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10
11 **UNITED STATES DISTRICT COURT**
12 **NORTHERN DISTRICT OF CALIFORNIA**
13 **SAN FRANCISCO DIVISION**

14 FOOD & WATER WATCH, INC., et al.,

15 Plaintiffs,

16 v.

17 UNITED STATES ENVIRONMENTAL
18 PROTECTION AGENCY, et al.,

19 Defendants.

Case No. 3:17-cv-02162 EMC

**DECLARATION OF
BRANDON N. ADKINS IN
SUPPORT OF DEFENDANTS’
OPPOSITION TO PLAINTIFFS’
MOTION TO LIFT THE STAY AND
TAKE THE CASE OUT OF
ABEYANCE, AND CROSS-MOTION
TO LIFT STAY TO DECIDE
MERITS ON TRIAL RECORD**

20 I, Brandon N. Adkins, submit the following declaration in support of Defendants’ Opposition to
21 Plaintiffs’ Motion to Lift the Stay and Take the Case Out of Abeyance, and Cross-Motion to Lift Stay to
22 Decide Merits on Trial Record:

23 1. I am a trial attorney within the Environment and Natural Resources Division of the United
24 States Department of Justice and lead counsel for Defendants in the above-captioned case.

25 2. In July 2022, Dr. Ellen Chang, Defendants’ expert epidemiologist in this case, informed
26 me that she is no longer available as an expert witness.

27 3. Based on a review of our records, the government has expended nearly \$450,000 on
28 expert witnesses (including fees paid to Plaintiffs’ experts) in this case.

4. Exhibit A is a copy of the Testimony of Michal Ilana Freedhoff, Assistant Administrator,
Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency, before the
Senate Committee on Environment and Public Works, on June 22, 2022.

1 I declare under penalty of perjury that the foregoing is true and correct.

2 Executed on September 26, 2022, in Washington, D.C.

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/s/ Brandon N. Adkins
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Exhibit A

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

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

JUNE 22, 2022

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The President's requested increase for TSCA, if enacted this fall, will be the type of investment the TSCA program needs to shift the trajectory and get it back on the right track

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

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

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

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

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

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

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

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

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

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

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

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

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

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