ORAL ARGUMENT NOT YET SCHEDULED

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 Final Action
by the United States Environmental Protection Agency

RESPONDENT EPA'S INITIAL BRIEF

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March 20, 2023

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

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

A. Parties and Amici.

All parties are listed in Petitioner's brief. In addition, American Chemistry Council, Physicians Committee for Responsible Medicine, and People for the Ethical Treatment of Animals have filed briefs of amicus curiae in support of Petitioner.

B. Rulings Under Review.

The agency action under review is a test order issued pursuant to the Toxic Substances Control Act Section 4(a)(2), 15 U.S.C. § 2603(a)(2).

C. Related Cases.

There are no related cases.

/s/ Laura J. Brown
LAURA J. BROWN

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GLOSSARY

1,1,2-TCA	1,1,2-Trichloroethane
EPA	United States Environmental Protection Agency
JA	Joint Appendix
NAMs	New Approach Methods to vertebrate testing
PETA	People for the Ethical Treatment of Animals
Test Order	Test Order issued under Section 4(a)(2) of the Toxic Substances Control Act for 1,1,2-Trichloroethane, EPA-HQ-OPPT-2018-0421
TSCA	Toxic Substances Control Act
USGS	United States Geological Survey

INTRODUCTION

1,1,2-Trichloroethane ("1,1,2-TCA") is a colorless liquid used as a solvent and in plastic and petrochemical manufacturing. Monitoring by the United States Geological Survey ("USGS") has detected 1,1,2-TCA in the air, water, sediment, soil, and biota. EPA is now evaluating 1,1,2-TCA to determine whether the chemical poses an unreasonable risk to human health or the environment. As part of that evaluation, EPA found only one existing study on 1,1,2-TCA's toxicity to birds. That study concluded that the chemical is toxic to chicken embryos when it is injected into chicken eggs. Because that study was limited to acute exposure, EPA determined that it needs additional data to fully assess whether birds' chronic exposure to 1,1,2-TCA in the environment is toxic. No such data is available. Thus, pursuant to its newly expanded authority provided in Section 4 of the 2016 Amendments to the Toxic Substances Control Act ("TSCA"), EPA issued the challenged Test Order requiring that certain manufacturers conduct a test that will produce the necessary toxicity data.

The 2016 Amendments to TSCA Section 6, 15 U.S.C. § 2605, require that EPA prioritize and evaluate chemical substances to determine whether they pose an unreasonable risk to health or the environment. EPA must then regulate those chemicals that present an unreasonable risk. The 2016 TSCA Amendments set aggressive deadlines. To help EPA complete the risk evaluations, the 2016 Amendments expanded EPA's authority under TSCA Section 4, 15 U.S.C. § 2603. Specifically, the Amendments authorize EPA to order chemical manufacturers and

processors to develop information about the hazards of the chemicals they produce when EPA determines the information is necessary to perform a risk evaluation and is not otherwise readily available. This authority adheres to TSCA's stated policy that "adequate information should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such information should be the responsibility of those who manufacture and those who process such chemical substances and mixtures." 15 U.S.C. § 2601(b)(1). This authority simplifies the process for EPA to require testing of chemicals, relative to the burdensome process required under the original version of TSCA.

The challenged Test Order directs the recipients to conduct an avian reproduction test. The test is designed to develop information on whether chronic exposure to 1,1,2-TCA is hazardous to birds. As noted, EPA ordered the test after it determined that no chronic hazard information is reasonably available, and that such information is necessary for the Agency to perform its risk evaluation for 1,1,2-TCA. This conclusion is supported by substantial evidence and must be upheld.

Petitioner Vinyl Institute asks this court to impose unnecessary and burdensome procedures on EPA as a prerequisite to issuing test orders. These procedures are not required by the statute and would create barriers to the collection of data, which the 2016 TSCA Amendments were designed to remove.

Petitioner also seeks, pursuant to TSCA Section 19(b), to submit additional information to the record. Petitioner asserts the new information could obviate the

need for the testing and asks the court to remand the matter and direct EPA to consider that information. Petitioner's request should be denied because such submissions are allowed only when "there were reasonable grounds for . . . failure to make such submissions . . . in the proceeding before the Administrator," and the information is "material." 15 U.S.C. § 2618(b). The Test Order explicitly sets forth a process through which Petitioner could have presented to EPA the information it now seeks to add to the record, yet Petitioner failed to take advantage of that process. No reasonable grounds exist for Petitioner's failure. Thus, the Court need not consider the materiality of the submission in denying Petitioner's motion. In any event, Petitioner has not shown that the submission is material, such that it would obviate the need for the Test Order.

Both Vinyl Institute's petition and its 19(b) motion should be denied.

STATEMENT OF JURISDICTION

Section 19 of TSCA, 15 U.S.C. § 2618(a)(1)(A), provides this court with jurisdiction to review the subject test order issued pursuant to TSCA Section 4, 15 U.S.C. § 2603.

STATEMENT OF THE ISSUES

1. Is EPA's conclusion that the avian reproduction test is necessary to perform a risk evaluation for 1,1,2-Trichloroethane supported by substantial evidence in the record taken as a whole?

2. Should the Court deny Petitioner's TSCA Section 19(b) motion to submit additional information for EPA's consideration when the Test Order explicitly set forth a process for Petitioner to present to EPA the information it now seeks to add to the record, Petitioner failed to take advantage of the process, and the information Petitioner seeks EPA to consider is unreliable and not scientifically justified?

PERTINENT STATUTES AND REGULATIONS

All pertinent statutes and regulations not submitted in Petitioner's addendum are included in the addendum filed with this brief.

STATEMENT OF THE CASE

I. Statutory Background

In 1976, Congress enacted TSCA, in part to prevent the unreasonable risks presented by certain chemical substances. *See* S. Rep. No. 94-698, at 1 (1976), *as reprinted in* 1976 U.S.C.C.A.N. 4491. Among other things, Congress required EPA to maintain an inventory of chemical substances manufactured and processed in the United States and provided EPA with discretionary authority to review and regulate those substances. 15 U.S.C. §§ 2604, 2606(a) (1976). However, the statute did not provide a specific process or timeline for EPA to evaluate whether chemical substances present unreasonable risk or a specific timeline for EPA to regulate any chemical substances found to present unreasonable risk. *See Safer Chems. Healthy Families v. EPA*, 943 F.3d 397, 406 (9th Cir. 2019).

In 2016, Congress passed the bipartisan Frank R. Lautenberg Chemical Safety for the 21st Century Act ("2016 TSCA Amendments" or "Amendments"), which, for the first time, substantively amended TSCA based on concerns that, as originally enacted, TSCA did not achieve its aim due to a variety of procedural and substantive complications. 162 Cong. Rec. S3511-01 (daily ed. June 7, 2016), at S3513 (discussing barriers to chemical testing), S3516 (discussing previous requirement for EPA to consider cost).

The 2016 TSCA Amendments "substantially increased EPA's obligation to evaluate and regulate dangerous chemicals." *Lab. Council for Latin Am. Advancement v. EPA*, 12 F.4th 234, 243 (2d Cir. 2021). The Amendments require EPA to evaluate and regulate unreasonable risk from existing chemicals, and they prescribe quotas and deadlines EPA must meet. *See* Pub. L. No. 114-182 (June 22, 2016). Specifically, EPA must first prioritize chemical substances as either "high-priority substances" that may present an unreasonable risk or "low priority substances." 15 U.S.C. § 2605(b)(1)(B). EPA must then conduct a "risk evaluation" for all high-priority substances to determine whether the substance presents an unreasonable risk of injury to health or the environment under the chemical's conditions of use. *Id.* § 2605(b)(3)-(4). If, through the risk evaluation, EPA determines that the chemical presents an unreasonable risk, EPA must engage in risk management, and ultimately regulate to address any unreasonable risks. *Id.* § 2605(a), (c).

A. Risk Evaluations.

As noted above, EPA must conduct risk evaluations for all high-priority substances. The 2016 TSCA Amendments require that EPA have ongoing—at any one time—at least 20 risk evaluations for high-priority substances. *Id.* § 2605(b)(2)(B). In evaluating a chemical's risk, EPA must assess the hazards (i.e., the adverse health and ecological effects) and exposures to the chemical substance without consideration of costs or other non-risk factors. *Id.* § 2605(b)(4)(F)(i), (iii). Six months after initiation of a risk evaluation, EPA must publish its scope, describing the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations EPA "expects to consider" in the risk evaluation. *Id.* § 2605(b)(4)(D). The risk evaluation must be completed within three years after its initiation, subject to a six-month extension. *Id.* § 2605(b)(4)(G).

B. EPA's Expanded Testing Authority.

Before the 2016 TSCA Amendments, EPA could require testing of chemicals only by rulemaking and only when EPA found that a substance either "may present an unreasonable risk of injury to human health or the environment" or is produced in substantial quantities and meets statutory targets for either exposure or entry into the environment. 15 U.S.C. § 2603(a)(1)(A)(i), (ii) (1976). While amending TSCA, Congress identified that one of the statute's "major flaws" was EPA's limited testing authority, which Congress described as a "Catch 22," because the trigger for testing is an "a priori finding that is often difficult to make in the absence of the information

that testing would provide." S. Rep. No. 114-67 (2015), 2015 WL 3852676. Congress was also concerned that the rulemaking process placed a "significant burden on EPA, and test rules can sometimes take many years to complete." *Id.* As described by former Senator Tom Udall, on the day of the Amendments passage:

> Americans are exposed to hundreds of chemicals from household items. . . . Some are known as carcinogens, others as highly toxic. But we don't know the full extent of how they affect us because they have never been tested. When this bill becomes law, there will finally be a cop on the beat. . . . [T]he old TSCA put[] burdensome testing requirements on the EPA. To test a chemical, the EPA ha[d] to show a chemical possesse[d] a potential risk, and then it ha[d] to go through a long rulemaking process. [Now] EPA will have authority to order testing without those hurdles.

162 Cong. Rec. S3511-01, at S3513 (June 7, 2016).

In the 2016 TSCA Amendments, Congress significantly expanded and expedited the execution of EPA's testing authority by allowing EPA to require testing through orders and consent agreements[1] (along with rulemaking). 15 U.S.C. § 2603(a)(1) (2016). Congress also expanded the occasions when EPA can require testing, to include when EPA determines new information is necessary for it to perform a risk evaluation. *Id.* § 2603(a)(2). As described above, EPA's expanded authority to require testing follows TSCA's stated policy that "adequate information should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such information should

[1] Prior to the 2016 Amendments EPA promulgated procedures for consent agreements under the rulemaking authority in TSCA Section 4, *see* 40 C.F.R. part 790. The 2016 Amendments were the first express authorization for such instruments.

be the responsibility of those who manufacture and those who process such chemical substances and mixtures." *Id.* § 2601(b)(1).

When requiring the development of new information for a risk evaluation, EPA must issue a "statement of need," which must: (1) "identify the need for the new information," (2) "describe how information reasonably available to the Administrator was used to inform the decision to require the new information," (3) "explain the basis for any decision that requires the use of vertebrate animals," and (4) "as applicable, 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).

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." *Id.* § 2603(a)(4).

The TSCA Amendments direct EPA to "reduce and replace, to the extent practicable, [and] scientifically justified," the use of vertebrate animals in the testing of chemicals. *Id.* § 2603(h)(1). Before requiring vertebrate testing, EPA must "take into consideration" reasonably available existing information, including alternative testing methods. *Id.* § 2603(h)(A). EPA must also encourage the use of scientifically valid test methods that reduce or replace vertebrate testing while providing "information of

equivalent or better scientific quality and relevance" to support regulatory decisions. *Id.* § 2603(h)(1)(B). To that end, the Amendments require EPA to develop a strategic plan to promote the development of new scientifically valid test methods and strategies to reduce, refine, or replace vertebrate testing. *Id.* § 2603(h)(2)(A). The Amendments require that in the strategic plan EPA include (and regularly update) a list of alternative test methods (i.e., "New Approach Methodologies" or "NAMs") that do not require new vertebrate animal testing and are "scientifically reliable, relevant, and capable of providing information of equivalent or better scientific reliability and quality to that which would be obtained from vertebrate animal testing." *Id.* § 2603(h)(2)(C).

EPA issued its "Strategic Plan to Promote the Development and Implementation of Alternative Test Methods within the TSCA Program" ("Strategic Plan") on June 22, 2018.[2] Strategic Plan (JA ____). EPA maintains and updates its list of approved NAMs on its website.[3] "List of Alternative Test Methods and Strategies (or New Approach Methodologies)," Second Update, Feb. 4, 2021, issued by EPA pursuant to TSCA Section 4(h)I ("NAMs List").

Finally, in carrying out TSCA Section 4, EPA is required to act in a "manner consistent with the best available science." 15 U.S.C. § 2625(h). As such, the statute

[2] https://www.epa.gov/sites/default/files/2018-06/documents/epa_alt_strat_plan_6-20-18_clean_final.pdf (JA ___)
[3] https://www.epa.gov/sites/default/files/2021-02/documents/nams_list_second_update_2-4-21_final.pdf (JA ___)

requires that in using scientific information, procedures, measures, methods, or models, EPA consider (1) whether they "are reasonable for and consistent with the intended use of the information" (2) whether they are "relevant for the Administrator's use in making a decision about a chemical substance or mixture;"(3) whether the "clarity and completeness" employed to generate them are documented (4) whether any variability and uncertainty in them has been evaluated and characterized; and (5) whether they have been independently verified or peer reviewed. *Id.*

II. Procedural Background

On December 30, 2019, EPA designated 1,1,2-TCA as a high-priority substance under TSCA Section 6(b)(1)(B)(i) and initiated its risk evaluation. 84 Fed. Reg. 71,924, 71,934. 1,1,2-TCA is a highly flammable liquid used in plastic and petrochemical manufacturing. As required by statute, in August 2020, EPA published a final scope document outlining the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Agency "expects to consider" in the risk evaluation.[4] EPA described the environmental exposure pathways for 1,1,2-TCA in the scope document. Test Order at 6 (JA ___). However, at the time EPA issued the scope, a policy was in effect that excluded from the scope of the risk evaluations certain exposure pathways and risks falling under the jurisdiction of other

[4] https://www.epa.gov/sites/default/files/2020-09/documents/casrn_79-00-5_112-trichloroethane_finalscope.pdf (JA ___).

EPA-administered statutes or regulatory programs (i.e., Clean Air Act, Clean Water Act, etc.). *Id.* EPA later reconsidered that policy and now expects to consider all exposure pathways in its risk evaluation for 1,1,2-TCA. *Id.*

On March 24, 2022, EPA issued the challenged Test Order to seven companies. The Test Order required recipients to conduct two tests: (1) an earthworm reproduction test, and (2) an avian reproduction test. Only the avian reproduction test is at issue here. In the Test Order, EPA included its "Statement of Need." Test Order at 5-9 (JA ___-___). EPA explained that it had found no information on the hazard (i.e., toxicity) of 1,1,2-TCA to birds based on chronic exposure and explained the process it used for searching for that information. *Id.* at 8 (JA ___). EPA also explained that it had identified a study demonstrating that 1,1,2-TCA caused developmental toxicity to embryos when injected into chicken eggs. *Id.* at 9 (JA ___). Because this study focused solely on acute exposure and resulted in toxicity to the birds, EPA identified a need for toxicity information for chronic exposure (e.g., dietary exposure) to evaluate 1,1,2-TCA's risk. *Id.* This decision was also informed by USGS monitoring data that demonstrated avian exposure. *Id.* USGS identified 1,1,2-TCA in soil, groundwater, sediment, surface water, and biota, to which birds (and other terrestrial vertebrates) are exposed. *Id.*

The Test Order gave recipients four options for responding: "Option 1," develop the information requested; "Option 2," submit existing information that the recipient believes EPA failed to consider that obviates the need for the order;

"Option 3," request an exemption; or "Option 4," claim that the company is not subject to the order. *Id.* at 3 (JA ___). EPA encouraged recipients to form a consortium and jointly conduct one or both tests, with the consortium able to select either response Option 1 or 2 for each test. *See id.* at 3, 19 (JA ___, ___). For response Option 2, submit existing information, the Test Order provided:

> If you choose to respond to this Order by submitting an existing study and/or other scientifically relevant information that you believe the EPA has not considered, your response . . . must . . . include the study(ies) and/or other scientifically relevant information, along with supporting rationale that explains how the study and/or other scientifically relevant information meets part or all of the information or obviates the need for the information described as necessary in [the Test Order].

Id. at 11 (JA ___). The Test Order further provided that EPA will consider whether the submitted information "satisfies the need in lieu of the testing required in this Order and/or the original testing requirement is no longer needed," and, if so, EPA "will extinguish those testing obligations from this Order that are no longer necessary." *Id.* The Test Order set a 30-day deadline from its effective date for submitting existing information, but provided that a recipient may request an extension of the deadline, which EPA may grant or deny at its discretion. *Id.* at 10-11 (JA ___-___).

In response to the Test Order, six of the seven recipient companies formed a consortium, as recommended in the Test Order. Petitioner, Vinyl Institute, submitted a response to EPA on the consortium's behalf on June 2, 2022. Vinyl Institute's Response to Test Order (JA ___). In that response, Petitioner elected Option 1, to

"develop information" with respect to both the avian and earthworm reproduction tests. *Id.* at 3 (JA ___). Neither Petitioner nor any of the other recipients submitted existing information to EPA for its consideration under the Test Order's Option 2 or communicated to EPA that any such information might exist, nor did they submit a request for the administrative record.

On May 23, 2022, Vinyl Institute filed its petition pursuant to TSCA Section 19(a), 15 U.S.C. § 2618 seeking judicial review of the Test Order. After EPA filed its Certified Index to the Administrative Record, Petitioner filed a TSCA Section 19(b) Motion. In that motion, Vinyl Institute sought to supplement the administrative record with a technical report related to the avian reproduction test that was prepared by a consultant (Stantec) on behalf of Petitioner (hereinafter the "Stantec Report"). Styled as a "critique" of EPA's approach and conclusion about the need for the avian reproduction testing, the report identifies and discusses information that Petitioner alleges EPA should have considered before it issued the Test Order. EPA opposed that motion. On December 1, 2022, the motions panel referred the Section 19(b) motion to the merits panel and directed the parties to address the issue in their merits brief rather than incorporating by reference their prior submissions.

Two amicus curiae briefs have been filed on Petitioner's behalf. The Physicians Committee for Responsible Medicine ("Physicians Committee") and People for Ethical Treatment of Animals ("PETA") jointly filed one, and American Chemistry Council ("ACC") filed the other.

SUMMARY OF ARGUMENT

EPA's Test Order requiring an avian reproduction test meets TSCA's statutory requirements and is supported by substantial evidence in the record. TSCA authorizes EPA to issue a test order if the information EPA seeks is necessary for it to perform a risk evaluation and is not otherwise reasonably available. In the 1,1,2-TCA risk evaluation, EPA must assess, *inter alia*, the hazards (i.e., the adverse health and ecological effects) and exposures to the chemical. After conducting a comprehensive search for reasonably available information, EPA identified only one study relating to the potential hazards 1,1,2-TCA poses to birds. That singular study showed that acute exposure to 1,1,2-TCA (via egg injection) is developmentally toxic to birds. EPA also explained that monitoring data shows that 1,1,2-TCA has been detected in the air, water, sediment, soils, and biota, to which birds are exposed.

Thus, because available information indicates both toxicity to birds after acute exposure (as shown in the egg-injection study), and avian exposures to the chemical in the environment, EPA determined that it needed information on the effects of chronic exposure to complete its risk evaluation. When EPA found no such information, it identified analogues (chemicals of similar structures) for which chronic toxicity data could be extrapolated to 1,1,2-TCA. But no chronic toxicity data existed for the analogues. In addition, to reduce vertebrate testing, EPA considered additional approved NAMs, but determined that none was appropriate for predicting avian toxicity based on chronic exposure. Thus, to obtain the data quickly and to

comply with EPA's impending statutory deadline, EPA issued the Test Order. EPA explained this approach in the Statement of Need issued with the Test Order, and the approach is supported by substantial evidence in the record. Thus, the Court should deny the petition.

In addition, Petitioner has not met its TSCA Section 19(b) burden "to make additional oral submissions or written presentations" respecting the Test Order. 15 U.S.C. § 2618(b). Such submissions are permitted only if the movant demonstrates that: (1) the submission is "material," and (2) "reasonable grounds" exist for the movant's "failure to make such submissions and presentations in the proceeding before the Administrator." 15 U.S.C. § 2618(b). Petitioner has not shown that reasonable grounds exist for its failure previously to submit the information in the Stantec Report to EPA. The Test Order's Option 2 allowed Petitioner to present any information it believed EPA failed to consider that would obviate the need to generate the data required under the Test Order.

Petitioner contends that, lacking access to the administrative record, it could not have submitted information as allowed by the Test Order because Petitioner could not determine whether EPA had already considered the information. This argument is meritless. Even if Petitioner could not determine that the information was new to EPA, nothing prevented Petitioner from submitting the information and explaining its significance. Failure to submit the information as allowed by the Test Order was therefore unreasonable. Petitioner's Section 19(b) motion can be rejected

on that basis alone, and the Court need not consider the materiality of the submission. And, in any event, Petitioner has not shown that the submission is material and would obviate the need for the Test Order.

STANDARD OF REVIEW

TSCA provides that test orders shall be set aside only if "not supported by substantial evidence in the record taken as a whole." 15 U.S.C. § 2618(c)(1)(B)(i)(II). Substantial evidence is defined as "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Consolo v. Fed. Mar. Comm'n*, 383 U.S. 607, 620 (1966). "This is something less than the weight of the evidence, and the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence." *Id.* This Court has noted that, "in their application to the requirement of factual support[,] the substantial evidence test and the arbitrary or capricious test are one and the same." *Daikin Applied Americas Inc. v. EPA*, 39 F.4th 701, 712 (D.C. Cir. 2022) (internal citation omitted).

Under this standard as provided in TSCA, a reviewing court must "give careful scrutiny to agency findings, and at the same time, accord appropriate deference to administrative decisions that are based on agency experience and expertise." *Env't Def. Fund, Inc. v. EPA*, 636 F.2d 1267, 1277 (D.C. Cir. 1980). "Because administrative decisions often involve judgments based on incomplete or even conflicting scientific data, the agency may have to fill gaps in knowledge with policy considerations." *Id.*

(internal citation omitted). In this case, EPA determined that it lacked the information to assess the risk of 1,1,2-TCA and therefore made the policy choice to require additional testing. That determination is supported by the record and entitled to this Court's deference.

In sum, the Court should affirm the Test Order because the evidence reasonably supports EPA's conclusion that the ordered testing is necessary for EPA to perform the risk evaluation. *See Chem. Mfrs. Ass'n v. EPA.*, 859 F.2d 977, 992 (D.C. Cir. 1988).

ARGUMENT

I. EPA's Test Order Requiring an Avian Reproduction Test Meets TSCA's Statutory Requirements and Is Supported by Substantial Evidence.

EPA satisfied its statutory obligations when it issued the Test Order.[5] When requiring testing, TSCA requires that EPA,

> [I]dentify 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.

15 U.S.C. § 2603(a)(3).

[5] Petitioner and Amicus ACC object to the number of test orders EPA has estimated it will issue. Pet. Br. at 20; ACC Amicus Br. at 3. Both the number of future test orders and the content of any test order other than the one under review are irrelevant here. TSCA authorizes EPA to issue test orders. That EPA has done so on other occasions and intends to do so in the future has no bearing on the validity of the challenged Test Order.

In the Test Order's Statement of Need, EPA explained that "no avian toxicity data following chronic exposures were identified for [1,1,2-TCA] or identified analogues." Test Order at 8 (JA ___). "Without toxicity data, EPA is unable to determine if chronic exposures to [1,1,2-TCA] pose a risk to terrestrial vertebrates," as needed to complete its risk evaluation. *Id.* As described in the Test Order, EPA searched for existing information, and used available information to inform its decision to order the testing: "[t]he testing requirement is reinforced by avian toxicity data captured in the peer-reviewed literature undergoing systematic review, which qualitatively indicates exposure to [1,1,2-TCA] caused developmental toxicity to chick embryos." *Id.* at 9. And EPA described that 1,1,2-TCA is detected in water, sediment, soil, and biota to which birds and other terrestrial vertebrates are exposed. *Id.* EPA further explained that vertebrate testing is necessary because no approved NAMs are available that predict avian toxicity after chronic exposure.[6] *Id.* at 8. As detailed below, each of these findings is supported by substantial evidence in the record. Finally, EPA explained that it required the testing by order, rather than by

[6] EPA described its findings in the Test Order. In some instances, EPA reported that it did not find any relevant or available information, which Petitioner and ACC characterize as "conclusory." Pet. Br. at 13; ACC Amicus Br. at 6. Petitioner and ACC take the unreasonable position that EPA must demonstrate the absence of such information in the Test Order's Statement of Need. While EPA has described the process it used to search for information, it should not be expected to prove a negative.

rulemaking or agreement, so that it could quickly obtain the information and complete its risk evaluation as required by TSCA.

Petitioner incorrectly asserts that EPA (1) failed to justify its decision to forgo a tiered testing approach; (2) did not substantiate why it rejected alternatives to reduce vertebrate testing; (3) failed to demonstrate an information gap that must be filled through chronic animal testing; (4) did not demonstrate that birds are exposed to 1,1,2-TCA in sufficient amounts to warrant testing; and (5) did not explain why a test order was necessary in lieu of a consent agreement. Each of these claims falls short, as explained below.

A. EPA Employed a Tiered Screening and Testing Process.

Petitioner first asserts that EPA failed to "justify" its decision to "forgo" a tiered testing approach. Petitioner quotes EPA's Statement of Need, which states that "[r]easonably available data, computational toxicology, or high-throughput screening methods and prediction models are not available and/or cannot be used to address the avian reproduction testing required by this Order." Pet. Br. at 30. Petitioner asserts that neither it nor the court can determine "from the face of the Test Order" how EPA evaluated tiered screening and testing processes, which ones the Agency evaluated, and why EPA concluded those processes would not be helpful. *Id.* at 31. Petitioner also argues that the Test Order does not identify the costs of the avian reproduction test, which Petitioner asserts could run to hundreds of thousands if not millions of dollars. *Id.*

Petitioner's argument is based on the incorrect premise that a "tiered screening and testing process" requires EPA to order screening-level tests before ordering additional tests. On the contrary, TSCA requires that EPA "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 available information "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) (emphasis added). As detailed below, EPA's assessment of available information about 1,1,2-TCA qualifies as the required tiered screening and testing process.

Substantial evidence in the record demonstrates that EPA "employed a tiered screening and testing process" through its "assessments of available information [to] inform" its decision to require avian testing. 15 U.S.C. § 2603(a)(4). In the Test Order, for example, EPA describes how it searched for information on 1,1,2-TCA's toxicity to soil invertebrates, mammals, and birds. Test Order at 6-7 (JA ___ - ___). This process included searching multiple peer-reviewed literature databases (identified by EPA in the Test Order) for studies using 1,1,2-TCA, searching "gray literature" (i.e., technical reports, reference books, dissertations, etc.), and reviewing relevant data submitted to EPA under TSCA. *Id.* EPA also used its "Analog Identification Methodology" software to identify substances similar in structure to 1,1,2-TCA for which data could be extrapolated or read-across to 1,1,2-TCA. *Id.* at 7 (JA ___). The

software identified seven analogues. *Id.* EPA then searched for toxicity information for 1,1,2-TCA and the analogues in EPA's ECOTOX Knowledgebase (a publicly available database) as well as information submitted to EPA under TSCA, the Federal Insecticide, Fungicide, and Rodenticide Act,[7] and the Endocrine Disruptor Screening Program to determine if any studies existed regarding the toxicity of 1,1,2-TCA or the seven identified analogues to birds. *Id.* at 8-9 (JA ___ - ___).

In the Test Order's Statement of Need, EPA explained that after conducting a systemic search and reviewing available information, the Agency found only one existing study on the toxicity of 1,1,2-TCA to birds (and no chronic studies for the identified analogues). *Id.* at 6-9 (JA ___ - ___). In that study, scientists injected varying doses of 1,1,2-TCA into chicken eggs at either two, three, or six days of age. Elovaara et. al 1979 at 113 (JA ____). The study showed that 1,1,2-TCA causes malformation (a chemical trait known as teratogenicity) or death in chick embryos. *Id.* The authors concluded that "[t]he results of the present study demonstrate toxicity of the tested compounds on chick embryos . . . the study should indicate a need for caution and further study on the adverse effects of the compounds." Elovaara et. al 1979 at 118 (JA ___). Even though environmental exposure of eggs to 1,1,2-TCA would not be via injection, EPA accepted this study as demonstrating acute effects on birds and did not order new acute studies. Test Order at 9 (JA ___).

[7] 7 U.S.C. § 136h *et seq.*

Because that study revealed some measure of toxicity to birds after acute exposure and because monitoring data showed that birds are exposed to 1,1,2-TCA in the environment, EPA determined that it needed information on whether chronic exposure to 1,1,2-TCA in the environment is hazardous to birds to perform its risk evaluation. *Id.* Thus, substantial evidence in the record demonstrates that EPA employed a tiered screening and testing process by assessing available information on the risks of acute exposure and on pathways of exposure, both of which informed its decision to require only the chronic exposure testing.

Additionally, contrary to Petitioner's assertion, the record includes EPA's cost evaluation of the avian reproduction test, which EPA estimated would cost a total of $288,283. Excel spreadsheet titled "Second batch tables," tab titled "112trichloro" (JA ___). While TSCA Section 4(b)(1) requires EPA to consider "costs of the various test protocols and methodologies which may be required," neither Section 4(b)(1) nor Section 19(a) requires that EPA describe its consideration of these costs in a test order's statement of need.

B. EPA Considered Alternatives to Vertebrate Testing

Next Petitioner claims that EPA failed to "substantiate" why it rejected alternative testing methods to reduce vertebrate testing. Pet. Br. at 32. TSCA requires that EPA explain the basis for its decision to require testing of vertebrate animals in the statement of need and that EPA reduce the use of vertebrate testing by considering: "(i) toxicity information, (ii) computational toxicology and

bioinformatics; and (iii) high-throughput screening methods and the prediction models of those methods." 15 U.S.C. § 2603(a)(3), (h). EPA stated in the Test Order that "[n]o approved or readily available new approach methodologies (NAMs) were identified that could be used to inform the data gap for avian toxicity following chronic exposure." Test Order at 8 (JA ___). Petitioner argues this statement is conclusory and insufficient because EPA does not describe what it considered in arriving at that conclusion. Pet. Br. at 33. Petitioner and Amicus ACC take the unreasonable position that TSCA requires EPA to demonstrate the absence of appropriate NAMs in the Test Order's Statement of Need. This position would send EPA on a wild goose chase, requiring that EPA consider any methodology, no matter how irrelevant or inappropriate, and document why each chase produced nothing of value, undermining Congress' goal of expediting the collection of data under TSCA Section 4. In the Test Order, as required by statute, EPA explained vertebrate testing is necessary because no data exist for toxicity following chronic exposure and because—as described further below—no approved NAMs could be used to obtain that information. That explanation satisfies TSCA Section 4's requirement, and EPA need not prove a negative in the Test Order's Statement of Need.

EPA has ordered the avian reproduction test to evaluate the hazards 1,1,2-TCA poses to birds in the environment. Before ordering the test, EPA sought to ensure that the animal testing burden under TSCA is reduced by using all available ecotoxicity data and tailoring data needs. First, as described above, EPA searched for

reasonably available existing toxicity information, which identified only the egg injection study that showed the substance is hazardous to birds based on acute exposure. Yet the Agency found no chronic avian toxicity data for 1,1,2-TCA, leaving the important question of chronic toxicity unresolved.

EPA then considered whether any approved NAMs were available that could be used rather than testing directly on birds. First, as described above, EPA used its Analog Identification Method Tool and identified seven analogues for 1,1,2-TCA, but no chronic avian toxicity data existed for the analogues. This process was detailed in the Test Order. Test Order at 7 (JA ___).

EPA then considered other NAMs but did not identify any that could be used to predict avian toxicity. Although the Test Order does not detail each of the NAMs EPA considered and rejected as inappropriate, the NAMs EPA considered are identified in the record. EPA tracked the NAMs it considered in a spreadsheet titled "Eco Data Gaps ECOSAR_072290_new chemical structure-ND" (hereinafter "Data Gap Spreadsheet"). Data Gap Spreadsheet (JA ___). The first tab of the spreadsheet titled "CHECKLIST" lists all the high-priority chemical substances under risk evaluation, and row nine identifies the information considered for 1,1,2 TCA. Data Gap Spreadsheet (JA ___). Columns M through AU of the spreadsheet identify the NAMs EPA considered for 1,1,2 TCA. The cells that are blank in row 9 for columns M through AU indicate EPA did not find relevant information. Data Gap Spreadsheet (JA ___).

Pursuant to TSCA Section 4(h)(2)(C), EPA publishes a List of Alternative Test Methods and Strategies ("NAMs List"), which is regularly updated and published on its website.[8] NAMs List (JA ___). The NAMs List largely consists of in vitro tests that have test guidelines approved by the Organization for Economic Cooperation and Development ("OECD") and software applications historically used in EPA's TSCA programs. In identifying the NAMs for inclusion on the NAMs List, as published at the time of the analysis, EPA considered the categories of "(i) toxicity information, (ii) computational toxicology and bioinformatics; and (iii) high-throughput screening methods and the prediction models of those methods." 15 U.S.C. § 2603(h). Most of the NAMs on the NAMs List are designed to address human health hazard and not environmental hazard.

The NAMs considered by EPA and identified in the Data Gap Spreadsheet reflect EPA's analysis of the NAMs List that could be informative for the environmental hazard assessment gap, organized by the categories of consideration. EPA considered the Chemical Assessment Clustering Engine (ChemACE) software, which uses the chemical structure logic underlying EPA's Analog Identification Methodology tool, but the software clusters a list of chemicals and is not designed to identify analogues. Data Gap Spreadsheet, CHECKLIST tab at row 9, column N (JA ___). This software did not identify any analogous chemicals and was not applicable

[8] https://www.epa.gov/sites/default/files/2021-02/documents/nams_list_second_update_2-4-21_final.pdf

for the data gap analysis. *Id.* EPA also considered the Ecological Structure-Activity Relationships Program (ECOSAR), an "in silico tool to predict aquatic hazard." *Id.* at row 9, columns N, AK-AQ (JA ___). ECOSAR predicts acute and chronic hazard for aquatic species, but not birds. Thus, ECOSAR was not an appropriate NAM for avian testing. Additionally, EPA considered "OncoLogic," an "in silico tool to predict potential to cause cancer in humans," again, this tool is not designed to predict avian toxicity. *Id.* at row 9, columns N, AR (JA ___). EPA also considered its "EPI (Estimation Program Interface) Suite," which estimates physical/chemical and environmental fate properties, such as bioconcentration and bioaccumulation. *Id.* at row 9, columns AS (JA ___). This tool also does not predict avian toxicity. Finally, EPA considered the ToxCast Estrogen Receptor Agonist Pathway Model and the use of high throughput assays and computational tools in the endocrine disruptor screening program. *Id.* at row 9, columns AT and AU (JA ___). These tools are largely developed for human health assessments and do not provide information applicable to fill the data gaps for birds. Ultimately, EPA was unable to identify any information relevant to predicting 1,1,2-TCA's hazard to birds using these screening tools.[9]

That EPA did not identify any available NAMs to fill the avian toxicity data gap is unsurprising, because, as EPA explained in its NAMs Strategic Plan, "for new and

[9] Columns R through AG identify OECD Test Guidelines for ecological testing, but no test data was available.

existing chemicals, few NAMs exist that reliably predict complex endpoints such as developmental, reproductive, and repeated-dose toxicity studies." Strategic Plan[10] at 14 (JA ___). In sum, EPA considered all the NAMs approved for environmental hazard data identified on its updated and publicly available NAMs List and determined no relevant data was available for the identified analogues, and that the remaining approved NAMs were not appropriate for predicting toxicity in birds. Test Order at 7-9 (JA ___-___).

C. The Test Order Demonstrates a Data-Need.

Petitioner challenges the fact that the Test Order does not identify all the studies EPA considered when determining that a data gap exists. Pet. Br. at 34. Petitioner argues that without this information, it cannot evaluate whether EPA appropriately weighed available scientific evidence when it issued the Test Order. *Id.* Petitioner also argues that even if a data gap exists, EPA has not shown that the avian reproduction test is necessary to complete its risk evaluation. *Id.* at 35.

In conducting a risk evaluation, TSCA *requires* that EPA assess the hazards (i.e., toxicity) and exposures (including duration, intensity, frequency) of the subject chemical to various receptors (i.e., humans, aquatic organisms, terrestrial organisms). *See* 15 U.S.C. § 2605(b)(4)(F). EPA issued the Test Order because it did not find any information on whether chronic exposure to 1,1,2-TCA is hazardous to birds.

[10] https://www.epa.gov/sites/default/files/2018-06/documents/epa_alt_strat_plan_6-20-18_clean_final.pdf

Petitioner incorrectly states that the Test Order "does not identify any of the studies EPA reviewed, [or] reveal the results of those studies." Pet. Br. at 13. That is not true. EPA explained in the Test Order's Statement of Need that its decision to issue the Test Order was based, in part, on the Elovaara et al. (1979) study in which injecting eggs with 1,1,2 TCA resulted in the deformation or death of chick embryos. Test Order at 9. (JA ___). As further explained in the Test Order, EPA concluded (and Petitioner agrees) that the Elovaara et al. (1979) study alone is insufficient for its risk evaluation because the exposure pathway (egg injection) is not comparable to environmental exposure. Test Order at 9 (JA ___). Indeed, even the egg dosing study's authors recommended additional toxicity testing. Thus, EPA has identified the need for the information on hazards associated with chronic exposure.

The court should reject Petitioner's position that EPA must identify in the Test Order all the studies it reviewed and explain why they do not provide the relevant information. Pet. Br. at 13, 34. Petitioner would have the Court require that EPA provide a comprehensive list of all search results from electronic databases and every book opened in a technical library, regardless of relevance. Nowhere in the statute does such a requirement appear. By contrast, in TSCA Section 26(j)(4), Congress required EPA to make public, "a list of the studies considered by the Administrator in carrying out each such risk evaluation, along with the results of those studies." 15 U.S.C. § 2625(j)(4). As the Supreme Court has instructed, "[w]e do not lightly assume that Congress has omitted from its adopted text requirements that it nonetheless

intends to apply, and our reluctance is even greater when Congress has shown elsewhere in the same statute that it knows how to make such a requirement manifest." *Jama v. Immigr. & Customs Enf't*, 543 U.S. 335, 341 (2005). No such requirement is included in TSCA Section 4, and, pursuant to the cannons of statutory construction, the Court should not read one into the statute. *See Jama*, 543 U.S. at 341.

Furthermore, requiring EPA to identify and analyze in the statement of need every study (and every NAM) that does *not* provide useful information would be burdensome and time consuming, and would (1) create barriers to requiring test data under TSCA Section 4, which the TSCA Amendments were intended to correct, and (2) render it extremely difficult, if not impossible, for EPA to meet its obligations to promptly complete multiple risk assessments under TSCA Section 6(b), which the TSCA Amendments were intended to facilitate. EPA explained in the Test Order's Statement of Need the process it used in searching for available information, and Petitioner can repeat that process to check EPA's work. Additionally, as discussed below, EPA provided Petitioner an opportunity to submit to EPA relevant information it believes EPA missed, a process that is not required by the statute but gives Test Order recipients an opportunity to rebut EPA's findings. Petitioner submitted no information to EPA in response to the Test Order and did not seek an extension to do so.

Finally, as noted above, the standard of review is based on the record as a whole, not just the Test Order. EPA's administrative record identifies other vertebrate studies EPA considered for 1,1,2-TCA and its analogue 1,1,1-TCA, but the Agency determined these studies did not close the chronic exposure data gap for birds. These studies are listed on the Data Gap Spreadsheet described above on the tab titled "1,1,2-trichloroethane" under the heading "Terrestrial Vertebrates" beginning at row 15, column "L," through row 20. Data Gap Spreadsheet (JA ___). Column "O" describes the length of each study, which ranged from four hours to fourteen days. *Id.* None of these are chronic exposure studies and, thus, do not fill the data need.

D. EPA Need Not Demonstrate Birds Are Exposed to Toxic Amounts of 1,1,2-TCA before Issuing the Test Order.

Petitioner asserts that EPA has not demonstrated that birds are exposed to 1,1,2-TCA in amounts significant enough to cause a risk. But Petitioner has it backwards. A TSCA Section 4(a)(2) test order does not require underlying supporting data on exposure and hazard. Rather, it is just the opposite; a test order requires data creation, so that EPA can evaluate risk. In other words, in the Test Order EPA need not (and cannot) show that birds are exposed to 1,1,2-TCA at toxic levels because EPA *does not have* information about the amount of 1,1,2-TCA that would be toxic to birds based on chronic exposure. Indeed, this lack of information is precisely the reason EPA has ordered the avian reproduction test. The TSCA Amendments

purposefully expanded EPA's authority to issue test orders when EPA determines it needs new information to complete its risk evaluation. The statute does not require that EPA make an "a priori showing" of a chemical's toxicity or exposure levels before issuing a test order.

This Court spoke definitively regarding a very similar issue presented under TSCA Section 4 as codified before the 2016 Amendments in *Chemical Manufacturers v. EPA*, 859 F.2d at 992. There, the petitioner, a trade association for companies subject to a TSCA Section 4 test rule, challenged a test rule that required toxicological testing to determine the health effects of 2–ethylhexanoic acid. Petitioner in that case challenged the test rule pursuant to Section 19(a), *id.* at 980, for which the standard of review ("supported by substantial evidence in the rulemaking record ... taken as a whole") was essentially unchanged by the 2016 Amendments to TSCA. There, as here, the petitioner argued that EPA had not demonstrated sufficient exposure to justify the required toxicological testing. There, as here, the petitioner engaged a consultant to challenge EPA's assessment of exposure. *Id.* at 981.

The Court described the issue as "whether EPA must produce direct evidence documenting human exposure in order to rebut industry-submitted evidence casting doubt on the existence of exposure." *Id.* at 988. The Court held that, with respect to

exposure, "[a] test rule is warranted when there is a more-than-theoretical basis for suspecting that some amount of exposure occurs."[11] *Id.*

As described in the Test Order, 1,1,2-TCA has been measured in air, water, and soil/sediment. Test Order at 6 (JA ___). Further, as explained in the Test Order, a USGS National Water Quality Council monitoring program has measured 1,1,2-TCA in biological tissue. *Id.* at 9 (JA ___). These environmental measurements suggest multiple exposure pathways to birds and other terrestrial organisms. Without information about chronic toxicity, EPA cannot conclude that birds will not be harmed by 1,1,2-TCA even when exposure is low. Thus, EPA has shown a "more-than-theoretical basis for suspecting that some amount of exposure occurs," and the Court should uphold EPA's testing requirement.[12] *Chem. Mfrs.*, 859 F.2d at 988.

E. EPA Explained its Use of a Test Order rather than a Rule or Agreement.

In the Test Order, EPA states that it issued an order rather than promulgate a rule or negotiate a consent agreement because an order would allow EPA to obtain the information more quickly. Petitioner asserts that this explanation is inadequate

[11] The Court made a similar holding regarding likelihood of hazard. *Id.* at 988.
[12] *Chemical Manufacturers* differs from this Petition in that the role of exposure in that case was a factor in the prerequisite finding in Section 4(a)(1)(A)(i) (the authority under which EPA issued the challenged rule). *See id.* at 980. The Test Order challenged here was issued under the (new) authority in Section 4(a)(2), that the required test data is necessary to perform a risk evaluation under Section 6(b). In this case EPA has a *lower* standard to meet than in *Chemical Manufacturers* so that Court's reasoning is even more powerful here.

because EPA has already told Congress that it will be unable to meet its statutory deadline for completing the 1,1,2-TCA risk evaluation.

EPA is allowed to issue test orders as long as it explains its basis for doing so, which it did here.[13] EPA explained that it issued an order, rather than undertaking a rulemaking or entering into a consent agreement, so it could obtain the information quickly. This is a legitimate and sufficient reason, even if Petitioner and amici do not like it. Pet. Br. at 37-38; *see also* Physicians Committee/PETA Amicus Br. at 13 and ACC Amicus Br. at 4. Petitioner and amici prefer, based on their own interests, that EPA require testing only by rulemaking. They seek to return to the pre-TSCA Amendments era, when EPA's authority was limited, and the Agency was hamstrung in enforcing the statute and regulating dangerous chemicals. However, the legislative history establishes that Congress expanded EPA's testing authority in the 2016 TSCA Amendments to reduce the previously burdensome process that constrained EPA from evaluating chemical substances, and to provide a mechanism by which EPA could efficiently obtain the information it needs to evaluate the risk of chemicals and meet its statutory deadlines. Petitioner's argument that EPA is already behind

[13] Amici Physicians Committee and PETA assert that Congress intended for rulemaking to take precedence over orders. Physicians Committee/PETA Amicus Br. at 9-12. This assertion is not supported by the legislative history, in which Congress expressed frustration that the rulemaking process placed a "significant burden on EPA, and test rules can sometimes take many years to complete." S. Rep. No. 114-67 (2015), 2015 WL 3852676. And even if rulemaking is preferred by amici, *see* Physicians Committee/PETA Amicus Br. at 7-9, it is simply not required by statute and not a basis for the Court to vacate the Test Order.

schedule does not mean that EPA should give up and not try to complete its risk evaluation as soon as possible. In sum, EPA adequately explained that it issued a test order to obtain the information quickly given its timeframe for completing the risk evaluation.

F. Petitioner Misstates the Statement of Need's Requirements.

Because the Test Order's Statement of Need complies with the statutory requirements, Petitioner attempts to rewrite these obligations. For instance, Petitioner asserts that the statute "explicitly provides" that EPA "explain how it ruled-out alternative testing methods when requiring vertebrate animal testing." Pet. Br. at 29. But TSCA includes no such requirement. As noted above, TSCA Section 26(h), 15 U.S.C. § 2625(h), requires that in carrying out Section 4, EPA make decisions using "the best available science" and consider whether (among other things) the studies, methodologies, or models "employed to generate the information are reasonable for and consistent with the intended use of the information;" and whether the information is relevant, peer reviewed or independently verified. *Id.* § 2625(h)(1), (2), (5). Thus, EPA would not consider information, studies, methodologies, or models that depart from intended use, are irrelevant, or unverified.

Petitioner also incorrectly asserts that EPA's Test Order is inadequate because it does not "cite to substantial evidence" in the record demonstrating that the avian reproduction test is necessary for the 1,1,2-TCA risk evaluation. Pet. Br. at 28; *see also* ACC Amicus Br. at 4 (arguing that EPA's test orders "fail to contain a full record of

EPA's review"). This argument conflates TSCA's Section 4 requirement that EPA issue a statement of need for required testing with TSCA Section 19(b)'s judicial review provision. TSCA Section 4(a)(3) describes what EPA must include in a statement of need. *See* 15 U.S.C. § 2603(a)(3). TSCA's relevant judicial review provision states "the court shall hold unlawful and set aside such order if the court finds that the order is not supported by substantial evidence in *the record taken as a whole.*" 15 U.S.C. § 2618(c)(1)(B)(i)(II) (emphasis added). Although the Court's review of the Test Order is based on substantial evidence in the entire record, TSCA does not require that EPA cite substantial evidence in the Test Order itself, nor that the Agency submit the record with the Test Order. Thus, the Court should not read into the statute a requirement that the Test Order's Statement of Need cite or include the administrative record, where such a requirement does not exist. *Jama*, 543 U.S. at 341. The record supports EPA's decision; the agency had no obligation to restate the record evidence in the Test Order itself.

In sum, EPA issued the challenged Test Order after determining that to perform a risk evaluation, the Agency needed information on whether chronic exposure to 1,1,2-TCA is hazardous to birds. EPA ordered the test after it determined that no such hazard information was reasonably available and no approved NAMs existed that could predict the toxicity data. These conclusions are supported by substantial evidence and must be upheld.

II. Petitioner's TSCA Section 19(b) Motion Should Be Denied.

TSCA Section 19(b) permits a party to move for leave "to make additional oral submissions or written presentations" respecting a TSCA Section 4 order, if the submissions are (1) "material" and (2) "reasonable grounds" exist for the movant's "failure to make such submissions and presentations in the proceeding before the Administrator." 15 U.S.C. § 2618(b). Several other statutes authorizing judicial review of agency decisions contain similar language requiring that before a court may compel an agency to consider additional information the movant must demonstrate both the materiality of the information and reasonable grounds for the failure to present the information to the agency before presenting it to the court. *See, e.g.*, 33 U.S.C. § 1369(c) (Clean Water Act); 15 U.S.C. § 78y (Securities and Exchange Act of 1934); 15 U.S.C. § 45(c) (Federal Trade Commission Act); 16 U.S.C. § 825*l*(b) (Federal Power Act); 15 U.S.C. § 717r(b) (Natural Gas Act); 29 U.S.C. § 160(e) (National Labor Relations Act). In interpreting the analogous provision under the National Labor Relations Act, for example, the Supreme Court explained that Congress required movants to establish both materiality of the additional evidence, and reasonable grounds for failure to submit it to ensure the provision be used "only for proper purposes, and not abused by resort to it as a mere instrument of delay." *Southport Petroleum Co. v. N.L.R.B.*, 315 U.S. 100, 104 (1942).

Petitioner had the opportunity to submit the information contained in the Stantec Report to EPA through the process set forth in the Test Order yet failed to

do so. Petitioner has not shown reasonable grounds for its failure. Thus, Petitioner has not met its burden under TSCA Section 19(b). While the Court need not determine the materiality of the Stantec Report given that Petitioner has no reasonable grounds for its failure to submit it pursuant to Option 2, if the court does reach that issue, the information in the Stantec Report does not obviate the need for the avian reproduction test, and thus is immaterial.

A. Petitioner Has Failed to Establish Reasonable Grounds for its Failure to Submit the Information to EPA in Response to the Test Order.

Petitioner's 19(b) motion should be denied because Petitioner has failed to establish that "reasonable grounds" exist for its failure to submit the data and information discussed in the Stantec Report to EPA as prescribed in the Test Order's Option 2. Petitioner asserts that reasonable grounds existed because: (1) Option 2 is irrelevant under Section 19(b) because that response option was only available after EPA issued the Test Order, which concluded EPA's "proceeding," and (2) Petitioner lacked access to the administrative record. For the reasons described below, the Court should reject these specious arguments.

1. EPA Is Authorized to Issue Test Orders without Stakeholder Input.

Petitioner asserts that reasonable grounds exist for its failure to submit the information in the Stantec Report to EPA because: (1) the Test Order was issued without public notice or an opportunity for stakeholder input, and (2) the companies

subject to the Order were never given the opportunity to submit additional evidence or assess the adequacy of EPA's decision to require avian reproduction testing. Pet. Br. at 55. With respect to the first assertion, Petitioner is correct that the Test Order was issued without public notice and comment. However, TSCA Section 4(a)(2) expressly authorizes EPA to require testing by order rather than rulemaking, which would be subject to notice and comment. *See* 15 U.S.C. § 2603(a)(2). As described above, Congress amended TSCA and gave EPA the authority to require chemical testing through orders, rather than just rulemaking, to reduce EPA's burden and allow EPA to obtain the necessary information quickly to regulate chemicals that pose an unreasonable risk. This does not mean, though, that the Petitioner was deprived of any opportunity to submit relevant information. Indeed, as discussed below, the Test Order was designed specifically to allow for the submission of information to EPA.

2. The Test Order's Option 2 Provided Petitioner with an Opportunity to Submit Information to EPA.

Contrary to Petitioner's assertion, it did have an opportunity to submit additional evidence to EPA. The companies subject to the Test Order (or the consortium formed on their behalf) had the opportunity to present additional evidence to EPA by exercising response Option 2, "submit existing information." Test Order at 3 (JA ___).

Petitioner asserts that Option 2 is "irrelevant" because Section 19(b) uses the term "in the proceeding before the Administrator," and the Test Order's proceeding

ended when EPA issued the Test Order. Pet. Br. at 55. Petitioner bases this argument on the fact that the word "proceeding" was used in the original version of TSCA when testing could only be required by rulemaking, and, thus, according to Petitioner, the "proceeding" would have ended when the rule was published, and the effective date passed. Pet. Br. at 56. However, issuing a test order, as now allowed by the statute, is procedurally distinct from rulemaking, so the comparison is inapplicable. Furthermore, by providing Option 2, EPA incorporated into its proceeding the ability to submit existing information. Indeed, if the recipients elected Option 2, the Test Order made clear that EPA would consider any such submission and "[i]f the Agency determines that the [submitted information] satisfies the need in lieu of the testing required . . . and/or the original testing requirement is no longer needed, the EPA will extinguish those testing obligations from the Order that are no longer necessary." *Id.* at 11 (JA ___). Additionally, timely election of Option 2 would have tolled the deadlines in the Test Order until EPA made a determination on the submission. *Id.* at 11 (JA ___).

The statute authorizes EPA to issue test orders unilaterally and the legislative history, discussed in Section I.B. above, demonstrates that the purpose was to allow EPA to obtain necessary information quickly so it could timely complete its risk evaluations. Notwithstanding, EPA, in its discretion, has provided test order recipients with the opportunity to rebut its finding that such information is not already available.

Contrary to Petitioner's assertion, allowing test order recipients an opportunity to submit existing information to EPA does not "impermissibly shift[] EPA's burden under Section 4 to Manufacturers." Pet. Br. at 63. In amending TSCA, Congress explained its policy goals that "information should be developed with respect to the effect of chemical substances . . . on health and the environment and that the development of such information *should be the responsibility of those who manufacture* . . . such chemical substances." 15 U.S.C. § 2601(b)(1) (emphasis added). In balancing that responsibility, Congress also explained that EPA's "authority over chemical substances . . . should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while . . . assur[ing] that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment." *Id.* § 2601(b)(3) EPA's Option 2 follows Congress' intent to balance both policy goals. In the Test Order, EPA identified a need for new information and directed manufacturers to develop that information, yet also provided a process through which manufacturers could present evidence to EPA that the testing was unnecessary and potentially avoid incurring costs associated with the testing. Petitioner and amicus ACC ultimately take issue with the responsibility Congress determined manufacturers must bear in ensuring that the chemicals they produce and sell do not pose unreasonable risk to human health or the environment.

Petitioner also argues that because Option 2 is not required by statute, the Court cannot enforce it as "an issue exhaustion requirement." Pet. Br. at 57. To support this position, Petitioner relies on *Darby v. Cisneros*, 509 U.S. 137 (1993). In that case the Supreme Court held that absent a statutory or regulatory requirement, courts have no authority to require parties to exhaust administrative procedures before seeking judicial review. *Id.* at 146. Petitioner also relies on *CSX Transportation Inc. v. Surface Transportation Board*, 584 F.3d 1076 (D.C. Cir. 2009). In that case, the court originally refused to consider an argument that the petitioner failed to raise during the rulemaking process. *Id.* at 1078. On petition for rehearing, the court reversed its decision after finding that the petitioner did not have notice of the issue during the rulemaking process and because petitioner was not required to submit a petition for rehearing to the agency, the petitioner was entitled to judicial review. *Id.* at 1079.

Both *Darby* and *CSX Transportation* are distinguishable. First, both cases dealt with rulemaking for which notice and comment is required, unlike the Test Order at issue here. They are also distinguishable because the issue before the Court here is not whether Petitioner is entitled to judicial review of the Test Order. Indeed, EPA has never asserted that Petitioner cannot seek judicial review of the Test Order based on its failure to exercise Option 2. Rather, EPA argues only that Option 2 gave Petitioner the opportunity to present the information it has now applied for leave to

submit. Because Petitioner has not shown reasonable grounds for its failure to submit the information according to Option 2, its Rule 19(b) motion should be denied.

Furthermore, it is not EPA's position that any test order recipient who fails to exercise Option 2 could not succeed on a Rule 19(b) motion. For instance, if a test order recipient failed to exercise Option 2 and subsequently filed a Rule 19(b) motion based on information that became available only after the deadline to submit new information, then the test order recipient would have reasonable grounds for its failure to submit the information. As discussed below, those are not the circumstances here.

3. Petitioner Did Not Require Access to the Administrative Record to Submit Existing Information.

Petitioner's only explanation for why it did not submit to EPA the information contained in the Stantec Report is because it lacked access to the Administrative Record. Pet. Br. at 58. That argument falls short for two reasons. First, if Petitioner really thought that it needed the Administrative Record to exercise Option 2, it could have asked EPA for access. Yet Petitioner made no such request. Second, contrary to its assertions, Petitioner did not need the administrative record before submitting to EPA information it believed obviates the need for avian reproduction test.

In the Test Order's "Statement of Need," EPA identified the process it used to evaluate the reasonably available information and explained where it identified data gaps, rendering the avian reproduction test necessary for the Agency to complete its

risk evaluation of 1,1,2-TCA. Test Order at 5-9 (JA ___-___). Citing the Stantec Report, Petitioner identifies existing data that it asserts EPA failed to consider. But none of the data discussed in the Stantec Report is new; it was all available to Petitioner when it responded to the Test Order in June 2022. Moreover, all of EPA's alleged "failures" were apparent on the face of the Test Order and not elucidated only through review of the administrative record; thus, petitioner was on notice that it needed to raise these alleged "failures" in its response to the Test Order.

Specifically, Petitioner asserts that EPA failed to consider (1) additional "analogues" to 1,1,2-TCA beyond the seven EPA considered and enumerated in the Test Order; (2) data associated with one of the additional analogues, as well as "acute avian toxicity studies" for one of the analogues identified by EPA; (3) screening or computational methods as part of a tiered testing approach and (4) data purporting to show that 1,1,2-TCA exposure to birds is low. Pet. Br. at 43-54.

First, the Test Order identifies the analogues EPA considered. Test Order at 7-8. (JA ___). If Petitioner believed additional analogues were relevant, it could have identified them (and any associated data) in its response to the Test Order. It did not need the administrative record to do so. Second, EPA stated in the Test Order that it identified acute exposure avian toxicity data for 1,1,2-TCA's analogue 1,1,1-trichloroethane, but did not identify data regarding chronic exposure (the purpose of the testing sought). *Id.* at 7-8 (JA ___- ___). If Petitioner believed the acute studies satisfied the need for testing on chronic exposure, it could have provided that

explanation in response to the Test Order without reviewing the administrative record.

Third, EPA stated in the Test Order that "computational toxicology, or high-throughput screening methods and prediction models are not available and/or cannot be used to address the avian reproduction testing required by this order." *Id.* at 8 (JA ___). Again, if Petitioner identified available screening/computational methods it thought were relevant, it could have identified those models in its response to EPA. Finally, fourth, if Petitioner had data demonstrating that avian exposure to 1,1,2-TCA was so low and would always remain so low that it rendered testing unnecessary, it could have submitted that data to EPA in response to the Test Order. Petitioner did not need to review the administrative record before submitting the information in response to the Test Order, which, had Petitioner done, EPA would have considered pursuant to the process laid out in the Test Order. *See id.* at 11 (JA ___).

Petitioner contends that without the administrative record, it could not have submitted information as allowed by the Test Order because Petitioner could not determine whether EPA had already considered the information.[14] Pet. Br. at 59.

[14] This premise is inaccurate. For instance, the Test Order cited the publicly available scope document and explained how EPA used that document to determine relevant exposure pathways and its systematic review of information. Test Order at 6. In addition, the Test Order stated that "no approved or readily available new approach methodologies (NAMs) were identified that could be used to inform the data gap for avian toxicity following chronic exposures." *Id.* at 8. This means that EPA did not identify a NAM that would fill the chronic toxicity need for birds. If Petitioner

Yet, even if Petitioner could not determine whether EPA had already considered the information, nothing prevented Petitioner from submitting the information and explaining its significance. Indeed, the Test Order states that recipients may submit an existing study or other relevant information "you *believe*" EPA has not considered, "along with supporting rationale that explains how the submittal(s) meets part or all of the information [required]." Test Order at 3 (JA ___) (emphasis added). There was no requirement that the recipients demonstrate that the information was, in fact, new for EPA to consider it. Failure to submit the information as allowed by the Test Order was therefore unreasonable, and Petitioner's Section 19(b) motion must be rejected on that basis.

In sum, Petitioner identifies no "reasonable grounds" as to why it failed to submit the information in the Stantec Report to EPA months ago pursuant to the process set forth in the Test Order. Indeed, no such reasonable grounds exist. Petitioner should not now be allowed to submit these materials in a judicial proceeding months after it had the opportunity to do so in response to the Test Order. To require EPA to make a finding that Petitioner's belated information does not satisfy the data need described in the Test Order could further delay testing under the Order and potentially delay EPA's risk evaluation for 1,1,2-TCA for which

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thought that EPA was wrong, it could have identified the NAM it believed filled the data gap.

Congress imposed ambitious statutory deadlines on EPA. *See Southport Petroleum*, 315 U.S. at 104.

B. Petitioner Failed to Establish that the Stantec Report is Material.

For the reasons described above, the Court need not make a finding on materiality because no "reasonable grounds" exist for Petitioner's failure to submit the information in the Stantec Report to EPA in response to the Test Order. However, even if the Court were to find that reasonable grounds exist, Petitioner's motion should be denied because Petitioner fails to establish that the information in the Stantec Report is material.[15]

As described above, to compel EPA to consider additional information TSCA Section 19(b) requires that the movant "show[] to the satisfaction of the court" that such information "would be material." 15 U.S.C. § 2618(b). "The test of materiality . . . is strict: does it clearly appear that the new evidence would compel or persuade to a contrary result." *Rocky Mountain Power Co. v. Fed. Power Comm'n*, 409 F.2d 1122, 1128 n.21 (D.C. Cir. 1969) (citation omitted) (explaining the materiality standard in the

[15] Contrary to Petitioner's assertions, EPA never opted "not to contest" the materiality of the Stantec Report. Pet. Br. at 55. Rather, in responding to the 19(b) motion, EPA requested that if the Court found that reasonable grounds existed for Petitioner's failure to submit the material, the Court refrain from deciding the materiality of the submission and hold the case in abeyance for 45 days to allow EPA to consider the information submitted by Petitioner and provide its response. Since the filing of that brief and the Court's decision to consider the issues during merits briefing, EPA has had the opportunity to review and consider the substance of the Stantec Report.

Federal Power Act, 16 U.S.C. § 825*l*(b), which, like TSCA Section 19(b), provides a mechanism for courts to compel the Commission to adduce additional evidence that a movant can "show to the satisfaction of the court . . . is material and that there were reasonable grounds for failure to adduce such evidence in the proceedings"); *see also Friends of the River v. Fed. Energy Regul. Comm'n* ("FERC"), 720 F.2d 93, 98 n.6 (D.C. Cir. 1983) (denying motion where additional evidence was "cumulative, unreliable, or not material"); *Conservation Law Found. v. FERC*, 216 F.3d 41, 49 n.11 (D.C. Cir. 2000). Petitioner has not met its burden here.

Petitioner asserts that the information in the Stantec Report "*could* have compelled EPA to forego issuing the Test Order or at least employ a more reasonable tiered testing approach." Pet. Br. at 42 (emphasis added). Importantly, Petitioner does not even try to establish that the information contained in the Stantec Report *would* compel EPA to modify or withdraw the Test Order, but only that it "could." And, as detailed below, the information proffered by Petitioner is unreliable and insufficient to obviate the need for the avian reproduction test required by the Test Order.

1. AIM Is the Approved NAM for Identifying Analogues.

Petitioner asserts that EPA should have used its Computational Toxicology Chemicals Dashboard ("CompTox") to identify 1,1,2-TCA analogues that *could* provide information on avian toxicity. Pet. Br. at 43-44. The preferred EPA-approved NAM for identifying potential chemical analogues is the Analogue

Identification Methodology (AIM) Tool — the tool EPA used to identify 1,1,2 TCA analogues, as described in Section I.A. above. Decl. of Denise Keehner ¶ 5.a., (JA ___-___).[16] The AIM Tool is specifically designed for identifying potential analogues to a chemical of interest. *Id.* ¶ 5.b. AIM conducts a comprehensive structural analysis using over 700 individual atoms, groups and super fragments indexed in a predefined database. *Id.* (JA ___-___). It then matches them to potential analogues from an inventory of over 86,000 chemicals with publicly available measured data. *Id.* The benefit of using the AIM Tool is that the analogues identified tend to be more closely related and it provides smaller subsets of analogues from which to choose. *Id.* EPA used AIM instead of CompTox because AIM is an approved NAM, which provides access to information based on structural similarity and evaluates the appropriate use of available data. *Id.*

2. Hexachloroethane Is Not an Appropriate Analogue to 1,1,2-TCA.

Relying on the Stantec Report, Petitioner asserts that EPA should have considered a "subchronic" inhalation study that exposed quails to hexachloroethane, that Stantec used to calculate potential "toxicity values," which showed that

[16] Judicial review under TSCA is limited to the administrative record compiled by the agency. 15 U.S.C. § 2618(c)(B)(ii). Therefore, the court should not consider any part of the Stantec Report in ruling on the merits. EPA submits the declaration of Denise Keehner, the Director of EPA's Office of Pollution Prevention and Toxics, for the limited purpose of responding to Petitioners' Section 19(b) request and the technical assertions made in the Stantec Report relied upon by Petitioner in Section II of its opening merits brief.

hexachloroethane is of "low toxicity potential to birds." Pet. Br. at 44-45. Hexachloroethane is one of the purported analogues Stantec identified using CompTox. Stantec Report at 17-18 (JA ___-___). EPA determined, however, that based on their physical and chemical properties, hexachloroethane and 1,1,2-TCA are not close enough structurally or chemically to be considered analogues. Keehner Decl. ¶ 6 (JA ___-___). The two chemicals move through the environment in different ways creating different exposure scenarios. *Id.* ¶ 6.a. (JA ___-___). In addition, EPA does not have sufficient hazard information (i.e., the same or similar test for both chemicals) to be confident that data on hexachloroethane could be extrapolated to 1,1,2-TCA based on toxicological similarity. *Id.* ¶ 6.b.-c. (JA ___-___).

3. Acute Studies Are Insufficient to Close the Data Gap.

Petitioner asserts that Stantec identified three acute exposure studies for 1,1,1-trichloroethane (an analogue to 1,1,2-TCA that EPA identified) that EPA should have considered. Pet. Br. at 46. However, as EPA discussed in the Test Order, it needs toxicity information based on chronic exposure, not acute exposure, which is why it has ordered the avian reproduction test. Test Order at 8-9 (JA ___-___).

4. Quantitative Structure-Activity (Toxicity) Relationship Models Are Not Validated.

Stantec contends that EPA could have used Quantitative Structure-Activity (Toxicity) Relationship (QSA(T)R) models to predict avian toxicity. Pet. Br. at 45-50.

But none of the models identified by Stantec has been validated for use as a predictor of avian toxicity. Keehner Decl. ¶ 8 (JA ___-___). QSAR model validation is essential for ensuring the reliability of predicted data when applying them to novel chemicals. *Id.* ¶ 8.a. (JA ___-___). If a computational model has not been validated for a specific use, then additional information is needed to validate the model for that use. *Id.* ¶ 8.b. (JA ___-___). Indeed, the avian toxicity data that EPA is requiring in the Test Order would be necessary to validate the computational models identified by Stantec. *Id.* ¶ 8.d. (JA ___-___). Because the model is not validated, EPA could not use the QSA(T)R models to reliably predict avian toxicity. *Id.* ¶ 8.c. (JA ___-___).

5. Best Available Science Does Not Support Using Web-ICE to Extrapolate from Mammals to Predict Avian Toxicity.

Petitioner (citing the Stantec Report) and Amici Physicians Committee and PETA assert that EPA could have used its Web-based Interspecies Correlation Estimation (Web-ICE) to extrapolate to birds existing toxicity data from a study on rats based on acute exposure to 1,1,1-trichlorothane. Pet. Br. at 50; Physicians Committee/PETA Amicus Br. at 18-19. This proposed use is not supported by best available science. Keehner Decl. ¶ 7 (JA ___-___). Web-ICE is a tool developed by EPA to estimate the *acute* toxicity of a chemical to a species, genus, or family from the known toxicity of the chemical to a surrogate species. *Id.* ¶ 7.a. (JA ___-___). Generally, toxicologists do not extrapolate mammalian acute toxicity data to birds because of the significant differences in the species, including differences in anatomy

and physiology and differences in sensitivity to contaminants. *Id.* ¶ 7.a. (JA ___-___). Previous studies have established that rodents may not adequately represent toxicity to other organisms. *Id.* In addition, the WebICE terrestrial models have limited underlying data and, for that reason, the avian and mammalian WebICE models are not yet approved, validated, or used by EPA for regulatory decision making. *Id.* Best available science does not currently support use of the mammalian model for acute toxicity in rats on Web-ICE to extrapolate to birds. *Id.* ¶ 7.c. (JA ___).

6. Even Assuming Exposure Levels Are Low, Chronic Testing Is Necessary.

Finally, Stantec has identified data allegedly showing that 1,1,2-TCA is infrequently detected in the environment, and when it is detected, it is at low levels. Stantec Report at 14 (JA _____). For instance, the Stantec Report asserts that EPA should have considered a Toxicological Profile for 1,1,2-TCA, produced by the Agency for Toxic Substances and Disease Registry (ATSDR) in 2021, which stated that where 1,1,2-TCA is detected in air, most levels range from 10 to 50 ppt. Stantec Report at 11 (JA ____). Stantec asserts that statement demonstrates that 1,1,2-TCA is detected in the air at low concentrations. *Id.* However, the preceding sentence in the ATSDR profile notes that the data is limited. Notwithstanding, and even accepting Stantec's characterization as true, this information does not obviate the need for additional testing to determine whether chronic exposures to 1,1,2-TCA, even if at low levels, pose a risk to birds as discussed in Section I.D. above.

In sum, Petitioner has not established that the information in the Stantec Report obviate the need for the avian reproduction test. The methodologies and models Stantec suggests are either inappropriate or unvalidated and, thus, their use would be inconsistent with "best available science." *See* 15 U.S.C. § 2625(h).

CONCLUSION

For all the reasons set forth above, Vinyl Institute's petition for review and Rule 19(b) Motion should be denied.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Fed. R. App. P. 32(a)(5) and (6) because it has been prepared in 14-point Garamond, a proportionally spaced font.

I further certify pursuant to Fed. R. App. P. 32(f) and (g) that this brief contains 12,978 words, excluding exempted parts of the brief, according to the count of Microsoft Word, and that this brief complies with the type-volume limitation set forth in Fed. R. App. P. 32(a)(7)(B)(i).

/s/ Laura J. Brown
LAURA J. BROWN

CERTIFICATE OF SERVICE

I hereby certify that on March 20, 2023, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit using the appellate CM/ECF system. The participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

/s/ Laura J. Brown