ORAL ARGUMENT NOT YET SCHEDULED
Case No. 22-1089

**UNITED STATES COURT OF APPEALS**
**FOR THE DISTRICT OF COLUMBIA CIRCUIT**

VINYL INSTITUTE, INC.,
*Petitioner*,
v.
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
*Respondent*.

On Petition for Review of a TSCA Chemical Testing Order of the United States Environmental Protection Agency

# BRIEF OF ENVIRONMENTAL DEFENSE FUND AND NATIONAL WILDLIFE FEDERATION AS AMICI CURIAE SUPPORTING ENVIRONMENTAL PROTECTION AGENCY

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## CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES AND CORPORATE DISCLOSURE STATEMENT

Pursuant to D.C. Circuit Rule 28(a)(1), the undersigned counsel for Amici Curiae certifies as follows:

### A. Parties and Amici

To counsel's knowledge, all other parties and amici appearing before this Court are as stated in the Brief of Respondent, United States Environmental Protection Agency ("EPA").

Pursuant to D.C. Circuit Rule 26.1, Environmental Defense Fund and National Wildlife Federation certify that they are nonprofit corporations that do not issue stock, have no parent companies, and in which no publicly held corporations have any form of ownership interest.

### B. Ruling Under Review

Reference to the EPA order under review appears in the Brief of EPA.

### C. Related Cases

This matter has not previously been before this Court or any other court, and Amici are not aware of any related cases.

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# GLOSSARY

| | |
|---|---|
| 1,1,2-TCA | 1,1,2-trichloroethane |
| EDF | Environmental Defense Fund |
| EPA | United States Environmental Protection Agency |
| NWF | National Wildlife Federation |
| TSCA | Toxic Substances Control Act |

## STATUTES AND REGULATIONS

Pertinent statutes and regulations appear in the addenda to the briefs of Petitioner, Vinyl Institute, and Respondent, EPA.

## INTEREST OF AMICI CURIAE[1]

### Environmental Defense Fund

Amicus Curiae Environmental Defense Fund ("EDF") is a national nonprofit organization that links science, economics, and the law to create innovative, equitable, and cost-effective solutions to urgent environmental problems. EDF is one of the world's largest environmental organizations, with hundreds of thousands of members across the United States and a staff of over 1,000 scientists, policy experts, and other professionals from around the world.

EDF was founded in 1967 to address the impacts of the toxic pesticide DDT, especially on osprey and bald eagles. Since then, EDF has continued to advocate for regulation of toxic chemicals. EDF played a central role in the 2016 bipartisan reform of the Toxic Substances Control Act ("TSCA"). In the decades before the law's passage, EDF staff published numerous reports documenting the original statute's problems, testified before congressional committees on the need for fundamental reform, and participated in many stakeholder meetings with EPA and congressional staff to discuss the needed changes.

Since passage of TSCA's 2016 amendments, EDF has closely tracked every aspect of implementation of the new law, continuously advocating for its health- and environment-protective implementation. EDF has filed thousands of pages of

[1] No people, other than Amici, authored this brief in whole or part, or contributed money to fund its preparation or submission.

comments on EPA's proposed actions and chemical risk evaluations, publicly reported on the Agency's policies and rules implementing the reforms, and engaged directly with EPA in public meetings, including of its Science Advisory Council on Chemicals.

**National Wildlife Federation**

Established in 1936, amicus curiae National Wildlife Federation ("NWF") is the largest non-profit conservation organization in the United States. Working in seven regions across the country, NWF has more than 7 million members and supporters and collaborates with 52 state and territory affiliates to protect wildlife populations and the communities that depend on them in a rapidly changing world. NWF is concerned about the protection of wildlife and people from the harmful effects of toxic chemicals. NWF believes that is vital that EPA have adequate information evaluate those risks.

NWF strongly supported the need for fundamental reform of TSCA, including to better protect wildlife from the adverse effects of toxic chemicals. Among other actions, NWF submitted letters of support for TSCA reform bills advancing in the House and Senate in 2015 and 2016 and urged final passage of a strengthened law. After passage, NWF provided comments to EPA on its proposed rule governing TSCA risk evaluations, urging that EPA conduct comprehensive assessments and use its full authority to obtain all information needed to do so.

**Interest of Amici in Filing**

This litigation falls squarely within EDF's and NWF's interests in appropriately ensuring that Congress's amendment of TSCA, which notably included major enhancements to EPA's authority to require chemical testing, is implemented in accord with Congressional intent. This case is the first to analyze a test order issued under the reformed TSCA, which for the first time gave EPA the authority to issue such orders, instead of requiring full rulemakings to require the development of test data. Amici are interested in filing this brief to help assure that a key purpose of Congress's reform of TSCA and of the original statute – to increase the development of information about chemicals of concern – is fulfilled.

**Authority to File**

EDF and NWF have authority to file this brief because EPA and Vinyl Institute have consented to their participation as amici curiae.

## SUMMARY OF ARGUMENT

Congress first enacted the Toxic Substances Control Act over 45 years ago with a primary goal of ensuring that adequate information would be available on the effects of chemicals on health and the environment. Congress was clear that those who manufacture and process the chemicals should bear the responsibility of developing this information. Congress sought to fulfill this purpose by allowing EPA to require companies to test their chemicals and provide the data to the Agency for evaluation.

In the years that followed, however, EPA struggled to use its authority, subjecting very few chemicals to testing. Concerned about this slow pace, Congress identified the problem as the procedures EPA was legally bound to follow: the Agency could require companies to test a chemical only through notice and comment rulemaking and only if it could make findings about the chemical's exposure or risks to health or the environment. Under these requirements, the Agency managed an average of less than one testing rule per year; in many years, it issued none.

Congressmembers recognized that bolstering EPA's authority to require chemical testing could have a "profound impact" on the efficiency and effectiveness of TSCA, and through numerous bills aimed at updating TSCA the legislators consistently proposed to expand EPA's powers to require chemical

testing. In 2016, when adopting its major reform of TSCA, Congress gave EPA the authority in Section 4 to issue orders to companies to test their chemicals. It also addressed the "Catch-22" the Agency often confronted, when it did not already have the information needed to make risk findings before it sought testing, by giving the Agency authority to require testing when it deemed the data necessary to determine a chemical's risk.

The new authority is critical to EPA's ability to fulfill its enlarged duties under the amended TSCA to fully evaluate chemicals it deems high priority, such as the chemical at issue in this petition, 1,1,2-trichloroethane. Existing data indicates that the chemical, which is produced by companies represented by Petitioner, Vinyl Institute, is toxic to birds. However, data that would allow EPA to evaluate the extent of the chemical's risk to birds is lacking, and this data gap led EPA to issue the challenged test order. The information sought will enable EPA to determine if the chemical is risky to birds at a level likely to result from its production and use, and will allow the Agency to craft regulation, if necessary, that is specifically tailored to address the risk.

In its brief, Vinyl Institute insists that EPA should have justified its test order by effectively determining the chemical's risk absent the requested information. Such an approach would place higher burdens on EPA in developing test data than it faced even before TSCA's reform. Vinyl Institute's preferred

procedure could also make it impossible for EPA to justify some or all of its test orders, as the Agency may be forced to provide up front the same information it lacks and seeks through its orders. In addition, Vinyl Institute claims that it should have a right to advance notice of a test order and an opportunity to tell EPA whether the order should be issued. But this position ignores the history, structure, and purpose of the 2016 reforms of TSCA, by which Congress explicitly afforded EPA the power to issue a test order when the Agency deemed it necessary for obtaining information on a high-priority chemical to determine its risk and decide what regulation of the chemical, if any, is necessary to protect health and the environment.

## ARGUMENT

### I. Congress gave EPA authority to issue test orders to fulfill a key TSCA policy and address decades of inadequate chemical safety review

#### A. Ensuring the development of test data by chemical manufacturers and processors is a foundational TSCA policy

This Court has recognized that "one of the chief policies" of TSCA is that:

> [A]dequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures.

*Chemical Mfrs. Ass'n v. EPA*, 859 F.2d 977, 980 (D.C. Cir. 1988) (citing the Toxic Substances Control Act, Pub. L. No. 94-469, § 2, 90 Stat. 2003 (Oct. 11, 1976)). Accordingly, Section 4 of TSCA, 15 U.S.C. § 2603, which provides for the testing of chemicals to determine their effect on health and the environment, has been

deemed one of the Act's "most important provisions." *Dow Chemical Co. v. EPA*, 605 F.2d 673, 676 (3d Cir. 1979). TSCA's focus on chemical data development stemmed from Congressional concern that, in the absence of a comprehensive chemical law, the environment and humans themselves would serve as test subjects:

> Presently, the Nation['s] population and environment provide testing grounds for determining the effects a toxic substance has on human or environmental health. The authority contemplated by the Toxic Substances Control Act would establish requirements for testing substances believed to pose an unreasonable risk before they are dispersed by various means throughout the environment and are difficult, if not impossible, to control.

*National Resources Defense Council, Inc. v. EPA*, 595 F. Supp. 1255, 1258 (S.D.N.Y 1984) (quoting H. Rep. No. 94-41, 94th Cong., 1st Sess. 213 (1975)).

### B. Before TSCA's reform, EPA rarely had adequate or timely information for the regulation of toxic chemicals when it was compelled to make findings to require testing through rulemaking

Before TSCA's reform in 2016, Section 4 limited EPA to requiring testing on substances only if the Agency could make certain findings about their exposure or risks to health or the environment. Pub. L. No. 94-469, § 4 (1976). Further, it could only require testing through resource-intensive notice and comment rulemaking. *Id*. Therefore, when Congress began to look seriously at TSCA reform starting in the late 2000s, it had over three decades of evidence before it about whether EPA had been effective in requiring the development of test data when confined by those limitations. The consensus was that the Agency had not been able to be

effective. "By most accounts, TSCA is badly in need of reform," said Representative Bobby Rush, chair of the House subcommittee responsible for TSCA oversight, in 2009. *Revisiting the Toxic Substances Control Act of 1976: Hearing Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm on Energy and Commerce*, 111th Cong. 7, at 1 (2009). He described, as a key concern, the failure of TSCA's original promise to develop information on the effects of chemicals:

> Even though sections 4 and 5 authorize EPA to force companies to test their chemical products and generate data, the hoops that the EPA must jump through in order to exercise this authority have been much too burdensome. Rulemaking takes years to finalize, costs hundreds of thousands of dollars and is subject to constant legal action by companies who do not want to comply. As the former EPA assistant administrator once said, it [*sic*] almost that we have to first prove that the chemicals are risky before we have the testing done to show whether the same chemicals are indeed risky.

*Id.* at 2.

To take a historical example, a full seven years after Congress had promulgated original TSCA, EPA had failed to finalize a single chemical test rule. *National Resources Defense Council*, 595 F. Supp. at 1261. The Southern District of New York observed that "Congress could not have intended (or envisioned) this result," *id.,* and ruled that the Agency had unreasonably delayed mandatory action on certain years-old testing proposals. *Id.* at 1269-1270.

In the years following, EPA continued to be hamstrung in issuing test rules. In 1994, Lynn Goldman – then leading the EPA office administering TSCA – told Congress:

> [W]e still are not closing the testing gaps at a pace originally envisioned by TSCA. The statute puts a significant burden on EPA, both in the findings it must make and the processes it must use, to obtain needed test data … [A] more effective and efficient procedure for promulgating testing requirements would significantly strengthen our ability to obtain priority test data in a reasonable timeframe.

*Reauthorization of the Toxic Substances Control Act: Hearings Before the Subcomm. on Toxic Substances, Research and Development of the Sen. Comm on Environment and Public Works*, 103rd Cong. 776, at 48 (1994).

A decade later, another official leading EPA's TSCA office, James Jones, testified that EPA still faced significant challenges in requiring testing under original TSCA because of the rulemaking requirement and because EPA also had "to make a finding that we have some reason to believe there may be an unreasonable adverse effect for such chemicals … You want the data because you don't know but you need to know something before you compel it." *The TSCA Modernization Act of 2015: Hearing Before the Subcomm. on Environment and the Economy of the H. Comm. on Energy and Commerce*, 114th Cong. 30, at 36 (2015). Even when the Agency managed to show potentially unreasonable adverse effects, it could only require testing through a rulemaking that would "take many, many years." *Id*.

As stark demonstration of the difficulty EPA has faced seeking chemical testing by way of rulemakings, EPA has issued less than one test rule a year on average over TSCA's 46 years. 40 C.F.R. part 799, subparts B and D (18 test rules issued). In recognition of these challenges, every TSCA reform bill introduced in Congress from at least as early as 2010 through the passage of the reform law in 2016 sought to expand EPA's powers to require testing by companies.[2]

Throughout, lawmakers repeatedly emphasized the need for this expansion. *See, e.g., Testing of Chemicals and Reporting and Retention of Information Under TSCA Sections 4 and 8*: *Hearing Before the Subcomm. on Environment and the Economy of the H. Comm. on Energy and Commerce*, 113th Cong. 114, at 2 (2014) (statement of Rep. John Shimkus) ("I want to remind everyone that last summer [the] former TSCA program director … testified before our committee that simply improving the way EPA is able to get information under Section 4 would have profound impact on improving TSCA's overall operation."); *Id*. at 89 (statement of Rep. Paul Tonko) ("With any reform, we must make sure EPA has adequate

[2] *See, e.g.*, Safe Chemicals Act of 2010, S. 3209, 111th Cong. (2010); Toxic Chemicals Safety Act of 2010, H.R. 5820, 111th Cong. (2010); Safe Chemicals Act of 2011, S. 847, 112th Cong. (2011); Safe Chemicals Act of 2013, S. 696, 113th Cong. (2013); Chemical Safety Improvement Act, S. 1009, 113th Cong. (2013); Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act, S. 725, 114th Cong. (2015); TSCA Modernization Act of 2015, H.R. 2576, 114th Cong. (2015); Frank R. Lautenberg Chemical Safety for the 21st Century Act, S. 697, 114th Cong. (2015).

authority to require testing to protect human health and the environment."); *The TSCA Modernization Act of 2015*, 114 Cong. 30, at 36 (2015) (statement of Rep. Diana DeGette) ("This discussion draft includes an important change to EPA's authority under section 4 of TSCA by empowering the EPA to require testing through order rather than rulemaking."); 162 Cong. Rec. S3513 (daily ed. June 7, 2016) (statement of Sen. Tom Udall) ("Today, the old TSCA puts burdensome testing requirements on the EPA. To test a chemical, the EPA has to show a chemical possesses a potential risk, and then it has to go through a long rulemaking process. Very soon, EPA will have authority to order testing without those hurdles.").

Congress's recognition of the high barriers to EPA requiring test data development contributed to its overall concern that the original version of TSCA was not achieving its purpose:

> In the nearly 40 years since TSCA's enactment, there have been persistent concerns about the pace of the EPA's work on chemicals, the ability of the Agency to meaningfully use its existing authority, and whether the statute prevents certain regulatory efforts.

162 Cong. Rec. H3026 (daily ed. May 24, 2016) (statement of Rep. Fred Upton).

## II. EPA's use of the expanded test authority is critical for effective regulation of toxic chemicals

Congress's years of concern about EPA's lack of effective authority to require companies to test their chemicals culminated in Congress expanding the

Agency's authority, reducing its burden, and simplifying its procedures. First, Congress granted EPA the authority to require testing through orders and consent agreements. Pub. L. No. 114-182 (June 22, 2016); 15 U.S.C. § 2603(a). In addition, along with the amended law's "separate risk evaluation process for determining whether a chemical substance presents or will present an unreasonable risk of injury," and tight deadlines for doing so, Congress gave EPA the power to issue orders for testing when the Agency deemed test data necessary to perform the risk evaluations. *Safer Chems. v. EPA*, 943 F.3d 397, 407 (9th Cir. 2019) (citing H.R. Rep. No. 114-176, at 23, 25(2015)); 15 U.S.C. § 2603(a)(2)(A)(i).

For this purpose, EPA is not required, as it was before the law was reformed, first to make a finding that a chemical "may present an unreasonable risk" or is or will be produced in substantial quantities that may lead to significant exposure to humans or the environment. 15 U.S.C. § 2603(a)(1). In celebrating the House's passage of the reform bill, Representative Gene Green stated that the expanded testing authority was one of the "most notable improvements" to TSCA. 162 Cong. Rec. H3029 (daily ed. May 24, 2016).[3] Through this improvement, Congress had addressed "two significant shortcomings identified in [the original] TSCA":

[3] "The most notable improvements in the bill are replacing current TSCA's burdensome safety standard with a pure, health-based standard; explicitly requiring the protection of vulnerable populations, like children, pregnant women, and workers at the plants; requiring a safety finding before new chemicals are allowed

> The requirement that testing be conducted only through rulemaking; and the 'Catch-22' that EPA must first make a finding of potential 'unreasonable risk' or substantial production and release or exposure before it can require testing by manufacturers or processors.

S. Rep. No. 114-67, at 10 (2015) (describing proposed amendments that were reflected in the bill that became law).

Congress also directed EPA in 2016 "to prioritize evaluations of the risks of chemicals considered to be the most dangerous," and then to regulate such substances. *Safer Chems.*, 943 F.3d at 407 (2019). Per that process, the chemical at issue in this petition was deemed such a "high-priority chemical," and is therefore undergoing a risk evaluation. 84 Fed. Reg. 71,924, 71,934 (Dec. 30, 2019). To determine the risk of a high-priority chemical, EPA must evaluate the hazards and exposures arising from all circumstances under which the chemical "is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4); EPA, *About Risk Assessment* (June 2022), https://www.epa.gov/risk/about-risk-assessment#whatisrisk. To make this broad determination on a sound basis, it is critical that EPA gather sufficient information about the chemical. "EPA's statutory authority is significant, and it must consider information from a wide variety of sources to make a holistic final risk assessment which informs its

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to go to market; and giving EPA new authority to order testing and ensure chemicals are safe, with a focus on the most risky chemicals." *Id.*

rulemaking efforts under Section 6 of TSCA." *Asbestos Disease Awareness Org. v. Wheeler*, 508 F. Supp. 3d 707, 721 (N.D. Cal. 2020).

While the expanded statutory authority is significant, it is not self-executing; to complete comprehensive chemical risk evaluations, EPA must issue the test orders when needed. EPA's own Science Advisory Committee on Chemicals, in reviewing EPA risk evaluations completed during the previous Administration, expressed concern about the Agency's failure to robustly employ its test order authority to gather various categories of risk information, including to form a full picture of organisms' exposure to certain high-priority chemicals. *See, e.g.*, TSCA Science Advisory Committee on Chemicals, *Peer Review for EPA Draft Risk Evaluation[] for 1,4-Dioxane* (2019), EPA-HQ-OPPT-2019-0238-0063, at 41.

## III. EPA's challenged order seeks to fulfill TSCA's purpose of efficiently and fully assessing the high-priority chemical's risks through development of needed data

In 2019, EPA designated 1,1,2-trichloroethane ("1,1,2-TCA") a high priority under TSCA, and accordingly has been evaluating its risks. 84 Fed. Reg. at 71,934. The chemical, widely[4] used in plastics and petrochemical manufacturing, can biodegrade into vinyl chloride, a chemical that causes multiple types of cancers in

[4] In most years since the 1980s, more than 100 million pounds of 1,1,2-TCA have been imported into or produced in the United States. EPA, *Use Report for 1,1,2-Trichloroethane* (Jan 2020), EPA-HQ-OPPT-2018-0421-0018, at 2-1, 2-2.

humans.[5] Based on the observed respiratory, neurological, and immunological harm caused by 1,1,2-TCA to animals, 1,1,2-TCA is presumed to cause such health effects in humans. *Toxicological Profile for 1,1,2-Trichloroethane* at 1-7, 11.

EPA has ordered five companies it identified as manufacturers and/or processers of the chemical to assess its potential chronic toxicity to birds. EPA's Response to Petitioner's Motion to Make Additional Submissions to the Record (Doc. No. 1964616), Exhibit A, at 19-21. The companies will split the costs of the testing as part of a cost-sharing consortium managed by Vinyl Institute. Petitioner's Brief at 1, 21.[6]

In its order, EPA explained to the Vinyl Institute companies that, although the previous Administration had issued a test order for 1,1,2-TCA, it had not included the key tests necessary to evaluate the toxicity of the chemical to aquatic

[5] *See, e.g.*, U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, *Toxicological Profile for 1,1,2-Trichloroethane* (March 2021), https://www.atsdr.cdc.gov/ToxProfiles/tp148.pdf, at 75; National Cancer Institute, *Vinyl Chloride* (Nov. 2022), https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/vinyl-chloride.

[6] Vinyl Institute represents manufacturers of vinyl chloride, polyvinyl chloride (PVC), and other chlorinated chemicals, including 1,1,2-TCA. Vinyl Institute, *Who We Are*, https://www.vinylinfo.org/who-we-are/; Petitioner's Brief at ii. As of March 2023, the Four Vinyl Institute members who received the test order – Occidental Petroleum ("Oxy"), Formosa Plastics, Westlake, and Shintech/Shin-Etsu (C-K Tech) – had a market capitalization of over $50 billion. Vinyl Institute, *Our Members*, https://www.vinylinfo.org/our-members/; Yahoo!Finance, https://finance.yahoo.com/ (market capitalization search on March 27, 2023).

and terrestrial organisms. Therefore, EPA ordered those tests to determine hazards to those animals. Response to Petitioner's Motion (Doc. No. 1964616), at 25-26. Indeed, during the risk evaluation process for any high-priority chemical, EPA may discover information gaps about the substance under review that must be filled in to adequately assess its risks. The Agency must be able to act quickly to fill these gaps so that the information can be incorporated into its evaluation to avoid delayed – or, even, scientifically incomplete – risk evaluations.

In its brief, Vinyl Institute focuses on the potential costs of the ordered tests to its cost-sharing consortium of companies. However, in a key reform of TSCA, Congress directed EPA not to take into account costs, or any other "non-risk factors," in determining whether a chemical poses unreasonable risk. 15 U.S.C. § 2605(b)(4)(F)(iii); *Labor Council for Latin Am. Advancement v. EPA*, 12 F.4th 234, 243 (2d Cir. 2021). While EPA must consider relative costs when choosing among protocols for ordered testing, 15 U.S.C. § 2603(b)(1), any argument that EPA is precluded because of cost from ordering the development of data needed to determine that chemical's risk must be rejected under TSCA.

Moreover, Vinyl Institute ignores potential benefits of chemical information development for the TSCA risk evaluation and risk management process. For example, the development of needed test data has the potential not only to allow EPA to identify risk, but also to exclude it. In regard to the challenged order, the

limited existing data indicate that 1,1,2-TCA is developmentally toxic to birds. However, the ordered testing could demonstrate that the chemical causes toxicity only at high levels and is risky only at a level of exposure unlikely to result from its production and use. In such a manner, information sought by test orders can lead to more tailored and potentially lower-cost risk management.

## IV. Vinyl Institute's preferred requirements for test orders are infeasible and contrary to TSCA

A TSCA test order is a tool for EPA to use to require the development of information needed to make sound determinations of the chemical's toxicity or exposure. However, Vinyl Institute argues that as a prerequisite to using the tool to develop information about its member companies' high-priority chemical, EPA must effectively pre-determine the chemical's level of risk. Petitioner's Brief at 36, 51-54.[7] Vinyl Institute's proposed procedure would make such a test order impossible to justify, as the Agency would have to already have the information it seeks. Moreover, in reforming TSCA, Congress intentionally lowered the bar for EPA to seek testing to identify chemicals like 1,1,2-TCA and to evaluate the risks of these high-priority substances. In using its additional authority, EPA is not required, as Vinyl Institute would have it, to demonstrate that such a chemical

[7] Vinyl Institute also attempts to undermine EPA's test order by posing its own risk assessment, which is scientifically deeply flawed, as a reason that EPA should not collect data needed to conduct a scientifically robust risk assessment. Respondent EPA's Initial Brief at 46-52.

poses a risk. Under Vinyl Institute's approach, the bar for EPA to exercise its test requirement authority would be raised even higher than it was before TSCA reform.

### A. It is contrary to TSCA to demand risk findings to justify orders for test data needed for the purpose of evaluating risk

Through its reform of TSCA, as described above, Congress gave EPA the ability to require testing where the Agency determines the information is necessary to complete a risk evaluation. Before that amendment, EPA was required to first make findings about potential risk or exposure to seek such testing. Pub. L. No. 94-469, § 4 (1976). Even when the Agency was subject to this earlier requirement, this Court recognized that it must not be equated with that required for the regulation of a chemical under TSCA. *Chemical Mfrs. Ass'n v. EPA*, 859 F.2d 977, 979 (D.C. Cir. 1988) ("The Act provides, not surprisingly, that the level of certainty of risk warranting a section 4 test rule is lower than that warranting a section 6 regulatory rule.") *See also id.* at 986 n.10. The Court cited a House report on the bill that became TSCA:

> Such a finding would defeat the purpose of the section, for if the Administrator is able to make such a determination, regulatory action to protect against the risk, not additional testing, is called for.

*Id.* at 985 (citing H.R. Rep. No. 1341, 94th Cong., 2d Sess. 17-18 (1976)). Now that EPA may order testing for risk evaluations without first having to make a finding about potential risk, it is even more indisputable that Congress did not

intend nor require the Agency to justify decisions to seek information on the basis of a determination regarding the level of risk posed by the chemical, as Vinyl Institute would appear to have it.

### B. Vinyl Institute's approach, if adopted, would undermine EPA's risk evaluation process

Vinyl Institute's attempt to limit EPA's use of the additional authority provided by Congress and to raise the test order bar is not only inconsistent with the statute but would undermine EPA's ability to implement TSCA in a way that protects public health and the environment. EPA often is unable to adequately determine a chemical's hazards or levels of exposure at which the chemical causes risks before obtaining the kind of information it seeks from Vinyl Institute in the challenged order; indeed, the purpose of risk evaluation test orders is to obtain the information necessary to determine hazard and exposure. If EPA were obligated to justify its test orders with hazard and exposure determinations, then in many cases the Agency would be unable to issue the orders at all. *Cf. Asbestos Disease Awareness Org.*, 508 F. Supp. 3d at 723, 727 ("EPA does not know what it does not know;" holding that EPA should have used its TSCA section 8 powers to collect information from companies about asbestos health risks). To require this of EPA would be to re-erect a "roadblock that … stymied the Agency for years," *Chemicals in Commerce Act: Hearing before the Subcomm. on Environment and the Economy of the H. Comm. on Energy and Commerce*, 113th Cong. 125, at 7

(2014) (statement of Rep. Harry Waxman), and that Congress specifically eliminated.

If EPA must again face such challenges, future chemical risk evaluations are likely to lack needed data. Reliant on deficient evaluations, the Agency would be unable to fulfill its duties under TSCA to comprehensively identify high-priority chemicals and determine whether these chemicals present unreasonable risks to human health and the environment, and, if so, to regulate them to the extent necessary to eliminate the risks. 15 U.S.C. § 2605.

The point of the ordered data development at issue in this case is to determine whether the high-priority chemical 1,1,2-TCA poses unreasonable risks to organisms, including what amounts of the chemical are potentially toxic to non-human animals. But Vinyl Institute is insisting that EPA should already have a refined picture of the chemical's risk – about both its hazard and exposure – before requiring testing on the toxicity of the chemical. Petitioner's Brief at 36 ("The Test Order would be unwarranted if birds are not exposed to 1,1,2-trichloroethane in amounts that are potentially toxic.") Apparently, Vinyl Institute prefers that EPA again be held back by the "Catch-22" that Congress long lamented and worked to fix. Sections I and II, *supra.*

## V. Vinyl Institute seeks to limit EPA's authority to issue test orders in favor of rulemakings or consent agreements

Although Vinyl Institute does not discuss the years of Congressional concern about the lack of chemical risk information, or the extent of Congress's support for increasing development of the information under TSCA, it does acknowledge that chemical testing was a driver of TSCA reform:

> EPA had grown concerned that it could only require that chemical manufacturers conduct toxicity testing through a notice and comment rulemaking process. Congress, therefore, granted EPA authority to issue test orders, without prior notice to the manufacturers, to help inform various agency activities, including newly required risk evaluations of certain chemicals to determine if they pose an unreasonable risk to health or the environment.

Petitioner's Brief at 18. And yet, Vinyl Institute insists without statutory support that EPA – before it issued the challenged test order – should have notified the test consortium companies of the Agency's plans, sought their input into whether the Agency should issue a test order, responded to all submissions, and revised or rescinded the order. Petitioner's Brief at 17, 22, 39. The demanded procedures closely resemble notice and comment rulemaking (except that the public would not be involved). But Congress made plain that EPA is no longer limited to notice and comment rulemaking in requiring chemical testing, and an argument that insists on involvement by the chemical industry before a test order is issued would erase this hallmark feature of TSCA reform.

Vinyl Institute's claim to have a right to advance notice and an opportunity to give input before EPA requires testing may also resemble the process EPA would use if seeking testing through a consent agreement with manufacturers. This is certainly an option available to EPA, but one to which it is plainly not limited. 15 U.S.C. § 2603(a). If Congress had intended every test requirement to be developed via bilateral negotiation with the chemical industry, it would not have delineated the test order and test consent agreement authorities as separate powers, either of which EPA may choose. *Id.*

EPA chose to require testing by order, and fully and sufficiently described its need for the ordered information. Respondent EPA's Initial Brief at 17-36. But the Agency also took a substantial and voluntary step in its order of giving Vinyl Institute's members the opportunity to provide information, for EPA's review. Response to Petitioner's Motion (Doc. No. 1964616) at 23. Vinyl Institute and its companies never took this opportunity, indicating that the intent behind the petition may be less about the specific test order than about mounting a challenge to EPA's general authority. *See* Petitioner's Brief at 3 ("This case involves EPA's authority under TSCA to issue test orders requiring chemical manufacturers, without prior notice, to conduct time-consuming and expensive toxicity testing on their products without adequately demonstrating a need for such data.")

Vinyl Institute protests that it "never had a chance to file comments or materials in the record." Petitioner's Brief at 22. But this was not a rulemaking, and Congress's grant of test order authority was intended to give EPA the flexibility to choose the most efficient way to gather needed information about high-priority chemicals, comprehensively determine their risks, and then regulate them as necessary to protection health and the environment.

## CONCLUSION

For all the reasons set forth above and in EPA's Initial Brief, this Court should deny Vinyl Institute's Petition and Rule 19(b) Motion.

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

This brief complies with the requirements of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7)(B) because, excluding the parts exempted by Federal Rule of Appellate Procedure 32(f) and D.C. Circuit Rule 32(e)(1), the brief contains 5,386 words.

This brief also complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this document has been prepared in Microsoft Word, using 14-point Times New Roman font, a proportionally spaced typeface.

*/s/ Samantha Liskow*
Samantha Liskow

**CERTIFICATE OF SERVICE**

I certify that today I electronically filed this Amici Curiae brief on all registered counsel through the Electronic Case Filing (ECF) system for the United States Court of Appeals for the D.C. Circuit.

DATED: March 27, 2023

*/s/ Samantha Liskow*
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