Commercial Products Association
INDA, Association of the Nonwoven Fabrics Industry
International Sleep Products Association
IPC – Build Electronics Better
National Association of Food Equipment Manufacturers
National Electrical Manufacturers Association
National Mining Association
Polyisocyanurate Insulation Manufacturers Association
Treated Wood Council
U.S. Chamber of Commerce
Vinyl Institute
Vinyl Siding Institute



January 24, 2024

The Honorable Tom Carper
Chair, Senate Committee on Environment and Public Works
410 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Shelley Moore Capito
Ranking Member, Senate Committee on Environment and Public Works
410 Dirksen Senate Office Building
Washington, DC 20510

Re: Hearing on **Oversight of Toxic Substances Control Act Amendments Implementation**

Dear Chairman Carper and Ranking Member Capito:

On behalf of the American Coatings Association (ACA) and the more than 310,000 employees in the paint and coatings industry, I write to express ACA's strong support for congressional oversight of the continued implementation of the Lautenberg amendments to the Toxic Substances and Control Act (TSCA) as it was intended by Congress in 2016.

As you may know, ACA is the premier trade association dedicated to advancing the interests of the coatings industry and represents paint and coatings manufacturers, suppliers, distributors, and technical professionals. Many of today's paints and coatings may go unnoticed by the consumer, but they play increasingly valuable roles in delivering high-quality foodstuffs, durable goods, housing, furniture, and thousands of other products to market. Formulators in the paint and coatings industry strive to enhance the performance characteristics of these products as well as develop innovations that take advantage of new chemistries that are more environmentally friendly and safer for human health. Innovation in the coatings industry relies upon successful navigation of the chemical review process under the *Lautenberg Act*.

ACA member companies consistently experience chronic problems with implementation of the *Lautenberg* amendments that continue to plague EPA and bottleneck the review process to the point where it has become a significant obstacle to innovation and competitiveness in the coatings industry. Several examples include:

Pre-manufacture notices (PMNs) - Coatings manufacturers continue to experience significant delays in the processing of PMNs well beyond the 90-day statutory timeframe.

These delays have been ongoing for several years and is as unacceptable now as they were then. Some companies are waiting 6-14 months for the completion of the review process. Occasionally, PMNs are delayed indefinitely, without further information from EPA. When seeking information about PMN status or further data needs, ACA members often do not receive a response from EPA. ACA is concerned that this backlog is causing the industry to lose valuable new technologies that are developed in the US to other countries such as Canada, Europe, and Asia where the review process is faster. Additionally, the length of time for toxicity study reviews, which can take up to three months for one study, remains problematic. Due to these delays, companies are now avoiding developing innovative new chemistries, including alternative “green chemistries,” due to uncertainties in planning for product introduction.

- **Significant new use rules (SNURs)** - The attachment of (SNURs) to new chemicals is stifling innovation and competitiveness in the US coatings industry. The strong negative impact of SNURs on downstream markets de-values new technologies almost instantly by introducing requirements that are not needed for protection of human health or the environment, and by creating additional administrative reporting burdens for our customers. Additionally, SNUR requirements are not designed for small volumes used in formulated products, resulting in handling requirements that are unnecessarily burdensome or simply cannot be implemented for downstream use of a formulated product. To avoid SNUR obligations, downstream customers choose not to purchase products formulated with new, innovative chemistries subject to a SNUR. As a result, many coatings companies continue to use older technologies, even when PMNs have been approved for more environmentally friendly chemistries. ACA strongly encourages EPA to narrowly tailor SNURs to avoid unintended regulatory requirements that act as a barrier to innovation and sustainability and the use of safer, more environmentally friendly chemistries.
- **EPA’s Proposed PMN Rules** – In May 2023, EPA proposed amendments to PMN procedural rules clarifying data submission and procedural requirements. EPA’s proposal does not address how EPA plans to deal with the existing backlog of PMNs and continued delays. Although the proposal attempts to stipulate PMN data requirements, EPA does not address critical issues in how it will use data. For example, currently EPA staff has broad flexibility when interpreting data and incorporating it into an assessment. In effect, the outcome of EPA’s PMN review and timing of review can vary greatly depending on the assigned EPA staff. Further, EPA often uses its own data and not that of a PMN submitter, resulting in further inaccuracies. EPA also modifies PMN review based on potential future chemical uses, in addition to those intended uses identified by a PMN submitter. TSCA requires EPA to consider foreseeable uses, but EPA does not address how foreseeable uses affect its understanding of risk from the intended uses of the PMN submitter. Consideration of foreseeable uses has led to an inaccurate understanding of risk. In effect, the rule, if finalized, would not address broader issues in the PMN process that are stifling innovation within the chemical industry.

- **Risk Evaluations** - ACA and its members are concerned that unwarranted assumptions during risk evaluation of chemicals already on the market will lead the agency down a path of unnecessarily restricting or banning chemical uses. Such assumptions can result in the agency overstating risk for a variety of downstream industrial, commercial, and consumer chemical uses, having a far-reaching impact. Examples include applying an assumption that PPE is not used properly in industrial settings, assuming unrealistically high exposure times and volumes, and identifying inappropriate chemical surrogates when conducting a risk evaluation. These invalid assumptions and lack of adequate data have resulted in EPA issuing risk assessments that diverge significantly from established understanding of risk within the community of industrial hygienists.
- **Risk Mitigation of Existing Chemicals** – After completion of a risk evaluation of a chemical already on the market, TSCA requires EPA to develop risk mitigation requirements. Because the underlying risk evaluation incorporates extreme assumptions, and inaccurate data sets, EPA unnecessarily bans uses or prescribes unnecessary risk mitigation requirements. EPA's process for issuing risk mitigation rules is deeply flawed. Under standard regulatory practice, an agency would issue requirements, allowing industry to comply or cease non-compliant operations, as needed. For TSCA mitigation requirements, EPA does not follow this standard practice. EPA instead proposes bans by industry sector based on its assessment of whether an industry sector can comply with EPA's proposed risk mitigation strategy, often with limited or no data about the industry sector. Industry has no prior notification of a proposed ban, only receiving notification with publication of the proposed rule. Industry then has a 60-day comment period to provide any information to EPA to prove it could comply with EPA's risk mitigation requirements. Through this process, EPA is creating an alternative worker safety regulatory regime without close coordination or support from OSHA or the broader community of industrial hygienists. ACA members are struggling with incorporating EPA chemical evaluations and requirements into existing safety practices and worker training since EPA's evaluations often mislead workers about the extent of risk and necessary safety practices. EPA's risk mitigation requirements can also result in safety practices that are unnecessarily focused on one chemical, to the detriment of considering aggregated risks and workplace practices, as currently evaluated by industrial hygienists.

Sound science must be the foundation for decision-making in the chemical review program. While ACA fully supports EPA's commitment to scientific integrity, their commitment is being undermined by substantive and procedural requirements imposed during the PMN process as well as the risk evaluation and mitigation processes. ACA has consistently commented to EPA on the matters noted herein. Several changes to EPA's TSCA implementation would better align the TSCA program with the statute. ACA requests that Congress require EPA to implement the following:

- EPA must consider standard risk mitigation practices including PPE when conducting a risk assessment and when developing risk mitigation rules for chemicals already on the market. EPA must evaluate and document situations where chemical users do not have access to PPE or other risk mitigation practices. If the evaluation warrants it, EPA may consider a

separate risk mitigation approach for this subset of chemical users, but it should not be allowed to ignore standard industry risk mitigation practices when developing an exposure limit and conducting a risk evaluation.

- EPA must work within the framework of the OSHA (Occupational Safety and Health Administrations) hazard classification system at 29 CFR 1910.1200 when identifying occupational hazards of a chemical. EPA risk evaluations are often based on an understanding of hazard that conflict with this OSHA standard.
- EPA should defer to OSHA as a resource to conduct workplace risk evaluations. Notably, EPA does not have broad jurisdiction over workplace safety nor do they have strong expertise in industrial hygiene to conduct such evaluations, and EPA policies noted above prevent accurate assessment of workplace risk.
- EPA is reaching beyond its jurisdiction into areas clearly within OSHA's statutory mandate and beyond its limited TSCA authority by proceeding unilaterally without adequate agency expertise, consultation with OSHA, or consultation with the broader scientific community.
- EPA must not propose risk mitigation requirements when its evaluation is based on unwarranted assumptions and inappropriate use of surrogate chemicals and surrogate chemical uses.
- EPA must not ban ongoing chemical uses based on an assumption that an industry sector cannot comply with new risk mitigation requirements. Rather than a ban, EPA must issue risk mitigation requirements and allow each industry sector choose to comply with the requirements or discontinue use, as appropriate.
- Regarding new chemical review, EPA must narrowly tailor SNURs to avoid unintended regulatory requirements that act as a barrier to innovation and sustainability and the use of safer, more environmentally friendly chemistries.
- Regarding new chemical review, EPA must focus its analysis on uses identified by the PMN submitter and limit risk mitigation actions based on future possible foreseeable uses. One approach would be to issue a SNUR for foreseeable uses requiring notification prior to initiating such use. This approach would allow EPA an opportunity to issue risk mitigation requirements specific to a foreseeable use, should a company want to initiate such use.
- Regarding new chemical review, EPA must communicate clearly to the PMN submitter regarding future, foreseeable uses it identifies, the related data sources, and how the inclusion of these additional foreseeable uses will affect review of the PMN submitters identified uses.
- Regarding new chemical review, EPA must develop an effective strategy for review of the existing backlog while streamlining procedures to meet the 90-day PMN review period. One way to achieve this goal is for EPA to focus its data review on information provided by the PMN submitter.
- Regarding new chemical review, EPA should be required to refund the PMN fee if it is unable to meet the 90-day review period.

If you have any questions regarding TSCA implementation issues or the coatings industry, please do not hesitate to reach out to me at hmcauliffe@paint.org.

Best Regards,

A handwritten signature in blue ink, reading "Heidi K. McAuliffe". The signature is written in a cursive style with a large, stylized "H" and "M".

Heidi K. McAuliffe
Senior Vice President, Government Affairs

Chris Jahn
President & CEO



November 8, 2023

The Honorable Tom Carper
Chairman
Committee on Environment and Public Works
United States Senate
410 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Shelley Moore Capito
Ranking Member
Committee on Environment and Public Works
United States Senate
410 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Carper and Ranking Member Capito:

The American Chemistry Council (ACC) represents over 190 companies who create and manufacture innovative products that make people's lives better, healthier, and safer, and help solve the greatest challenges facing our country and the world. From supply chain, climate, and sustainability challenges to national security and infrastructure needs, our nation depends on the products and innovations made by America's chemical industry.

For America to succeed it is vital that we develop sound chemical management policies that protect human health and the environment while also promoting economic growth and innovation. We urge the Committee to hold a hearing to review the Environmental Protection Agency's (EPA) policies, in particular its implementation of the 2016 Frank R. Lautenberg Chemical Safety for the 21st Century Act, which reformed the Toxic Substances Control Act (TSCA).

The Committee last conducted an oversight hearing on TSCA in June of 2022. In the subsequent year and a half, there has been a significant amount of regulatory activity. More recently, the House Committee on Energy and Commerce held a hearing to investigate regulations on the chemical industry on October 18, 2023.

Sustained Congressional oversight is important to ensure effective and efficient implementation of TSCA, in accordance with the bipartisan compromise. As you may be aware, the ACC has expressed concerns with the approach EPA is taking in reviewing both new and existing chemicals and its impact on innovation and American competitiveness.

We appreciate your attention to the challenges surrounding implementation of TSCA and look forward to working with you to hold a productive examination of EPA's chemical management policies. The ACC and our members stand ready to be a resource to you as we move forward.

Sincerely,

Chris Jahn



January 23, 2024

The Honorable Tom Carper
Chairman
Committee on Environment and Public Works
United States Senate
410 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Shelley Moore Capito
Ranking Member
Committee on Environment and Public Works
United States Senate
410 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Carper and Ranking Member Capito,

The undersigned associations, all of whom are vital contributors to emerging technologies for fuels and promoting America's circular economy, respectfully urge the Committee to examine the Environmental Protection Agency's (EPA) new chemicals review policies for implementing a "robust, consistent, and efficient process to assess the risk and apply mitigation measures, for substitutes to petroleum-based fuels and fuel additives that use biobased or waste-derived sources" to produce gasoline, diesel, and other fuels.¹

This coalition represents a broad spectrum of U.S. businesses and industries across all segments of America's petrochemical and fuels industries dedicated to the development of plastic waste-to-fuels and circularity for plastics. Our industries support more than ten million U.S. jobs and are involved in all major facets of the chemical and fuels supply chain—from crude oil and natural gas production to refinery production of fuels and other products, including the manufacture of petrochemical building blocks, and service companies using chemicals. A recent Government Accountability Office (GAO) Report on EPA Toxic Substances Control Act (TSCA) new chemical reviews revealed that the Agency only completes ten percent of its new chemical reviews within its statutory deadlines².

In a positive development, on January 21, 2022, the EPA announced a new effort to streamline TSCA review of new substances that could be used as fuels with a lower carbon footprint than existing fuels. The Agency states that the streamlined review is consistent with EPA's overall goals under the Renewable Fuel Standard (RFS) program³, as well as the National Strategy to Prevent Plastic Pollution,⁴ and the 2021 Climate Adaptation Action Plan⁵.

In direct contradiction to its streamlining goals, EPA proposed TSCA Significant New Use Rules (SNURs) last summer for fuel-related substances from plastic waste that will dramatically affect molecular and chemical recycling, two advanced techniques to turn plastic waste into value-added products.⁶ This action has had the effect of impeding the production of emerging

¹ EPA Announces Effort to Help Bring Climate-Friendly New Chemicals to Market to Reduce Greenhouse Gas Emissions January 22, 2020.

² GAO Report: "The EPA Lacks Complete Guidance for the New Chemicals Program to Ensure Consistency and Transparency in Decisions", August 2, 2023.

³ Congress created the renewable fuel standard (RFS) program to reduce greenhouse gas emissions and expand the nation's renewable fuels sector while reducing reliance on imported oil. This program was authorized under the Energy Policy Act of 2005 and expanded under the Energy Independence and Security Act of 2007.

⁴ EPA, Draft National Strategy to Prevent Plastic Pollution (Apr. 2023) at 15, https://www.epa.gov/system/files/documents/2023-04/Draft_National_Strategy_to_Prevent_Plastic_Pollution.pdf

⁵ EPA Publishes its 2021 Climate Adaptation Action Plan <https://www.epa.gov/newsreleases/epa-publishes-its-2021-climate-adaptation-action-plan>

⁶ Proposed TSCA Significant New Use Rules on Certain Chemical Substances (23–2.5e), 88 Federal Register 39804–39818, June 20, 2023.

alternative transportation fuels and delaying the development of most, if not all advanced recycling projects for plastics. EPA's SNUR proposal involves a highly questionable approach that does not comport with the TSCA statute and its implementing regulations.

The Agency proposes to subject any chemical from advanced recycling or a plastic waste-to-fuel process to its burdensome and onerous new chemical review program. EPA is already far behind in its work with a backlog of hundreds of chemicals, and has regulated 90 percent of the new substances that it has reviewed since enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.⁷ EPA's justification for this auxiliary action is based on the discovery that plastic waste feedstocks *may* contain additives and impurities, yet in the proposed SNURs the Agency provides no measured data to substantiate such contamination. In comments submitted to the docket for the SNURs, industry associations have encouraged EPA to substantiate its assumptions of contamination. Additionally, industry has pointed out the fact that the chemicals that the Agency is calling "new," such as naphthas, distillates, and butane-rich gases, have been around and used safely for decades.

We encourage this Committee to hold EPA accountable for its paradoxical commitment to recycling and alternative fuels, and work with our industry to streamline the process that gets these value-added products from plastic waste to market. EPA's Assistant Administrator for the Office of Chemical Safety and Pollution Prevention, Michal Freedhoff, stated, "Using sound science to streamline the review of more environmentally friendly chemical substitutes will help advance the Agency's climate goals and protect human health and the environment."⁸ We have yet to see any measurable progress from EPA to match the Assistant Administrator's sentiments.

Our coalition is supportive of fixing the TSCA new chemical program. Congress has a key role to play in realizing a Premanufacture Notice (PMN) process that advances fuels with lower carbon footprints, supports recycling efforts, and enhances choices for American consumers. Congress has the authority to oversee the effectiveness, resources, and overall strategy of the new chemicals review process at EPA. We urge this Committee to use its authority and ensure that the United States remains a viable place for recycling, alternative fuels, and the building blocks for American manufacturing.

Thank you for your continued attention to the challenges surrounding EPA's implementation of TSCA and the backlog of PMN applications. The undersigned associations appreciate the opportunity to work with this Committee and EPA on fixing existing problems and identifying common sense solutions.

Sincerely,

American Fuel & Petrochemical Manufacturers
American Petroleum Institute

⁷ GAO Report: "The EPA Lacks Complete Guidance for the New Chemicals Program to Ensure Consistency and Transparency in Decisions", August 2, 2023.

⁸ EPA Announces Effort to Help Bring Climate-Friendly New Chemicals to Market to Reduce Greenhouse Gas Emissions, January 21, 2022
<https://www.epa.gov/newsreleases/epa-announces-effort-help-bring-climate-friendly-new-chemicals-market-reduce>



January 24, 2024,

The Honorable Thomas R. Carper
U.S. Senate
513 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Shelley Moore Capito
U.S. Senate
170 Russell Senate Office Building
Washington, D.C. 20510

Dear Chairman Carper and Ranking Member Capito,

The American Cleaning Institute (ACI)ⁱ appreciates the opportunity to provide this letter for the record for the Senate Environment and Public Works Committee hearing titled *Oversight of Toxic Substances Control Act Amendments Implementation*.

ACI urges the Committee members to ensure the EPA abides by statutory obligations under TSCA for reviewing new chemicals. Most urgently, the Agency still needs to meet its statutory obligation to review and make final determinations on new chemicals within 90 days. ACI urges the Committee's consideration of the following as it examines TSCA implementation matters:

- EPA has considerably slowed the Pre-manufacture Notice (PMN) and Significant New Use Notice (SNUN) review process. Accordingly, an exceptional number of Notice submitters are being asked to "voluntarily" suspend the review process to respond to EPA information and data requests. EPA often seeks unnecessary information for the Agency to conduct its assessment under Section 5. Many reviews are now taking nearly two years to complete, resulting in significant delays, and the backlog appears only to be increasing.
- New chemical specialty products represent innovative new chemistries produced using improved manufacturing and processing techniques that reduce risk, exposure, and energy use. Discouraging the introduction of these new products by unnecessarily delaying market entry and imposing testing costs, often involving resource and time-intensive animal testing, will impede the commercial use of such risk-reducing products and their methods of manufacture and processing in the U.S.

Chemical innovation forms the foundation of most products in society and is key to a growing and vibrant, sustainable economy, including job creation. ACI stands ready to work with the Committee and EPA staff to implement the New Chemicals Review Program as the TSCA statute prescribes.

Sincerely,

Blake Nanney
Director, Government Affairs

ⁱ ACI represents the \$60 billion U.S. cleaning product supply chain. ACI members include the manufacturers and formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and chemical distributors. ACI serves the growth and innovation of the U.S. cleaning products industry by advancing people's health and quality of life and protecting our planet. ACI achieves this through a continuous commitment to sound science and being a credible voice for the cleaning products industry.



Amanda Parsons DeRosier
 Vice President of Public Affairs
 and Investor Relations

The Honorable Tom Carper
 The Honorable Ranking Member Shelley Moore Capito
 Senate Environment and Public Works Committee
 410 Dirksen Senate Office Building
 Washington, D.C. 20510

February 9, 2024

RE: Regulatory Impact on Innovation in the Chemical Industry

Dear Chairman Carper & Ranking Member Capito:

I write on behalf of Global Clean Energy Holdings, Inc. to thank you for holding a hearing in the Senate Environment and Public Works Committee on the Toxic Substances Control Act (TSCA). While TSCA plays an important role in ensuring the ongoing safety of the nation's chemical review process, companies like Global Clean Energy that are seeking to provide renewable fuel solutions, anticipate that delays to the TSCA approval process will hamper our ability to operate and deliver novel chemical solutions that meet the needs of American consumers. Global Clean Energy welcomes the opportunity to provide comments urging the U.S. Environmental Protection Agency (EPA) to address the administrative burdens delaying the TSCA approval process.

Global Clean Energy is a vertically integrated nonfood feedstock and finished renewable fuels company focused on producing sustainable, low-cost renewable fuels using camelina as a feedstock. Global Clean Energy currently contracts with 140 agricultural operations across 10 U.S. states on nearly 45,000 designated camelina acres to grow our patented camelina without causing land use change. The fuel produced from camelina has a significantly lower carbon intensity score than traditional fossil fuels, as well as many existing biofuels, and can play an important role in helping the United States reduce carbon emissions in a sustainable and economically feasible way. We are in the process of opening a production facility that will refine ultra-low carbon renewable diesel, renewable propane, and renewable naphtha, which will lower the carbon intensity score of our finished fuels even further.

Although our facility would provide important upstream and downstream benefits to the energy sector, rural communities, and the country, our ability to produce finished fuels is being hampered by delays from the TSCA approval process. With these comments, we hope to highlight that although we support the EPA's goal of ensuring public safety and environmental protection, the current delays in the regulatory process are economically burdensome and negatively impact the ability of companies like ours to bring innovative solutions to market.



Chairman Carper & Ranking Member Capito
February 9, 2024
Page 2

Despite the Biden-Harris Administration's deep commitment to incentivizing sustainable fuels, EPA's evaluation of our Pre-Manufacture Notice (PMN) for renewable naphtha threatens our ability to open our new production facility on time. The agency's repeated extensions of the PMN evaluation process for our product has delayed approval well beyond the 90-day review period detailed in statute. When Global Clean Energy met with the agency to discuss these issues, we were told that this process was delayed by administrative concerns and staffing shortages rather than any inherent issue with our product or filing.

While we applaud the EPA's chemical review process for ensuring the safety of consumers and the environment, the delayed timelines accompanying the process are negatively impacting our company's ability to deliver innovative renewable fuels to the market. At a time when there is increasing demand for renewable fuels, it is imperative that permits not be further delayed by unnecessary regulatory burdens. To meet the demands of this moment, it is pivotal that EPA maintains a chemical review process that is thorough and upholds safety without stifling innovation through repeated permitting delays.

We thank you again for the committee's attention to this issue. Should you have any questions or need for follow up information, please do not hesitate to reach out.

Sincerely,

A handwritten signature in black ink, appearing to read "A. DeRosier", with a stylized flourish at the end.

Amanda Parsons DeRosier
Vice President of Public Affairs and Investor Relations
Global Clean Energy



Solugen, Inc.
14549 Minetta St,
Houston, TX 77035

February 14, 2024

The Honorable Tom Carper
The Honorable Ranking Member Shelley Moore Capito
Senate Environment and Public Works Committee
410 Dirksen Senate Office Building
Washington, D.C. 20510

Subject: Regulatory Impact on Innovation in the Chemical Industry

Dear Chairman Carper & Ranking Member Capito:

I write on behalf of Solugen, Inc. to thank you for holding a hearing in the Senate Environment and Public Works Committee on the ongoing implementation of the Lautenberg Chemical Safety Act amendments to the Toxic Substances Control Act (TSCA). While this law is critical to ensuring the safety of new and existing chemicals, it also creates challenges for companies like Solugen that wish to bring safer, less toxic chemicals to market within an economically viable timeframe. Solugen welcomes the opportunity to provide comments for the hearing record on the current TSCA program. Solugen urges the U.S. Environmental Protection Agency (EPA) to address barriers to new chemical entry in its current TSCA processes. Solugen also encourages lawmakers to consider meaningful, common-sense changes to the program that would make it easier for businesses like ours to succeed while still supporting the law's underlying goal to protect public health and safety.

Solugen is a groundbreaking technology company on a bold mission to decarbonize the physical world. At the heart of our innovation is the world's first sustainable molecule factory—the Bioforge™. This unique manufacturing platform uses a chemienzymatic process to convert plant-derived substances into essential materials that have historically been made from fossil fuels. The Department of Energy (DOE) has acknowledged our work on key building blocks for the bioeconomy, starting with glucaric acid, a recognition that aligns with Solugen's commitment to advancing sustainable solutions. This work underscores the vital connection between domestic biochemical manufacturing and the enduring security and self-reliance of the United States while simultaneously reducing America's carbon footprint.

We commend the EPA's commitment to upholding public safety and environmental standards within the chemical industry. However, with these comments, we wish to highlight the hurdles faced by start-ups and smaller ventures in navigating the regulatory landscape, particularly concerning Pre-Manufacture Notices (PMNs) and Significant New Use Rules (SNURs).

Solugen



In 2023, EPA honored Solugen with the Green Chemistry Award, recognizing our high-yield and low-waste chemenzymatic technology. This innovative process facilitates the conversion of renewable materials, such as sugar and cardboard waste, into environmentally friendly chemicals, providing sustainable alternatives to legacy products. Despite this recognition, we have encountered ongoing challenges with the EPA's evaluation of Solugen's PMNs. The agency's limited consideration of pollution prevention and the prevalence of biobased chemicals in nature during the PMN evaluation process has led to substantial delays that far exceed the 90-day review period required by law.

The EPA's thorough review process for new chemicals, while necessary for ensuring safety and environmental protection, also often results in prolonged timelines. This delay significantly impacts innovative solutions, hampering their timely introduction to the market. New chemicals, competing with incumbent products relying on 'source-based' naming conventions, encounter considerable regulatory challenges. The EPA's "hazard-based" approach primarily subjects new chemicals to stringent regulations, unlike older, generally riskier chemicals that are not subjected to risk review for decades. This places newer chemicals and their production technologies at a marked competitive disadvantage.

Furthermore, the application of SNURs, designed to enhance safety measures, imposes noteworthy constraints on the use of newer, safer, and biobased chemicals. These limitations adversely affect various sectors, obstructing the market entry of innovative solutions across industries like household, industrial, and institutional (HI&I) cleaning, industrial water treatment, and agriculture. The administrative requirements imposed by SNURs, while intended for compliance and safety, introduce considerable complexities and administrative burdens for businesses and their customers. Customers are often unwilling to take on the additional reporting requirements that accompany chemicals which have received a SNUR, and therefore may stick with an older, potentially more dangerous chemical instead of transitioning to a safer alternative.

For start-ups and smaller ventures such as ours, these stringent regulatory requirements impose substantial administrative burdens and financial costs. Adhering to SNURs not only amplifies operational complexities but also presents formidable financial hurdles, particularly for entities operating with limited resources. A SNUR placed on a new chemical is effectively a market death sentence, deterring customers who seek to avoid the intricate regulatory hurdles linked to SNUR compliance.

The EPA's indication of a shift towards automatically implementing SNURs for most new chemicals entering the market signifies a pivotal change in regulatory oversight. While aiming to fortify safety and environmental standards, this regulatory shift assumes unrealistic and rapid market acceptance, posing significant challenges for new chemical applicants and their prospective customers. Without action from the EPA, or Congress, that would fundamentally change the EPA's current approach to SNURs, they will continue to serve as a deterrent for new chemical adoption.

Solugen



We firmly believe that fostering an environment that encourages innovation while upholding robust safety and environmental standards is pivotal for the chemical industry's growth. A collaborative effort involving Congress, industry stakeholders, and regulatory bodies is imperative to strike a balance that facilitates innovation without compromising safety.

Thank you again for your attention to this matter. Should you require further information or wish to discuss this matter in detail, please do not hesitate to contact me.

Sincerely,

Bryan J. Soukup, Esq.

A handwritten signature in black ink, reading "Bryan J. Soukup". The signature is fluid and cursive, with a long horizontal stroke extending to the left.

Head of Government Relations
Bryan.soukup@solugentech.com
Solugen, Inc.

Solugen



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December 5, 2023

The Honorable Tom Carper
Chairman
Committee on Environment and Public Works
United States Senate
410 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Shelley Moore Capito
Ranking Member
Committee on Environment and Public Works
United States Senate
410 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Carper and Ranking Member Capito:

As a member of the American Chemistry Council (ACC), Univar Solutions distributes for over 1,800 chemical and ingredient suppliers around the world as we work to fulfill our purpose and help keep our communities healthy, fed, clean and safe. From supply chain, climate, and sustainability challenges to national security and infrastructure needs, our nation depends on the products and innovations made by America's chemical industry.

For America to succeed it is vital that we develop sound chemical management policies that protect human health and the environment while also promoting economic growth and innovation. We urge the Committee to hold a hearing to review the Environmental Protection Agency's (EPA) policies, in particular its implementation of the 2016 Frank R. Lautenberg Chemical Safety for the 21st Century Act, which reformed the Toxic Substances Control Act (TSCA).

The Committee last conducted an oversight hearing on TSCA in June of 2022. In the subsequent year and a half, there has been a significant amount of regulatory activity. More recently, the House Committee on Energy and Commerce held a hearing to investigate regulations on the chemical industry on October 18, 2023.

Sustained Congressional oversight is important to ensure effective and efficient implementation of TSCA, in accordance with the bipartisan compromise. As you may be aware, the ACC has expressed concerns with the approach EPA is taking in reviewing both new and existing chemicals and its impact on innovation and American competitiveness.

We appreciate your attention to the challenges surrounding implementation of TSCA and look forward to working with you to hold a productive examination of EPA's chemical management policies. The ACC and our members stand ready to be a resource to you as we move forward.

Sincerely,

Dwayne Roark
Vice President
Public Affairs, Government Relations & Communications



A Message from Chris Jahn, President & CEO of the American Chemistry Council:

This report provides valuable insight into the impact of the tremendous rise in chemical regulations and how they adversely impact national priorities and American manufacturing. The findings are the result of a survey of ACC member companies doing business in the U.S.

The chemical industry supports a vast supply chain and creates economic activity across the country. With \$639 billion worth of shipments in 2022, the United States accounts for 11% of the world's total chemical production. American chemistry comprises 1.1% of the U.S. GDP and provides more than half a million jobs, with an average pay of more than \$97,000 per year. For every chemistry industry job, more than six jobs are supported elsewhere in the economy.

Chemical manufacturing is also the backbone of products and innovations ranging from computer chips to high-tech automotive parts and electric vehicles. It also helps build smart devices, affordable housing, modern healthcare technology, and climate and energy technologies, all critical components of our supply chain.

Despite tremendous growth in recent years, the United States is second to China in global chemical production. U.S. chemical manufacturers continue to face challenges from persistent inflation, competition overseas, and a dramatic increase in regulations at home.

In fact, chemical manufacturing is the most heavily regulated subsector of manufacturing with the total number of regulations that apply to the industry doubling in the past 20 years. Adding to this growing regulatory burden there are a great number of planned rules targeting chemical manufacturing that will increase compliance costs by 50%.

Some aim to outright ban certain chemistries. Others may regulate important chemicals to levels where manufacturing becomes unviable or impossible. If enacted, these restrictions could have a detrimental impact that extends beyond the chemical industry. They could harm the supply chains for vital technologies, including semiconductors, clean energy solutions like electric vehicles, and many modern healthcare applications.

Not only is there a huge rise in the number of regulations that may negatively impact the chemical industry, but 30 percent fewer regulations are being reviewed by the Office of Management and Budget (OMB) compared to the last Democratic administration. The dramatic increase in the volume of regulations along with a decrease in quality control is a troubling one-two punch for U.S. innovation and manufacturing.

Unless policymakers take a different approach to how they develop and apply regulations, critical chemistries will suffer along with the important products supported by chemistry.



A stylized, handwritten signature in white ink, consisting of a large 'C' followed by a series of loops and a long horizontal stroke.

Chris Jahn
President and CEO
American Chemistry Council



Chemistry Contributes to Supporting National Priorities

Clean Energy

72% of chemical manufacturers report producing a chemical input used in clean energy. They produce chemicals and synthetic materials used in batteries, hydrogen fuel cells and electrolyzers, wind turbines, solar panels, and carbon capture and sequestration.

Infrastructure

62% of chemical manufacturers report producing a chemical input used in infrastructure. They produce chemicals and synthetic materials used in road construction, large infrastructure projects (i.e., bridges, dams), water treatment and distribution, energy-efficient buildings, and EV charging stations.



Health Care

62% of chemical manufacturers report producing a chemical input used in health care. They produce chemicals and synthetic materials used in lifesaving pharmaceuticals and vaccines, medical devices, and implants. They also produce chemistries used in high-purity air cleaning and biocides to improve patient safety.

Semiconductors

52% of chemical manufacturers report producing a chemical input used in making semiconductors. They produce chemicals, gases, and synthetic materials used in the production of semiconductors used throughout the modern economy. Advanced manufacturing of semiconductors includes multiple steps that require chemistry, including the creation of silicon crystals, wafer cutting, and polishing, and chemicals to etch complex circuitry.

Biotechnology/ Biomanufacturing Products

34% of chemical manufacturers report producing a chemical input used in biotechnology/biomanufacturing products. They produce chemicals and synthetic materials used in vaccines, bio-based materials used across the economy, seed, crop protection, crop nutrition, and animal feed products for the farm sector.

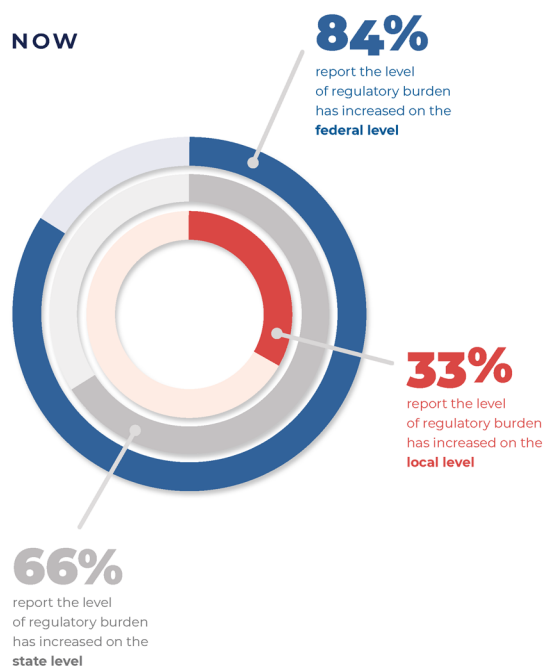
Chemical manufacturers also contribute important products to support National Defense and Transportation.

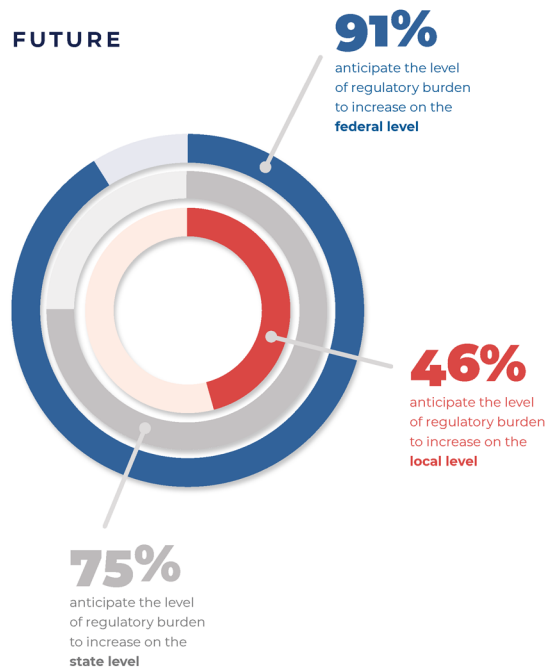


Growing Regulatory Burden

Most chemical manufacturers report that overall regulatory burden has increased across all levels of government. And they expect the number of regulations to continue to increase over the next year.

NOW







Impact of Regulations on National Priorities

Many of the chemical manufacturers that produce chemical inputs to products/industries prioritized by the Administration reported that the current and/or forthcoming regulatory burden negatively impacts their ability to competitively produce the chemical input(s) in the U.S. Across chemical manufacturers participating in the survey, this was found to be the case for:

Clean Energy

67%

Semiconductors

57%

Biotechnology/
Biomanufacturing Products

56%

Health Care

48%

Infrastructure

42%

% of producers reporting current and/or forthcoming regulatory burden negatively impacts ability to competitively produce chemical input(s) in U.S.



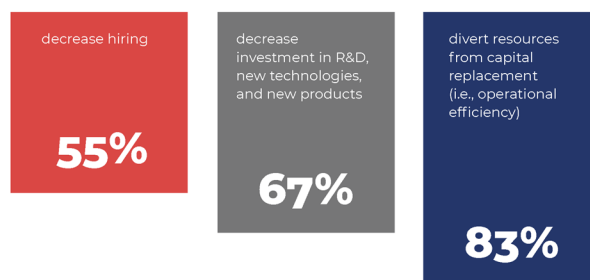
Impact of Regulations on Manufacturing

Over the past year, about 2/3 of chemical manufacturers reported having been adversely affected due to government delay in making a regulatory decision and/or taking a regulatory action on a permit, license, or product approval in the United States.

Companies said new regulatory policies:

- 43% Impacted ability to obtain permits
- 12% Led company not to expand U.S. operations
- 9% Led company to move operations out of the U.S.

Asked to consider a scenario where existing regulatory compliance costs were **suddenly and permanently increased** significantly, manufacturers report they would:



Chemical Manufacturers Say:

“By not acting in a timely manner, EPA is effectively keeping new and innovative chemistries out of commerce. This affects not only our company but US consumers and, in many cases, the environment by foreclosing newer, more sustainable chemistries from approval or approving them only with significant restrictions unappealing to customers. Ironically, this results in older chemistries remaining on the market while newer, more effective, more sustainable, or otherwise better ones are available to replace them.”

“Our products are essential in the production of semiconductors and are used in applications such as solar cells, LEDs, smartphones, and other electronics. Increased cost of compliance, inconsistent and aggressive enforcement, and delayed permitting/decision-making at regulatory agencies all make it more challenging to be competitive with outside markets.”



“We develop and produce essential materials for the production of medical supplies. Such materials can be sourced from overseas. As regulatory costs rise, we become less competitive.”



“ Unexpected delays in PMN [Pre-manufacture Notice] approvals will impact the Administration's intent for 100% production of key ingredients of the EV Battery Supply Chain in the US.”

“ At the federal level, EPA's misguided actions on PFAS [per- and polyfluoroalkyl substances] that are not tied to science-based outcomes (e.g., MCLs, HALS, CERCLA designations) are creating significant regulatory uncertainty and dramatically increasing the risk profile of necessary large (capex intensive) manufacturing capacity expansions designed to meet exponential demand for specific fluoropolymers for battery, hydrogen and semiconductor supply chains. Make no mistake, Chinese competitors are trying to take advantage of this uncertainty by scaling up production in China in an effort to meet global demand (not just Chinese demand), engaging in predatory pricing to drive out global chemical players, and infringing on IP [Intellectual Property].”

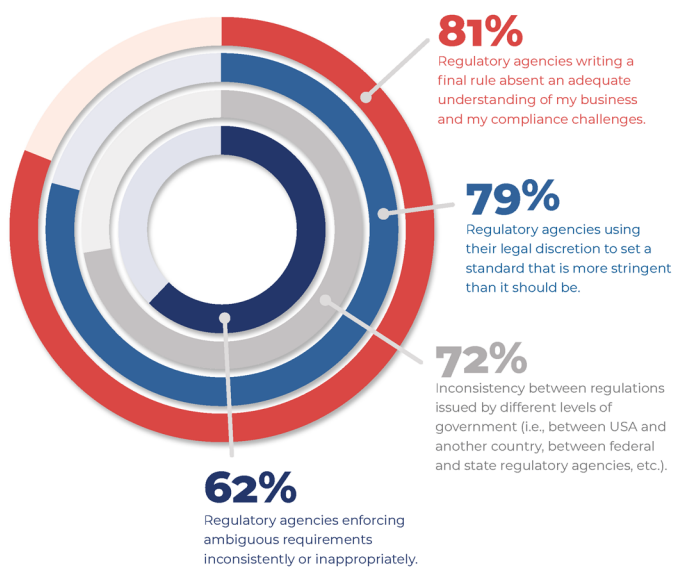
An earlier survey of ACC members examining EPA's New Chemicals Program exposed its stifling impact on U.S. innovation.

The survey found that **70% of chemical manufacturers decided to introduce new chemicals outside the U.S.** given the uncertainties and challenges of EPA's New Chemicals Program, including systemic delays, disregarded company-submitted data, and inconsistent reviews.



Regulatory Challenges and Issues

Chemical manufacturers reported that the most challenging regulations to comply with are due to:

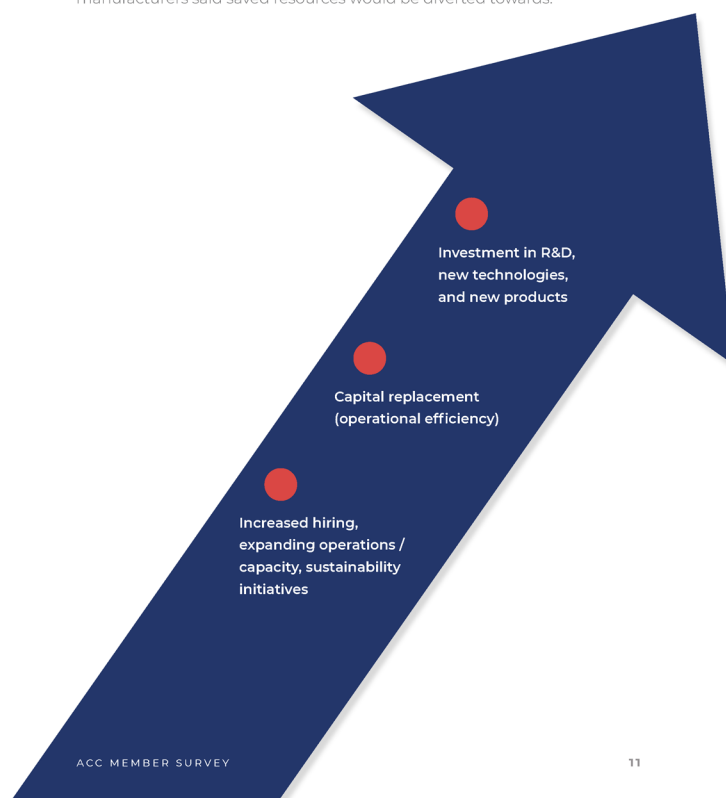


And companies mentioned other reasons, including decision timelines that are inconsistent or delayed; slow responses to regulatory permits; new substance PMN is expensive and takes too long to approve; regulations and reporting burdens that do not reflect the risk to human health and the environment; and regulations based on improper or inadequate science.



Big Return on Fixing Regulations

Asked to consider a scenario where existing regulatory compliance costs were **suddenly and permanently reduced significantly**, chemical manufacturers said saved resources would be diverted towards:





Methodology

In September of 2023, the American Chemistry Council (ACC) conducted a survey of member companies doing business in the U.S. to better understand how they are being impacted by regulations. 58 companies participated in the survey. 38% of the companies surveyed are "small businesses" employing 550 or less full-time equivalents (FTEs).

Every effort has been made in the preparation of this publication to provide the best available information. However, neither the American Chemistry Council, nor any of its employees, agents, or other assigns, makes any warranty, expressed or implied, or assumes any liability or responsibility for any use, or the results of such use, of any information or data disclosed in this material.

This report was prepared by ACC's Economics and Statistics Department. Questions about the survey and findings may be directed to:

Emily Sanchez | Director, Economics & Data Analytics
emily_sanchez@americanchemistry.com



