## TESTIMONY OF MICHAL ILANA FREEDHOFF, PH.D. ASSISTANT ADMINISTRATOR OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION U.S. ENVIRONMENTAL PROTECTION AGENCY BEFORE THE COMMITTEE ON ENERGY AND COMMERCE UNITED STATES CONGRESS OCTOBER 27, 2021

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

As many of you know, I have spent the majority of my career here on Capitol Hill – in both personal House and Senate offices and on five different committee staffs, including this one. One of the most professionally rewarding and challenging opportunities I had during that time was to work on the much-needed legislative reforms to TSCA. I still recall feeling the tremendous sense of gravity and responsibility that came with being a part of rewriting one of the nation's bedrock environmental laws – a law that for nearly 40 years had largely failed to serve its purpose. It was exciting. There was a true and rare sense of bipartisanship born out of an acknowledgement – across the political spectrum – that TSCA was broken, and that the public deserved better protections against dangerous chemicals. Those ideals brought together Republicans and Democrats, the chemical industry, public health advocates, the environmental community, the states and so many others, and carried the TSCA reform conversation for years through countless technical and policy discussions, negotiations, debates and, ultimately, to the Lautenberg Act. And I can still remember gathering at the White House on June 22, 2016 – now over 5 years ago

– to witness the President signing the bill into law, along with some of you. Those same diverse stakeholders stood shoulder-to-shoulder to celebrate the historic achievement and the promise of a TSCA that would deliver long overdue health and environmental protections for the American people.

And now at the EPA in the Office of Chemical Safety and Pollution Prevention or OCSPP, I am fortunate to be able to work directly on the implementation side. Despite the fact that more than half a decade has passed since the reforms became law, there is still much more work to do in order to fully realize the promise of new TSCA. I am certain that, like the Clean Air Act, the Clean Water Act, the Safe Drinking Water Act, and other statutes that have defined environmental protections in this country, TSCA can and will play a significant role in helping the Agency advance its overall mission.

Before I arrived at the EPA, I already knew that certain parts of TSCA implementation during the last administration had veered off course. Each day I seem to learn more. For the work of our office to be successful and sustainable, our policies and processes must be scientifically sound and legally defensible; we must be respectful of the deadlines that drive our forward progress; and we must deliver the outcomes that were always expected under TSCA: meaningful protections against chemical risks. Getting our implementation efforts back on track will take time. But I'm absolutely committed to making the changes necessary to do so, as are the remarkably creative, dedicated, and resilient career staff in OCSPP.

There are a few critical building blocks of a sustainable TSCA program that I'd like to emphasize. First, resources. The Office of Pollution Prevention and Toxics or OPPT has been – and remains – incredibly underfunded. Despite widespread Congressional support for making sure the EPA had the resources it needed to implement this new law, I was shocked to learn when I arrived at the Agency that the EPA had never once made a budget request that meaningfully added any new funding to reflect its new statutory responsibilities. Our enacted budget in OCSPP has remained flat since Fiscal Year 2017, despite the fact that TSCA has required us to more than double our existing chemicals workload. Although the 2016 amendments gave the EPA new authority to collect up to 25 percent of most implementation costs through fees paid by chemical companies, the first fees rule wasn't finalized until late 2018, and didn't include the collection of any fees whatsoever from the highest-cost activity: the first ten TSCA risk evaluations. On top of that, the baseline cost estimates that drove the fee amounts in that rule were artificially low, based on lack of experience carrying out these activities and policy choices made by the previous administration like the exclusion of entire exposure pathways and conditions of use from our assessments. Correcting these issues and implementing appropriate policies will necessarily increase our overall implementation costs. Additionally, the 2018 fees rule has not come close to collecting 25 percent of costs through fees as Congress envisioned. Our fee revenue has been roughly half that – 13 percent on average and that's 13 percent of an already too-low baseline.

These resource constraints in part explain why the previous administration missed its statutory deadlines to complete 9 of the first 10 risk evaluations conducted under TSCA. But it is not just the existing chemicals program that requires resources. We estimate that we have less than 50

percent of the resources necessary to implement the new chemicals program as Congress had intended. On top of that, the information technology systems that the program relies on — including those that support new chemical workflows, review of confidential business information, the ChemView database and various existing chemical program functions — are frequently inoperable, making it difficult to function at the speed of modern times.

We certainly welcome the boost in funding that the Fiscal Year 2022 President's budget would provide as it is a significant down payment that can start to chip away at the four years of compounding errors that we are facing. We hope to build on this in future years.

The second building block of a sustainable TSCA program is strong science and scientific integrity. Science must always be the backbone of our work at the EPA. Scientific integrity is a fundamental principle for Administrator Regan and me – and the President, as evidenced by his memorandum on "Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking." Scientific integrity ensures that our science is robust and is essential for earning and maintaining the public's confidence in our decision-making.

Courts have already rejected some of the last administration's actions that were not supported by science. The public has as a result grown skeptical of the Agency's pronouncements of chemical safety. And these instances have eroded the trust that the American public has in the EPA, the quality of our science, and our ability to protect their health and the environment. That distrust, litigation, and its outcomes, in turn, create regulatory uncertainty for industry.

As this committee knows, concerns have been raised about violations of scientific integrity in OCSPP. Those allegations are deeply concerning to me. One of my top goals, expressed during my confirmation process and upon joining the EPA, is to promote the highest level of scientific integrity across OCSPP. We have already taken strong actions to this end. Shortly after joining OCSPP, I issued an office-wide memo affirming my commitment to act with scientific integrity and asserting my expectation that all OCSPP staff, likewise, embody the principles and spirit of scientific integrity in their work with me and each other. Since then, we have held several meetings and training opportunities focused on matters related to scientific integrity. I will soon be recruiting for a new senior position in my immediate office to serve as OCSPP's deputy scientific integrity official and to work closely with me and other OCSPP senior leaders on emerging science policy and scientific integrity matters. And we also announced the formation of a new internal OCSPP advisory council to provide support and advice on science, science policy and scientific integrity issues that arise within our program offices, that could also leverage expertise from around the Agency. This new group – the OCSPP Science and Policy Council or OSPC – will also facilitate more informal opportunities for collaboration and exchange of ideas among our career scientists.

When the EPA says that a chemical found in products used in homes, schools and workplaces is safe, it is in everyone's interest for the public to be able to believe us. Our scientific conclusions should be synonymous with integrity and underpinned by the ideals of service to the public.

A third building block for a sustainable TSCA program is ensuring that the policies and processes used to evaluate and reduce risk from chemicals will lead to legally and scientifically defensible and protective chemical safety actions. I would like to highlight just a few of the more significant policy changes and work we've been doing across program offices for existing and new chemicals under TSCA.

The last administration finalized 10 existing chemical risk evaluations and began work on the next 20 risk evaluations as well as some requested by manufacturers. While some of our policy changes may entail some supplemental analysis for some of the completed 10 risk evaluations, our goal is to do that extra work only when a failure to do so would lead to a less protective outcome once we get to the rulemaking stage. A great deal of work and analysis was done as part of these risk evaluations, and the faster we can move into the risk management phase, the faster we can begin to provide the chemical safety protections the law promised, and the faster we can get our TSCA implementation efforts back on track.

One key policy change we are already implementing is to reverse the previous administration's assumption that personal protective equipment, or PPE, is always used by workers in certain occupational settings. There is clear evidence that PPE is not always an effective control measure to protect workers. And evidence indicates that PPE is not always provided to workers, not always maintained properly, not always replaced as needed, or not always used correctly. Additionally, state and local government workers in states that do not have an OSHA-approved State Plan and self-employed workers are not covered by the Occupational Safety and Health Administration, or OSHA, worker protection standards. As such, we will no longer simply

assume that all workers are always properly protected with PPE when we make our risk determinations, although we will continue to analyze this and other occupational risk scenarios in the risk evaluations. Instead, the EPA will consider any information on the use of PPE, or other ways that industry protects its workers, as a potential way to address unreasonable risk during the risk management process. We fully recognize that many companies do provide and require PPE for their workers, comply with applicable OSHA standards, and go well beyond what OSHA requires to keep their employees safe. We have been in close consultation with OSHA and the National Institute for Occupational Safety and Health in order to ensure that our rules will reflect a sensible consideration of all the real-world steps companies take to protect their workers in the risk management phase.

Another key change we've been pursuing on our risk evaluations is to reincorporate analysis of specific exposure pathways – for example, exposures through air or water – that were excluded from consideration in most risk evaluations by the previous administration based on arguments that the exposures were, or theoretically could be, regulated under other EPA-administered laws. This approach likely left some chemical exposures to the general population unaccounted for, including exposures to fenceline communities that are near industrial facilities and that may be disproportionately exposed to the substance over a long period of time. While TSCA is not intended to substitute for laws like the Clean Air Act or the Safe Drinking Water Act, TSCA does require us to assess exposures that occur when people breathe air or drink water that contains the chemical substance being evaluated. And under Executive Order 12898, this administration is incorporating environmental justice and equity considerations into our decisions.

As a first step towards ensuring that the failure to account for these exposures in many of the first 10 risk evaluations will not lead to rules that are not as protective as they should be the EPA will evaluate additional relevant exposure routes using a screening methodology to account for fenceline communities' air and/or water exposures and determine whether they present unreasonable risks. If the screening methodology shows that there are not likely added fenceline community risks for a substance, we will advance to rulemaking quickly. But if the screening methodology indicates unreasonable risk that the Agency couldn't effectively address without revisiting the underlying risk evaluation, we will perform additional analysis and supplement the risk evaluation prior to proposing a rule. In so doing, we are following the law and ensuring protections for these vulnerable populations.

In terms of next steps on each of the 10 completed risk evaluations, the EPA plans to apply the screening methodology to assess the potential for fenceline air or water exposures for six chemicals: methylene chloride (MC), trichloroethylene (TCE), carbon tetrachloride, perchloroethylene, N-Methyl-2-pyrrolidone (NMP), and 1-bromopropane. For 1,4-dioxane, it is clear that the risk evaluation finalized under the previous administration did not include all exposure pathways or conditions of use, and we have determined we will need to proceed with a supplemental analysis. It is my belief that of the first 10 chemicals, 1,4-dioxane will probably be the last to undergo rulemaking. For the remaining three chemicals – HBCD, PV29, and asbestos (part 1) – we believe that the completed risk evaluations are likely sufficient to inform the risk management approaches being considered, and that these approaches will be protective.

Asbestos has always been the poster child for TSCA reform. Despite the undeniable risks to human health supported by years of analytical effort, the EPA tried – and largely failed – to regulate asbestos under old TSCA. It was only fitting that the EPA selected asbestos as one of its first 10 risk evaluations – an opportunity to confirm whether TSCA's new risk-based safety standard will finally support strong public health protections. It is also likely to be the first risk management rule to be proposed. We expect to send that proposed rule to the Office of Management and Budget for interagency review before the end of this year. Around the same time, we are also aiming to release of a draft scope for "part 2" of the asbestos risk evaluation, which will cover legacy uses, associated disposals, and all fiber types.

I also want to highlight some of the significant work we have been doing to improve implementation of the TSCA new chemicals program. From the start of the Biden-Harris administration, we were asked to comprehensively review our policies, procedures, guidances, and regulations to ensure they adhere to statutory requirements, new executive orders, and other directives. For the TSCA new chemicals program, this has been an opportunity for a reset – a realignment of the program with both the overall mission of the Agency and the statutory objectives in TSCA. We are renewing our focus on what matters most: conducting risk-based assessments of new chemicals; identifying potential risks to human health or the environment; and addressing those risks prior to new chemicals entering commerce.

As part of this effort, for example, we announced important changes to ensure that our determinations on new chemicals and associated risk management efforts provide appropriate protections for workers. We also announced the end of a practice that previously allowed the

EPA to greenlight new chemicals based on our review of just a subset of their uses, instead of the consideration of all intended, known as reasonably foreseen "conditions of use" as anticipated by Congress.

More broadly, the EPA's new chemicals program has been engaging in targeted, all-hands-on-deck efforts to catalogue, prioritize and improve its procedures, recordkeeping and decision-making practices related to review and management of new chemicals under TSCA. We expect more forthcoming announcements and changes in policy and process based on this work. In addition, the new chemicals program has already implemented several important changes to provide additional opportunities for resolution of differing scientific opinions, and to allow input into the decision-making by EPA subject matter experts outside of the division. This includes, for example, a revised process for review and finalization of human health risk assessments, and the formation of a new advisory body within the program to review and consider both scientific and science policy issues related to new chemical submissions.

Importantly, we are also working to promote a culture of respect, collaboration and collegiality in OCSPP. Last month, starting with the new chemicals program, OCSPP initiated a process to capture feedback from employees and management about any potential workplace barriers and opportunities for improvement. We expect to learn a great deal from this effort and will use the feedback to inform changes in OCSPP's work practices moving forward.

I do want to acknowledge some of the concerns with respect to speed of new chemical reviews. I can assure you that there is no one in OCSPP who does not want to improve our efficiency. And

it is true that TSCA imposes a statutory deadline for completing reviews of new chemicals, and that some submissions have been in the queue for long periods of time. But it is not true that the program has ground to a halt in the face of the policy changes we've made. The number of chemicals under review by the EPA at any given time fluctuates based on the volume of submissions and other factors, but, typically, that number has been around 300 cases. The previous administration issued a press release in August 2017 in which it declared that the 308 chemicals with EPA for review at that time represented a "typical active workload." As of October 12, 2021, the number of cases with EPA for review stands at 319. And 50 of those cases are actually awaiting action from the submitter, not EPA, bringing the number of cases actually awaiting EPA action down to 269.

The program continues to work expeditiously to review new chemical submissions – respecting both the statutory timeframes and the point of the law, which is to ensure that reviews result in decisions that are protective of human health and the environment. We believe that the added resources in the President's FY 2022 Budget will help us do better at achieving both of these goals.

Lastly, I want to echo the sentiments of Administrator Regan in his recent announcement on perand poly-fluorinated substances, or PFAS, and addressing the urgent public health and
environmental threat they pose to communities across the United States. PFAS can be found
nearly everywhere - in surface water, groundwater, soil, and air, and from remote rural areas to
densely-populated urban centers. A growing body of scientific evidence shows that exposure at
certain levels to specific PFAS can adversely impact human health. Despite these concerns,

PFAS continue to be used in many products and processes. Since April 2021, the new EPA PFAS Council has been working to develop a comprehensive strategy, building on the agency's prior and ongoing work, to both better understand and ultimately reduce the potential risks caused by these chemicals. And just last week, the EPA Administrator released the PFAS Strategic Roadmap – a description of EPA actions leveraging a range of statutory authorities and a whole-of-agency approach to guide us on a meaningful path to safeguard communities from PFAS contamination. I'd like to briefly describe some of the actions my office is taking to address PFAS.

One of the biggest challenges we face is that most of the hundreds of PFAS that are in commerce have limited or no toxicity data, which means we can't write a drinking water standard or set a clean-up level, because we can't characterize the health effects of these substances. If we continue to work on this one PFAS at a time, we will never be able to fully understand or address the risks from these substances. Last week, as part of the release of the Roadmap, the Agency announced a National PFAS Testing Strategy. The strategy builds upon the work of Congress in the 2020 National Defense Authorization Act, which called on the EPA to group PFAS into categories based on potential for human exposure to, toxicity of, and other available information. For each category, we are also scouring all sources of information to identify important gaps in existing data and to select representative chemicals within identified categories for additional testing. TSCA section 4 provides us with the authority to order PFAS manufacturers to develop and pay for this new information. We plan to issue the first test orders to PFAS manufacturers later this year, and will be prioritizing PFAS categories for which we lack human health effects data. These orders will provide the agency with critical information on more than 2,000 other

similar PFAS that fall within the categories. In addition, we are working to finalize our new PFAS reporting rule under TSCA section 8 and to enhance our collection of PFAS data through the Toxics Release Inventory or TRI program – both requirements of the 2020 NDAA - which will ultimately provide the EPA with better data to inform our future research, monitoring, and regulatory efforts.

The EPA also plays an important gatekeeper role in ensuring the safety of new chemicals — including new PFAS - before those chemicals first enter U.S. commerce. As strengthened in the 2016 amendments, the process under TSCA now requires that, for all new chemicals, the EPA make an affirmative determination regarding the potential for risks. And where risks are identified, the EPA must first mitigate those risks before any manufacturing activity can commence. Since early 2021, my office has taken steps to ensure that new PFAS are subject to rigorous reviews and appropriate safeguards, in addition to the broader efforts we've been making to strengthen new chemical reviews under TSCA. Based on the complexity of PFAS chemistry, potential health effects, and their longevity and persistence in the environment, we have also taken a new stance on allowing new PFAS onto the market through certain exemptions that don't allow time for a sufficiently rigorous safety review. In April 2021, we announced that we generally expect to deny pending and future PFAS low volume exemption submissions, or LVEs, and launched a stewardship program to encourage companies to voluntarily withdraw previously granted PFAS LVEs.

The EPA is also taking a close look at PFAS already on the market. Some PFAS were never reviewed through the TSCA new chemicals program before it was strengthened in the 2016

TSCA amendments. We have identified instances where protections are non-existent or insufficient. Under TSCA section 5, we could impose additional notice requirements to ensure that the EPA has the opportunity to further review those PFAS before they are used in new ways that might present concerns. Other PFAS have not been actively manufactured for many years, or may have a subset of past uses that have been abandoned. Absent restriction, however, manufacturers are free to begin using those abandoned chemicals or resume those abandoned uses at any time. We're considering how to use the TSCA "significant new use" authority to help close the door on unsafe PFAS or uses, and to ensure that any new uses or new PFAS do not cause additional air and water pollution.

In conclusion, I am fully committed to getting our TSCA implementation efforts back on track and to using those authorities to ensure protections against dangerous chemicals for the American people. I welcome and appreciate Congress' support to this end. Thank you again for the opportunity to testify today, and I look forward to your questions.