

TSCA Confidentiality Protections Upheld by D.C. Circuit Court



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In a landmark decision, the D.C. Circuit Court invalidated an aspect of a U.S. Environmental Protection Agency (EPA) rule concerning confidential business information (CBI) under the Toxic Substances Control Act (TSCA). The December 20, 2024 [opinion](#) denied the petition for review filed by the Environmental Defense Fund (EDF) and granted the petition for review filed by the American

Chemistry Council (ACC) and American Fuel and Petrochemical Manufacturers (AFPM) requesting review of EPA's [final rule](#) which updated the requirements concerning the assertion and treatment of CBI, 40 C.F.R. Part 703 and related regulations.

The court agreed with ACC and AFPM and vacated the EPA's rule to the extent it requires entities reporting by non-confidential accession numbers and without knowing the underlying chemical identity to assert CBI claims for the underlying chemical identity to maintain its confidentiality. The ruling also upholds EPA's definition of "health and safety study," and the exemption for pre-commercialization of CBI claims from the requirement to substantiate those claims.

Background

Section 14(c) of TSCA requires companies to substantiate their CBI claims "in accordance with such rules as the Administrator has promulgated or may promulgate." The substantiation requirement ensures that the information they seek to protect is genuinely confidential and that there is a reasonable basis to conclude that its disclosure would cause substantial harm to their competitive position. The section mandates periodic review of CBI claims. It requires companies to reassert and justify their claims after 10 years.

The case, *Environmental Defense Fund v. United States Environmental Protection Agency*, 124 F.4th 1 (5th Cir. 2024), centers on EPA's final rule implementing section 14 of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

EDF challenged several aspects of the rule, arguing that it failed to comply with the statutory requirements of section 14, particularly in terms of substantiation and review of CBI claims. It argued that the rule's definition of "health and safety study" excluded critical information from public disclosure by excluding certain data elements of studies from mandatory disclosure, undermining TSCA. EDF also challenged EPA's decision not to mandate substantiation and routine review of pre-commercialization CBI claims after commercialization.

ACC and AFPM argued that the CBI rule unlawfully permits disclosing information protected by section 14(a) of TSCA. The rule's preamble stated,

EPA has consistently maintained and provided public notice of its position that if *any* submitting entity chooses not to assert and/or substantiate a confidentiality claim for a chemical identity as required by TSCA section 14, the chemical identity is no longer entitled to confidential treatment and may be published on the public portion of the TSCA Inventory.

The industry groups contended that TSCA prohibits EPA from publicly disclosing a specific chemical identity once a reporting entity has satisfied the requirements for asserting and substantiating a CBI claim for that chemical identity. ACC and AFPM argued that downstream entities may lack knowledge of a substance's specific chemical identity and, therefore, cannot assert and substantiate a CBI claim in accordance with the rule's requirements.

Court Decision

The court upheld the EPA's definition of the term "health and safety study," agreeing with industry groups that it appropriately excludes information unrelated to the effects of a chemical substance on health or the environment. The court found that EPA's definition is neither arbitrary nor capricious. Citing the Supreme Court's decision overruling *Chevron* deference to agency interpretations of their statutes, [Loper Bright Enterprises v. Raimondo](#), the D.C. Circuit said that it must "exercise our 'independent judgment' and 'apply[] all relevant interpretive tools to reach 'the best reading of the statute.'" It did not defer to EPA's interpretation of the statutory term "health and safety study," but rather determined that "EPA's definition is consistent with the best reading of the statute."

It also confirmed that under section 14(c)(2)(G), CBI claims for specific chemical identities made before commercialization are exempt from substantiation and review until a post-commercialization claim is made or another statutory trigger occurs. The court supported the EPA's use of permissive language in certain provisions, finding it consistent with TSCA and reasonably explained.

Turning to industry concerns, the court held that the rule's requirements for asserting and substantiating CBI claims were unlawful when applied to entities reporting by accession numbers. The court noted that these entities cannot assert or substantiate CBI claims for unknown identities, and EPA requiring them to do so would result in the loss of confidentiality protection for upstream entities that properly asserted and substantiated their CBI claims.

Significance of the Court Decision

This ruling has significant implications for both environmental regulation and industry practices. It enhances the protection of proprietary information by upholding the exemption for pre-commercialization CBI claims, allowing companies to safeguard their sensitive data until commercialization.

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