ORAL ARGUMENT NOT YET SCHEDULED

No. 22-1089

THE 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 U.S. Environmental Protection Agency's
TSCA Test Order
EPA-HQ-OPPT-2018-0421

BRIEF OF *AMICUS CURIAE* AMERICAN CHEMISTRY COUNCIL IN SUPPORT OF PETITIONER VINYL INSTITUTE, INC.

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), *Amicus Curiae* American Chemistry Council (ACC) certifies the following:

(A) **Parties and *Amici***.

Except for the following, all parties appearing in this Court are listed in the Petitioner's Opening Brief. Physicians Committee for Responsible Medicine and People for the Ethical Treatment of Animals have notified this Court they intend to participate as *amici curiae*.

(B) **Rulings Under Review.** This petition challenges a test order issued by the United States Environmental Protection Agency (EPA) pursuant to Section 4(a)(2) of the Toxic Substances Control Act. EPA, Order Under Section 4(a)(2) of the Toxic Substances Control Act, Docket ID No: EPA-HQ-OPPT-2018-0421 (amended version dated August 5, 2022) (JA001– 032).

(C) **Related Cases.** An accurate statement regarding related cases appears in the Brief for Petitioner.

FEDERAL RULE 26.1 DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and D.C. Circuit Rule 26.1, *Amicus Curiae* ACC hereby submits the following corporate disclosure statement:

ACC states that it is a non-profit, tax-exempt organization incorporated in New York. ACC has no parent corporation, and no publicly held company has 10% or greater ownership in ACC.

STATEMENT REGARDING AUTHORSHIP, AND FINANCIAL CONTRIBUTIONS

ACC represents that no counsel for a party authored this brief in whole or in part, and no person other than the *amicus curiae*, its members, or its counsel contributed money that was intended to fund the preparation or submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E).

STATEMENT REGARDING SEPARATE BRIEFING

Pursuant to D.C. Circuit Rule 29(d), counsel for *Amicus Curiae* ACC certifies that a separate brief is necessary to provide the broad perspective of the businesses that ACC represents. *Amicus Curiae* is particularly well-suited to provide the Court important context on these subjects, which will assist the Court in resolving this case.

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*Authorities upon which *Amicus Curiae* ACC chiefly relies are marked with asterisks.

GLOSSARY OF TERMS

ACC	American Chemistry Council
EPA	U.S. Environmental Protection Agency
TSCA	Toxic Substances Control Act
OPP	Office of Pesticide Programs

STATUTES AND REGULATIONS

All applicable statutes, etc., are contained in the Brief for Petitioner.

STATEMENT OF *AMICUS CURIAE* REGARDING IDENTITY, INTEREST AND AUTHORITY TO FILE

ACC is a trade association representing leading companies engaged in the multibillion-dollar business of chemistry. ACC members apply the science of chemistry to make innovative products, technologies, and services that make people's lives better, healthier, and safer. ACC is committed to improved environmental, health, safety, and security performance through Responsible Care®; common sense advocacy addressing major public policy issues; and health and environmental research and product testing. ACC members and chemistry companies are among the largest investors in research and development, and are advancing products, processes, and technologies to address climate change, enhance air and water quality, and progress toward a more sustainable, circular economy.

ACC participates on behalf of its members in administrative proceedings and, at times, in litigation arising from those proceedings. ACC members manufacture (including import) and process some of the high-priority substances that have been identified by EPA for risk evaluation under the Toxic Substances Control Act (TSCA). Several ACC members are also subject to the January 2021 and March 2022 test orders issued by EPA under TSCA Section 4(a) and ACC

manages consortia responding to EPA test orders for five of these chemical substances.[1]

Pursuant to Federal Rule of Appellate Procedure 29(a)(2), all parties have consented to ACC's filing of an *amicus* brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

EPA has regularly failed to meet its statutory obligations when exercising its relatively new test order authority. EPA fails to show that the test orders are necessary and to implement tiered approaches to testing, as TSCA requires. This has resulted in significant cost to industry, since these tests can bear six-figure costs, and has resulted in delays to EPA's obligations to take actions under Section 6 of TSCA. EPA plans to increase its test order output to more than one per week, on average, highlighting that these problems would worsen if these practices were to continue.

ARGUMENT

I. EPA'S STATUTORY VIOLATIONS ESTABLISHED BY PETITIONER HAVE AND WILL PRESENT RECURRING PROBLEMS FOR INDUSTRY.

Petitioner correctly identifies numerous EPA statutory violations presented by the challenged Test Order Under Section 4(a)(2) of the Toxic Substances

[1] The chemical substances are 1,2-dichloropropane, o-dichlorobenzene, p-dichlorobenzene, tetrabromobisphenol A, and triphenyl phosphate.

Control Act [for 1,1,2-Trichloroethane] ("Test Order") (JA001 – 032).[2] ACC wishes to inform the Court that each deficiency identified by Petitioner has occurred in nearly every test order EPA has issued since TSCA was amended in 2016. Further, EPA expects the rate of test orders to increase dramatically in the next few years,[3] making it essential that EPA's unlawful pattern cease. If not halted by this court, ACC estimates that this could lead to millions of dollars in needless annual testing.

A. EPA Plans To Issue 75 Test Orders Per Year

Since TSCA was amended in 2016, EPA has issued test orders for twelve chemical substances, including 1,1,2-trichloroethane. The most recent of these test orders was issued on January 4, 2023, less than two weeks before Petitioner submitted its merits brief. EPA recently estimated it will increase that rate to 75 test orders per year between fiscal years 2023 – 2025.[4] If unaddressed by this

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[2] *Modification to Order Under Section 4(a)(2) of the Toxic Substances Control Act [for 1,1,2-Trichloroethane]*, EPA (Aug. 5, 2022), https://www.epa.gov/system/files/documents/2022-08/9544-01_testorder-112-tca_aa_signature.pdf.

[3] *Technical Support Document, Supplemental Notice of Proposed Rulemaking; Fees for the Administration of the Toxic Substances Control Act (TSCA) (RIN 2070-AK46)*, EPA at 2, https://downloads.regulations.gov/EPA-HQ-OPPT-2020-0493-0084/content.pdf ("The Agency believes it reasonable to assume that approximately 75 test orders per year will be initiated between fiscal year 2023 and fiscal year 2025.").

[4] *Id.*

Court, the problems described by Petitioner will recur on average more than once per week, perhaps indefinitely. They must be addressed now.

B. Other EPA Test Orders Contain The Same Level Of Conclusory Analysis Identified By Petitioner

Nearly all of the test orders issued by EPA since the 2016 TSCA amendments have used the same template and form language. Nearly all are similar in length and fail to contain a full record of EPA's review. Nearly all contain the same paragraph-long form language excusing EPA's failure to pursue a rule or consent agreement. In each such case, the sole justification for issuing an order is that the test order can be produced "more quickly."[5] This single reason,

[5] *See, e.g.*, *Modification to Order Under Section 4(a)(2) of the Toxic Substances Control Act [for 1,2-Dichloroethane]*, EPA at 8 (Aug. 5, 2022), https://www.epa.gov/system/files/documents/2022-03/9544-01_testorder-12-dca_aa_signature.pdf; *Order Under Section 4(a)(2) of the Toxic Substances Control Act [for 1,2-Dichloropropane]*, EPA at 10, https://www.epa.gov/system/files/documents/2022-06/9544-01_TestOrder%201%2C2_DCP_v2_signed.pdf (last visited Jan. 22, 2023); *Modification to Order Under Section 4(a)(2) of the Toxic Substances Control Act [for 4,4'-(1-methylethylidene)bis[2,6-dibromophenol] (TBBPA)]*, EPA at 9 (Aug. 5, 2022), https://www.epa.gov/system/files/documents/2022-03/9544-01_testorder-tbbpa_aa_signature.pdf; *Modification to Order Under Section 4(a)(2) of the Toxic Substances Control Act [for o-Dichlorobenzene]*, EPA at 10 (Aug. 5, 2022), https://www.epa.gov/system/files/documents/2022-03/9544-01_testorder_odcb_aa_signature.pdf; *Modification to Order Under Section 4(a)(2) of the Toxic Substances Control Act [for p-Dichlorobenzene]*, EPA at 8 (Aug. 5, 2022), https://www.epa.gov/system/files/documents/2022-03/9544-01_testorder-pdcb_aa_signature.pdf; *Modification to Order Under Section 4(a)(2) of the Toxic Substances Control Act [for Phosphoric acid, Triphenyl Ester]*, EPA at 8 (Aug. 5, 2022), https://www.epa.gov/system/files/documents/2022-08/9544-01_testorder-

offered every time, nearly word-for-word, cannot be what Congress intended when it commanded EPA to "explain why issuance of an order is warranted instead of promulgating a rule or entering into a consent agreement." 15 U.S.C § 2603(a)(3). These repeated violations can only be expected to continue – and accelerate – unless this Court acts.

C. EPA Has Not Developed Any Test Order Guidance

EPA has not developed any methodology or decision framework for issuing, revising, or extinguishing test orders. Because of this, it is not clear why certain substances are selected for testing and others are not or why a test is required for some substances but not others. It is also not clear why certain companies are selected to receive a test order and others are not.[6] Under EPA's current process, the only way to extinguish a test requirement is "Option 2," which, as discussed below, is typically ineffective, even when existing information is provided to the Agency. There is no process to incorporate tiered testing as required by the statute.

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tpp_a.pdf; *Modification to Order Under Section 4(a)(2) of the Toxic Substances Control Act [for trans-1,2-Dichloroethylene]*, EPA at 10 (Aug. 5, 2022), https://www.epa.gov/system/files/documents/2022-06/9544-01_TestOrder%20trans1%2C2%20DCE_v2_signed.pdf.

[6] For example, test orders requiring consumer exposure testing were not issued to the companies that make the consumer products to be tested. Instead, EPA is requiring manufacturers of the high-priority substance subject to the test order to locate, purchase, and test consumer products that are outside their business.

Without such guidance, EPA will continue to require unwarranted and imbalanced testing, without materially improving risk evaluation.

II. EPA HAS NOT SHOWN THAT THE TEST ORDERS ARE NECESSARY.

TSCA Section 4(a)(2)(A)(i) allows EPA to "require the development of new information relating to a chemical substance or mixture if the Administrator determines that the information is necessary … to perform a risk evaluation under" TSCA Section 6. *Id.* at (a)(2)(A)(i) (emphasis added). A test order must include a Statement of Need in which EPA must:

> identify the need for the new information, describe how information reasonably available to the Administrator was used to inform the decision to require new information, explain the basis for any decision that requires the use of vertebrate animals, and, as applicable, explain why issuance of an order is warranted instead of promulgating a rule or entering into a consent agreement.

Id. at (a)(3). Each test order contains a section designated as the Statement of Need, but this appears to be boilerplate language and lacks any technical, chemical-specific discussion. EPA is providing a mere conclusion unsupported by the facts or reasoning necessary to justify the Test Order itself. *See* Test Order at 5 (JA007).

In carrying out TSCA Sections 4, 5 and 6, EPA is required to "use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science…." 15

U.S.C. § 2625(h).[7] The use of best available science includes consideration of "the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information" and "the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture." *Id.* at (h)(1), (2) (emphasis added). Here, the decision at hand is whether a chemical presents unreasonable risk at the end of the risk evaluation step in the form of a risk determination.

EPA's test orders to date, including the one at issue in this case, have consistently failed to establish that the required testing is needed for risk evaluation. EPA has identified purported "data gaps" that it has ordered testing to fill. However, a "data gap" is not the same as a "data need." Consistent with TSCA's scientific standards, EPA must consider whether the testing requirements "are reasonable for and consistent with the intended use of the information," *i.e.*, will the information affect the outcomes of the TSCA Section 6 risk evaluation.

[7] EPA defines "[b]est available science" as "science that is reliable and unbiased. Use of best available science involves the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)." 40 C.F.R. § 702.33.

EPA has not established that the required testing is "fit for purpose" for risk evaluation or that the resulting data would be relevant to EPA's decision making, which should necessarily include consideration of physical and chemical properties, conditions of use, and exposure potential of the substance. 40 C.F.R. § 702.33(1).

III. EPA HAS NOT IMPLEMENTED TIERED APPROACHES TO TESTING.

TSCA also requires EPA to:

> employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary, unless information available to the Administrator justifies more advanced testing of potential health or environmental effects or potential exposure without first conducting screening-level testing.

15 U.S.C. § 2603(a)(4).

This is particularly important when the required testing is on vertebrate animals. TSCA requires EPA to "reduce and replace, to the extent practicable, scientifically justified, and consistent with the policies of this subchapter, the use of vertebrate animals in the testing of chemical substances or mixtures." 15 U.S.C. § 2603 (h)(1). Among other things, the Agency is required to consider reasonably available existing information, including "toxicity information; computational toxicology and bioinformatics; and high-throughput screening methods and the prediction models of those methods…" *Id.* at (h)(1)(A)(i) – (iii).

EPA has not employed a tiered screening and testing process when requiring the development of new information for TSCA risk evaluations. There are regulatory precedents within EPA regarding the use of tiered screening and testing processes, and tools and data are readily available to apply in decision-making regarding the development of new information for TSCA risk evaluations including vertebrate animal testing. *See infra*. Section III.

For example, EPA's Office of Pesticide Programs (OPP) has policies and guidelines regarding requirements for environmental toxicity testing as part of pesticide registration actions that include tiered approaches.[8] These policies apply exposure-based and hazard-based triggers for testing and are approaches that could be used in decision-making regarding the requirements for data generation under TSCA Section 4 test orders for high priority chemicals. Specifically, OPP has developed guidance for waiving sub-acute avian dietary tests.[9] OPP has also developed a decision framework for sediment testing that emphasizes

[8] Gina M. Hilton, *et al.*, *Evaluation of the Avian Acute Oral and Sub-Acute Dietary Toxicity Test for Pesticide Registration*, 105 Reg. Toxicology & Pharmacology 30 (2019).

[9] EPA, Office of Pesticide Program, *Final Guidance for Waiving Sub-Acute Avian Dietary Tests for Pesticide Registration and Supporting Retrospective Analysis*, EPA (Feb. 2020), https://www.epa.gov/sites/default/files/2020-02/documents/final-waiver-guidance-avian-sub-acute-dietary.pdf.

consideration of environmental exposures.[10] EPA has not explained why it declines to consistently apply these same approaches to testing under TSCA.

IV. EPA'S APPROACH IS RESULTING IN UNWARRANTED COSTS AND EXTENDED TIMELINES FOR TSCA SECTION 6 ACTIVITIES.

TSCA provides the Agency with limited time to complete risk evaluation and risk management activities, *see* 15 U.S.C. § 2605(b)(4)(G), (c)(1). EPA, therefore, states that it can issue orders "to obtain the information quickly, as needed to meet its own statutory deadlines for completing its risk evaluation." EPA's Resp. Br. to Mot. to Make Additional Submissions to the R. at 10. However, EPA's approach to issuing test orders is inefficient and results in unwarranted costs and extended timelines.

An avian reproduction study can cost over $200,000, including analytical method development and validation, test material substance range findings, execution of the definitive study, report composition, and data quality validation. Some existing test orders require ecological and toxicological tests in addition to in-field studies on industrial hygiene.[11] EPA has issued test orders with little to no

[10] Donald J. Brady, Ph.D., *Toxicity Testing and Ecological Risk Assessment Guidance for Benthic Invertebrates* (Memorandum), EPA(Apr. 10, 2014), https://www.epa.gov/sites/default/files/2015-08/documents/toxtesting_ecoriskassessmentforbenthicinvertebrates.pdf.

[11] *See, e.g., Modification to Order Under Section 4(a)(2) of the Toxic Substances Control Act [for 6:2 Fluorotelomer sulfonamide betaine]*, EPA (Oct. 20, 2022),

notice and no opportunity for dialogue with the Agency before testing is ordered. EPA also has authority under TSCA Section 8 to gather information before using its Section 4 authority. *See* 15 U.S.C. § 2607(a). This would help EPA evaluate what data is currently available to inform risk evaluation before issuing a test order. EPA issued a Section 8(d) data call-in on June 29, 2021, but given the deadline for submission of the data it is not clear whether that information was sufficiently reviewed and considered by EPA to inform whether these test orders were necessary. *See* 86 Fed. Reg. 34147 (June 29, 2021). Pre-issuance dialogue and data collected during a Section 8 data call-in could be used to inform what, if, any, test orders are needed to fill data needs.

In its Response to Petitioner's Motion to Make Additional Submissions to the Record, EPA argues that the test orders provide recipients with an opportunity to submit existing information that recipient believes EPA failed to consider that obviates the need for the order, referred to as "Option 2." EPA's Resp. Br. to Mot. to Make Additional Submissions to the R. at 10 – 11. ACC's experience with Option 2, however, indicates that it is not generally a viable alternative to testing. For example, in response to two test orders, recipients resubmitted a test that EPA already had in its possession from an earlier response to a 2004 test order. 69 Fed.

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https://www.epa.gov/system/files/documents/2022-10/9829-01_testorder-6_2_Fluorotelomer_sulfonamide_betaine_modified_10_20_22.pdf

Reg. 22402 (Apr. 26, 2004). Although the protocols and requirements for the test remain the same as the testing previously conducted and submitted, EPA rejected the studies and is requiring new testing that would nonetheless follow the same protocols and requirements. This testing is duplicative and does not fill a data need. EPA has also summarily rejected modeling and screening assessment information that either demonstrated the data was not needed for risk evaluation or provided satisfactory information in lieu of testing. In some cases, EPA has not responded to "Option 2" submissions for almost two years. Finally, this argument is not consistent with the requirements in TSCA Section 4(a)(3) that EPA identify the need for information. Instead, EPA is attempting to shift the burden to test order recipients to show that the information is not needed.

There are a number of steps that must be completed to comply with test order requirements for ecological and toxicological tests:[12]

- Submission of draft study plans to EPA
- Submission of final study plans to EPA
- Test protocol review and approval
- Test material shipment and Purity and Certificate of Analysis confirmation

[12] Certain test orders also require collection of occupational exposure data, which involves a different, but also extensive, set of steps.

- Analytical method development and validation
- Test media stability and homogeneity assessments
- Preliminary range-finding exposures
- Definitive testing
- Data collation, review, and approval
- Draft report preparation
- Draft report review(s) and approval
- Report finalization
- Final Report and data submission.

Each of these steps relies on the availability of a qualified laboratory. There is only one Good Laboratory Practice-certified contract research organization in the United States that provides comprehensive avian testing services. This laboratory's capacity is likely to be constrained by increased demand for its testing services, furthering delaying the testing timeline.

Depending on the test ordered, the cost of testing may be in the tens of thousands to hundreds of thousands of dollars per test. Further, each Section 4 order could require several tests. Moreover, many of the tests that EPA has ordered either do not have validated methods or are not appropriate for the chemicals that are subject to the test order. For instance, due to the physical and chemical properties of some test substances (i.e., potential volatility), additional

time and cost is needed to develop the analytical methodology and to demonstrate the appropriate stability/homogeneity in test media, such as avian diets. Then, range-finding studies are often required to demonstrate diet stability and the robustness of the analytical method.

CONCLUSION

Based on the foregoing, this Court should grant the Vinyl Institute's Petition for Review and vacate and remand the Test Order regarding avian testing for further agency proceedings.

Dated: May 5, 2023

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FED. R. APP. P. 32(G) CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 2,645 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point, Times New Roman font.

Dated: May 5, 2023

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CERTIFICATE OF SERVICE

I hereby certify that on May 5, 2023, I electronically filed the foregoing with the Clerk of Court using ECF. I also certify that the foregoing document is being served this day on all counsel of record via transmission of Notice of Electronic Filing generated by ECF.

/s/ Ryan J. Carra
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