



May 2, 2019

Via Electronic Mail

Alexandra Dapolito Dunn, Assistant Administrator
Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
Email: dunn.alexandra@epa.gov

Phillip Dupré, Trial Attorney
U.S. Department of Justice
Environment and Natural Resources Division
Email: phillip.r.dupre@usdoj.gov

RE: *EDF v. EPA*, Case No. 17-1201, and EPA's proposed rule, EPA-HQ-OPPT-2018-0320

Dear Assistant Administrator Dunn and Trial Attorney Dupré:

The D.C. Circuit's judgment in *EDF v. EPA*, 17-1201, (Opinion attached) requires EPA to act on remand to address the problems identified by the Court, and it also has immediate, time-sensitive implications for EPA's ongoing rulemaking for another proposed rule: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory, EPA-HQ-OPPT-2018-0320. 84 Fed. Reg. 16,826 (April 23, 2019) ("proposed rule"). In addition to addressing these problems in EPA's regulations promulgated pursuant to its final Inventory Notification Rule, EPA will need to modify its proposed rule to ensure consistency with the D.C. Circuit's Opinion and the representations made by the government in the course of that litigation. Currently, EPA is accepting comments on its proposed rule until June 24, 2019, but given the Court's decision, EPA must modify its proposal and accept comments on a modified proposal that complies with the rulings of the Court.

First, the Court's decision in *EDF v. EPA* identifies a key flaw with the substantiation questions set forth in 40 C.F.R. § 710.37(c), and EPA's current proposed rule expressly incorporates those flawed questions. 84 Fed. Reg. at 16,833 (to be codified at 40 C.F.R. § 710.45). EPA cannot proceed with the same substantiation questions which have already been rejected by the Court. The Court found these substantiation questions flawed because they failed

to inquire into “a chemical identity’s susceptibility to reverse engineering,” which “effectively excised a statutorily required criterion from the substantiation process.” Op. at 12. “The Inventory Rule is arbitrary and capricious to the extent that it omits any substantiation requirement pertaining to reverse engineering.” Op. at 13. EPA will need to revise the substantiation questions to comply with the Court’s ruling.

Second, the preamble to the proposed rule describes the substantive standard that EPA plans to use when reviewing claims, but that proposed substantive standard does not require EPA to consider whether a chemical identity is susceptible to reverse engineering. See 84 Fed. Reg. at 16,830. The Court found that EPA *must* consider this factor when analyzing whether to grant a claim for confidentiality. “[I]t makes no sense to treat as confidential the chemical identity of a substance that can readily be discovered through reverse engineering—as the EPA itself agrees. Oral Argument Tr. 24:48–24:59 (‘[D]oes the EPA agree that if something is readily reversibly engineered [then] it doesn’t qualify for confidential treatment?’ [Agency counsel]: ‘Yes.’)” Op. at 13. EPA must modify its substantive standard for reviewing confidentiality claims to align with the Court’s decision and the representations that EPA made to the Court in its briefing and at argument.

Third, the proposed rule allows persons to rely on the voluntary substantiations they submitted as part of the Inventory notification process. See 84 Fed. Reg. at 16,833 (to be codified at 40 C.F.R. § 710.43(b)). But the Court’s Opinion in *EDF v. EPA* establishes that these substantiations are inadequate because they fail to address a chemical’s susceptibility to reverse engineering, and EPA will need to modify the proposed rule to require companies to provide substantiations that address this statutory factor for confidentiality claims.

EDF requests a meeting at your earliest convenience to discuss the appropriate next steps to address the Court’s opinion on remand in *EDF v. EPA*, 17-1201, and with respect to EPA’s current proposed rule. Please feel free to contact me at (202) 572-3398 or rstockman@edf.org.

Respectfully,

/s/Robert P. Stockman

Robert P. Stockman

Environmental Defense Fund

cc: Dr. Jeffery Morris, Morris.jeff@Epa.gov
Elizabeth Thaler, Thaler.elizabeth@Epa.gov
Scott Sherlock, Sherlock.scott@epa.gov