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Confidential Business Information/Toxic Substance Control Act: Environmental Defense Fund Opening D.C. Circuit Court of Appeals Brief Challenging U.S. EPA Rule

11/13/2023

The Environmental Defense Fund (“EDF”) filed an opening brief with the United States Court of Appeals for the D.C. Circuit (“D.C. Circuit”) challenging a United States Environmental Protection Agency (“EPA”) Toxic Substances Control Act (“TSCA”) rule. See *Environmental Defense Fund v. United States Environmental Protection Agency, et al.*, No. 23-1166.

The final rule provides the procedures addressing confidential business information (“CBI”) issues associated with company submission of data as required by TSCA. See 88 Fed. Reg. 37,155 (June 7, 2023) (“CBI Rule”).

TSCA is a federal statute enacted by Congress in 1976 to comprehensively regulate chemicals in order to prevent unreasonable risk or injury to health or the environment. See 15 U.S.C. § 2601 et seq. Various provisions require that EPA review and approve new chemicals before they enter the United States market. Further, EPA is tasked in the appropriate circumstances, to review and regulate chemicals that are already present on the market.

In order to carry out such mandates, companies must supply certain information. Sensitivities can be raised since TSCA provisions mandate that EPA makes certain information accessible to the public. However, Section 14 of TSCA provides provisions addressing CBI.

TSCA was comprehensively amended in 2016. See Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182. TSCA provisions amended included those involving the procedures for asserting confidentiality claims associated with CBI.

As a result, EPA promulgated the previously referenced CBI rule to implement these TSCA amendments. The proposed rule was published on May 12, 2022. See 87 Fed. Reg. 29,078.

EDF is challenging EPA’s CBI rule in the D.C. Circuit. The organization takes the position that the relevant TSCA amendments significantly limit the extent to which companies can assert and EPA can withhold information as confidential. Subsection 2613(a) is cited as providing that EPA may not withhold information unless the company claiming confidentiality establishes that:

1. The information meets the requirements for a trade secret or privileged and confidential information under the Freedom of Information Act; and
2. The information meets the TSCA-specific requirements for confidentiality established in 15 U.S.C. § 2613(c).

EDF's opening brief challenges three aspects of the EPA CBI rule, arguing:

- Narrows what it describes as TSCA's expansive definition of "health and safety study," undermining Congress' mandate that "any information" from a health and safety study, including underlying information, is "information not protected from disclosure," subject to too narrow exceptions (also arguing that EPA failed to respond meaningfully to commenters' concerns about definitional carveouts)
- Blocks access to chemicals' identities when companies claim them confidential in the health and safety documents they submit with their applications to make or import a new chemical in the United States (arguing the CBI rule would exempt claims from substantiation and review by EPA)
- Contains unlawful discretionary provisions that will result in the denial of public access to information because it provides that EPA only "may" deny confidentiality when a company fails to meet the requirements for making a valid claim and that it only "may" release information to the public when it cannot be validly withheld under TSCA (arguing EPA replaced regulations that properly implemented Congress' disclosure mandates)

A copy of the EDF brief can be downloaded [here](#).