United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued December 1, 2023 Decided July 5, 2024

No. 22-1089

VINYL INSTITUTE, INC.,
PETITIONER

v.

ENVIRONMENTAL PROTECTION AGENCY,
RESPONDENT

On Petition for Review of a Final Action
of the Environmental Protection Agency

Eric P. Gotting argued the cause for petitioner. With him on the briefs were *Peter L. de la Cruz* and *Gregory A. Clark*.

Jonathan R. Mook and *M. Jarrad Wright* were on the brief for *amici curiae* Physicians Committee for Responsible Medicine and People for the Ethical Treatment of Animals in support of petitioner.

Ryan J. Carra was on the brief for *amicus curiae* American Chemistry Council in support of petitioner.

Laura J. Brown, Attorney, U.S. Department of Justice, argued the cause for respondent. With her on the brief was *Todd S. Kim*, Assistant Attorney General.

Samantha Liskow and *James Murphy* were on the brief for *amici curiae* Environmental Defense Fund and National Wildlife Federation in support of respondent.

Before: HENDERSON, WALKER and PAN, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* HENDERSON.[*]

KAREN LECRAFT HENDERSON, *Circuit Judge*: In March 2022, the Environmental Protection Agency (EPA) issued an order directed to seven chemical manufacturers/processors (hereafter "targeted entities"),[1] requiring them to test the chronic toxicity of 1,1,2-Trichloroethane (1,1,2-TCA) pursuant to the Toxic Substances Control Act (TSCA), 15 U.S.C. §§ 2601–2629. Vinyl Institute, a trade organization that manages a consortium of the seven targeted entities, challenged the order based on the EPA's failure to comply with several statutory requirements.[2] *See* 15 U.S.C. § 2603. Vinyl Institute also moved to supplement the administrative record with a scientific consultant's report. *See* 15 U.S.C. § 2618(b).

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[*] Judge Walker concurs in the judgment and concurs in the opinion except as to Parts II.B.4 and .5.

[1] We use "targeted entities" to describe the chemical manufacturers/processors that are required to respond to a test order—including the seven targeted entities to which the March 2022 Test Order was directed. Those seven targeted entities formed a consortium, managed by Vinyl Institute, to respond to the order.

[2] Several amici have participated in this case. The Environmental Defense Fund (EDF) and National Wildlife Federation filed a brief in support of the EPA. The American Chemistry Council (ACC) filed a brief in support of Vinyl Institute, as did the Physicians Committee for Responsible Medicine (PCRM) and People for the Ethical Treatment of Animals (PETA).

As detailed *infra*, we grant Vinyl Institute's petition for review. The EPA's non-public part of the administrative record is not part of "the record taken as a whole" subject to our heightened substantial evidence review of TSCA test orders. 15 U.S.C. § 2618(c)(1)(B)(i)(II). To the extent it relies on non-public portions of the administrative record, the EPA has failed to provide substantial evidence that meets its statutory mandate. We vacate and remand to the EPA to satisfy that mandate with "substantial evidence in the record taken as a whole." *Id.* We also deny Vinyl Institute's motion to supplement the record with scientific information it could have—and should have—submitted earlier. *See* 15 U.S.C. § 2618(b).

I. BACKGROUND

A. TSCA Testing

In 1976, the Congress became concerned that many chemical substances expose humans and the environment to "an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2601(a)(2). In order to "prevent unreasonable risks of injury," the Congress enacted the TSCA, Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified at 15 U.S.C. §§ 2601–2629). S. REP. NO. 94-698, at 1 (1976). Under the TSCA, entities that manufacture and process such chemicals must develop and maintain adequate data. 15 U.S.C. § 2601(b) (1976). The statute requires the entities to test substances to determine whether their manufacture, distribution, processing or use "does or does not present an unreasonable risk of injury to health or the environment." *Id.* § 2603(a)(2) (1976). Before promulgating its "testing" rule, however, the EPA is first required to find that (1) the chemical "*may* present an unreasonable risk of injury to health or the environment"; (2) the EPA lacks sufficient data and experience to determine or

predict the chemical's effects; and (3) testing "is necessary to develop such data." *Id.* § 2603(a)(1)(A) (1976) (emphasis added). Once the EPA determines that a chemical substance poses an unreasonable risk, the TSCA authorizes it to regulate the substance. *See id.* § 2605 (1976).[3]

By the 2010s, the Congress expressed "persistent concerns" regarding the EPA's slow pace in implementing the TSCA, H.R. REP. NO. 114-176, at 12 (2015), and so—recognizing shortcomings based on statutory structure, court decisions and the EPA's interpretation of those decisions—it revised the statute via the 2016 Amendments. S. REP. NO. 114-67, at 2 (2015); Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, 130 Stat. 448 (2016) (codified at 15 U.S.C. §§ 2601–2629). The 2016 Amendments require the EPA to designate chemicals as "high-priority" or "low-priority." 15 U.S.C. § 2605(b)(1). The EPA then conducts a risk evaluation for each high-priority chemical to determine whether it presents an "unreasonable risk of injury to health or the environment." *Id.* § 2605(b)(3)–(4). If it concludes the chemical presents an unreasonable risk of injury, it can then regulate the chemical through a rulemaking. *Id.* § 2605(a). The 2016 Amendments instruct the EPA to complete high-priority risk evaluations within 3 years. *Id.* § 2605(b)(4)(G); H.R. REP. NO. 114-176, at 25. Significant to this litigation, they also supplement the EPA's existing test rule authority—codified at Section 2603(a)(1)—with "[a]dditional testing authority" under Section 2603(a)(2). That authority allows the EPA to impose a testing requirement on targeted entities via "rule, order, or consent agreement" and applies whenever new information "is necessary" in order to perform a risk evaluation. 15 U.S.C. § 2603(a)(2); H.R. REP. NO. 114-

[3] The post-2016 TSCA retains each of these requirements. *See* 15 U.S.C. §§ 2601(b), 2603(a)(1), 2605(a).

176, at 22–23. The EPA may choose whether to proceed under Section 2603(a)(1) or (a)(2). *See* 15 U.S.C. § 2603(a)(2) ("*In addition* to the authority provided under paragraph (1), the Administrator may [develop information] by rule, order, or consent agreement . . . ." (emphasis added)).

Before the EPA can compel targeted entities to test—"by rule, order, or consent agreement"—under its Section 2603(a)(2) authority, it must take several steps. *Id.* First, it must provide a Statement of Need that (1) identifies "the need for the new information"; (2) describes how "reasonably available" information informs the EPA's decision; (3) "explain[s] the basis for any decision that requires the use of vertebrate animals"; and (4) if applicable, explains its rationale for issuance of a test order instead of a rule or consent agreement. *Id.* § 2603(a)(3). Next, the EPA must address how a screening test or other available information supports additional testing. *Id.* § 2603(a)(4). A rule, order or consent agreement must identify the chemical substance to be tested and the protocols and methodologies for developing the required information. *Id.* § 2603(b)(1). In determining protocols and methodologies, it must consider the costs as well as the reasonably foreseeable availability of facilities to perform the testing. *Id.* In addition to explaining the basis for vertebrate testing in its Statement of Need, the EPA must consider "existing information" such as toxicity, computational toxicology, bioinformatics and high-throughput screening methods. *Id.* § 2603(h)(1)(A).[4] Finally,

[4] "High-throughput screening" is a "[p]rocess that allows automated testing of large numbers of chemical and/or biological compounds for a specific biological target." *High-Throughput Toxicology*, EPA, https://perma.cc/V3TE-ZH2P. The EPA refers to toxicity information, computational toxicology, bioinformatics and high-throughput screening methods as New Approach Methodologies (NAMs). *Strategic Plan to Promote the Development and Implementation of Alternative Test Methods Within the TSCA*

the EPA must conduct each risk evaluation consistent with the "best available science" and its decision must be based on the "weight of the scientific evidence." *Id.* § 2625(h), (i); *see also* 40 C.F.R. § 702.33.

B. 1,1,2-Trichloroethane

This case involves the EPA's risk evaluation of 1,1,2-TCA, a colorless, sweet-smelling liquid used in chemical production. *See Final Scope of the Risk Evaluation for 1,1,2-TCA*, EPA Doc. # EPA-740-R-20-003, at 11 (Aug. 2020), https://perma.cc/N78Z-QGX5 (Final Scope Doc.). The EPA established a list of twenty high-priority substances, including 1,1,2-TCA. High-Priority Substance Designations Under the TSCA, 84 Fed. Reg. 71924, 71934 (Dec. 30, 2019). This designation triggered TSCA's Section 2605(b)(3)–(4) risk evaluation. *See id.* ("[A] final designation as a High-Priority Substance initiates the risk evaluation for the chemical substance.").

Following 1,1,2-TCA's high-priority designation, the EPA issued a lengthy 1,1,2-TCA final scope document that outlined hazards, exposures, conditions of use and potentially exposed sub-populations. Final Scope Doc. Next, the EPA issued a test order under its Section 2603(a)(2) authority. *Order Under Section 4(a)(2) of the Toxic Substances Control Act*, EPA-HQ-OPPT-2018-0421 (Jan. 14, 2021), https://perma.cc/LW7Z-AZX5 (January 2021 Test Order). The test order required a chronic toxicity exposure study of aquatic benthic midges and occupational studies on inhalation and dermal exposure to humans and included a Statement of Need. *Id.* at 2–8. The

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Program, EPA Doc. # EPA-740-R1-8004, at 6 (June 22, 2018), https://perma.cc/4NY3-93GG; *see also List of Alternative Test Methods and Strategies (or New Approach Methodologies [NAMs])*, EPA (Feb. 4, 2021), https://perma.cc/4GYA-66D8.

targeted entities can use various options to respond, including developing the information via testing (Option 1) or submitting existing studies and other relevant information to the EPA (Option 2). *Id.* at 13–16.

In March 2022, the EPA issued a second 1,1,2-TCA test order that Vinyl Institute challenges here. *Order Under Section 4(a)(2) of the Toxic Substances Control Act*, EPA-HQ-OPPT-2018-0421 (March 24, 2022), https://perma.cc/KQ57-LPFA (March 2022 Test Order).[5] The test order requires reproductive testing of earthworms and birds for chronic toxicity. *Id.* at 6. The avian reproduction test involves administering 1,1,2-TCA continuously to the northern bobwhite quail's diet. *See Ecological Effects Test Guidelines: OCSPP 850.2300 Avian Reproduction Test*, EPA-HQ-OPPT-2009-0154-0012 (Jan. 2012), https://perma.cc/5W8L-XEQJ. The EPA provided a Statement of Need explaining how: it lacks data on 1,1,2-TCA's chronic toxicity to earthworms and birds; reasonably available information does not close the data gap; a test order allows the EPA to gather the needed information more quickly than the rulemaking and consent agreement routes do; and no new approach methodologies (NAMs) can replace the ordered vertebrate testing for chronic toxicity. March 2022 Test Order at 5–9. The test order acknowledged a previous acute toxicity study regarding chicken embryos—the 1979 Elovaara study—but explained that it failed to fill the chronic toxicity data gap. *Id.* at 9. The EPA also cited data on potential vertebrate exposure to 1,1,2-TCA from the U.S. Geological Survey's (USGS) National Water Quality Monitoring Council. *Id.* The test order gave the seven targeted entities multiple response options, including developing the information by testing

[5] The EPA amended the March 2022 Test Order in April 2022 to correct an error and again in August 2022 to remove two targeted entities.

(Option 1) or submitting existing studies and other relevant information "that [they] believe the EPA has not considered" (Option 2). *Id.* at 11.

C. Procedural Posture

On June 2, 2022, Vinyl Institute responded to the March 2022 Test Order on behalf of the seven targeted entities by selecting Option 1—developing information by conducting both the avian and earthworm reproduction tests. But previously, on May 23, Vinyl Institute had timely petitioned the Court for review of the March 2022 Test Order. *See* 15 U.S.C. § 2618(a). Vinyl Institute challenges only the avian reproduction test. In August 2022, Vinyl Institute moved to supplement the administrative record pursuant to 15 U.S.C. § 2618(b) with a report prepared by scientific consultant Stantec (Stantec Report). A motions panel referred the motion to us.

We have jurisdiction of the petition for review under 15 U.S.C. § 2618(a)(1)(A) and of the Section 2618(b) motion under 15 U.S.C. § 2618(b).

II. SECTION 2603(A)(2) TEST ORDER REQUIREMENTS

A. Standard of Review

The 2016 Amendments instruct us to "hold unlawful and set aside" a test order if it "is not supported by substantial evidence in the record taken as a whole." 15 U.S.C. § 2618(c)(1)(B)(i)(II). Our interpretation of this standard of review presents an issue of first impression.

Under the pre-2016 TSCA, as noted *supra*, the EPA could compel manufacturers to test via a rulemaking only, 15 U.S.C. § 2603 (1976), and judicial review of a TSCA rule weighed

"substantial evidence in the *rulemaking record* . . . taken as a whole." 15 U.S.C. § 2618(c)(1)(B)(i) (1976) (emphasis added); *see also Env't Def. Fund, Inc. v. EPA*, 636 F.2d 1267, 1277 (D.C. Cir. 1980). Section 2618 defined "rulemaking record" as the rule under review, any required findings and any oral transcripts or written submissions made during the rule's promulgation. 15 U.S.C. § 2618(a)(3) (1976). In *Chemical Manufacturers Association v. EPA* (*CMA*), we determined that the TSCA's "substantial evidence" review of a test rule is "more searching" and "demanding" than the APA's substantial evidence review. 859 F.2d 977, 992 (D.C. Cir. 1988) (quotation omitted). The Congress "contemplated that the TSCA standard should be viewed as a distinct standard." *Id.* at 991. And the legislative history indicated Congressional intent to make the TSCA substantial evidence standard *stricter* than its APA counterpart. *Id.* at 991–92 (citing H.R. REP. No. 94-1679, at 96 (1976) (Conf. Rep.)).

The 2016 Amendments granted the EPA additional authority regarding test orders, 15 U.S.C. § 2603(a)(2), and again included a judicial review provision, 15 U.S.C. § 2618(c)(1)(B)(i)(II). A court will "hold unlawful and set aside" a test order if it "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). The only difference between the review of *test orders* and the review of Section 2603(a)(1) *test rules* (now codified at 15 U.S.C. § 2618(c)(1)(B)(i)(I)) is the omission of "rulemaking" from the former.[6] Thus, as it did with the test rule standard at issue in *CMA*, the Congress explicitly rejected the application of the APA's substantial evidence standard and drafted an alternate standard for test order review.

[6] The 2016 Amendments made one other minor adjustment to the judicial review provision by deleting the statutory definition of "rulemaking record" in 15 U.S.C. § 2618(a)(3) (1976).

See CMA, 859 F.2d at 991–92; 15 U.S.C. § 2618(c)(1)(B)(i)(II). Test order review, then, is distinct from APA review. *See CMA*, 859 F.2d at 991. In *CMA*, we described the required review of the test rule being challenged there as "fairly rigorous" and more "searching" than the APA standard. *Id.* at 992. The same standard applies here. But *CMA* did not address *what documents* constitute the record "taken as a whole," the issue we must now decide in the test order context.

The record of course includes the test order itself—including the statutorily required Statement of Need. *See* 15 U.S.C. § 2603(a)(3). But the parties dispute whether the non-public portion of the administrative record—provided to Vinyl Institute only after it filed suit—is to be considered part of the record. The non-public portion of the 1,1,2-TCA administrative record contains several spreadsheets addressing the applicability of NAMs to high-priority substances, studies considered by the EPA, estimates of testing costs and burdens and the 1979 Elovaara Study. There was—and is—no public access to this portion of the record. The EPA argues that we should consider facts and data in the entire administrative record—both public and internal—because the "standard of review is based on the record as a whole, not just the Test Order." EPA Br. 32; *see* Oral Arg. Tr. 21:16–23:24. Vinyl Institute protests that the EPA's use of the non-public portion constitutes prohibited post hoc reasoning because the EPA failed to provide *all* of the data on which it relied.

We agree with Vinyl Institute that "the record taken as a whole" cannot lawfully include those non-public portions that the EPA did not reveal until this litigation began. First, the EPA's reliance on an administrative record that keeps portions thereof from the public is in tension with a bedrock principle of administrative law: agency action is upheld only "upon the validity of the grounds upon which the [agency] itself based its

action." *SEC v. Chenery Corp.* (*Chenery I*), 318 U.S. 80, 88 (1943); *see also* Kevin M. Stack, *The Constitutional Foundations of* Chenery, 116 YALE L.J. 952, 992–98 (2007) (*Chenery I*'s reason-giving requirement increases democratic accountability and reduces arbitrariness). When the EPA requires testing via rulemaking, the court reviews the "rulemaking record"—information fully available to the public—for substantial evidence. 15 U.S.C. § 2618(c)(1)(B)(i)(I). And when the EPA chooses the test order alternative, as it did with the March 2022 Test Order, it cannot rely on a non-public reason to satisfy its Section 2603 burden. *See Algonquin Gas Transmission Co. v. FERC*, 948 F.2d 1305, 1316 (D.C. Cir. 1991) (declining to consider FERC's record evidence that "was nowhere considered in either of the Commission's orders below"). Section 2618(c)(1)(B)(i)(II)'s review of the record "taken as a whole" does not permit the EPA to rely on undisclosed supporting data. *Cf. Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983) ("It is well-established that an agency's action must be upheld, if at all, on the basis articulated by the agency itself.").

Second, the text offers no support for the EPA's claim that the statute's "record taken as a whole" language allows us to review the entire record—whether or not portions thereof have been made public. EPA Br. 38. It is well established that we may review agency action only on "the grounds upon which the [agency] itself based its action." *Chenery I*, 318 U.S. at 88. The Congress could not have intended that the record "taken as a whole" encompasses non-public information that the EPA failed to disclose at the time of its final action. We do not countenance an agency's reliance on "a body of private law." *Tax Analysts v. I.R.S.*, 117 F.3d 607, 619 (D.C. Cir. 1997).

The agency's counterarguments lack merit. It claims Vinyl Institute could have asked to see any undisclosed portion of the

administrative record before initiating litigation. But that option—if it existed—does not relieve the EPA of its statutory burden to satisfy Section 2603's requirements with substantial evidence in the record "taken as a whole." 15 U.S.C. § 2618(c)(1)(B)(i)(II).[7] The EPA cannot rely on the non-public administrative record to meet its evidentiary burden.

B. The EPA's Section 2603 Burden

Having set forth the substantial evidence standard applicable to TSCA test orders, we now review whether the EPA provided substantial evidence to meet its Section 2603 burden regarding six discrete matters.

1. Need for New Information

As part of the required Statement of Need, the EPA "shall identify the need for the new information." 15 U.S.C. § 2603(a)(3). Need is determined by the scope of the EPA's risk evaluation of a given chemical as it is required to "integrate

[7] Defining "the record" to include only the public portions thereof does not limit the court's review to the test order only. We also consider other publicly available documents relied on by the EPA. The EPA's classification of 1,1,2-TCA as a high-priority chemical substance is part of "the record." *See* 84 Fed. Reg. at 71934. After its initial risk evaluation, the EPA must publish a final scope document addressing hazards, exposures, conditions of use and potential exposed sub-populations that it intends to weigh in evaluating high-priority substances. 15 U.S.C. § 2605(b)(4)(D). The 119-page final scope document for 1,1,2-TCA is also part of "the record." *See* Final Scope Doc. Indeed, the March 2022 Test Order incorporates the final scope document by reference. March 2022 Test Order at 6, 21. The January 2021 Test Order for 1,1,2-TCA is also publicly available and cited in the March 2022 Test Order. *Id.* at 5, 21. The EPA can—and does—rely on all of these publicly available documents as part of the record.

and assess available information on hazards and exposures." *Id.* § 2605(b)(4)(F)(i). The Statement of Need also requires the EPA to "describe how information reasonably available to the Administrator was used to inform the decision to require new information." *Id.* § 2603(a)(3). We uphold its identification of a need for, and description of, information only if it provides substantial evidence therefor within the meaning of Section 2618(c)(1)(B)(i)(II).

Based on 1,1,2-TCA's final scope document, the EPA determined that it needed to assess environmental hazards and risks to aquatic and terrestrial plants, invertebrates and vertebrates. March 2022 Test Order at 7. The test order explained how it evaluated data for 1,1,2-TCA and analogous chemicals (analogues). *Id.* It used its Analog Identification Methodology (AIM) software to identify seven analogues to 1,1,2-TCA. *Id.* It searched for hazard data pertaining to 1,1,2-TCA and the analogues in its ECOTOX Knowledgebase and from information submitted to it via the TSCA and other programs. *Id.* The March 2022 Test Order noted the earlier January 2021 Test Order that addressed aquatic data gaps. *Id.* After assessing this information, the EPA identified 1,1,2-TCA *acute* exposure data for soil invertebrates, mammals and birds as well as *chronic* exposure data for mammals and vegetation. *Id.* at 7–8. But it failed to identify *chronic* exposure data—for 1,1,2-TCA or the analogues—for soil invertebrates and birds. *Id.* Monitoring data from USGS' National Water Quality Monitoring Council identified 1,1,2-TCA in media, including ground water, sediment, soil and surface water, to which birds can be exposed. *Id.* at 9. Accordingly, the EPA issued the March 2022 Test Order to close the chronic toxicity data gap. *Id.* at 7.

Nonetheless, it failed to provide substantial evidence of how the reasonably available information informed the

decision to require new avian testing. In Table 1, the EPA acknowledged hazard data for acute bird exposure to 1,1,2-TCA and 1,1,1-TCA (an analogue). *Id.* at 8 tbl.1. The test order described the 1,1,2-TCA acute exposure data, captured in the 1979 Elovaara egg injection study. *Id.* at 9. The EPA adequately explained that its acute toxicity finding in chick embryos indicated the need for additional data on "potential effect following chronic dietary exposure." *Id.* Its reference to this one study only, however, fails our "searching" substantial evidence review. *See CMA*, 859 F.2d at 991. The EPA failed to explain or even identify the *1,1,1-TCA* bird acute exposure study in the test order itself. March 2022 Test Order at 8. It also noted the 1,1,2-TCA mammalian chronic exposure data in Table 1 but failed to identify the study. *Id.* Nor did it explain whether mammalian chronic exposure data can be extrapolated to birds. *Id.* Yet in a declaration submitted only to us, an EPA official explains that "toxicologists do not extrapolate mammalian toxicity data to birds because there are significant differences between the anatomy and physiology of birds and mammals and uncertainty in comparisons increases with larger taxonomic distances." J.A. 114. The EPA should have explained why it could not extrapolate mammalian chronic exposure data to avian chronic exposure in its Statement of Need description of reasonably available information. Identifying close but ultimately inapplicable studies and explaining, *in the record*, why it could not extrapolate other potentially relevant findings *could* constitute substantial evidence of "how information reasonably available to the Administrator was used to inform the decision to require new information." 15 U.S.C. § 2603(a)(3).

Again, we find the EPA's counterarguments unavailing. Another provision of the TSCA requires the EPA to publish "a list of the studies considered by the Administrator in carrying out each such risk evaluation, along with the results of those

studies." *Id.* § 2625(j)(4). According to the EPA, the Congress would have written a similar requirement into Section 2603 if it had wanted the agency to include *all* studies it either reviewed or rejected in the Statement of Need, but that requirement would have contradicted the Congress' intent to expedite TSCA risk evaluations. *See* S. REP. NO. 114-67, at 10. Although the EPA need not list every study in the test order's Statement of Need to satisfy our substantial evidence review, it must provide substantial evidence of the need for new information as well as an assessment of available information. 15 U.S.C. § 2603(a)(3).[8]

2. Basis for Vertebrate Testing

The Statement of Need also requires the EPA to "explain the basis for any decision that requires the use of vertebrate animals." 15 U.S.C. § 2603(a)(3). Before requiring vertebrate testing, the EPA must consider "reasonably available existing information," including new approach methodologies (NAMs) of toxicity information, computational toxicology, bioinformatics and high-throughput screening methods and their prediction models. *Id.* § 2603(h)(1)(A). By requiring the agency to consider NAMs, the Congress intended the EPA to reduce its use of vertebrate animal testing. *Id.* § 2603(h)(1).

As explained in the March 2022 Test Order, the EPA considered computational toxicology and bioinformatics in determining a need for new information. March 2022 Test Order at 8. In particular, it applied the AIM tool to identify

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[8] One of the non-public administrative record's data spreadsheets does identify 1,1,2-TCA studies the EPA considered. J.A. 37–41 (referencing studies reflected in Table 1 of the March 2022 Test Order at 8); *see also* EPA Br. 32. But we cannot consider these data spreadsheets because they were not publicly available when the EPA issued its March 2022 Test Order.

analogues. *Id.* It concluded, however, that "[r]easonably available data, computational toxicology, or high-throughput screening methods and predictions models are not available and/or cannot be used to address" 1,1,2-TCA's chronic toxicity to birds. *Id.* And "[n]o approved or readily available [NAMs] were identified that could be used." *Id.*

Under our searching substantial evidence review, these conclusory statements fail to *explain* the basis for vertebrate testing or to demonstrate adequately the EPA's consideration of NAMs. The non-public administrative record reflects that the EPA did consider several NAMs, including ChemACE, ECOSAR and OncoLogic. J.A. 33 (Data Gap Spreadsheet). And in its brief, the EPA succinctly explains why the NAMs it considered were inapplicable. For example, ChemACE did not identify any analogous chemicals to 1,1,2-TCA; ECOSAR predicted hazards for aquatic species, not birds; and OncoLogic addressed cancer in humans, not birds. EPA Br. 28. As part of its Statement of Need, the EPA should (1) indicate that it considered NAMs before requiring vertebrate testing and (2) explain why vertebrate testing is needed. Although the non-public administrative record and the EPA's brief cover these matters, they are not part of the record subject to our review for substantial evidence. *See supra* Section II.A.

3. Tiered Screening and Testing

The TSCA imposes an additional requirement when the EPA considers whether to conduct additional testing of a specific chemical. If "information available to the Administrator justifies more advanced testing . . . without first conducting screening-level testing," the EPA can proceed with advanced testing. 15 U.S.C. § 2603(a)(4). Otherwise, the EPA "shall employ a tiered screening and testing process." *Id.* It

does so by considering "results of screening-level tests *or* assessments of available information." *Id.* (emphasis added).

Vinyl Institute protests that the EPA did not conduct screening tests. Vinyl Institute construes the disjunctive "or" to require that the EPA use both screening-level tests *and* assessments of available information. It relies on the justification clause, through which the EPA can bypass the tiered screening and testing process.[9] *See* 15 U.S.C. § 2603(a)(4). According to Vinyl Institute, the Congress would not have included the justification clause if the EPA could choose between screening tests or assessing available information to complete the tiered screening and testing process. We disagree. Section 2603(a)(4) instructs the EPA to first consider if available information *justifies* bypassing the tiered screening and testing process altogether. If the EPA does not find support for a bypass—a high standard—it "*shall* employ a tiered screening or testing process." *Id.* (emphasis added).

The EPA claims that it conducted the tiered screening and testing process by assessing available information. It searched peer-reviewed literature databases for studies involving 1,1,2-TCA. March 2022 Test Order at 6–7. It also searched "gray literature" such as technical reports, reference books and dissertations. *Id.* at 7. It evaluated public comments submitted to the agency regarding 1,1,2-TCA. *Id.* Then, as discussed, it identified analogues, searched for toxicity studies and considered relevant NAMs. *See supra* Subsections II.B.1 and 2. It thus assessed available information before ordering the

[9] The justification clause allows the EPA to bypass the tiered screening and testing process if available information "justifies more advanced testing . . . without first conducting screening-level testing." 15 U.S.C. § 2603(a)(4).

seven targeted entities to conduct the avian chronic toxicity testing.

Nonetheless, the record lacks substantial evidence that the EPA *adequately* assessed available information. As discussed *supra*, the EPA failed to identify and explain sufficiently the relevant available studies or to address the (in)applicability of any NAMs. *See* 15 U.S.C. § 2603(a)(3). The assessment of available information in the Section 2603(a)(4) tiered screening and testing process thus rises and falls with Statement of Need requirements in Section 2603(a)(3).

4. Order versus Rule or Consent Agreement

The EPA may exercise its new "[a]dditional testing authority" "by rule, order, or consent agreement." 15 U.S.C. § 2603(a)(2). If it chooses the test order route, the Statement of Need must address "why issuance of an order is warranted instead of promulgating a rule or entering into a consent agreement." *Id.* § 2603(a)(3).

The EPA explained that the March 2022 Test Order will allow it "to obtain the needed information more quickly than if the EPA were to issue a . . . rulemaking or consent agreement." March 2022 Test Order at 8. Vinyl Institute believes "[t]his is not an adequate explanation" but it points to no statutory language barring the EPA from choosing the test order route based on that route's comparative speed. Vinyl Institute Br. 37; *see also* ACC Amicus Br. 4–5. Indeed, the 2016 Amendments' legislative history expressly discussed reducing barriers to EPA's testing authority. *See* H.R. REP. NO. 114-176, at 22–23; S. REP. NO. 114-67, at 10. In 2022, an EPA official testified before the Congress that many chemical risk evaluations have fallen behind schedule and would not be completed by their 2023 deadlines. *Testimony of Michal Ilana Freedhoff before the Senate Committee on the Environment and Public Works*,

at 6–7 (June 22, 2022), https://perma.cc/H7WQ-MEHJ; *see* 15 U.S.C. § 2605(b)(4)(G) (requiring that risk evaluations be completed within three years, subject to one six-month extension); 84 Fed. Reg. at 71,925 (designating 1,1,2-TCA in December 2019, with a June 2023 deadline). The EPA's choice to use the more expeditious test order method makes sense to us—the agency is, after all, behind schedule.[10] The EPA provided a sufficient explanation for why it issued a test order instead of a rulemaking or consent agreement.

5. Demonstration of Bird Exposure to 1,1,2-TCA

Vinyl Institute argues the EPA must provide some demonstration of avian exposure to 1,1,2-TCA at potentially toxic levels before issuing a test order. Granted, Section 2625(k) requires the agency to take hazard and exposure information into consideration. But Section 2603 does not instruct the EPA to address exposure in the test order. Vinyl Institute's argument reverses the TSCA's allocation of burdens. The development of chemical effects 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). The TSCA imposes many burdens on the EPA before it can issue a test order under Section 2603(a)(2)—including issuing a Statement of Need, implementing a tiered

[10] Amici PCRM and PETA argue that the Congress listed "rule, order, or consent agreement" in that order to indicate a hierarchy. PCRM/PETA Amicus Br. 9–10. Under their interpretation, the EPA must first consider rulemaking, then test orders and finally consent agreements. *Id.* The text does not support their reading. The Congress' use of the disjunctive "or" suggests that all three options—rule, order *or* consent agreement—are equally available. *See Encino Motorcars, LLC v. Navarro*, 584 U.S. 79, 87 (2018) ("or" is "almost always disjunctive" unless statutory context overcomes its ordinary meaning).

screening and testing process and considering costs and availability of facilities—but targeted entities have the ultimate burden to test 1,1,2-TCA for avian chronic toxicity.

After instituting a TSCA risk evaluation but before issuing a Section 2603(a)(2) test requirement, the EPA must "determine[] that the information is necessary" "to perform a risk evaluation." *Id.* § 2603(a)(2)(A). The 1,1,2-TCA risk evaluation requires an assessment of hazard and risk to plants, invertebrates and vertebrates—including birds. March 2022 Test Order at 7. After considering the avian *acute* toxicity data from the 1979 Elovaara study and the USGS' monitoring data demonstrating potential exposure to birds, the EPA reasonably determined that it needed avian *chronic* toxicity data. *Id.* at 8–9. Substantial evidence in the record indicates that avian chronic toxicity information is necessary for the EPA to complete its 1,1,2-TCA risk evaluation. It did not need to demonstrate a certain level of exposure before issuing the test order.[11]

6. Costs and Reasonable Availability

A test order must identify the chemical substance for which testing is required, the protocols and methodologies for

[11] The parties dispute how the exposure standard set forth in *CMA* applies here. Under the original TSCA test rule provision, the EPA had to find that a chemical "may present an unreasonable risk of injury to health or the environment" before issuing a test rule. 15 U.S.C. § 2603(a)(1)(A) (1976); *see also id.* § 2603(a)(1)(A)(i)(I) (2016). In *CMA*, we concluded that the EPA must have a "more-than-theoretical basis for inferring the existence of exposure." 859 F.2d at 988. Because the EPA issued the March 2022 Test Order under Section 2603(a)(2)'s "[a]dditional testing authority," however, *CMA*'s interpretation of Section 2603(a)(1)'s unreasonable risk requirement is inapplicable.

testing and the period needed to complete the testing. 15 U.S.C. § 2603(b)(1). "In determining the protocols and methodologies and period to be included," the EPA's "considerations shall include the relative costs of the various test protocols and methodologies . . . and the reasonably foreseeable availability of the facilities and personnel needed to perform the testing." *Id.* According to the EPA, this provision imposes two distinct requirements: it must identify the chemical substance, protocols and time period *in the test order* but it must simply *consider* costs and availability of facilities, presumably pre-test order. It submits that it did consider costs, demonstrated by a spreadsheet in its non-public administrative record that estimated avian reproduction testing costs at $288,283. Vinyl Institute insists that the EPA had to identify the relative costs of, and the availability of facilities for, the avian reproduction tests in the test order itself.

Again, we review the "the record taken as a whole" for substantial evidence. 15 U.S.C. § 2618(c)(1)(B)(i)(II). The EPA did not publish the cost estimate spreadsheet at the time it issued the March 2022 Test Order and it is therefore not in the record "taken as a whole." *See supra* Section II.A. To satisfy Section 2603(b)(1), the EPA must provide substantial evidence that it considered the relative costs of the protocols and the reasonably foreseeable availability of facilities and personnel to conduct the testing. 15 U.S.C. §§ 2603(b)(1); 2618(c)(1)(B)(i)(II).[12] The EPA did not provide substantial evidence of these factors—again, in the record as the TSCA defines it—that is, "taken as a whole."

[12] The EPA gave no consideration to the reasonably foreseeable availability of facilities and personnel in either the record under review or the non-public portion of the administrative record. *See* 15 U.S.C. § 2603(b)(1).

III. SECTION 2618(B) MOTION

Under TSCA Section 2618(b), a party can move for leave to "make additional oral submissions or written presentations" for the EPA's consideration. A movant must show "to the satisfaction of the court" that the additional information (1) "would be material" and (2) "there were reasonable grounds for the submissions and [for] *failure to make* such submissions and presentations in the proceeding before the Administrator." 15 U.S.C. § 2618(b) (emphasis added). Once the movant makes these showings, the court "may order the Administrator to provide additional opportunity" to the movant to submit the information. *Id.* Although no court has yet reviewed a TSCA Section 2618(b) motion, other regulatory statutes contain similar materiality and reasonable grounds tests. *See, e.g.*, 15 U.S.C. § 45(c) (Federal Trade Commission Act); 16 U.S.C. § 825*l*(b) (Federal Power Act); 29 U.S.C. § 160(e) (National Labor Relations Act); 33 U.S.C. § 1369(c) (Clean Water Act). The Supreme Court has endorsed the materiality and reasonable grounds requirements because they ensure that such motions are "used only for proper purposes, and not abused by resort to [them] as a mere instrument of delay." *Southport Petroleum Co. v. NLRB*, 315 U.S. 100, 104 (1942). Vinyl Institute seeks to admit the Stantec Report pursuant to Section 2618(b).

A. Extent of "Proceeding"

The movant must demonstrate "reasonable grounds" for failing to submit the additional evidence "in the proceeding before the Administrator." 15 U.S.C. § 2618(b). The parties disagree on the date the proceeding ended. Vinyl Institute claims it ended upon issuance of the March 2022 Test Order. The EPA argues the proceeding continued after issuance because the EPA can consider submissions from targeted

entities and may even extinguish a testing obligation. Looking at the text's plain meaning and the Congress' intent, we find that the "proceeding" continues after the EPA issues a Section 2603(a)(2) test order.

Before 2016, the EPA could compel testing only via a rulemaking but a party could nonetheless move to supplement under Section 2618(b), so long as the party could show materiality and reasonable grounds for failing to submit during the proceeding. 15 U.S.C. § 2618(b) (1976). "[P]roceeding" referred to the rulemaking proceeding because at that time that was the only procedural mechanism to compel testing. The 2016 Amendments amended Section 2618(b), extending its application to "*an action* under this section *to review . . . an order* under section 2603." 15 U.S.C. § 2618(b) (emphases added).

In general, "Proceeding" means "business conducted by a court or other official body." *Proceeding*, Black's Law Dictionary (11th ed. 2019). An "administrative proceeding" means a "hearing, inquiry, investigation, or trial before an administrative agency." *Administrative Proceeding*, Black's Law Dictionary (11th ed. 2019). The March 2022 Test Order does not mark the end of an inquiry, but the beginning. The EPA's investigation of 1,1,2-TCA's toxicity requires targeted entities to develop information to aid the EPA in its investigation. The March 2022 Test Order is only part of the EPA's ongoing inquiry. The test order's text supports the ongoing nature of the inquiry because, at least under Option 2, the EPA considers "whether the study and/or other relevant information [submitted by targeted entities] satisfies" the test order and may "extinguish those testing obligations from this Order that are no longer necessary." March 2022 Test Order at

11.[13] A submission under Option 2 can potentially end the EPA's investigation of a specific chemical. Thus, the "proceeding" continues after the EPA issues the test order.

The Congress' intent also supports our reading of "proceeding." The 2016 Amendments gave the EPA the authority to issue test orders without notice to, or past engagement with, a targeted entity. *See* S. REP. NO. 114-67, at 10; H.R. REP. NO. 114-176, at 22–23. The targeted entity necessarily, then, has no opportunity to submit information to the EPA before the test order issues because it has no notice of the test order. Vinyl Institute's interpretation of "proceeding" would violate the canon against surplusage because *every* Section 2618(b) movant following the test order issuance would have "reasonable grounds" for failing to supplement. *See TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001).

B. Reasonable Grounds for Delayed Submission

Vinyl Institute claims it had a reasonable ground for failing to submit additional information pursuant to Option 2 because it did not know what information the EPA had already considered and the EPA improperly shifted the burden to prove the test order's necessity to it. We conclude that Option 2 gave Vinyl Institute a fair opportunity to submit the Stantec Report. Vinyl Institute's failure to avail itself of Option 2 does not constitute reasonable grounds for its delayed submission. It need not know exactly what information the EPA considered

[13] Under Option 2, the EPA has extinguished several test orders after receiving sufficient studies. With regard to Phosphoric acid Triphenyl Ester (TPP), the EPA reviewed a study submitted by the target entity and "extinguish[ed] this testing requirement for the TSCA Section 4(a)(2) order for TPP." *Memo Extinguishing OCSPP 850.4500 Testing Requirement*, EPA-HQ-OPPT-2018-0458-0054 (Apr. 30, 2021), https://perma.cc/F7P5-F7SU.

to avail itself of Option 2, which instructs it to "[u]se this option to submit an existing study and/or other scientifically relevant information that *you believe* the EPA has not considered." March 2022 Test Order at 3 (emphasis added). Option 2 encourages the targeted entity to submit responsive information because it "may be in possession of studies unknown or inaccessible to the Agency." *Test Orders Under TSCA Section 4: Questions and Answers*, EPA Doc. # EPA 705-G-2021-3737, at 3 (Jan. 2022), https://perma.cc/B8QQ-WJTB. Vinyl Institute need not submit only information that the EPA has not yet considered. The March 2022 Test Order itself provides significant information to which Vinyl Institute can respond under Option 2. Vinyl Institute had access to the 119-page final scope document on 1,1,2-TCA risk evaluation, the EPA explanation of the "information reasonably available to the Administrator" and the agency's evaluation of the 1979 Elovaara study. *See* 15 U.S.C. § 2603(a)(3). Vinyl Institute could have submitted a responsive report based on the information it believed the EPA had not considered.[14] March 2022 Test Order at 3. Although Option 2 provides only 30 days to respond, the March 2022 Test Order explicitly allows for a deadline extension if requested. *Id.* at 9–10. Vinyl Institute did not request an extension.

In addition, Option 2 does not improperly shift burdens. Although Section 2603(a) details duties the EPA must perform before issuing a test order, the TSCA ultimately assigns "those

[14] As discussed *supra*, the complete test order administrative record is not available to targeted entities—at least until they institute litigation. Vinyl Institute claims it must review the administrative record before responding under Option 2. This raises another surplusage issue because, according to Vinyl Institute, a targeted entity without access to the non-public administrative record will *always* have reasonable grounds for failing to respond under Option 2.

who manufacture and those who process such chemical substances" the burden to develop information regarding "the effect of chemical substances and mixtures on health and the environment." 15 U.S.C. § 2601(b)(1); *see CMA*, 859 F.2d at 980. After the EPA satisfies its Section 2603(a)(2) duties and issues the order, the burden then shifts to the target entity to follow one of the test order options. Option 1 places the burden of testing on Vinyl Institute and Option 2 places the burden of submitting studies and other scientifically relevant information on Vinyl Institute. March 2022 Test Order at 11. The EPA can extinguish any further testing obligation if it receives sufficient information under Option 2.[15] Vinyl Institute could have submitted the Stantec Report under Option 2. Its failure to do so dooms its motion to supplement.

For the foregoing reasons, we grant Vinyl Institute's petition for review, vacate the March 2022 Test Order and remand to the EPA for proceedings consistent with this opinion. We deny Vinyl Institute's motion to supplement.

So ordered.

[15] *See supra* note 13.