Case No.: 22-1089

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

VINYL INSTITUTE INC.,

Petitioner,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

Petition for Review of EPA TSCA Test Order
EPA-HQ-OPPT-2018-0421

PETITIONER VINYL INSTITUTE INC.'s OPENING BRIEF

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Dated: January 17, 2023

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), Petitioner Vinyl Institute, through its undersigned counsel, submits this Certificate as to Parties, Rulings, and Related Cases.

I. Parties, Intervenors, and Amici

A. Petitioners

Vinyl Institute Inc.

B. Respondents

U.S. Environmental Protection Agency

C. Intervenors and Amici

None at this time

II. Rulings Under Review

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) (JA___-___).

III. Related Cases

None

/s/ *Eric P. Gotting*

CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1 and Circuit Rule 26.1, Petitioner Vinyl Institute hereby submits this Corporate Disclosure Statement. The Vinyl Institute is a trade association representing the leading manufacturers of vinyl, vinyl chloride monomer, and vinyl additives and modifiers. Relevant to this case, the Vinyl Institute manages a consortium of companies that is subject to the challenged Test Order. The Vinyl Institute does not have any parent corporation or publicly held corporation that owns 10 percent of more of its stock.

/s/ *Eric P. Gotting*

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APA	Administrative Procedure Act
EPA	U.S. Environmental Protection Agency
TSCA	Toxic Substances Control Act
USGS	United States Geological Service

STATEMENT OF JURISDICTION

Petitioner Vinyl Institute seeks review by this Court of the U.S. Environmental Protection Agency's ("EPA") *Order Under Section 4(a)(2) of the Toxic Substances Control Act*, Docket Identification Number: EPA-HQ-OPPT-2018-0421 ("Test Order"). The Test Order was issued on March 24, 2022, and amended on April 20, 2022, and again on August 5, 2022 (the latest amended version is attached at JA___-___). The Vinyl Institute filed its Petition for Review on May 23, 2022, within the statutory 60-day appeal deadline set forth in the Toxic Substances Control Act's ("TSCA") judicial review provision. 15 U.S.C. § 2618(a). This Court has jurisdiction under TSCA, 15 U.S.C. § 2618, and the Administrative Procedure Act ("APA"), 5 U.S.C. § 701, *et seq.*

STATEMENT OF ISSUES

Petitioner Vinyl Institute seeks this Court's review of the U.S. Environmental Protection Agency's ("EPA") *Order Under Section 4(a)(2) of the Toxic Substances Control Act*, Docket Identification Number: EPA-HQ-OPPT-2018-0421 ("Test Order") (JA___-___). The Test Order requires that certain chemical manufacturers, who are members of a consortium managed by the Vinyl Institute, conduct avian reproduction

toxicity testing on a chemical substance, 1,1,2-trichloroethane, which is manufactured by those companies. EPA asserts that data from such testing would be used by EPA to inform an on-going Toxic Substances Control Act ("TSCA") risk evaluation of the chemical substance. This case raises the following issues:

1. Did EPA violate TSCA and the Administrative Procedure Act ("APA") when it failed to: (i) provide an adequate Statement of Need in the Test Order, as required by TSCA Section 4 (15 U.S.C. § 2603) (ADD051-058), explaining why avian reproduction testing is "necessary" to conduct the risk evaluation; and (ii) cite to "substantial evidence" in "the record taken as a whole," as directed by TSCA Section 19 (15 U.S.C. § 2618) (ADD059-060), that justifies the Test Order?

2. Should this Court grant the Vinyl Institute's motion under TSCA Section 19 to submit additional data and information in the Test Order's administrative record where: (i) the Test Order was issued without notice to the Vinyl Institute or opportunity for comment before the order was issued; and (ii) such additional data and information would allow EPA to make a more informed decision on the Test Order's necessity and facilitate any subsequent judicial review?

STATEMENT OF THE CASE

I. TSCA Chemical Risk Evaluations

This case involves EPA's authority under TSCA to issue test orders requiring chemical manufacturers, without prior notice, to conduct time-consuming and expensive toxicity testing on their products without adequately demonstrating a need for such data. In 2016, Congress amended TSCA, tasking EPA with determining whether certain chemical substances present an unreasonable risk of injury to health or the environment. 15 U.S.C. § 2605(b)(4). Chemicals undergoing a risk evaluation are selected by EPA through a prioritization process where a chemical is designated as a high-priority or low-priority substance. 15 U.S.C. § 2605(b)(1)(B).

Chemicals designated as a high-priority substance go through a three-year risk evaluation, in which EPA considers a chemical's potential hazards, routes of exposure, and risk. 15 U.S.C. § 2605(b)(4)(F). A finding by EPA that a chemical presents an unreasonable risk for one or more conditions of use (i.e., manufacture, processing, distribution, use, and/or disposal), *see* 15 U.S.C. § 2602(4) (definition of "conditions of use"), triggers a risk management

rulemaking to address any identified unreasonable risks, 15 U.S.C. § 2605(a) (e.g., limiting the amount of the substance that may be distributed in commerce, restricting methods of disposal, etc.).

II. EPA's Test Order Authority

During a risk evaluation, EPA may "require the development of new information relating to a chemical substance…if the Administrator determines that the information is *necessary*." 15 U.S.C. § 2603(a)(2)(A)(i) (emphasis added). EPA has three options through which it may require a manufacturer or processor to develop new information – by rule, order, or consent agreement. 15 U.S.C. § 2603(a)(2). EPA, however, does not have unbounded authority to simply issue a test order; rather, TSCA requires EPA to demonstrate that testing is necessary and to explain that showing in what the statute calls a "Statement of Need." 15 U.S.C. § 2603(a)(3).

Specifically, in the Statement of Need, EPA must: "identify the need for the new information"; (ii) "describe how information reasonably available to the Administrator was used to inform the decision to require new information"; (iii) "explain the basis for any decision that requires the use of vertebrate animals"; and (iv) "explain why issuance

of an order is warranted instead of promulgating a rule or entering into a consent agreement" with the manufacturer(s). *Id.*

Collectively, these factors obligate EPA to demonstrate that new testing is "necessary." First, because of the significant resource and financial burdens associated with chemical testing, TSCA obligates EPA to rely on tiered or screening tests before requiring more robust studies. *See* S. Rep. No. 114-67, at 10 (2015), 2015 WL 3852676 (noting test orders should be as "efficient and cost-effective as possible").[1] EPA "shall 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." 15 U.S.C. § 2603(a)(4). EPA may proceed to more advanced testing only when available information justifies not first requiring companies to carry-out more reasonable screening-level testing. *Id.* Indeed, TSCA instructs EPA to consider the "relative costs of the various test protocols and methodologies" before issuing an order. 15 U.S.C. § 2603(b)(1).

[1] This report relates to an earlier version of the proposed TSCA amendments with provisions nearly identical to Section 4.

Second, when amending TSCA, Congress placed a high priority on minimizing vertebrate animal testing. The statute mandates that EPA reduce and replace such testing whenever practicable and scientifically justified. 15 U.S.C. § 2603(h)(1). As with tiered testing, EPA must consider reasonably available alternatives to animal testing, such as existing toxicity information, computational toxicology and bioinformatics, high-throughput screening methods, and the prediction models of high-throughput screening methods. 15 U.S.C. § 2603(h)(1)(A)(i)-(iii).[2] Indeed, EPA must encourage and facilitate the development of non-animal testing methods, as well as group similar chemicals for testing and allow companies to operate through consortia, to avoid duplicative animal tests. 15 U.S.C. § 2603(h)(1)(B).

Third, any EPA decision to require additional testing must be based on "the weight of the scientific evidence." 15 U.S.C. § 2625(i). EPA defines "[w]eight of scientific evidence" in regulations governing risk evaluations to mean:

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[2] Testing alternatives such as computational toxicology and informatics tools are referred to as "New Approach Methodologies" or "NAMs." Test Order at 8 (JA___).

> a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.

40 C.F.R. § 702.33. Thus, TSCA does not allow EPA to determine the need for a test order based on a cursory review of available evidence, irrelevant studies, or an incomplete administrative record.

Fourth, EPA must implement its test order authority "consistent with the best available science." 15 U.S.C. § 2625(h). EPA's risk evaluation regulations define "[b]est available science" to mean:

> 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. As such, when EPA "makes a decision based on science," 15 U.S.C. § 2625(h), it must, at a minimum, address material deficiencies in studies or research cited for support.

Fifth, in considering a test order, EPA must "take into consideration information…that is reasonably available to" EPA, including "exposure information." 15 U.S.C. § 2625(k).

Finally, when adopting TSCA, Congress explicitly instructed EPA to carry out its responsibilities, which includes its test order authority, "in a reasonable and prudent manner." 15 U.S.C. § 2601(c). Indeed, Congress cautioned "EPA [to] use its [test order] authority to require the development of new information *judiciously*, and only when needed to implement key provisions of the Act." S. Rep. No. 114-67, at 10 (2015), 2015 WL 3852676 (emphasis added).

III. 1,1,2-Trichloroethane Test Order

The chemical at issue in this case, 1,1,2-trichloroethane, is used primarily as a solvent and an intermediate in the production of other chemicals. It was designated a high-priority substance as part of a set of 20 chemicals slated for risk evaluation.[3] EPA issued the Test Order on March 24, 2022, requiring that certain companies conduct studies on

[3] EPA, *High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA) and Initiation of Risk Evaluation on High-Priority Substances; Notice of Availability*, 84 Fed. Reg. 71,924 (Dec. 30, 2019).

1,1,2-trichloroethane, which EPA maintains are necessary to assess potential risks to the environment.[4] Test Order at 2 (JA___). The Test Order requires two studies assessing ecotoxicity – an earthworm reproduction test and an avian reproduction test. *Id.* at 6 (JA___).

This is not the first time EPA has required these companies to conduct testing on 1,1,2-trichloroethane during the risk evaluation. In January 2021, EPA issued a test order requiring ecotoxicity testing on aquatic organisms, dermal absorption testing, worker inhalation exposure, and worker dermal exposure.[5] Test Order at 5 (JA___).

Only the avian reproduction study is being contested here. The Test Order requires that the study be conducted pursuant to EPA's *Ecological Effects Test Guidelines* (OCSPP 850.2300). Test Order at 14, 29 (JA___,___).[6] This is a feeding study using Bobwhite quail, a ground-dwelling bird native to the United States. Test Order at 29 (JA___). It is

[4] The Test Order originally applied to seven companies. On August 5, 2022, EPA amended the Test Order to remove two companies.

[5] Collectively, the cost of completing all of the studies required by the two test orders could exceed $1 million. The avian reproduction study will, at a minimum, cost $200,000. ADD050.

[6] *See* EPA-HQ-OPPT-2009-0154-0012_content (1).pdf.

a multi-generational study, where adult birds are given food containing 1,1,2-trichloroethane for their daily diet both prior to the onset of breeding and continuing for an extended period after egg laying. Effects on adult birds, embryos, and hatchlings are monitored throughout the exposure period to assess the potential reproductive impact.[7] At the conclusion of the exposure period, all birds are sacrificed and subjected to gross necropsy. While a final report on the results of the testing was initially due 295 days after the effective date of the Test Order (or January 18, 2023), given the complexities of testing and laboratory scheduling, extensions will push that date into 2024. ADD049.

IV. The Test Order's Statement of Need

The Test Order contains a brief Statement of Need intended to show why the avian reproduction test is "necessary" for the risk evaluation. Test Order at 5-9 (JA___-___).

Tiered Testing: As to whether testing burdens could be reduced by first requiring tiered testing or computational screening methods, which could then inform a decision as to whether more substantial

[7] *See supra* note 6 at 2.

avian reproduction studies are justified, EPA simply 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." Test Order at 8 (JA___) (emphasis added). The Test Order does not explain how EPA made this determination, what alternative methods EPA evaluated, or why they are infeasible. The Test Order also never compares the costs of such streamlined approaches to more comprehensive testing methodologies.

Vertebrate Animal Testing: Regarding efforts to minimize vertebrate animal testing, the Test Order only maintains 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." *Id.* at 8 (JA___). Again, as with the tiered testing requirement, the Test Order does not identify the alternative testing methods considered, why they were rejected, or how EPA otherwise reached this conclusion.

Existing Toxicity Data and Analogues: To determine whether relevant toxicity data already exists, EPA states that it searched for

studies on 1,1,2-trichloroethane in peer-reviewed literature databases, gray literature (technical reports, reference books, dissertations), and information submitted to EPA during the prioritization process and under other TSCA programs. *Id.* at 6-7 (JA___-___).

EPA also searched for existing toxicity data on chemical analogues for 1,1,2-trichloroethane. Chemical analogues are commonly used to provide relevant information on substances with chemical structures similar to the target chemical that can be used to fill unmet data needs. *Id.* at 8 (JA___). The Test Order identifies seven analogues of 1,1,2-trichloroethane.[8] According to the Test Order, EPA relied on its Analog Identification Methodology (AIM) software to identify these analogues, and searched for studies in EPA's ECOTOX Knowledgebase, as well as in submissions made to EPA under other TSCA provisions and environmental programs. *Id.* at 7 (JA___). The Test Order, however, is silent as to why other tools that are typically used by EPA to identify

[8] 1,1,1-trichloroethane (with Chemical Abstracts Service Registry Number (CASRN) 71-55-6); trichloroethane (CASRN 25323-89-1); 1,2,3-trichloropropane (CASRN 96-18-4); 1,2,3,4-tetrachlorobuta-1,3-diene (CASRN 1637-31-6); 1,1,5,5-tetrachloropentane (CASRN 17655-64-0); 1,1,2,3-tetrachloropropane (CASRN 18495-30-2); and 1,2,3,4-tetrachlorobutane (CASRN 3405-32-1).

analogues were not employed, or whether EPA's searches on analogues included peer-reviewed literature databases and gray literature.

The Test Order generally indicates that there is acute exposure data for birds covering 1,1,2-trichloroethane and one other analogue. *Id.* at 8 (JA___). It then concludes that "[n]o avian toxicity data following chronic exposures were identified for 1,1,2-trichlorethane or identified analogues for any endpoints." *Id*. According to EPA, it therefore needs to fill this unmet data need because "[w]ithout toxicity data, the EPA is unable to determine if chronic exposures to 1,1,2-trichlorethane pose a risk to terrestrial vertebrates." *Id.*

In doing so, however, the Test Order does not identify the basis for these conclusory statements. It does not identify any of the studies EPA reviewed, reveal the results of those studies, discuss whether EPA ruled out any other potentially relevant research, and if so why, or explain why no studies provide any insight into potential chronic effects. *Id.* Moreover, the Test Order does not provide information sufficient to gauge EPA's efforts, such as whether it may have missed relevant information on 1,1,2-tricholorethane and its analogues.

The only specific toxicity data cited by EPA came from a 1979 study that "qualitatively indicates exposure to 1,1,2-trichloroethane caused developmental toxicity to chick embryos," but with EPA admitting that "the nature of this endpoint (egg injection) is not directly comparable to other chemical toxicities following dietary exposure." *Id.* at 9 (JA___) (citing Elovaara, *et al.*, 1979). Nevertheless, the Test Order concluded without explanation that "the [study's] evidence of teratogenicity in chick embryos indicates that additional data are needed to understand the potential effect following chronic dietary exposure." *Id.* Nowhere does EPA address, however, the relevance of this study under a "weight of the scientific evidence" approach or if it constitutes "best available science," including any shortcomings in the study design and relationship to potential environmental exposure.

Environmental Exposure: As to whether birds may be exposed to 1,1,2-trichloroethane in amounts that would warrant additional testing, EPA cites to a flow chart (or "conceptual model") contained in a two-year-old "scope" document issued early in the risk evaluation

process. *Id.* at 7 (JA___).[9] That flowchart shows "potential" pathways of exposure, including to terrestrial species, but does not contain any data regarding environmental exposure levels. *Id.*

Regarding the latter point, EPA instead cites in the Test Order to a single source of information, merely stating that "[m]onitoring data from USGS's [the U.S. Geological Survey's] National Water Quality Monitoring Council has also identified 1,1,2-trichloroethane in media to which terrestrial vertebrates may be exposed, including ground water, sediment, soil, surface water, and biota." Test Order at 9 (JA___).

The Test Order, however, does not identify the specific detection rates or concentration levels found in the USGS monitoring data purportedly supporting EPA's conclusion, or otherwise explain how this information indicates that avian species are being exposed to 1,1,2-trichloroethane at levels sufficient to merit concern. Even the Test Order itself merely refers to potential exposure of "terrestrial vertebrates" but makes no specific statement that birds are exposed.

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[9] *See Final Scope of the Risk Evaluation for 1,1,2-Trichloroethane* (EPA-740-R-20-003), at Fig. 2-15, pgs. 43-44 (Aug. 2020).

Need for Order as Opposed to a Rule or Consent Agreement: The Test Order states that, to meet regulatory timetables, an order "will allow [EPA] to target known manufacturer and processor recipients to obtain the needed information more quickly." *Id.* at 8. The statutory deadline for completing the risk evaluation for 1,1,2-trichloroethane is June 2023. *See* 15 U.S.C. § 2605(b)(4)(G) (risk evaluation must be completed within three years after EPA initiates the evaluation, subject to a six-month extension); 40 C.F.R. § 702.17 (the risk evaluation is initiated when the substance is designated as a high-priority chemical); 84 Fed. Reg. at 71,925 (EPA designating 1,1,2-trichloroethane as a high-priority substance in December 2019).

However, in June 2022, EPA's Assistant Administrator for the Office of Chemical Safety and Pollution Prevention stated in testimony before Congress that EPA will not finish risk evaluations for the 20 high-priority substances within the statutory deadlines due to a lack of resources.[10] The amended Test Order does not further address this

[10] *See Toxic Substances Control Act Amendments Implementation: Hearing Before the S. Comm. on Environment and Public Works*, at 6-7 (testimony of Michal Freedhoff, Assistant Administrator, Office of Chemical Safety and Pollution Prevention, U.S. Environmental

apparent inconsistency, explain why EPA waited over a year after issuing the first test order in January 2021 to issue the one challenged here, or discuss why EPA could not have entered into a consent agreement with the Vinyl Institute's consortium in a timely manner.

V. The Test Order's Option 2

The Test Order gives the Vinyl Institute the option (informally called "Option 2") to submit existing studies or other scientifically relevant information that it believes EPA did not consider but which may satisfy the information/data need or obviate the need for the Test Order. Test Order 3, 11 (JA___,___). However, Option 2 was only available after the Test Order was finalized and issued. The Vinyl Institute had no prior notice of the Test Order or opportunity to offer input into whether it was "necessary" under Section 4.

Moreover, Option 2 limited the Vinyl Institute to a review of the Test Order itself. The Vinyl Institute did not have access to the administrative record so it could ascertain, as required by Option 2,

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Protection Agency). ADD044-045 (excerpt) (stating that EPA will not finish at least half of these risk evaluations before 2025).

what studies and scientific information EPA did or did not consider in deciding why the Test Order was necessary for the risk evaluation.

SUMMARY OF THE ARGUMENT

This appeal seeks to hold Respondent U.S. Environmental Protection Agency ("EPA") to a key compromise struck in 2016 when Congress substantially amended the Toxic Substances Control Act ("TSCA"). Prior to the amendments, EPA had grown concerned that it could only require that chemical manufacturers conduct toxicity testing through a notice and comment rulemaking process. Congress, therefore, granted EPA authority to issue test orders, without prior notice to the manufacturers, to help inform various agency activities, including newly required risk evaluations of certain chemicals to determine if they pose an unreasonable risk to health or the environment.

But Congress, in realizing the impropriety of granting EPA unfettered authority, placed numerous conditions on the agency that must be satisfied before EPA can, without warning, require expensive and resource-intensive testing. Overall, the test order must be "necessary" to conduct the chemical risk evaluation. There must be a

demonstrated need for the information and data that would be generated by the specified testing method. *Supra* at 4-5.

Specifically, EPA must show there is a critical information gap that cannot be filled through more efficient means, such as first employing tiered or screening tests that would help decide whether more exhaustive toxicity studies are warranted. Similarly, to guard against excessive testing involving animals, EPA must investigate alternative testing methods (like computer modeling or *in vitro* methods) to minimize the number of animals harmed or sacrificed. When determining whether an unmet information need actually exists, EPA cannot rely on a cursory review of available scientific evidence; rather, it must base its decision on a "weight of scientific evidence" approach, rely on the "best available science," and consider "reasonably available" evidence. *Supra* at 6-8.

Significantly, when issuing a test order, EPA must show its work. EPA cannot merely claim it considered these issues and be done with it; rather, under Section 4, EPA must explain in a "Statement of Need" how it eliminated a tiered testing approach, decided animal testing was

unavoidable, and determined that existing exposure and toxicity information was insufficient. *Supra* at 4-6.

Further, EPA must specifically cite to evidence in the record justifying the test order. The manufacturer must be able to discern what facts EPA relied upon for support. *See* 15 U.S.C. § 2618(c) (setting forth TSCA's "substantial evidence" standard of review).

Finally, EPA must explain why it issued a test order instead of cooperatively working with manufacturers, as permitted under TSCA, to negotiate a consent agreement that requires an appropriate level of testing. In short, EPA was granted test order authority, but for which Congress demanded a degree of scientific rigor and transparency.

It is imperative that EPA comply with these obligations. While the number of test orders issued during the prior administration were few, the current administration has dramatically escalated the use of such authority. EPA recently estimated that it will be issuing approximately 75 test orders per year between fiscal years 2023-25.[11] If EPA is not

[11] EPA, *Technical Support Document: Supplemental Notice of Proposed Rulemaking; Fees for the Administration of the Toxic Substances Control Act (TSCA) (RIN 2070-AK46)* (Nov. 2022).

held to TSCA's test order requirements, the chemical industry may face a parade of unsubstantiated test orders over the next three years and bear significant testing costs, collectively totally tens of millions of dollars, if not more.

This case is the first time a federal court will have an opportunity to ensure EPA is meeting its test order obligations. In its Petition for Review, the Vinyl Institute challenges a Test Order requiring named manufacturers to conduct avian reproduction testing on 1,1,2-trichloroethane. The Vinyl Institute manages the consortium that would fund the study. Unfortunately, in this instance, EPA failed to satisfy TSCA's prerequisites for issuing a test order. In this appeal, the Vinyl Institute demonstrates the following:

1. The Test Order and Statement of Need are supported with only conclusory statements. The Statement of Need does not identify what information EPA considered or explain how EPA evaluated tiered testing approaches, alternatives to vertebrate animal testing, or existing information and data that could obviate the need for additional toxicity studies. Moreover, nowhere in the Statement of Need does EPA cite to a body of "substantial evidence" in the record as a whole

warranting avian reproduction studies. EPA also does not adequately explain why it issued the Test Order in lieu of a negotiated consent agreement. As such, the Test Order should be vacated and remanded for further consideration by EPA.

2. EPA issued the Test Order without approaching the Vinyl Institute or the consortium's members, with whom the agency had been communicating on the risk evaluation, to discuss whether additional avian reproduction testing is necessary. The Vinyl Institute also never had a chance to file comments or materials in the record. Accordingly, the Vinyl Institute filed a motion with this Court (which has subsequently been referred to this merits panel) for leave to supplement the administrative record so that EPA could review additional, reasonably available information and to facilitate, if needed, any subsequent judicial review. That motion was supported by two expert reports showing that EPA had, in fact, not considered readily available and relevant information (*e.g.*, toxicity studies on quail), and failed to conduct required analyses when issuing the Test Order.

3. EPA resisted the Vinyl Institute's motion. The Test Order contained an "Option 2," which allowed the Vinyl Institute to submit,

after the Test Order was issued, studies or other scientific information that the Vinyl Institute believed were missing from the administrative record. According to EPA, this Court does not have authority to grant the motion because the Vinyl Institute did not avail itself of Option 2. That is incorrect. Section 19(b) permits this Court in the circumstances present in this case to grant leave to the Vinyl Institute to supplement the record when it was not given the opportunity to submit comments before the Test Order was finalized. Moreover, even if the Vinyl Institute had tried to follow Option 2, it could not have reasonably determined what was missing from the administrative record because the Test Order did not include or even reference such a record or its contents; instead, the Vinyl Institute's review was limited to the face of the otherwise conclusory Test Order. Option 2 was wholly inadequate. This Court should, therefore, grant the motion.

4. Option 2's significance to this case actually lies elsewhere. If given effect by this Court, Option 2 essentially allows EPA, after issuing a cursory test order, to avoid the burden of demonstrating that a test order is "necessary" and, instead, place the burden on the order's recipient to show that additional testing is "unnecessary." In fact,

because the order recipient will not have the benefit of the administrative record, EPA is forcing any company with concerns about the adequacy of a test order to broadly recreate EPA's purported review of the scientific literature and available testing methods with the hope that such an effort identifies anything that was missed. Clearly, this type of burden shifting is not permitted under TSCA.

STANDARD OF REVIEW

When a manufacturer challenges a test order, TSCA's judicial review provision requires that this Court proceed under the Administrative Procedure Act ("APA"), 5 U.S.C. § 701, *et seq.* 15 U.S.C. § 2618(c)(1). Generally, the standards of review found in 5 U.S.C. § 706 apply; however, the standard set forth at Section 706(2)(E) is inapplicable, and this Court instead must "hold unlawful and set aside [a test order] if the court finds that the order is not supported by substantial evidence in the record taken as a whole." *Id.*

STANDING

The Vinyl Institute has "associational" standing to challenge the Test Order on behalf of its member companies. In this Court, such standing exists if: (i) at least one member would have standing to sue on

its own behalf; (ii) the interests the group seeks to protect are germane to the organization's purpose; and (iii) neither the claim asserted nor the relief requested requires participation of individual members in the lawsuit. *Hearth, Patio & Barbecue Ass'n v. EPA*, 11 F.4th 791, 801-02 (D.C. Cir. 2021) (citation and internal quotations omitted). The Vinyl Institute satisfies all three factors.

First, four members of the Vinyl Institute are subject to the amended Test Order – Formosa Plastics Corp. USA, Westlake Chemical Corp., C-K Tech Inc. (a subsidiary of member Shintech, Inc.), and Occidental Chemical Holding Co. (an affiliate of member Oxy Vinyls, LP). Test Order at 1 (JA____); ADD047-048. Each company would have Article III standing because it has suffered an injury-in-fact that is directly traceable to the Test Order and would be redressed by a judicial decision vacating and remanding the order. *Burlington Northern and Santa Fe Railway Co. v. Surface Transp. Bd.*, 403 F.3d 771, 775-76 (D.C. Cir. 2005). Regulated entities almost always have standing. "[I]f the complainant is an object of the action…at issue…there should be little question that the action…has caused [complainant] injury, and that a judgment preventing…the action will address it." *Sierra Club v.*

EPA, 292 F.3d 895, 899-900 (D.C. Cir. 2002) (citation and internal quotations omitted). Here, the companies must comply with a test order, and expend money and resources in doing so, that is not supported by an adequate Statement of Need or justified as "necessary" based on substantial evidence in the record as a whole. ADD048, 050.

Second, this challenge goes to the heart of the Vinyl Institute's organizational purposes. Generally, the Vinyl Institute is a trade organization representing the leading manufacturers of vinyl, vinyl chloride monomer, and vinyl additives and modifiers, including members who manufacture and/or process 1,1,2-trichloroethane. ADD046-047. As relevant to this case, the Vinyl Institute manages the consortium of companies subject to the Test Order and is responsible for the day-to-day work in responding to the Test Order, including engaging with EPA on testing protocols and benchmarks, hiring and working with consultants carrying out the required testing, and representing the interests of the consortium members in all aspects of the Test Order process. ADD048.

Third, the underlying claim and relief sought in the Vinyl Institute's petition do not require the participation of individual

members in the lawsuit. As this case is brought under TSCA's judicial review provision (15 U.S.C. § 2618(c)) and the APA challenging the necessity of the Test Order and the adequacy of its Statement of Need, each company is impacted in the same manner – each is responsible for implementing a test order that it claims is unlawful. No company is seeking unique relief or damages.

Finally, in addition to those three factors, each member company is a "person adversely affected" by the Test Order and thus falls within the zone of interests regulated under TSCA. *See* 5 U.S.C. § 702 (allowing judicial review where a person has been "adversely affected or aggrieved by agency action"). In this Court, to overcome prudential concerns, "[i]t is enough that the litigant's interest is arguably one *regulated*…by the statutory provision at issue." *Burlington Northern*, 403 F.3d at 776 (citation and internal quotations omitted). Here, TSCA Section 4 sets forth numerous requirements EPA must satisfy before issuing a test order that are aimed at protecting recipient

manufacturers by ensuring the test order is necessary and does not impose unwarranted costs and burdens. 15 U.S.C. § 2603.[12]

ARGUMENT

I. EPA Failed To Provide An Adequate Statement of Need Or Cite To Substantial Evidence In The Record Demonstrating The Test Order Is "Necessary" For The 1,1,2-Trichloroethane Risk Evaluation

Taken together, TSCA Section 4 (test order provision) and Section 19 (judicial review provision) impose a significant burden on EPA to adequately justify the need for a test order. Here, in determining whether EPA demonstrated that avian reproduction testing is "necessary" to conduct the risk evaluation, 15 U.S.C. § 2603(a)(2)(A)(i), this Court must apply TSCA's distinct version of the "substantial evidence" standard of review, 15 U.S.C. § 2618(c)(1)(B).

As this Court observed in *Chem. Mfrs. Ass'n v. EPA*, 859 F.2d 977, 991 (D.C. Cir. 1988) ("*CMA*"), Congress intended for courts under

[12] The Vinyl Institute itself also has standing as it has a concrete interest directly impacted by the Test Order. Section 4 permits the use of industry consortia to carry out test orders. 15 U.S.C. § 2603(h)(1)(B)(iii). The Vinyl Institute manages the 1,1,2-trichloroethane consortium and, in that sense, is subject to the Test Order requirements. ADD048-049.

Section 19's "substantial evidence" standard to "engage in a *searching review* of [EPA's] reasons and explanations for [its] conclusions" (emphasis in original). Citing to TSCA's legislative history, *CMA* held that this standard is a "demanding one" and it is more "rigorous" than the deferential "arbitrary and capricious" review typically applied in APA cases. *Id.* at 991-992. The Court must ensure EPA has "identif[ied] the facts that underlie its determination" and that its action is "supported by [the] record" taken as a whole. *Id.* at 992. As always, the Court cannot substitute its own judgment for that of EPA. *Id.*

Consistent with this approach, Section 4's "necessary" standard obligates EPA to not only consider various factors necessitating a particular type of testing, but also identify the facts considered and explain its underlying rationale. 15 U.S.C. § 2603(a)(3). Section 4 explicitly provides that the Statement of Need: (i) "describe" how EPA used evidence in the record to conclude that a test order is necessary, which would include any decision not to proceed with tiered testing; (ii) "explain" how it ruled-out alternative testing methods when requiring vertebrate animal testing; and (iii) "explain" why it issued a test order

rather than crafting a consent agreement. *Id.* EPA, in other words, cannot issue a test order based on mere conclusory statements.

Indeed, without such analysis, this Court would lack a basis on which to apply the "substantial evidence" standard and conduct a "rigorous" or "searching review." TSCA obligates EPA to show its work and, in this regard, EPA entirely failed.

A. EPA Failed To Justify Its Decision To Forego A Tiered Testing Approach

Section 4 requires EPA to rely on tiered testing and screening processes before deciding to order extensive, high-level testing like the avian reproduction study. 15 U.S.C. § 2603(a)(4). Only when information in the record justifies more advanced testing may EPA forgo a tiered approach. *Id.* But in the Test Order, EPA had almost nothing to say on this point. EPA simply 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." Test Order at 8 (JA___) (emphasis added).

Nowhere does EPA set forth the "reasons and explanations for [its] conclusions." *CMA*, 859 F.2 at 991. Neither this Court nor the Vinyl Institute can know, from the face of the Test Order, how EPA evaluated tiered or screening processes, which testing approaches were considered and excluded, and why EPA concluded that tiered testing would not be helpful in deciding whether additional testing is necessary. In fact, the Test Order does not cite any evidence, let alone substantial evidence, justifying EPA's decision to go straight to an avian reproduction study.[13]

Just as concerning is EPA's failure to identify the relative costs of the avian reproduction test. Because toxicity testing can cost hundreds of thousands dollars, if not millions, ADD049, Congress directed that each Test Order examine such costs. 15 U.S.C. § 2603(b)(1). Only then will this Court be assured that EPA sufficiently considered the

[13] In guidance describing how EPA will implement its Section 4 test order authority, EPA notes that it will "typically take[] EPA weeks to months to complete [its evaluation of tiered testing options], depending on the complexity of the tiered testing being considered." EPA, *Overview on Activities Involved in Issuing a TSCA Section 4 Order*, at 2 ("Section 4 Guidance"), available at https://tinyurl.com/yad3e6cr. Surely, EPA would have something to say in the Test Order if it had followed this process. Indeed, the lack of any informative discussion or comment in the Test Order on tiered testing raises legitimate questions as to whether EPA conducted an adequate analysis.

economic impacts of requiring robust tests in lieu of more reasonable tiered approaches. Yet there is no discussion whatsoever of relative costs in the Test Order.[14]

B. EPA Did Not Substantiate Why It Rejected Testing Alternatives To Reduce Vertebrate Animal Testing

Section 4 also directs EPA to "explain the basis for any decision that requires the use of vertebrate animals" in lieu of other methods. 15 U.S.C. § 2603(a)(3). As discussed above, the avian reproduction test here (OCSPP 850.2300) involves Bobwhite quail. *Supra* at 9-10. To eliminate, or at least reduce, the need for vertebrate animal testing, EPA must consider alternatives before issuing a test order, such as existing toxicity information and New Approach Methodologies (or NAMs) (e.g., computational and bioinformatics, or high-throughput screening methods and prediction models). 15 U.S.C. § 2603(h)(1).

[14] Section 4 also obligates EPA to assess the "reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the" test order. *Id.* This is a significant factor impacting the ability of manufacturers to conduct studies according to the protocols set forth in the test order and to complete the work by EPA's deadlines. ADD048-049. The Test Order never addresses this issue.

However, as with tiered testing options, the Test Order remains all but silent on EPA's underlying rationale. It merely concludes "[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___). EPA never discusses any relevant considerations. For instance, it does not estimate how many birds will be sacrificed (it is in the hundreds (ADD048)) or how many could be spared with other types of tests. EPA also fails to list what New Approach Methodologies were evaluated or explain why they were rejected. Indeed, any effort by this Court to discern EPA's reasoning here, even on a basic level, would be to no avail.[15]

C. EPA Failed To Demonstrate An Information Gap That Must Be Filled Through Chronic Animal Testing

While EPA provides some discussion regarding its efforts to determine whether there are any unmet data needs, this too falls short

[15] EPA maintains that examining alternative testing methods will "typically…take EPA weeks to months…depending on the complexity of the methods being considered." *Supra* note 13 at 2. Again, it is curious that the Test Order never discusses this aspect of the analysis, particularly if it involved such a concerted effort, which begs the question what EPA actually did.

under Section 4 and the heightened "substantial evidence" standard. EPA says it looked for 1,1,2-trichloroethane studies and used its Analog Identification Methodology (AIM) to identify any chemical analogues and related studies. *Supra* at 12. The Test Order then indicates in a chart that it located seven unidentified studies regarding acute exposures, with two involving birds, and one related to chronic exposures in mammals. Test Order at 8 (JA___). From this, the Test Order concludes there is no avian toxicity data for chronic exposures and, thus, this information gap must be filled. *Supra* at 13.

The Test Order, however, does not allow this Court to determine how EPA actually reached this conclusion and whether it is based on substantial evidence. The Test Order never identifies the studies comprising the chart. As such, there is no way to determine whether those are, in fact, only acute studies or whether they contain information that could be used to estimate chronic effects.

Moreover, EPA does not identify other studies in the record that it considered as part of the Test Order and why they were deemed irrelevant. There is no way to evaluate whether EPA appropriately weighed available scientific evidence, *see* 15 U.S.C. § 2625(i) and 40

C.F.R. § 702.33, and reasonably concluded there were no other pertinent sets of data, *see* 15 U.S.C. § 2625(k) (EPA must consider reasonably available data). Indeed, it is difficult to confirm whether EPA may have missed key studies or analogues. Instead, EPA asks that the manufacturers and this Court take all of this on faith. But that is not the standard under TSCA. More is required.

Finally, even if the Test Order's discussion is sufficient to establish a data gap, it still does not, standing alone, demonstrate an unmet data need; *i.e.*, that avian reproduction testing is necessary for the risk evaluation. EPA must establish, based on substantial evidence in the record as a whole, that tiered testing would be inadequate and reduced vertebrate animal testing is infeasible. As discussed above, however, EPA failed to make those showings.[16]

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[16] The Test Order briefly cites a single study (Elovaara, 1979) involving chick eggs that were injected with different solvents, including 1,1,2-trichloroethane, which showed developmental toxicity in the embryos. Test Order at 9 (JA___). EPA concluded these results confirm the need for additional information on chronic effects of dietary exposure. But the Test Order simultaneously casts doubt on its own conclusion. EPA concedes that egg injection is not directly comparable to potential toxicities following dietary exposure to 1,1,2-trichloroethane. *Supra* at 14. EPA then fails, as required under TSCA, to explain how this study, based on a "weight of scientific evidence" approach (which includes

D. EPA Did Not Demonstrate That Birds Are Exposed To 1,1,2-Trichloroethane In Amounts Warranting A Test Order

The Test Order would be unwarranted if birds are not exposed to 1,1,2-trichloroethane in amounts that are potentially toxic. *See* 15 U.S.C. § 2625(k) (requiring EPA to consider reasonably available evidence regarding "exposure"). Aware of this, EPA cites to a USGS database, initiated in 1991, to show that terrestrial vertebrates may be exposed to 1,1,2-trichloroethane in ground water, sediment, soil, surface water, and biota. *Supra* at 15. The Test Order, however, does not identify which data it relies upon, including 1,1,2-trichloroethane detection rates and concentrations, denying this Court the ability to verify that birds are potentially exposed at levels posing a potential risk. Neither this Court nor the Vinyl Institute can identify the USGS data upon which EPA purportedly relied.

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evaluating the limitations and relevance of a given study) (*see* 15 U.S.C. § 2625(i) and 40 C.F.R. § 702.33), justifies the need for dietary exposure studies. Moreover, EPA fails to discuss, again as required under TSCA, whether this study qualifies as "best available science" and is based on reliable study methods (*see* 15 U.S.C. § 2625(h) and 40 C.F.R. § 702.33)).

E. EPA Did Not Explain Why A Test Order Was Required In Lieu Of A Consent Agreement

EPA simply maintains that it issued the Test Order, instead of a rule or entering into a consent agreement with the Vinyl Institute's consortium, because this was the quickest way to obtain information within applicable timeframes. Test Order at 8 (JA___). This is not an adequate explanation as required by Section 4, particularly as a consent agreement would have allowed EPA and the Vinyl Institute to work together in meeting EPA's needs while at the same time protecting the manufacturers from unwarranted testing requirements.[17]

In fact, EPA's stated rationale is contradicted by its own public statements. EPA notified Congress three months after issuing the Test Order and several months before last amending it that EPA will not be able to meet the statutory deadlines for risk evaluations on the 20 chemicals designated as high-priority. *Supra* at 16. Given this timeline, EPA certainly could have, at a minimum, discussed entering into a

[17] A consent order cannot be assumed to be a longer process. EPA's authority to issue test orders during TSCA risk evaluations gives the agency leverage to push a consent agreement to conclusion, and that process also gives the agency access to the industry's knowledge and expertise, and better prepares industry to proceed with testing.

consent agreement with the manufacturers it had already targeted for the Test Order. Indeed, the majority of companies subject to the Test Order when issued were already part of a consortium collaborating with EPA on the first test order for 1,1,2-trichloroethane. ADD049-050. All of this was feasible and would not have had a material effect on any deadline because EPA already knew it could not meet the June 2023 statutory cutoff.

Moreover, the risk evaluation was initiated in late 2019 and EPA issued the first test order for 1,1,2-trichloroethane more than a year later, in early 2021. *Supra* at 8-9. Yet EPA does not explain why it waited for another year to issue the Test Order challenged here. If time was truly of the essence, it was an emergency of EPA's own creation.

F. Conclusion

EPA may issue a test order without first seeking input from manufacturers and other stakeholders. But in exchange for that privilege, Congress imposed on EPA a duty of transparency and an obligation to provide enough information so that all concerned, including this Court, can adequately evaluate EPA's reasoning and determine whether a test order is truly necessary. Indeed, without such

analysis, we cannot know whether EPA exercised its test order authority "judiciously" and in a "reasonable and prudent manner." *Supra* at 8. Based on the foregoing, the Test Order clearly does not satisfy this standard and thus should be vacated and remanded to EPA.

II. This Court Should Grant The Vinyl Institute's Section 19(b) Motion To Make Additional Submissions To The Test Order's Administrative Record

On August 26, 2022, the Vinyl Institute filed a motion (Doc. #1961119) with this Court pursuant to Section 19(b) of TSCA, 15 U.S.C. § 2618(b), for leave to make additional written submissions in the Test Order's administrative record because EPA issued the Test Order without any prior notice or opportunity for comment. The Vinyl Institute moved to supplement the record with additional materials to help EPA determine whether the Test Order is "necessary" to conduct the risk evaluation and to facilitate any subsequent judicial review.[18]

On December 1, 2022, the motions panel elected not to resolve the motion and, instead, issued an Order (Doc. #1975824) referring the

[18] In addition to the Section 19(b) motion and brief, the parties made the following submissions – EPA's response (Doc. #1964616), the Vinyl Institute's reply (Doc. #1967027), EPA's sur-reply (Doc. #1968146), and the Vinyl Institute's sur-reply response (Doc. #1968489).

Section 19(b) motion to this merits panel. The parties were further directed to address the Section 19(b) matter in their merits briefs rather than incorporating by reference their prior submissions. Accordingly, the Vinyl Institute presents the following argument and previously submitted expert reports in support of its Section 19(b) motion.

A. TSCA Section 19(b)

Section 19(b) allows a petitioner to seek leave from the Court to submit additional comment, information, and data for inclusion in a test order's administrative record. The Court may grant the request if the additional submissions would be "material" and there are "reasonable grounds" for petitioner's failure to submit the information during the underlying "proceeding." 15 U.S.C. § 2618(b).[19] *See also* 15 U.S.C. § 2625(k) (requiring EPA as part of its test order authority to consider information "reasonably available to the Administrator").

[19] Specifically, under Section 19(b), the petitioner must show that the additional "submissions and presentations would be material and that there were reasonable grounds for the submissions and failure to make such submissions and presentations in the proceeding before the Administrator." ADD059-060.

If the petitioner makes the requisite showings, the Court may order EPA to re-open the administrative proceeding so that EPA can consider the newly submitted material, and decide whether to modify or set aside the test order. To the extent EPA amends the order and the petitioner does not withdraw its petition, the Court would then review the new order. It would review the original order on the new record if EPA does not amend the order. 15 U.S.C. § 2618(b). As shown below, the Vinyl Institute satisfies both Section 19(b) requirements.

B. Independent Third-Party Review Of The Test Order

In support of its motion, the Vinyl Institute retained Cardno ChemRisk (now known as Stantec), a scientific consulting firm that specializes in characterizing environmental risk, to assess whether EPA followed Section 4's requirements, and specifically whether EPA sufficiently identified a need for an avian reproduction study. Stantec's initial and rebuttal reports submitted to the motions panel are attached in the Addendum (ADD001-033; ADD034-042).

Stantec not only reviewed the Test Order and the materials cited in the Certified Index produced by EPA (Doc. #1956004) in this litigation, but also: (i) conducted an independent review of publicly

available studies regarding 1,1,2-trichloroethane and analogues discussed in the Test Order; (ii) utilized several EPA-approved tools to identify additional analogues not mentioned in the Test Order; (iii) reviewed publicly available environmental data for 1,1,2-trichloroethane; and (iv) investigated New Approach Methodologies that could have been used as a form of tiered testing to minimize animal testing and otherwise reduce testing burdens. This information was reasonably available to EPA prior to issuing the Test Order.

As discussed below, Stantec's review concluded that relevant information and data not considered at all by EPA or, at a minimum, not specifically analyzed in the Statement of Need, could have compelled EPA to forego issuing the Test Order or at least employ a more reasonable tiered testing approach. Tellingly, EPA did not contest in its motion briefing the fact that the additional information and data presented by the Vinyl Institute through Stantec are "material" as to the need for the Test Order and avian reproduction testing.

C. EPA Did Not Identify In The Test Order Or The Administrative Record A Complete List Of 1,1,2-Trichloroethane Analogues That Could Provide Relevant Toxicity Data

To begin, the Test Order did not consider or even mention readily available toxicity data indicating that 1,1,2-trichloroethane is not toxic to birds. As EPA noted in the Test Order, it is common practice when assessing a chemical's toxicity to rely on existing data for "analogues" – chemicals with similar structures to the substance of interest – to fill any data needs instead of conducting new tests. Test Order at 8 (JA___); ADD006.[20] In the Test Order, EPA used its Analog Identification Methodology (AIM) software to identify seven analogues. Test Order at 7 (JA___); ADD006. It then, in conclusory fashion, noted that one analogue, 1,1,1-trichloroethane, had associated with it some hazard data regarding acute exposure in birds, but the Test Order did not identify the underlying study(ies) or provide further analysis as to whether such data would be helpful in assessing environmental risk. Test Order at 8 (Table 1) (JA___).

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[20] This process of using known information from one chemical to predict the same property in another substance without corresponding information is known as "read-across." *Id.*

To better inform the process, Stantec employed another tool created by EPA and often used for the identification of structural analogues, the CompTox Chemicals Dashboard, which resulted in the identification of seven additional analogues for 1,1,2-trichloroethane not listed in the Test Order. ADD007-008 (Table 2). Nowhere in the Test Order or administrative record did EPA consider these other analogues and whether they could be leveraged to provide more information on avian toxicity. ADD008-009. The Vinyl Institute, therefore, should have the opportunity to supplement the record so that all relevant analogues are identified, evaluated, and used to inform any EPA decision to issue a test order for avian reproduction testing.

D. EPA Did Not Include In The Administrative Record Data For Analogues Identified By Stantec Or Initially Listed By EPA Demonstrating The Low Toxicity Of 1,1,2-Trichloroethane

Based on an initial review of the analogues identified by Stantec and those listed by EPA, Stantec found at least one additional analogue that has avian subchronic data associated with it, and another analogue listed in the Test Order with three acute avian studies that were never considered by EPA. ADD008-009.

Stantec located a repeated dose (subchronic) inhalation study for hexachloroethane – one of the analogues overlooked by EPA – that could address the purported data need for 1,1,2-trichloroethane. The study, which exposed Japanese quails to hexachloroethane vapor over a six week period, found virtually no toxicological impacts of concern (e.g., mortality, clinical signs, body weight changes, or gross tissue or organ changes). ADD009-010.

Stantec was then able to use this study and publicly available information to calculate potential chronic toxicity values like those sought in the avian reproduction study required by the Test Order, and concluded that the study "indicates that…hexachloroethane is of low toxicity potential to birds; thus providing further support that 1,1,2-trichloroethane is anticipated to have a low toxicity potential in birds when administered under realistic conditions." ADD010. As this subchronic study helps address the unmet data need alleged in the Test Order – i.e., chronic avian toxicity – it is unclear why EPA did not identify or consider it. ADD009 (Stantec observing that "[s]ubchronic studies are routinely relied upon to extrapolate to chronic toxicity by regulatory agencies, including EPA.").

Moreover, based on its own public literature review, Stantec found three acute avian toxicity studies for 1,1,1-trichloroethane, an analogue identified by EPA, that were not otherwise acknowledged or considered in the administrative record or Test Order. ADD008-009. Importantly, these dietary studies, with two involving Bobwhite quail, "demonstrate that high concentrations/doses (which are not environmentally relevant) would need to be administered to birds to lead to toxic effects or mortality." ADD008. Thus, based on a standard read-across approach, 1,1,2-trichloroethane would be expected to have low toxicity potential in birds when administered an oral diet or by inhalation. ADD009.

Finally, as already discussed, EPA cited a single acute toxicity study (Elovaara, 1979) as confirming the need for the Test Order. Test Order at 9 (JA___). That study involved injecting high doses of solvents, including 1,1,2-trichloroethane, into eggs, which resulted in several embryo deaths. ADD010. Stantec concluded, however, that this study does not provide any insight into whether 1,1,2-trichloroethane would be toxic to birds exposed in the environment and therefore does not provide any support for the Test Order.

First, Stantec agreed with EPA's admission in the Test Order that the route of exposure (egg injection) is not environmentally relevant. *See* Test Order at 9 (JA___); ADD010. Indeed, Elovaara used doses of 1,1,2-trichloroethane that would be much higher than the dietary exposures used in the avian reproduction test. ADD010. As such, this raises yet more questions whether EPA complied with TSCA's admonition that test order decisions be made based on a "weight of scientific evidence" approach. 15 U.S.C. § 2625(i); 40 C.F.R. § 702.33.

Second, Stantec identified a number of study design and analytical weaknesses. These include: (i) attributing the embryo deaths to toxicity instead of the behavior inside the egg of various physical properties of 1,1,2-trichloroethane (e.g., volatility); and (ii) the authors' failure to perform a statistical analysis to determine whether the reported effects were likely related to exposure and not random chance. ADD010. In other words, Elovaara is an insufficient reference point upon which to require multi-generation avian testing, particularly when more relevant subchronic and acute avian test results could have been placed in the administrative record and fully analyzed.

In the end, according to Stantec, had EPA included the additional avian toxicity information for analogues in the administrative record, it could have then reached a conclusion that there is no evidence 1,1,2-trichloroethane is toxic to birds, and thus there is no basis for requiring a statutorily disfavored vertebrate test. ADD006.

E. EPA Failed To Include In The Administrative Record Various Computational Tools That Could Aid In Tiered Testing And Minimize The Use Of Animals

As shown above, EPA also did not explain, as required under TSCA, how it considered less burdensome tiered testing methods and alternatives to vertebrate animal testing. 15 U.S.C. §§ 2603(a)(4), (h). "Tiered testing" under Section 4 includes not just screening-level tests, but also "assessments of available information." 15 U.S.C. § 2603(a)(4). These can take the form of shorter duration studies (e.g., acute *in vivo* studies), non-animal toxicity tests (e.g., *in vitro* studies), or computational approaches (e.g., computer-based prediction modeling). ADD015-016. Under TSCA, if the results of tiered testing indicate a low likelihood of toxicity, then EPA and test order recipients can save time and money, as well as avoid sacrificing a large number of animals, by

foregoing chronic and multi-generational toxicity studies.[21] *Id.* Despite these regulatory obligations, the Test Order never explicitly discussed tiered testing options and dismissed with a mere wave of the hand any alternatives to vertebrate testing. This is insufficient.

Stantec was able to identify several screening methods that could be used to confirm the low toxicity potential of 1,1,2-trichloroethane which, as discussed above, are based on subchronic and acute toxicity studies for analogues. For instance, Stantec found no less than six computational methods that have been recently documented to accurately estimate avian toxicity, including in Bobwhite quails, based on quantitative structure-activity (toxicity) relationship (QSA(T)R) models. ADD020-022. "Collectively, the studies indicate that several computational methods have been or can be developed to enable high-throughput screening level toxicity assessments of chemicals in birds."

[21] Tiered testing would help address Section 4(h)'s directive that EPA minimize vertebrate testing. Stantec estimates acute testing would involve as few as 5 birds, while avian reproductive toxicity testing required by the Test Order would involve over 100 birds (even before sacrificing offspring resulting from mating). ADD016.

ADD020. But EPA did not consider these computational methods; they do not appear in the Test Order or administrative record. ADD022.

Similarly, as discussed in the following section, Stantec used EPA's Web-ICE application to extrapolate toxicity data from other animals and conclude that 1,1,2-tricholoethane has low acute toxicity, as well as infer based on that modeling output that the chemical also has low chronic toxicity. ADD016-020. Significantly, four additional analogues (i.e., hexachloroethane, 1,1,1,2,2-pentachloroethane, 1,1,1,2-tetrachloroethane, and 1,1,2,2-tetrachloroethane) which were not identified by EPA in the Test Order, but were identified by Stantec using EPA's own CompTox Chemicals Dashboard, proved helpful in that analysis. ADD007, 019.

Yet none of these approaches were included in the administrative record. As such, Stantec concluded that if "EPA had considered these tools in assessing the need for chronic avian testing on 1,1,2-tricholorethane, this could have impacted its decision that an avian reproduction test is necessary." ADD022.

F. Neither The Test Order Nor The Administrative Record Contain Any Analysis Of Environmental Data Showing 1,1,2-Trichloroethane Exposures To Birds Are Extremely Low And Do Not Warrant A Test Order

Lastly, avian testing is unwarranted if birds are not exposed in the ambient environment to 1,1,2-trichloroethane sufficient to pose a risk. ADD011. Neither the Test Order nor administrative record, however, contained any analysis of this important factor. *Id.* EPA, in one sentence, merely cited to the entire USGS Water Quality Portal database for the proposition that 1,1,2-tricholorethane has been found in various environmental media (ground water, surface water, sediment, soil, biota). Test Order at 9 (JA___). What EPA did not do is discuss that data or acknowledge that: (i) 1,1,2-trichloroethane's detection frequency is virtually *de minimis* across all key environments; and (ii) the concentration levels typically found would pose little risk to birds based on available evidence regarding toxicity.

Indeed, Stantec's comments would provide much needed analysis if included in the administrative record. Except for groundwater, to which birds have no direct route of exposure, the detection frequency for air, soil, sediment, surface waters, and subsurface waters over many

decades ranged from 0%-1.2%. ADD011-014. As to surface waters, the most likely exposure route for birds, the detection frequency was just 0.8%. ADD014 (Table 14). For soils, it was 0.5%. *Id.* In air, 1,1,2-trichloroethane never exceeded the limit of detection.[22] *Id.*

A similar conclusion can be drawn from the low concentration levels detected in the environment. Stantec used an EPA computational tool (Web-ICE) to calculate the hazardous concentration (HD_5) level of 1,1,2-trichloroethane (21.79 mg/kg) that would be protective of 95% of exposed vertebrate species. ADD016-020. This concentration level, which is applicable to acute toxicity, was extrapolated in the model by using known toxicity levels for other species. ADD016-017. The HD_5 level calculated for 1,1,2-trichloroethane is several orders of magnitude higher than would result from environmental concentrations typically reported in the USGS Water Quality Portal database. ADD019-020

[22] Stantec also explained why a low detection frequency (3.0%) and concentration levels found in saltwater and freshwater fish, a dietary component for certain bird species, would also pose little risk to avian species, as 1,1,2-trichloroethane has a low potential for bioaccumulation in fish. ADD013.

(giving examples for surface waters).[23] In other words, it would be "improbable that birds would be exposed to levels in the environment that are sufficiently high to cause adverse effects."[24] ADD019.

Stantec also inferred based on the HD_5 for 1,1,2-trichloroethane that there is little risk of chronic toxicity to birds. Stantec noted "[a]cute toxicity…can be used to inform potential chronic toxicity and is often used as a step in a tiered testing strategy to determine whether chronic testing is warranted." ADD016-017. For example, given a Bobwhite quail's average daily water ingestion, weight, and life span, the amount of 1,1,2-trichloroethane consumed via exposure to surface waters "over its lifetime would still be below the HD_5." ADD020 (i.e., even if a bird consumed water contaminated with 1,1,2-trichloroethane every day for

[23] By way of example, given the maximum levels of 1,1,2-trichlorethane detected in streams and lakes, a Bobwhite quail would have to consume water in amounts orders of magnitude above their estimated daily ingestion rate to reach a level of concern for acute toxicity. ADD020.

[24] Similarly, Stantec cited a recent report issued by the Agency for Toxic Substances and Disease Registry (ATSDR), a federal public health agency, containing environmental exposure data for air. The concentrations of hexachloroethane, an analogue of 1,1,2-trichloroethane, that produced adverse effects in birds via inhalation was approximately 5,000,000-fold higher than the maximum concentration of 1,1,2-trichloroethane reported by ASTDR. ADD011.

its entire lifetime, with no metabolization or excretion of the substance, it would still not reach a dose predicted to cause toxicity); *see also* ADD014 (Stantec concluding "the infrequent detection of 1,1,2-trichloroethane in environmental samples indicates that chronic exposure scenarios for birds are unlikely (i.e., birds are unlikely to have a continuous exposure to 1,1,2-trichloroethane because it is not regularly found in environmental media.")).

Not surprisingly, Stantec concluded these data as a whole "indicate that 1,1,2-trichloroethane is rarely detected in environmental samples, and if it is, the environmental concentrations would be well below the doses used in acute and chronic studies" – i.e., "the potential risk for these species is low." ADD011. As Stantec points out, this raises serious questions as to whether any avian testing should be required under Section 4. *Id.* ("As exposure is a critical component for a chemical to represent a risk, the absence of 1,1,2-trichloroethane in most environmental samples suggests additional hazard testing for [the chemical] is not a critical data need."). This type of analysis, however, does not appear in the administrative record or the Test Order.

III. The Test Order's Option 2 Does Not Preclude This Court From Granting The Section 19(b) Motion

In opposing the Vinyl Institute's Section 19(b) motion, EPA opted not to contest "materiality." Instead, it relied solely on the "reasonable grounds" prong, maintaining the Vinyl Institute could have availed itself of Option 2 in the Test Order and submitted the data and comments from the initial Stantec report after the Test Order was finalized. EPA's argument is without merit.

A. Option 2 Is Irrelevant Under Section 19(b)

EPA misreads Section 19(b). That provision only asks if the recipient could have made additional submissions and presentations "in the *proceeding* before the Administrator." 15 U.S.C. § 2618(b) (emphasis added). Here, the proceeding was complete once the Test Order was issued. As Option 2 was offered only after the relevant "proceeding" was over – a proceeding in which the Vinyl Institute had no prior notice or opportunity to submit comments – it is irrelevant to whether this Court may grant the Section 19(b) motion.

Indeed, Section 19's plain language makes clear the "proceeding" ended when the Test Order was issued. Under Section 19(a), the Test

Order is a final agency action that is immediately subject to judicial review. 15 U.S.C. § 2618(a). There is nothing in that provision requiring the petitioner to exhaust post-issuance remedies or take any other action before filing suit. *See* 5 U.S.C. § 704 (providing that "[e]xcept as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented…an application…for any form of reconsideration"). As such, Section 19(b)'s reference to a petitioner's failure to submit comments during the "proceeding before the Administrator" cannot be fairly read to include Option 2, allowing for the submission of materials after the petitioner could have filed a petition for review and a Section 19(b) motion.

Section 19(b)'s history confirms this reading. When TSCA was originally adopted in 1976, Section 19(b) only applied to testing established by rule. TSCA, Pub. L. 94-469, § 19(b), 90 Stat. 2003 (1976). In the context of notice and comment rulemaking, the "proceeding before the Administrator" would have ended when the rule was published in the Federal Register and the effective date had passed. When TSCA was amended in 2016, Congress simply made conforming

changes to Section 19(b) to reflect the fact that testing requirements could now be imposed by order under Section 4. Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. 114-182, § 19(m), 130 Stat. 508 (2016). Thus, the only reasonable interpretation of the phrase "in the proceeding before the Administrator" is that it refers to the time period before a test order is issued and comes into effect. There is no indication Congress intended to expand that phrase beyond its plain and common sense meaning when it amended TSCA to include some undefined period of time *after* a test order has been finalized. *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 47-51 (1987) (looking to "common sense" meaning of statutory language).

Further, if Option 2 is not covered by Section 19(b)'s reference to "proceeding," this Court cannot otherwise enforce Option 2 as an "issue exhaustion" requirement. The Supreme Court in *Darby v. Cisneros*, 509 U.S. 137, 154 (1993), held that absent a statutory or regulatory requirement, courts have no authority to require that parties exhaust administrative procedures in APA cases. This holds particularly true when the petitioner did not have an opportunity during the underlying proceedings to raise an issue or submit comments. *CSX Transp. Inc. v.*

Surface Transp. Bd., 584 F.3d 1076, 1078-79 (D.C. 2009) (holding petitioner did not waive issue where it did not have prior notice and there was no statutory or regulatory requirement to file a motion for reconsideration after the agency action became final). Here, Section 19(b) did not obligate the Vinyl Institute to file a motion to reconsider (essentially Option 2) before moving under Section 19(b) and EPA has not cited to any regulatory provisions requiring the same. In fact, Option 2 itself is permissive and does not explicitly require exhaustion prior to requesting leave under Section 19(b).[25]

B. The Vinyl Institute Had "Reasonable Grounds" For Not Submitting A Response Under Option 2

Even if the Court were to agree with the proposition that the "proceeding before the Administrator" extends to a post-issuance invitation to submit information and data, the Vinyl Institute had "reasonable grounds" under Section 19(b) for not pursuing Option 2

[25] In its motion briefing, EPA accuses the Vinyl Institute of using Section 19(b) as an instrument of delay. EPA Resp. at 9. The record shows that claim to be demonstrably false. The Vinyl Institute has and continues to work toward the Test Order's requirements. ADD049. Moreover, the purpose of the Section 19(b) motion is to correct the numerous shortcomings in EPA's analysis, ensuring that this Court has a full administrative record on which to review the Test Order.

because EPA limited any review to the face of the Test Order and without the benefit of the entire administrative record. Option 2 required the Vinyl Institute to identify studies and other scientific information that it "believe(s) the EPA has not considered." Test Order at 3, 11 (JA___, ___). But the Vinyl Institute could not ascertain what EPA had or had not considered given, as demonstrated above, the Test Order's cursory Statement of Need. As such, Option 2 was no real option at all.

Before the motions panel, EPA argued that the Vinyl Institute "did not need access to the administrative record before submitting to EPA the information contained in the Stantec Report" and that the "alleged failures [by EPA to consider other data or information] were apparent on the face of the Order and not elucidated only through the production of the administrative record." EPA Resp. at 11-12. Stantec's rebuttal report demonstrates otherwise. Stantec notes:

> The administrative record was not available at the time the Test Order was issued, and a review of the record was necessary to inform the identification of additional information that EPA may not have considered in issuing the Test Order…Notably, the documentation provided in the Test Order itself lacked methodological detail and transparency and resulted in overly simplified conclusions

> that were not well-supported by clear findings…These deficiencies in the Test Order precluded an understanding of how EPA reached [its] conclusions, whether [EPA] considered and eliminated other sources of information, or how [EPA] interpreted information [it] identified. Consequently, a review of the administrative record was necessary …to clarify the methods, interpretation, and the completeness of EPA's review before addressing any remaining gaps in [its] review.

ADD037. Simply put, the Vinyl Institute could not allege, as required by Option 2, that EPA missed a study, failed to employ analytical software, or inadequately analyzed a particular issue without verifying as much in the administrative record.

For instance, the Test Order summarily concludes that no New Approach Methodologies were identified that could be used to meet TSCA's dual directives of eliminating or reducing animal testing or implementing less burdensome tiered testing. ADD040-041. But EPA did not describe how it verified the lack of such approaches or other modeling tools. As Stantec notes, it was therefore "necessary to review the administrative record in an effort to identify any documentation that would reveal EPA's methodology and findings." ADD041. As that review "did not reveal any additional details," only then was it clear

that there was a gap in EPA's work, which could be filled via a Section 19(b) submission. *Id*.

As another example, the Test Order concludes in just one sentence that environmental monitoring data contained in a USGS database show that terrestrial vertebrates could be exposed to 1,1,2-trichloroethane at potential levels of concern. Again, as noted by Stantec, EPA did "not provide enough information to identify the monitoring data the EPA reviewed" or "include details about the concentrations or detection frequencies of 1,1,2-trichloroethane in environmental media that would be relevant to avian exposures." ADD040. As a result, the "administrative record needed to be reviewed…to identify the data that the EPA used to conclude that avian species could be exposed…" *Id.* This review, however, turned up no indication EPA had "conducted an analysis of the monitoring data to understand overall likelihood of exposure" and thus it was appropriate for Stantec to independently review the USGS data and other publicly available information to show that avian species are not, in fact, exposed to material amounts of 1,1,2-trichloroethane in the environment that would justify the Test Order. *Id*.

Indeed, Stantec's rebuttal report shows this holds true for all issues identified (albeit briefly) in the Statement of Need. ADD037-040 (Stantec noting EPA's conclusory statements regarding its "systematic" literature review, pointing out the lack of any detailed discussion of EPA's findings resulting from that review in the administrative record, and concluding that it could identify pursuant to Section 19(b) several additional toxicological studies on a 1,1,2-trichloroethane analogue that EPA apparently missed); ADD038 (Stantec noting the administrative record revealed EPA had used analytical tools not mentioned in the Test Order in an effort to identify 1,1,2-trichloroethane analogues, observing that the results of those analyses were inconsistent with the results reported in the Test Order, and thus concluding that submitting additional evidence under Section 19(b) would be helpful in identifying a complete list of analogues).[26]

[26] EPA, in its sur-reply (at 5), noted that the Test Order references a two-year-old "Final Scope" document (issued as part of EPA's broader risk evaluation). However, EPA never identified anything in that document that specifically addresses the issues Section 4 requires to be analyzed in a Statement of Need. In fact, EPA says it only relied on the Final Scope as a "starting point" and explicitly cites to a flow chart that envisions potential exposure routes for 1,1,2-trichloroethane. Test Order at 6-7 (JA___-___). That flow chart, however, does not identify the

As such, it strains all credulity for EPA to argue the Vinyl Institute had, under Option 2, a meaningful opportunity to review the Test Order without having first reviewed the administrative record.

C. Option 2 Is Contrary To TSCA's Substantial Evidence Standard Of Review And Impermissibly Shifts EPA's Burden Under Section 4 To Manufacturers

In arguing the Vinyl Institute did not need access to the administrative record, EPA ignores the broad nature and scope of TSCA's judicial review provision. This Court must ask whether the Test Order is "supported by substantial evidence in the record *taken as a whole*." 15 U.S.C. § 2618(c) (emphasis added). There is something entirely incongruous in hamstringing the Vinyl Institute by limiting its review to the face of the Test Order (and a conclusory one at best) when it has a right to ask this Court to review the Test Order under the heightened substantial evidence standard.

The Vinyl Institute cannot facilitate judicial review and ensure this Court has before it a full and complete record if the Vinyl Institute

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frequency or concentration levels of "potential" exposure to birds. Moreover, Stantec reviewed the Final Scope document and still found it necessary to review the entire administrative record in order to determine what EPA had done before issuing the Test Order. ADD024.

cannot, in the first instance, determine how EPA came to its decision. By limiting the Vinyl Institute to Option 2 and preventing it from adequately evaluating EPA's finding of necessity on the "whole record," EPA is in turn frustrating this Court's ability to do the same.

And it gets worse. What EPA has done here is actually shift its burden under TSCA to demonstrate that a test order is "necessary" onto the order recipient, who is now required to prove under Option 2 that the test order is "unnecessary." In fact, because the order recipient does not have the administrative record to review, it must broadly recreate what EPA purportedly did in terms of reviewing scientific literature and other available testing methods, with the hope that such an effort is comprehensive enough to identify anything that was missed.

Accordingly, if this Test Order is allowed to stand, EPA will be able to continue issuing cursory and unsubstantiated test orders under Section 4 knowing full well that they will be upheld by courts as "necessary" and that EPA can significantly hinder recipients under an Option 2 from making a contrary showing. Fortunately for the Vinyl Institute, that is not how TSCA works, and it is certainly not what

Congress intended when it gave EPA test order authority. EPA has the burden under Section 4, not the Vinyl Institute.

D. Conclusion

Thus, this Court should grant the Section 19(b) motion and allow the Vinyl Institute to supplement the record for EPA's further consideration and to facilitate any subsequent judicial review.

CONCLUSION

Based on the foregoing, this Court should grant the Vinyl Institute's Petition for Review, vacate and remand the Test Order regarding avian testing for further agency proceedings, and grant the Section 19(b) motion.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7) and Circuit Rule 32(e) because it contains 12,388 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

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/s/ *Eric P. Gotting*

CERTIFICATE OF SERVICE

I certify that, on January 17, 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 through the CM/ECF system, which will serve all parties electronically.

/s/ *Eric P. Gotting*