Court Vacates TSCA Section 4 Test Order, Grant's Vinyl Institute's Petition for Review

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On July 5, 2024, the U.S. Court of Appeals for the District of Columbia Circuit issued its decision in *Vinyl Institute, Inc. v. EPA* (No. 22-1089). As reported in our May 31, 2022, blog item, on May 23, 2022, the Vinyl Institute, Inc. (VI) filed suit against the U.S. Environmental Protection Agency (EPA), seeking review of EPA's March 2022 test order for 1,1,2-trichloroethane (1,1,2-TCA) issued under Section 4(a)(2) of the Toxic Substances Control Act (TSCA). The court states that "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." According to the court, to the extent EPA relies on non-public portions of the administrative record, it "has failed to provide substantial evidence that meets its statutory mandate." The court vacated the test order, remanding to EPA to satisfy that mandate with "substantial evidence in the record taken as a whole." The court also denied VI's motion to supplement the record "with scientific information it could have — and should have — submitted earlier."

The court reviewed whether EPA provided substantial evidence to meet its Section 2603 burden regarding six discrete matters:

- Need for New Information: According to the court, 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. The court states that "[i]dentifying 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."
- Basis for Vertebrate Testing: The court states that as part of its Statement of Need, EPA should (1) indicate that it considered new approach methodologies (NAM) before requiring vertebrate testing; and (2) explain why vertebrate testing is needed. The court notes that although the non-public administrative record and EPA's brief cover these matters, they are not part of the record subject to its review for substantial evidence.
- Tiered Screening and Testing: According to the court, TSCA Section 4(a)(4) instructs EPA to consider first if available information justifies bypassing the tiered screening and testing

process altogether. The court states that "[i]f the EPA does not find support for a bypass — a high standard — it 'shall employ a tiered screening or testing process." (Emphasis added by the court). The court notes that nonetheless, the record lacks substantial evidence that EPA adequately assessed available information.

- Order versus Rule or Consent Agreement: The court states that "EPA's choice to use the
 more expeditious test order method makes sense to us the agency is, after all, behind
 schedule." According to the court, EPA provided a sufficient explanation for why it issued a
 test order instead of a rulemaking or consent agreement.
- Demonstration of Bird Exposure to 1,1,2-TCA: The court rejected VI's argument that EPA
 must provide some demonstration of avian exposure to 1,1,2-TCA at potentially toxic levels
 before issuing a test order. According to the court, "[s]ubstantial 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."
- Costs and Reasonable Availability: According to the court, to satisfy TSCA Section 4(b)(1), 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. The court states that EPA did not provide substantial evidence of these factors "– again, in the record as the TSCA defines it &m

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