

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

ENVIRONMENTAL DEFENSE FUND, <i>et al.</i> ,)	
)	
Plaintiffs,)	
)	Civil Action No. 1:20-cv-762 (LLA)
v.)	
)	
LEE ZELDIN, Administrator, U.S.)	
Environmental Protection Agency, in his official)	
capacity, <i>et al.</i> ,)	
Defendants.)	

**PLAINTIFFS’ OPPOSITION TO DEFENDANTS’ MOTION TO GOVERN
PROCEEDINGS IN LIGHT OF NEW RELATED LAWSUIT**

Just days before its production deadline, EPA seeks—yet again—to avoid producing any of the 84 unredacted PMNs that are subject to confidentiality claims and are part of the administrative record that this Court ordered EPA to produce. *See* Defs.’ Mot. to Govern Proceedings in Light of New Related Lawsuit, ECF No. 77 (“Defs.’ Mot.”). And though styled as a motion to govern, EPA asks the Court to not only delay its production obligation, but to effectively stay this case until the Court can resolve a separate, newly filed case, in which a single chemical company, Arkema, objects to the production of portions of the record relating to two of its applications to manufacture new chemicals (hereinafter “PMNs”). *Id.* at 1 & ¶ 9.

In other words, based on a dispute about 2 out of 84 unredacted PMNs that are part of the record, EPA asks this Court to bring this case to a complete halt, deny Plaintiffs their day in court, and instead move Arkema to the front of the line, notwithstanding Arkema’s six-year delay in asserting its rights. The law of the case doctrine, the Toxic Substances Control Act (“TSCA”), Circuit precedent, and traditional equitable principles require the Court to reject EPA’s approach.

BACKGROUND

1. The issue of whether EPA must produce material claimed as confidential as part of the administrative record has been exhaustively litigated in this case and decided by this Court. EPA has resisted producing documents claimed as confidential throughout this litigation. Indeed, even after the Court granted Plaintiffs' motion to compel production of the administrative record, EPA continued to resist production, requiring a further order by this Court. *See* Memorandum Opinion and Order, ECF No. 65; Joint Statement Regarding the Scope of the Record, ECF No. 69 ("Joint Statement"); Order, ECF No. 75 ("December 2025 Order").

2. In its most recent order of December 24, 2025, the Court: (1) reaffirmed that the administrative record includes unredacted versions of PMNs, even where a submitter has claimed information in the PMN is confidential; (2) ordered EPA to produce to Plaintiffs the public PMN files by January 23, 2026; and (3) ordered EPA to produce to Plaintiffs the unredacted PMNs within the scope of the record by March 23, 2026. December 2025 Order at 2-3. EPA timely produced the public PMN files with bate stamping. There are 84 different unredacted PMNs that are part of the record for review that EPA is obligated to produce by March 23, 2026. Defs.' Mot. at 2; First Amended Complaint tbls. 5-8, ECF No 16.

3. On March 13, 2026, nearly six years after this suit was filed, Arkema brought a separate lawsuit seeking to enjoin EPA from complying with this Court's December 2025 Order, but only as to two unspecified PMNs submitted by Arkema. *See* Corrected Complaint ¶¶ 65, 81, *Arkema v. EPA*, No. 1:26-cv-886 (D.D.C. Mar. 16, 2026), ECF No. 6 ("*Arkema* Complaint") (discussing "two PMNs"). Arkema asserts concern over the potential competitive harm that could result from the disclosure of these two particular Arkema PMNs but does not make claims

regarding the other 82 PMNs that are the subject of this lawsuit. *See generally Arkema* Complaint.

ARGUMENT

1. The Court already decided which PMNs are within the scope of the record and that EPA must produce, which includes all 84 unredacted PMNs that are the subject of confidentiality claims. *See* December 2025 Order. Having considered and decided EPA's production obligations, the December 2025 Order and the 2024 Memorandum Opinion and Order control and require production of the two Arkema PMNs. EPA's motion confirms that it intends to relitigate EPA's court-ordered production obligations and the currently-in-force protective order as to all 84 PMNs, using *Arkema* as its stalking horse. *See* Defs.' Mot. at 3-4 (¶¶ 6-9).

Ordinary law of the case principles prevent EPA from relitigating these issues. "The law of the case: must be followed in all subsequent proceedings in the same case in the trial court or on a later appeal in the appellate court, unless the evidence on a subsequent trial was substantially different, controlling authority has since made a contrary decision of the law applicable to such issues, or the decision was clearly erroneous and would work a manifest injustice." 18B Wright & Miller's Federal Practice & Procedure § 4478 (3d ed. 2025) (cleaned up). None of those conditions are met here, and following the law of the case here reflects "good sense" and the need "to protect both court and parties against the burdens of repeated reargument by indefatigable diehards," like EPA. *Id.*

2. EPA's argument that the Court should resolve *Arkema* before resolving this case rests on a misreading of TSCA, simply ignoring controlling provisions that foreclose EPA's reading. EPA argues that "[g]enerally, subject to 15 U.S.C. § 2613(d), if a disclosure lawsuit is

filed, EPA cannot disclose the relevant CBI until after the court rules on the lawsuit.” Defs.’ Mot. at 3 (citing 15 U.S.C. § 2613(g)(2)(D)(ii)). TSCA does establish certain procedures for PMN submitters: (1) to be notified before EPA discloses unredacted versions of PMNs they claim as confidential; and, subsequently (2) to bring an appeal in a district court to challenge and prevent EPA from making the disclosure (i.e., what EPA calls a “disclosure lawsuit”). Defs.’ Mot. at 3. However, EPA omits any discussion of the applicable threshold provisions that trigger these notification and appeal procedures. These threshold provisions make clear that EPA’s supposedly “general rule” does not apply here.

Specifically, the “Appeals” provision on which EPA relies (and on which Arkema bases its suit) applies only “[i]f a person receives a notification under this paragraph” that EPA intends to disclose information the person has claimed is confidential. 15 U.S.C. § 2613(g)(2)(D)(i); *see id.* § 2613(g)(2)(A). Thus, statutory notification is a precondition for a company to bring a disclosure lawsuit. *Id.* § 2613(g)(2)(A), (D)(i). But the statute establishes express exceptions to the statutory notification requirement, including that “[n]otification shall not be required ... for the disclosure of information under paragraphs (1), (2), (7), or (8) of subsection (d).” *Id.* § 2613(g)(2)(C)(iii). Where one of these exceptions applies, there is no statutory notification to the submitter and there is no basis in TSCA for a submitter to bring a lawsuit to prevent disclosure by EPA.

This case falls within a number of these exceptions, meaning that neither notification to Arkema and other manufacturers nor the subsequent *Arkema* lawsuit were proper under TSCA. Most relevant, the information here “is required to be made public under any other provision of Federal law,” *id.* § 2613(d)(8), as this Court has already found that the Administrative Procedure Act requires disclosure of these materials, *see* Memorandum Opinion and Order 31-33;

December 2025 Order at 2-3.¹ Second, EPA itself has previously admitted that production here was required under § 2613(d)(7), Joint Statement at 11 (citing 15 U.S.C. § 2613(d)(7)), which applies because “disclosure is relevant in a proceeding under this chapter”—i.e., the information is relevant to this lawsuit under TSCA, 15 U.S.C. § 2613(d)(7).

In sum, because exceptions to statutory notification apply here, statutory notification was not triggered, *id.* § 2613(d)(7), (8), (g)(2)(C)(iii), and because there was no required statutory notification, the threshold requirements for Arkema’s suit appealing to this Court have not been met, *id.* § 2613(g)(2)(D)(i). In the absence of these preconditions having been met, there is no basis for Arkema’s suit meaning that the provision preventing disclosure until such a suit is resolved is inapplicable, *id.* § 2613(g)(2)(D)(ii)(I) (barring disclosure “that is the subject of an appeal under this paragraph” (emphasis added)).

EPA ignores these provisions, but they are fatal to its argument that *Arkema* must be resolved before EPA can comply with the Court’s December 2025 Order. *See* Defs.’ Mot. (absence).

3. EPA effectively asks this Court to stay this case until the Court has resolved the *Arkema* case, Defs.’ Mot. at 1, 4, but has not met its burden to receive such relief. “[O]nly in rare circumstances will a litigant in one cause be compelled to stand aside while a litigant in another settles the rule of law that will define the rights of both.” *Belize Soc. Dev. Ltd. v. Gov’t of Belize*, 668 F.3d 724, 732 (D.C. Cir. 2012) (quoting *Landis v. N. Am. Co.*, 299 U.S. 248, 255 (1936)). As the movant, EPA must “make out a clear case of hardship or inequity in being required to go forward” with this case. *Landis*, 299 U.S. at 255-56 (explaining that “the burden of making out the justice and wisdom” of a stay “lay[s] heavily” on the movant).

¹ Exception § 2613(d)(1) also likely applies.

EPA does not even argue it faces any hardship from proceeding here and EPA's failure to do so, alone, requires denial of its motion. *Belize Soc. Dev. Ltd.*, 668 F.3d at 731-33 (finding district court erred where it granted a stay where there was "no articulation of need, pressing or otherwise"). On the other side of the ledger, the harm to Plaintiffs is evident as they would face yet more delay on top of the nearly six-years and counting this case has been pending. *Id.* at 732 ("[S]ufficient damage consist[s] of undue delay of the kind [Plaintiffs] suffers here."). And, though harms to Arkema cannot stand in for harms to movant EPA, there are no cognizable harms to Arkema. *See infra* at 6-7.

Moreover, EPA's conduct in this case is further reason to deny it what is essentially equitable and discretionary relief. EPA created the situation we are now in. It should have been evident to EPA that these documents are excepted from TSCA's procedures for statutory notification and pre-disclosure appeals to the district court: this Court's orders held that a specific provision of federal law required disclosure of the documents and EPA itself represented that this falls within another one of the exceptions. *See supra* at 4-5. Nevertheless, EPA voluntarily sent a letter to Arkema and the other manufacturers incorrectly stating they had a right to appeal by filing a new lawsuit in district court to collaterally attack the December 2025 Order. Defs.' Mot. at 2; *Arkema* Complaint ¶¶ 76, 81. Now that a single manufacturer has submitted such an appeal, EPA turns around and asks this Court yet again to halt production of all 84 PMNs containing purportedly confidential information in the record, even the 82 PMNs of other manufacturers. EPA's voluntary actions created this situation.

Yet EPA never informed the Court there was a possibility of additional lawsuits collaterally attacking any order requiring production of unredacted PMNs. At the time EPA requested that this Court provide it time to notify the manufacturers, *see* Joint Statement at 11, if

EPA believed that a manufacturer could file an appeal in district court that could enjoin EPA from complying with orders of this Court requiring production of unredacted PMNs, then EPA should have disclosed that possibility to the Court as a matter of candor. Instead, it remained silent, thereby inviting the current procedural mess. *See* Joint Statement (absence). EPA should not be rewarded for this litigation conduct.

4. Setting aside the merits of the *Arkema* lawsuit, the proposed relief EPA seeks—stopping production of all purportedly confidential portions of the record—is also improper because it is far broader than what Arkema seeks, let alone could obtain, in its separate action.

Arkema seeks to block production of their two PMNs and does not seek to block the production of the other 80-plus PMNs at issue here. *See Arkema* Complaint ¶ 81 (discussing the protected CBI in Arkema’s “two PMNs”); *id.* ¶ 85 (seeking protection of “[Arkema’s] PMN submissions”); *id.* at 21 (“Prayer for Relief” asking for protection of “Arkema’s CBI”). Indeed, the provision of TSCA that Arkema has sued under, 15 U.S.C. § 2613(g)(2), allows a person, who submits information to EPA that they assert to be confidential and that EPA intends to disclose, to sue to block the disclosure of their submissions. It does not allow a person to block the release of information submitted and claimed confidential by others.

The *Arkema* Complaint does not ask for the relief EPA seeks. Indeed, no other company asks this Court to block release of information they claimed confidential. This further demonstrates the overbreadth of EPA’s request.

5. And though harm to Arkema is irrelevant because they have chosen not to participate in this case, requiring EPA to produce the record documents on schedule would not harm Arkema in any cognizable way. TSCA is designed to protect against disclosures that would result in competitive harms. *See* 15 U.S.C. § 2613(c)(1)(B)(iii). Indeed, one of the statutory

preconditions for protection is that the submitter believes “disclosure of the information is likely to cause substantial harm to the competitive position of the [submitter.]” *Id.*

But here, Plaintiffs are not Arkema’s competitors, but non-profit advocacy groups, who could not and will not use this information to Arkema’s commercial detriment. And any suggestion that they might not sufficiently protect this information, such that it could get into the hands of Arkema’s competitors, rests on a chain of speculation that is too tenuous to credit. *See Arkema Complaint* ¶¶ 68, 78-80.

For that reason, EPA’s argument against splitting production—that doing so would disclose the specific PMNs Arkema submitted, which is itself purportedly confidential—is also meritless. Defs.’ Mot. at 3-4. Again, Plaintiffs are not Arkema’s competitors, so their knowledge of which PMNs are Arkema’s cannot competitively harm Arkema.

And in any event, it is possible that Arkema has already disclosed this information as to at least one, if not both, PMNs it seeks to protect in its collateral suit. For at least two sanitized PMNs that EPA has already produced as part of the non-confidential portions of the administrative record, the submitter claimed its identity was confidential throughout the PMN but included one or more other attachments that identify Arkema as the likely submitter. For P-18-0307, the submitter included a safety data sheet that identified “Arkema Coating Resins” as the company. PUB-FIL-0085533.² Similarly, for P-18-0042, the submitter included a number of documents with Arkema’s letter head. *E.g.*, PUB-FIL-0055033; PUB-FIL-0055352.

6. Finally, it would be especially inequitable to delay Plaintiffs’ ability to access the record and proceed with this case given that Arkema has slept on its rights. This case has been

² This represents the EPA bate stamping of the portions of the administrative record EPA produced on January 23, 2026.

pending for roughly six years, and the possibility that Arkema's PMNs would be disclosed has been present from the outset. Yet, Arkema has only sought to block production of its PMNs now, nearly six years on. It is notable that Arkema never claims that it did not know of this lawsuit or the potential implications for its PMNs, but instead has carefully worded its allegations to say "Arkema was never been made aware [sic] that EPA and third parties were actively discussing the scope and terms of release of Arkema's CBI." *Arkema* Complaint ¶ 86.

It is implausible that, until receiving EPA's notice in February 2026, Arkema did not know of Plaintiffs' lawsuit or its potential for disclosure of Arkema's two claimed-confidential PMNs. This is a widely publicized suit, with virtually every twist and turn covered in the specialty trade press that provides regulatory updates to the chemical industry, including that this Court ordered the production of unredacted PMNs. Attachment 16 (summarizing the Court's December 2025 Order requiring the production of unredacted PMNs); *see also, e.g.*, Attachment 1 (covering filing of the complaint in this case, with links to the complaint); Attachment 5 (discussing the implications of settlement of the case for the industry); Attachment 15 (summarizing the Court's August 2024 memorandum opinion and order); *see generally* Attachments 1-16 (documenting the history of this case in depth). Arkema is a multi-billion-dollar chemical manufacturer with highly learned regulatory counsel. Indeed, Arkema's lawyers have been aware of this lawsuit since Plaintiffs filed their notice of intent letter, months before this case was initiated, blogging about it and its implications for its chemical industry clients. *Earthjustice Notifies EPA of Intent to Sue for Failure to Disclose Information about New Chemical Substances*, Bergeson & Campbell PC (Sept. 17, 2019),

<https://www.lawbc.com/earthjustice-notifies-epa-of-intent-to-sue-for-failure-to-disclose-information-about-new-chemical-substances/>.³

The only way Arkema could not know about this case, is if it was not paying attention and that lack of diligence should not be used to prejudice Plaintiffs by throwing this case into disarray and subjecting Plaintiffs to further delay.

7. To the extent the Court has concerns about the production of the two Arkema PMNs in unredacted form and does not believe that its existing orders sufficiently address those concerns, the Court should simply order EPA to produce all of the other record materials on schedule and leave the Arkema PMNs to be decided later after the parties have had an opportunity to meet and confer.

8. Finally, EPA's alternative request to quickly hold a status conference to address its obligations under the Court's December 2025 Order is unnecessary and premature. *See* Defs.' Mot. ¶ 9. EPA's obligations under the December 2025 Order are clear, and its unwillingness to comply does not necessitate a hearing.

Instead, the Court should direct the parties, both here and in *Arkema*, to meet and confer to discuss the possibilities for coordination and efficiencies between the cases, including the potential for consolidation and the possibility of modifying the protective order in a manner that

³ Arkema's counsel, Bergeson & Campbell regularly helps clients apply for PMNs, *Toxic Substances Control Act (TSCA)*, Bergeson & Campbell PC, <https://www.lawbc.com/practices/chemical-regulation-under-tsca/> (last visited Mar. 19, 2026) ("One of the core aspects of our business is assisting clients with TSCA Section 5 new chemical notifications and with broadening their business reach with marketing the new products made possible by a successful Section 5 notification."); publicly touts its expertise on TSCA CBI issues, *Search Results: CBI*, Bergeson & Campbell PC, <https://www.lawbc.com/?s=CBI> (last visited Mar. 19, 2026); and oversees a coalition of chemical companies, which is dedicated to new chemical reviews under TSCA, *TSCA New Chemicals Coalition*, Bergeson & Campbell PC, <https://www.lawbc.com/news/knowledge-resources-tsca-new-chemicals-coalition/> (last visited Mar. 19, 2026).

could satisfy Arkema. The parties could then update the Court by the existing April 20, 2026, deadline for motions to govern in this case. That is more than enough time, given EPA's response to Arkema's complaint is not due for 60 days from the date of service, Fed. R. Civ. P. 12(a)(3), which falls well after April 20. Indeed, before EPA filed the instant motion, Plaintiffs' counsel suggested to EPA's counsel that the parties confer rather than engage in contested motions practice, and Plaintiffs remain ready and willing to do so.

CONCLUSION

The Court should reject EPA's efforts to essentially relitigate the record issues and to place Plaintiffs at the back of the line, behind late-coming plaintiff, Arkema. The time has long since passed for EPA to produce the entire administrative record to Plaintiffs so that merits briefing on this case may begin.

Dated: March 19, 2026

Respectfully submitted,

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Attachment 1



Environmentalists Sue EPA Over ‘Black Box’ New Chemicals Program

March 18, 2020

Post

Environmental groups have made good on their threat to sue EPA over inadequate transparency in its new chemicals review program, charging it's a "black box" that violates requirements in the Toxic Substances Control Act (TSCA) as well as the Administrative Procedure Act (APA).

TSCA grants "the public ... a right to know and provide input about new chemicals EPA is reviewing. Instead, EPA repeatedly and unlawfully conceals documents, and ignores other transparency rules," the groups say in a March 18 statement on [their lawsuit](#), filed the same day in the U.S. District Court for the District of Columbia.

"This unlawful secrecy prevents the public from weighing in before EPA allows new, potentially dangerous chemicals into commerce," the statement says. It adds that last year, the Trump EPA "approved without restrictions and while hiding all studies, a new [per- and polyfluoroalkyl substances (PFAS)], a member of a class of nearly indestructible chemicals linked to birth defects, infertility and cancer."

"The agency approves hundreds of chemicals in a similar fashion."

Along with the suit, the groups released a report detailing [an Earthjustice and EDF investigation](#) into the details underlying the suit. The investigation shows EPA doesn't notify "the public when a new chemical is under review and may soon be approved to go on the market, as required by law"; "allows companies to conceal crucial information about chemicals under review" and "doesn't audit companies' [confidential business information (CBI)] claims to determine whether they are warranted," the groups' statement says.

In the suit *Environmental Defense Fund (EDF) et al. v. Administrator Andrew Wheeler et al.*, the environmentalists are urging a federal court to find each of EPA's "failures to take action" as described within the new chemicals program is a failure to perform a required action under the APA and also a violation of TSCA 15 U.S.C. § 2619(a)(1) or its implementing rules and order EPA to remedy those failures to meet an "expeditious" court-ordered deadline.

The five plaintiffs -- Environmental Health Strategy Center, Center for Environmental Health, Natural Resources Defense Council (NRDC), EDF, and the Sierra Club, who are represented by Earthjustice -- also ask the court to find EPA's failures to act "a pattern or practice" and order the agency "to refrain from further failing to perform" acts required by TSCA, and award them the costs of the lawsuit, among other requests.

The suit is not surprising given environmental groups' longstanding concerns with EPA's approach to the review of new chemicals following TSCA reform.

The new law, which requires EPA to review new chemicals before they are allowed to enter the market, set a new requirement that EPA formally determine whether the new chemical poses an unreasonable risk to human health or the environment. This marks a change from the original TSCA, when EPA could allow some chemicals to enter the market simply by not challenging them within the statutory 90-day review period.

EPA Framework

While industry groups have been vocal about their concerns over the delays and backlog in new chemicals review, environmentalists are also unsatisfied, arguing that the new approach is too deferential to industry concerns, does not adequately consider risks to workers and excludes uses that should be considered, among other concerns.

Late last year, the groups [threatened to sue EPA](#) over what they charge is the agency's inadequate release of information about new chemicals. The notice of intent to sue cited the citizen suit provisions of TSCA section 20(a) "for

EPA's repeated and ongoing failures to comply with TSCA's nondiscretionary mandates to disclose to the public information about new chemical substances reviewed by EPA."

"In response the agency said it would make some changes, but these actions were insufficient to address the continuing lack of disclosure," the groups' statement says.

The groups' suit comes as EPA has been working to revise its framework for reviewing applications for new chemicals to enter the commercial market -- a document that EPA **released last December**, though it took comments on the document through February. Interestingly, in early comments, industry also **sought greater transparency** from EPA's new chemicals program, though targeting a different aspect than environmentalists.

The latest framework, intended to improve EPA's review process in light of the changes Congress required in TSCA reform, has been controversial since the first version was released in November 2017. That version was not implemented after NRDC sued the agency over it.

NRDC later dropped the suit after EPA officials stipulated the framework had not been put into practice.

Now, the environmental groups are arguing that even the original TSCA requires the agency to inform the public of new pre-manufacture notice (PMN) applications within five business days of receipt.

Changes to the new TSCA, they argue, require that only information that specifically falls within the TSCA's section 2613's confidential business information criteria can be withheld.

"Crucially, Congress wanted the public to have access to information about the health and safety of chemical substances undergoing premanufacture review and, thus, provided that 'any health and safety study' along with 'any information...from a health and safety study' submitted with a PMN is categorically ineligible to be treated as confidential by EPA, even if it would otherwise meet the requirements of subsection 2613(a)," the groups' suit states.

"EPA has an affirmative duty to disclose the entire PMN application and supporting documentation," the complaint says, citing 15 U.S.C. section 2604(d)(1), 40 C.F.R. § 720.95, "and may only withhold information included in the PMN application from the public if that information meets the confidentiality requirements of section 2613."

"Thus, if a manufacturer's claim that information is confidential does not meet the requirements of [section] 2613, EPA cannot withhold that information from the public file."

'Black-Box Approach'

The groups charge that EPA has not met these requirements. "When Plaintiffs have sought to utilize the disclosure provisions of TSCA, by requesting the public files for PMN applications in order to gain information on new chemicals being reviewed by EPA, they have been repeatedly stymied by EPA's black-box approach." Further, they argue that EPA continues to approve to market "potentially dangerous new chemicals," citing the examples of two classes of chemicals, PFAS and isocyanates. "Despite the known dangers of these classes of chemicals, EPA continues to approve the unregulated manufacture of new PFAS and isocyanates."

The groups argue that despite growing concern over PFAS' discovery in the environment and human bodies, "EPA continues to approve the manufacture of new PFAS chemicals under TSCA § 2604 ... EPA has approved at least 15 PMN applications to manufacture new PFAS since 2017, with varying levels of protection."

Similarly, for isocyanates, the groups write that "EPA continues to approve the manufacture of new isocyanate chemicals without imposing needed restrictions, determining that they are 'not likely' to present unreasonable risk, despite the fact that isocyanate chemicals are known to cause significant harms to human health and the environment, including death. ... Despite these dangers, chemical companies continue to seek to manufacture new isocyanates -- submitting numerous PMN applications for new isocyanates since TSCA was amended in 2016 -- and EPA continues to approve the manufacture of some new isocyanates without restriction, concluding that they are 'not likely' to pose unreasonable risk." -- *Maria Hegstad* (mhegstad@iwppnews.com)

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Attachment 2

INSIDE EPA'S

INSIDE TSCA

Exclusive news and analysis on the new
Toxic Substances Control Act

Environmentalists Amend Suit Over TSCA New Chemical Reviews

June 25, 2020

Post

A coalition of environmental groups has amended its legal complaint accusing EPA of blocking public access to industry requests for the use of new chemicals under the Toxic Substances Control Act (TSCA), a move that essentially restarts the clock in the case with the government expected to file another response.

“Congress...mandated that EPA operate this premanufacture review process transparently, including requiring that EPA timely disclose to the public all non-confidential information in the application,” the group wrote in its original complaint.

But in [the amended complaint](#), filed in the U.S. District Court for the District of Columbia June 19, the groups add that “Congress did so to provide the public with knowledge about new chemicals that might enter the market and so that interested persons can provide input into EPA’s decision-making.”

Such additions are among dozens the groups added to their suit though none changes the substantive arguments and general thrust of the complaint.

The environmental coalition, led by Earthjustice, accuses EPA of operating the TSCA section 5 program as a “black box” that prevents the public from having input on the agency’s decisions about the use of new chemicals.

“Seeking to exercise their statutory rights to information about the new chemicals EPA is reviewing, Plaintiffs have requested information about hundreds of new chemicals being reviewed by EPA. But EPA has repeatedly denied Plaintiffs and the public the information to which they are entitled under TSCA,” the group argues in the amended complaint.

[The lawsuit was filed on March 18](#) by five environmental groups, including the Environmental Defense Fund, the Natural Resources Defense Council and Sierra Club.

“This unlawful secrecy prevents the public from weighing in before EPA allows new, potentially dangerous chemicals into commerce,” the coalition said in announcing the suit. It adds that last year, the Trump EPA “approved without restrictions and while hiding all studies, a new [per- and polyfluoroalkyl substances (PFAS)], a member of a class of nearly indestructible chemicals linked to birth defects, infertility and cancer.”

Along with the suit, *Environmental Defense Fund (EDF) et al. v. Administrator Andrew Wheeler et al.*, the groups released a report detailing [an Earthjustice and EDF investigation](#) into the details underlying the suit. The investigation shows EPA doesn’t notify “the public when a new chemical is under review and may soon be approved to go on the market, as required by law”; “allows companies to conceal crucial information about chemicals under review” and “doesn’t audit companies’ [confidential business information (CBI)] claims to determine whether they are warranted,” the groups’ statement says.

The Justice Department on behalf of EPA [responded to the complaint](#) on May 29, rejecting as “vague and ambiguous” the allegations by environmentalists.

The government said the allegations in the complaint “consist of vague and ambiguous characterizations and expressions of opinion, and EPA lacks sufficient information to admit or deny them.”

EPA and DOJ are expected to respond to the revised complaint within the next several months.

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Attachment 3

INSIDE EPA'S

INSIDE TSCA

Exclusive news and analysis on the new
Toxic Substances Control Act

Litigants Seek More Time To Discuss TSCA 'Transparency' Suit

October 13, 2020

Post

Lawyers for EPA and a coalition of environmentalists are asking a federal district court for more time to continue negotiating procedural matters in a lawsuit that accuses the agency of failing to provide “transparency” in its review of new chemicals under TSCA section 5.

In an **Oct. 9 filing** in *Environmental Defense Fund et al., v. EPA*, the parties’ lawyers asked the U.S. District Court for the District of Columbia to give them until Nov. 2 to report back on the progress of ongoing talks on key procedural issues, while reiterating they “do not believe there is a realistic possibility of settling the case.”

Last week’s “joint case management statement” was the latest of an approximate monthly update to the court on a case filed by environmentalists in March charging EPA has unlawfully failed to provide adequate data about pre-manufacture notices (PMNs) seeking approval for new chemicals as well as other portions of the agency’s Toxic Substances Control Act (TSCA) new chemicals program.

The lawsuit centers on the availability of documents related to PMNs, and parties in the case have been negotiating on an administrative record for EPA decisions on chemical risks in determining the ability of plaintiffs to access those documents.

Environmentalists **amended their complaint** in June to emphasize that Congress revised TSCA in 2016 “to provide the public with knowledge about new chemicals that might enter the market and so that interested persons can provide input into EPA’s decision-making.”

“The parties agree that this case can be resolved by motions for summary judgment,” states the latest joint filing in the case. “However, as detailed below, the parties disagree about whether administrative records exist in this case and the availability and scope of discovery. Resolution of those questions will implicate the timing for any discovery, the appropriate deadline for the parties to submit final amended pleadings, and the appropriate schedule for summary judgment briefing. The parties are currently discussing options to resolve as many of those questions as possible.”

As those negotiations continue, the parties “do not believe there will be a need for a trial,” the filing states, adding, “So there should be no disputes over the protection of trial-preparation material.”

Also, the parties reject the usefulness of “alternative dispute resolution procedures” or the assignment of “a magistrate judge for any purpose,” according to the filing.

The suit was filed earlier this year by five environmental groups, including Earthjustice, EDF, Natural Resources Defense Council and Sierra Club.

Along with the suit, the groups released a report detailing an Earthjustice and EDF investigation into the details underlying the suit. The investigation shows EPA doesn’t notify “the public when a new chemical is under review and may soon be approved to go on the market, as required by law”; “allows companies to conceal crucial information about chemicals under review”; and “doesn’t audit companies’ [confidential business information (CBI)] claims to determine whether they are warranted,” the groups said in a statement.

The Justice Department on behalf of EPA responded to the complaint on May 29, rejecting as “vague and ambiguous” the allegations by environmentalists.

But in July, the parties indicated they had agreed on a handful of procedural steps in the suit over the transparency of the new chemicals program, including that they expect the court to eventually resolve the case in response to summary

judgment motions because they are not likely to settle the matter. Parties filed “joint statements” to the court in August and September.

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EPA, EDF To Update Court On TSCA 'Transparency' Case

November 5, 2020

Post

EPA and environmentalists say they will update a federal district court before month's end on procedural negotiations in a lawsuit accusing the agency of failing to provide "transparency" in its pre-market review of new chemicals required under TSCA section 5.

In a [Nov. 2 filing](#), the litigants say they will update the U.S. District Court for the District of Columbia by Nov. 23 on the progress of talks on the scope of documents to be submitted in the case and other key procedural issues, while reiterating they "do not believe there is a realistic possibility of settling the case."

The "joint case management statement" filed in *Environmental Defense Fund et al., v. EPA* is [the latest update to the court](#) on a case filed by environmentalists last March charging EPA unlawfully failed to provide adequate data about pre-manufacture notices (PMNs) from companies seeking approval for new chemicals to enter the market as well as other portions of the agency's Toxic Substances Control Act (TSCA) new chemicals program.

The lawsuit centers on the public availability of documents related to PMNs. Parties in the case have been negotiating on an administrative record for EPA decisions on chemical risks in determining the ability of plaintiffs to access those documents.

The disagreement over the record stems from differences in how the parties view the case. Environmentalists argue that EPA has affirmatively violated the TSCA and should therefore have a record documenting its actions.

On the other hand, EPA argues the claims allege a failure to act and therefore it lacks a record.

The parties are seeking to resolve their procedural differences so the court can address their substantive claims via summary judgment motions.

Environmentalists [amended their complaint in June](#) to emphasize that Congress revised TSCA in 2016 "to provide the public with knowledge about new chemicals that might enter the market and so that interested persons can provide input into EPA's decision-making."

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Industry Fears 'Bad News' From Settlement Talks In New-Chemicals Suit

August 25, 2021

Post

Industry attorneys say an expected settlement between EPA and environmental groups in litigation seeking more transparency on TSCA reviews of new chemicals could result in "bad news" for regulated firms, with possible consequences including broader releases of companies' safety data and public involvement in approval decisions.

"The environmentalists are asking for a very, very wide range of relief here, . . . and it does sound like some sort of settlement is on the horizon," Herb Estreicher, a partner at the law firm Keller & Heckman, said during a recent webcast on Toxic Substances Control Act (TSCA) issues hosted by the firm.

"It's probably bad news," he said later during the Aug. 18 event.

EPA and environmental groups told the U.S. District Court for the District of Columbia on Aug. 6 that they are **in settlement talks** regarding "some or all" aspects of the suit *Environmental Defense Fund (EDF), et al. v. EPA*, which charges that the agency is failing to provide adequate information to the public on pre-manufacture notices (PMNs) for new chemicals and other aspects of the review program.

While neither side in the suit has signaled which issues are under negotiation, Erik Baptist, a former Trump EPA official now with the law firm Wiley Rein, recently told *Inside TSCA* that opening the PMN process to public scrutiny could have far-reaching implications for chemical reviews by giving third parties a role in any decisions.

If EPA agrees to release preliminary chemical findings and regulatory actions, such as enforcement orders, for public comment it would allow citizen groups to act as "an additional party at the table" in the new-chemicals program for the first time, Baptist said.

"That is something that's unprecedented in the new chemicals program -- usually it's just between EPA and the submitter," he continued.

Baptist said the plaintiffs in the suit have sought "a more public stakeholder engagement process on new chemicals," but it is unclear how those changes would work in practice -- or how they would comply with TSCA.

He continued that public engagement on individual PMNs "is not really envisioned by the statute, nor should EPA allow another party to weigh in on the process, because it would only further delay what I believe to be a continued backlog of new chemicals submissions."

However, environmentalists have argued that Congress revised TSCA in 2016 "to provide the public with knowledge about new chemicals that might enter the market and so that interested persons can provide input into EPA's decision-making."

Although EDF and its allies filed their suit in March 2020, it has not yet reached substantive briefing. Rather, the two sides have been negotiating on an administrative record for EPA decisions about chemical risks in determining plaintiffs' ability to access those documents.

And while the Trump administration insisted it would not settle the case, Biden officials have already signaled plans to overhaul PMN reviews, including chemicals chief Michal Freedhoff's **March announcement** that the agency would tighten Trump-era practices on consent orders and stepping up use of data-gathering authority.

Confidential Data

Estreicher focused his talk on a settlement's implications for data transparency. He said any deal is likely to force EPA to disclose a host of information that industry includes in PMN submissions but has so far been protected from public release, like exposure data and toxicity findings, and narrow its test for what material is confidential business information (CBI) shielded from release.

"My prediction for this is that you'll see EPA denying a lot of CBI claims that are associated with PMNs, or challenging those claims. And I think you'll see EPA putting health and safety studies in their dockets -- studies that are submitted in connection with PMNs," he said.

While "some things are clearly CBI," like chemical identities and specific industrial processes, "certainly the number of workers that are exposed, [and] the number of hours" of exposure would be more difficult to shield, he said. "I think EPA may take the position that, in response to settling with the environmental groups, that it's going to release that."

However, Baptist said data releases are likely to pose less of a hurdle for industry than any new public-engagement process.

"It's not just protecting CBI -- EPA is going to do what they need to do with CBI . . . but to me the bigger concern is that there's going to be an additional party at the table," he said.

EPA and the *EDF* plaintiffs are due to update the court on their negotiations by Sept. 3. -- *David LaRoss* (dlaross@iwpnews.com)

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Talks Fail In Suit Seeking 'Transparency' On TSCA New Chemicals Reviews

February 2, 2022

Post

Settlement talks have fallen through in Environmental Defense Fund's (EDF) suit claiming EPA unlawfully withheld from the public information on its TSCA pre-market reviews of new chemicals, with the two sides jointly telling a federal court that they "terminated" negotiations that might have resolved the case.

The parties explain in a [Jan. 31 joint case management statement](#) that they met to discuss a potential settlement several times last summer and even "exchanged settlement proposals on October 3 and November 19, 2021. The parties were unable to reach an agreement and have terminated those settlement discussions."

EDF and EPA first indicated to the court in August that they [might be able to settle](#) "some or all" of the group's claims that officials failed to provide "transparency" on pre-market reviews of new chemicals as required under section 5 of the Toxic Substances Control Act (TSCA) -- a significant change from the Trump administration when the parties said there was no chance of a deal.

The failure of those negotiations is perhaps the latest bad news for EPA's struggling TSCA new chemicals division, which chemicals chief Michal Freedhoff has said has less than half of the funding needed to fulfill its statutory duties. The office has faced a consistent backlog of new chemicals applications, due in part to the 2016 overhaul of TSCA that requires EPA to make risk findings on all new-chemical applications, but without allowing a gradual phase in of those requirements nor loosening the deadlines for those reviews.

The combination of a plethora of tight deadlines and lack of resources have contributed to a persistent morale problem in the office, as shown in a [recent staff survey](#), where employees described overwork and stressful conditions there. It has also faced whistleblower allegations that some managers had intervened in new-chemicals reviews to speed their completion and make risk findings more palatable to industry -- allegations now under investigation by the agency Inspector General.

Chemicals chief Michal Freedhoff noted in response to the survey that she has sought assistance from scientists in EPA's research office in reviewing some of the human health assessments in certain new chemicals reviews -- though she acknowledged that the only long-term solution is a funding boost from Congress, which has yet to pass a fiscal year 2022 budget for EPA.

But the end of settlement talks could come as a boon to industry, after attorneys warned last fall that a settlement could bring ["bad news" for regulated firms](#), as it might have required broader releases of companies' safety data and public involvement in approval decisions, among other reforms sought by environmentalists.

PMN Transparency

First filed in March 2020, the lawsuit centers on the lack of public availability of documents related to TSCA pre-manufacture notices (PMNs). EDF says that EPA has unlawfully failed to provide adequate information about the notices it receives from companies seeking approval for new chemicals to enter the market as well as other portions of the agency's TSCA new chemicals pre-market review program.

Last year, the group amended its complaint to emphasize that Congress revised TSCA in 2016 "to provide the public with knowledge about new chemicals that might enter the market and so that interested persons can provide input into EPA's decision-making."

However, the two sides have yet to begin active litigation on the subject. Rather, they have been at odds over how to establish the factual record for the case, and the Jan. 31 statement says those negotiations are ongoing.

They explain that “parties disagree about whether an administrative record exists in this case and the availability and scope of discovery” and explain they are “negotiating joint stipulations to resolve certain factual disputes and (2) engaging in motions practice to resolve the remaining dispute regarding the administrative record.” They add that they expect to finalize the agreements over the factual disputes by the end of February.

The litigants tell Judge Emmet Sullivan that they expect he will be able to resolve the case with a summary judgement ruling, rather than requiring a trial. They ask him to waive further requirements for status updates until they have completed ongoing negotiations over the facts of the case. -- *Maria Hegstad* (mhegstad@iwnews.com)

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Suit Over Transparency Of EPA's New Chemicals Program Heads To Court

March 14, 2022

Post

EPA and environmental groups are poised to begin active litigation as soon as this month in the groups' long-pending suit seeking greater transparency and public engagement on TSCA reviews of new chemicals, following more than a year of negotiations that both sides now say will conclude this month.

In a [joint case management statement](#) dated March 2, both sides in *Environmental Defense Fund (EDF), et al., v. EPA* say they plan to file "by the end of March" stipulations on several disputed issues of fact that have been the focus of closed-door talks since the case was filed in March 2020, to be followed "shortly after" by a motion where the plaintiffs will seek to force EPA to turn over administrative records from the new-chemicals program.

"[B]ecause the joint stipulations have not resolved the parties' disagreements related to the administrative record, Plaintiffs intend to file a motion to compel production of the administrative record shortly after the parties have finalized the joint stipulations," the filing says.

That motion will mark the first concrete step toward having the U.S. District Court for the District of Columbia decide the issues EDF and its allies raised in their complaint nearly two years ago -- with potentially far-reaching consequences for Toxic Substances Control Act (TSCA) new-chemicals reviews.

The groups are claiming that agency officials [unlawfully failed](#) to provide "transparency" on their handling of pre-market reviews of new chemicals as required under section 5 of TSCA.

In the complaint, they emphasized that when Congress overhauled the law in 2016 it required EPA "to provide the public with knowledge about new chemicals that might enter the market and so that interested persons can provide input into EPA's decision-making" -- language they say requires the agency to "timely disclose to the public all non-confidential information" in each pre-manufacture notice (PMN) it receives.

EPA and the environmental groups at one point said they were engaged in settlement talks that could resolve at least some aspects of that claim, but they told the court in a Jan. 31 filing that they "were [unable to reach an agreement](#) and have terminated those settlement discussions."

At the time, attorneys had warned that a settlement could be "bad news" for regulated firms, as an agreement from EPA to release preliminary chemical findings and regulatory actions could set a precedent for broader releases of companies' safety data, and increased public involvement -- precedent that could still come to pass if EDF and its allies prevail on the merits of their claims.

"The environmentalists are asking for a very, very wide range of relief here," Herb Estreicher, a partner at the law firm Keller & Heckman, said during an August 2021 webinar.

'Factual Disputes'

The March 2 filing says the parties have agreed on "negotiating joint stipulations to resolve certain factual disputes" and "engaging in motions practice to resolve the remaining dispute regarding the administrative record."

According to past summaries of the parties' negotiations, EPA has long maintained that no administrative record exists in the case, because plaintiffs cannot request evidence that the agency failed to take a particular action.

"In a failure-to-act case, there is, by definition, no agency action for which an administrative record already exists," reads the March 2 filing. "Repackaging an alleged failure to act as an affirmative action -- as affirmatively doing less than what is legally required -- does not alter the fundamental claim . . . it does not change the fact that no

administrative record exists here. That said, EPA is willing to work with Plaintiffs to explore possible ways to address their desire to see various documents.”

However, the joint filing says EDF and its allies continue to dispute that claim, and will ask the court to force EPA to compile and turn over the documents they seek.

“Second, because the joint stipulations have not resolved the parties’ disagreements related to the administrative record, Plaintiffs intend to file a motion to compel production of the administrative record shortly after the parties have finalized the joint stipulations,” the filing reads. “Following the Courts’ resolution of the motion, the parties would file an updated case management statement.”

The parties write that they agree the case can be resolved by motions for summary judgment, but reiterate that they “disagree about whether an administrative record exists in this case and the availability and scope of discovery. Resolution of those questions will implicate the timing for any discovery, the appropriate deadline for the parties to submit final amended pleadings, and the appropriate schedule for summary judgment briefing.” -- *Diana DiGangi* (ddigangi@iwpnews.com)

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Court Urged To Order EPA To Produce Record In TSCA New Chemicals Case

May 2, 2022

Post

Environmentalists are urging a federal court to order EPA to produce the administrative record for their long-running case seeking to increase transparency in the TSCA new chemicals program, arguing that the suit challenges a series of discrete agency actions that can be challenged and is not the “failure to act” case that the agency says it is.

In an [April 29 motion to compel](#), environmentalists cited a series of *Federal Register* notices and agency production of pre-manufacture notice (PMN) applications that they say are deficient or otherwise unlawful -- and show there is a record that could be produced.

The plaintiffs add that an agency action that can be challenged demonstrates the existence of an administrative record that should be produced within 30 days in order for the litigation to proceed.

The case, *Environmental Defense Fund (EDF), et al., v. EPA*, was first filed in March 2020, after environmentalists had warned EPA they planned to sue the agency over inadequate transparency in the new chemicals review program, calling it a “black box” and saying the lack of public knowledge and input into the program violates requirements in the Toxic Substances Control Act (TSCA) and Administrative Procedure Act (APA).

“EPA repeatedly and unlawfully conceals documents, and ignores other transparency rules,” alleged the plaintiffs of the Environmental Defense Fund, Center for Environmental Health, Defend Our Health, Natural Resources Defense Council, and Sierra Club in the lawsuit which is pending in the U.S. District Court for the District of Columbia.

But the parties have struggled to litigate on the merits as they failed to resolve their differences on key procedural issues, including whether there is an administrative record that the agency could produce.

Earlier this year, however, they gave up on negotiations and agreed they would [ask the court](#) to resolve their differences.

Now, the plaintiffs are asking that court to compel EPA to produce an administrative record in the case, challenging the agency’s claim that records regarding a lack of action by EPA don’t exist and therefore cannot be produced. They charge that this claim is “in defiance of the local rules and black letter administrative law.”

“EPA’s argument that this is a failure-to-act-case cannot be squared with Plaintiffs’ First Amended Complaint, which specifically identifies discrete EPA actions that Plaintiffs challenge as unlawful,” the plaintiffs argue in their motion.

Among other things, the plaintiffs allege ‘insufficient notice,’ which they say is proven by a series of actions, including EPA’s publication of *Federal Register* notices informing the public that the agency had received PMN applications after the statutory deadline, publication of other notices without statutorily required information, and “untimely publication in the *Federal Register* of notices of receipt of applications for test marketing exemptions.”

They also note that Count IV of their complaint “details EPA’s failure to place the PMNs in an online docket at [www.regulations.gov](#) as required to comply with its own regulations,” the motion states. “Critically, EPA admits it took the actions that Plaintiffs challenge. EPA admits that it published the Federal Register notices that Plaintiffs challenge as untimely and incomplete in Counts I--III. And EPA admits that it produced the application files that Plaintiffs challenge as incomplete in Counts V--X.”

APA Violations

The plaintiffs say that in not producing the administrative record, the agency is in violation of the Administrative

Procedure Act (APA) as well as local rules governing the district court.

“These record materials are necessary for Plaintiffs to move for summary judgment, and without them, Plaintiffs will be prejudiced,” they claim. “Moreover, the Court will be unable to comply with the requirement that judicial review be based on the administrative record. Accordingly, Plaintiffs seek relief from this Court to compel compliance with the APA and LCvR 7(n)(1).”

The motion to compel also notes that since the suit was first filed in 2020, “the parties have conferred on numerous occasions to resolve this dispute,” and that both parties discussed developing “a set of joint factual stipulations as to the contents of the documents that comprise the administrative record.”

“The intended purpose of the stipulations was to allow the Court to resolve this case on cross-motions for summary judgment by establishing all the relevant facts contained within the record documents, such that the Court would not need to review the record documents and thereby making Defendants’ failure to produce an administrative record immaterial,” the plaintiffs write.

However, the parties were not able to agree on a “list of stipulations sufficient to allow Plaintiffs to move for summary judgment on all their claims and to enable the Court to fully adjudicate this case.” -- *Diana DiGangi* (ddigangi@iwpnews.com)

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Groups Say EPA Bid To Dismiss New Chemicals Suit Dodges 'Record' Need

July 1, 2022

Post

Environmentalist plaintiffs in a long-stalled suit seeking increased transparency in TSCA reviews of new chemicals are arguing that EPA's motion to dismiss the case is invalid, as the agency has not yet produced an administrative record that could be vital to their eventual response to its arguments on the merits of their case.

In a [June 23 filing](#), plaintiffs in *Environmental Defense Fund (EDF), et al., v. EPA* ask the U.S. District Court for the District of Columbia to suspend briefing on the agency's motion seeking a final decision in the case -- writing they cannot properly respond to those arguments, and the court cannot fully consider them, without an administrative record.

"[T]his Court's rules, black letter administrative law, and the law of this Circuit mandate that plaintiffs in a record-review case should have access to the administrative record when responding to a dispositive motion," the environmentalists say.

EDF and its allies are claiming that in the six years since Congress rewrote the Toxic Substances Control Act (TSCA), EPA failed to provide required information to the public about its process for reviewing and approving new chemicals under TSCA, and to allow for public input into its decisions on individual chemicals.

But the case has been mired in procedural disputes for two years, most prominently over the administrative record. The environmentalists are seeking release of documents detailing EPA's decision-making on new chemicals, but the agency insists there can be no underlying record in a case over its alleged failure to take required actions.

Following lengthy closed-door negotiations, the plaintiffs filed a formal motion [to compel production of a record](#) on April 29, under a schedule agreed to by all sides. However, EPA then filed its own motion seeking ["judgment on the pleadings,"](#) where it said the court should sidestep that dispute and reject the case immediately.

EDF and its allies now say that contradicts the "framework for resolving the disputed issues regarding the record" that the parties developed in April, under which the plaintiffs "would file a Motion to Compel Production of the Administrative Record, which would enable the Court to resolve the record dispute and which the parties would brief on a jointly agreed upon schedule."

The agency "unilaterally attempts to upend this joint framework by filing a Motion for Judgment on the Pleadings while the Motion to Compel is still being briefed," they continue. "EPA urges the Court to resolve their Motion for Judgment on the Pleadings and simply ignore Plaintiffs' Motion to Compel."

And the environmentalists argue that deciding the merits of the case before resolving the dispute over an administrative record would unfairly deprive them of the chance to use agency documents in their defense.

"[T]his Court's review of any dispositive motion must be based on 'the whole record'; and ruling on EPA's Motion for Judgment on the Pleadings without providing Plaintiffs with the administrative record would constitute prejudicial error," they say.

"The Court should require that the case proceed on the joint framework EPA agreed to, and it should decide Plaintiffs' Motion to Compel before the parties continue briefing EPA's Motion for Judgment. That is what the law requires."

'Expeditious Resolution'

The plaintiffs further argue that deciding their motion before EPA's would be more efficient for the court, allowing it to return to issues already argued once relevant documents arrive.

Suspending consideration of the motion for judgment on the pleadings “would avoid the potential for multiple rounds of dispositive briefing inherent in EPA’s unilateral approach, thereby conserving the resources of the Court and the parties while ensuring an expeditious resolution of this case,” they add.

By contrast, the motion continues, if the court follows the joint framework and addresses the motion to compel before EPA’s substantive filing, “this case can be resolved in a single round of dispositive briefing.”

It concludes, “If the Court concludes that Plaintiffs have indeed challenged agency actions for which there is an administrative record, then: (1) the Court could compel production of the record; and (2) Plaintiffs could cross-move for summary judgment using that record.”

EPA, however, has argued in its May filing that there is no need for the court to address the administrative-record issue. “[T]he Court should not entertain Plaintiffs’ efforts to gain access to information designated as confidential under the guise of a motion to compel an administrative record,” EPA wrote. “Those requests make little sense on their merits.”

The agency also argued that EDF and its allies have no right to “seek review of EPA’s overall administration of TSCA under the citizen suit provision that authorizes suit against ‘any person . . . who is alleged to be in violation’ of the statute, because that provision allows suit against parties subject to TSCA’s substantive provisions, not administering agencies.”

And it argued more generally that EDF and its allies cannot seek relief under the Administrative Procedure Act (APA), “because their allegations do not concern ‘agency action’ (or a failure to take ‘agency action’) as defined by the APA, much less final agency action.”

But the plaintiffs’ new filing pushes back against the agency’s claims that the dispute is “purely legal,” saying that argument “is inconsistent with the local rules” as well as the APA.

“These rules do not make any exception for “purely legal” issues because “when an agency action is challenged[,] [t]he entire case on review is a question of law,” the environmentalists write.

“[I]f accepted, EPA’s purported exception for “purely legal issues” would apply in every case challenging agency action, swallowing the rule that the agency must produce the administrative record,” they say, describing the case as similar to the 2018 suit *Physicians for Social Responsibility v. Wheeler*, where former members of agency advisory boards sued Trump-era Administrator Andrew Wheeler for dismissing them.

“Again, these are the very same arguments EPA advanced and the Court rejected in *Physicians for Social Responsibility*,” EDF and its allies write -- [Diana DiGangi \(ddigangi@iwppnews.com\)](mailto:DianaDiGangi@iwppnews.com)

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EPA, Plaintiffs Intensify Claims On New Chemicals Transparency Suit

July 19, 2022

Post

EPA and environmentalist plaintiffs are renewing and expanding on their arguments in the long-stalled suit over transparency in the TSCA new-chemicals program, over both the environmental groups' push to secure an administrative record detailing reviews of individual substances and the agency's bid to dismiss the case outright.

The two sides in *Environmental Defense Fund (EDF), et al., v. EPA*, filed separate briefs on July 14, as the U.S. District Court for the District of Columbia weighs the plaintiffs' motion to compel release of a record, and the agency's competing request to quickly decide the case "on the pleadings."

Both briefs center on underlying questions of how to define "agency action" subject to judicial review under the Administrative Procedure Act (APA), and whether EDF and its allies are claiming that EPA failed to perform mandatory actions, or instead took action that fell short of the Toxic Substances Control Act's (TSCA) requirements for public engagement, disclosure and other transparency measures.

"Contrary to EPA's assertions, the Agency is required to produce an administrative record even when informal agency actions are in dispute," the plaintiffs write in [their latest brief](#). "EPA claims that because the actions were 'clerical', the Agency was not required to contemporaneously produce an explanation of its decision, and therefore no administrative record exists to provide to the Plaintiffs."

The environmentalists say EPA has failed to provide data on how it reviews and approves new chemicals mandated by the reformed TSCA and improperly refused to publish data on chemicals' health and safety under protections for confidential business information (CBI), in violation of both the toxics law and the APA.

However, the agency has argued that the plaintiffs lack standing to bring their claims under either the APA or TSCA's citizen-suit provisions.

In particular, EDF and its allies are asking the court to force release of an administrative record that they say would give insight into EPA's reviews of new chemicals, but the agency insists that there can be no record for a case dealing with an alleged failure to act and is urging the court [to dismiss the case](#) without waiting to resolve the plaintiffs' motion.

The groups' July 14 filing specifically aims to counter EPA's argument that "there are no administrative records for EPA's publication of a notice or compiling of a public file, which are clerical in nature and not the type of 'agency actions' (let alone 'final agency actions') for which an administrative record exists."

But they say the agency's claims that it cannot produce a record for "clerical" actions is improper, as "there is no 'clerical' exemption from the record review requirement, as the text of the APA subjects all challenges to agency action to record review."

'Informal' Actions

The plaintiffs argue that the APA "expressly makes all 'agency action[s]' subject to judicial review on the 'whole record,' without exception. The class of agency actions subject to record review includes the exercise of 'every form of agency power,' regardless of the type of procedure the agency uses."

That "is true even for informal actions," they continue, citing precedent from the 1987 U.S. Court of Appeals for the District of Columbia Circuit case *Occidental Petroleum Corp. v. S.E.C* which states that "in order to allow for meaningful judicial review, the agency must produce an administrative record that delineates the path by which it reached its decision."

And they say that although “EPA also suggests it has reformed its processes to disclose more information . . . none of the purported reforms resolves EPA’s persistent, unlawful withholding of health and safety studies. EPA acknowledges that manufacturers continue to improperly claim that health and safety studies and safety data sheets are CBI even though such items are not entitled to confidential treatment.”

Despite the agency’s assurances, they conclude, “as EPA describes its own current practices, it will continue to withhold any document that a manufacturer asserts is confidential, including health and safety studies and safety data sheets.”

“Plaintiffs need a ruling from this Court, which requires a record,” they add.

EPA Claims

Meanwhile, [EPA’s July 14 brief](#) disputes many of the environmentalists’ claims, reiterating [its argument](#) that “Plaintiffs’ claims are not cognizable under TSCA, and they lack standing to bring the claims that might be reviewable under the statute.”

The agency adds, “Nor are Plaintiffs claims reviewable under the APA because they do not concern ‘agency action,’ as defined by the statute, or a failure to take such ‘agency action.’”

EPA argues that the court must determine whether the plaintiffs’ claims are “subject to judicial review” before ruling on whether to compel EPA to “hundreds of purported administrative records,” and renews its argument that because the groups lack standing under the APA and TSCA, their case should be swiftly dismissed.

It also urges the the court should decide the pending motion for judgment on the pleadings “in tandem” with the plaintiffs’ motion to compel, “because, in support of its own motion and in opposition to Plaintiffs’ motion, EPA presents first-order questions for the Court to resolve.”

The agency adds, “As explained, the Court should not even hear this case because plaintiffs lack standing and do not have valid causes of action under TSCA and the APA.” -- *Diana DiGangi* (ddigangi@iwpnews.com)

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INSIDE EPA'S

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Dismissing TSCA Suit Would Reward EPA 'Rulebreaking,' EDF Says

July 25, 2022

Post

Environmentalist plaintiffs in a long-stalled suit over transparency in the TSCA new-chemicals program are asking the judge to consider their request to order EPA to produce an administrative record before the agency's push to dismiss the case, saying ruling on dismissal first would give the agency the "full benefit of its violation of the rules" on document disclosure.

In a [July 21 brief](#) filed by Environmental Defense Fund (EDF) and other plaintiffs in support of their motion to stay the proceedings, they reiterate their argument that EPA must produce an administrative record in this case before the judge can rule on whether to dismiss it, this time adding that allowing EPA to file a dispositive motion without first producing the record would reward the agency for its failure to produce documents on its Toxic Substances Control Act (TSCA) reviews of new chemicals.

The plaintiffs argue that the court's local rules mandate "certification of the record and filing the certified list 'simultaneously' with the filing of the dispositive motion, and the [Administrative Procedure Act (APA)] requires that review of agency actions be based on the 'whole record.'"

Under that principle, "[i]f Plaintiffs are correct that this case involves a challenge to agency action, then EPA's request for relief from record production was untimely and unjustified," the brief reads. "Thus, considering EPA's dispositive motion without providing Plaintiffs the record would give EPA the full benefit of its violation of the rules."

The case, *EDF, et al., v. EPA* has been stalled in the U.S. District Court for the District of Columbia for two years by a variety of procedural disputes, chiefly over whether the agency must produce an administrative record of documents from its implementation of the TSCA new-chemicals program.

The plaintiffs say EPA must release a record of its decision-making on what they claim is a long pattern of transparency lapses surrounding pre-manufacture notice (PMN) applications and *Federal Register* notices acting on them, but the agency says no such record exists because the environmentalists are claiming a "failure to act" -- non-action, it says, can never be the subject of an administrative record.

In a July 14 brief, [EPA asked the court](#) to weigh its pending request to dismiss the case "in tandem" with the plaintiffs' motion to compel the administrative record because the dismissal motion "presents first-order questions for the Court to resolve," having claimed that the plaintiffs lack standing and have shown no cause of action under either the APA or TSCA.

It also denies that the steps being challenged by EDF and its allies -- the groups Center for Environmental Health, Defend Our Health, Natural Resources Defense Council and Sierra Club -- constitute "agency actions" that are subject to judicial review under the APA.

But the environmentalists say the court cannot fully consider that question without whatever record it ultimately decides EPA must produce, in part because the two sides have raised material disputes about the underlying facts of the case.

"Because EPA's justiciability arguments depend on *post hoc* assertions that directly contradict Plaintiffs' allegations, Plaintiffs should be given the record to enable them to disprove EPA's assertions," the July 21 brief says.

Environmentalists' Standing

They also dispute EPA's argument that they lack standing in the case, citing EPA's concession, offered in 2020, that it did fail to publish certain items associated with PMNs, and the fact that "Plaintiffs advocate for stronger protections at

the local, state, and national level” -- goals they say were materially harmed by EPA’s failure to disclose key details of PMN reviews to the public.

“The information about new chemicals that EPA withheld from Plaintiffs would have helped in these activities. Indeed, Congress’ intent in enacting these disclosure obligations was to facilitate the public’s right to know and public engagement with EPA,” the brief reads. “Thus, Plaintiffs have been injured and will continue to be injured by EPA’s unlawful conduct.”

They conclude, “Plaintiffs’ standing is so clear that EPA is unable to advance a colorable standing argument for any count alleging that EPA produced unlawfully incomplete PMN applications. . . . Plaintiffs plainly have standing on all six counts relating to the incomplete PMN applications. Accordingly, EPA cannot escape its obligation to produce the record.”

And they reiterate that by filing a motion to dismiss EPA has departed from the two sides’ agreed-upon “joint framework” for resolving the case.

EPA argued in its July 14 brief that its motion to dismiss “resulted in part from the parties’ longstanding efforts to resolve many of these issues through stipulations in which EPA identified each instance where it failed to provide certain information, conceded to those omissions, and told Plaintiffs that it would make such information available to Plaintiffs via a public website,” but the plaintiffs write that this is insufficient to justify its latest step.

“At the time EPA agreed to the joint framework, EPA was fully aware that Plaintiffs would be filing a motion to compel production of the whole administrative record and had nonetheless agreed to the stipulations and to the joint framework,” they write.

The brief adds, “Because EPA knowingly entered into the joint framework, its attempt to depart from the framework is unjustified and the Court should not allow EPA to unilaterally change course.” -- *Diana DiGangi* (ddigangi@iwpnews.com)

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Environmentalists Say 'Right To Know' Supports TSCA Transparency Suit

August 17, 2022

Post

Environmental groups suing EPA over transparency in the TSCA new-chemicals program are touting “freestanding ‘right to know’” provisions in the toxics law to counter the agency’s bid for a quick dismissal, arguing that court precedent supports suits to enforce such protections.

In an [Aug. 15 brief](#), plaintiffs in *Environmental Defense Fund (EDF), et al. v. EPA* urge the U.S. District Court for the District of Columbia to let them continue to seek disclosure of key documents from Toxic Substances Control Act (TSCA) reviews of new chemicals, including industry pre-manufacture notices (PMNs), despite the agency’s argument that those claims are unreviewable under both TSCA and the Administrative Procedure Act (APA).

They argue that “right to know” provisions Congress added to TSCA when it amended the law in 2016 “[continue] even after EPA has completed” its review of a new chemical, and allege that EPA “routinely and repeatedly thwarted” their efforts to examine new chemical applications.

“Consistent with this freestanding right to know, EPA must make a PMN available to an interested person at any time, not just during the PMN review process,” they argue. “Thus, as consistently interpreted by EPA, TSCA’s transparency provisions establish freestanding rights to information, which exist even after EPA’s PMN review process has ended.”

Further, the plaintiffs claim that EPA has admitted to “violating TSCA’s transparency and disclosure requirements for years, just as Plaintiffs allege. Even though judicial review is available and EPA admits it has persistently violated the law, EPA seems to imply that there is still no need for the Court to review Plaintiffs’ claims.”

The Aug. 15 filing comes after EDF and its allies [previously countered EPA’s motion to dismiss](#) in a July 21 reply brief, but that document largely focused on the plaintiffs’ standing to sue under the APA, rather than the role of TSCA’s transparency provisions.

The environmentalists now say the U.S. District Court for the District of Columbia had previously held in *Judicial Watch* that certain agency inactions such as “[f]ailure to make available for public inspection . . . [agency] records’ and [f]ailure to publish timely notice. . . in the *Federal Register*’ are final agency actions subject to APA review.”

EDF and its allies argue that EPA has acknowledged that Congress “enacted TSCA’s disclosure mandates to establish the public’s ‘right to know’ about potentially toxic chemicals they might encounter in their homes and workplaces,” and “explained that these are ‘affirmative’ disclosure obligations that Congress placed on the Agency.”

Thus, the new filing says, their claims fall within the precedent set by the D.C. District Court’s 2001 case *Judicial Watch v. National Energy Policy Development Group*, under which “publishing (deficient) notices in the *Federal Register* and making (incomplete) agency records available for public examination . . . are precisely the kinds of final agency actions this Court has held are subject to judicial review.”

‘A Straightforward Rule’

“This Court adopted a straightforward rule of decision in *Judicial Watch*: where Congress gives the public a right to agency records and places an affirmative obligation on an agency to produce those records, the agency’s compliance with that legal duty is reviewable under the APA,” the plaintiffs write.

They add, “Just as in *Judicial Watch*, TSCA grants Plaintiffs “enforceable right[s] to information” about new chemicals. These freestanding rights include the right of interested persons to ‘exam[in]e’ PMN applications and the right to Federal Register notices that timely summarize the contents of those applications.”

EPA argued in its motion to dismiss the case that while it “has conceded and identified its past violations of TSCA,” those lapses are not “final actions” that can support an APA suit -- or an administrative record of related documents, another key dispute between the two sides.

The plaintiffs are asking the district court to force EPA to produce an administrative record, following protracted negotiations that helped postpone active litigation in the case for two years after they filed it in early 2020.

In its motion to dismiss, EPA had argued that the plaintiffs lack standing under TSCA as well as the APA, stating, “Plaintiffs cannot seek review of EPA’s overall administration of TSCA under the citizen suit provision that authorizes suit against ‘any person . . . who is alleged to be in violation’ of the statute, because that provision allows suit against parties subject to TSCA’s substantive provisions, not administering agencies.”

EDF and its allies note in a footnote to their new reply that if the court accepts this argument and dismisses their claims under the citizen suit provision of TSCA, “then TSCA’s citizen suit provision does not provide an ‘adequate remedy’ for challenging EPA’s unlawful actions, and Plaintiffs may proceed on their APA claims,” since that law allows suits over alleged statutory violations with “no other adequate remedy.” -- *Diana DiGangi* (ddigangi@iwpnews.com)

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INSIDE EPA'S

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EPA Tells Court It Has 'Completed' New-Chemicals Data Releases

January 6, 2023

Post

EPA has told the court hearing environmentalists' long-running suit over transparency in its TSCA new-chemical reviews that it has "completed its efforts" to make all non-confidential data the plaintiffs sought publicly available, though whether the groups will accept that claim remains to be seen.

The agency filed a [Jan. 4 notice](#) in *Environmental Defense Fund (EDF), et al., v. EPA* stating that it conducted a "thorough investigation" of the plaintiffs' claims that it improperly withheld documents related to Toxic Substances Control Act (TSCA) pre-manufacture notices (PMNs), and released all such materials online.

"EPA has now completed its efforts to make that information available to Plaintiffs. The Agency has posted all complete versions of the relevant [pre-manufacture notices (PMNs)] (including attachments) to its public website, ChemView, subject to the submitter's confidentiality designations. . . . Plaintiffs and the rest of the public can presently access those materials," reads the agency's filing to the U.S. District Court for the District of Columbia.

That notice comes less than two months after EPA in November announced [the release of "thousands" of industry submissions](#) related to TSCA reviews of new chemicals on ChemView, while vowing to pair continued look-backs at previously undisclosed documents with "near real-time" publication of newly filed material.

Then, the agency touted what it called "improved public access to certain reports submitted by chemical companies" under TSCA and promised to step up releases of such documents -- particularly new-chemicals reviews governed by section 5 of the law, and a section 8(e) requirement for firms to report discoveries of "substantial" health risks from their chemicals.

EPA now appears to be tying that step to its response to claims by EDF and its allies that the agency has long violated TSCA's transparency requirements for the new chemical review program. They are asking the court to both compel the agency to publish a swath of records from past reviews, and to release similar materials from new submissions on an ongoing basis.

While the plaintiffs have yet to respond to EPA's filing, they have repeatedly argued in past briefs that its voluntary releases of chemical data and PMN records since the suit began still fall short of what TSCA requires.

Further, while the agency has admitted to past violations of TSCA's disclosure requirements, it also maintains that the case cannot go forward because publishing or failing to publish a required document in the course of a chemical review is not "final action" subject to judicial review and has asked the court [to dismiss the case](#).

Judge Emmet G. Sullivan, however, wrote in a Nov. 2 docket entry that he has no plans to hold a hearing on EPA's motion or the plaintiffs' [competing request to compel release](#) of a broad administrative record before deciding on either, despite the environmentalists' request for oral argument.

"Should the Court determine that a hearing is necessary to rule on the pending motions, the Court will so inform the parties," that entry says. It remains Sullivan's most recent action in the case.

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INSIDE EPA'S

INSIDE TSCA

Exclusive news and analysis on the new
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Judge Sets Hearing In Long-Stalled Suit Over Transparency In TSCA Reviews

February 29, 2024

Post

The federal district judge who recently took on oversight of environmentalists' long-running suit accusing EPA of unlawfully concealing documents and data key to its TSCA new-chemicals review program has set a hearing on a pair of motions seeking to resolve major elements in the case that have been pending since mid-2022.

In a Feb. 28 docket entry, Judge Loren AliKhan announced that she will convene a May 1 hearing in *Environmental Defense Fund (EDF), et al., v. EPA* on dueling motions first filed in 2022 -- the agency's bid for "judgment on the pleadings," and environmentalists' request to compel production of an administrative record, including many documents the government has claimed are confidential under the Toxic Substances Control Act (TSCA).

If it goes forward as scheduled, the hearing would be the case's first substantive action since January 2023, when the two sides filed dueling letters with the U.S. District Court for the District of Columbia on whether EPA's voluntary disclosures of TSCA documents went far enough to address the plaintiffs' claims. At that point, the two outstanding motions had been fully briefed for several months.

Further, the announcement comes soon after AliKhan assumed responsibility for the *EDF* litigation in December, replacing Senior Judge Emmet Sullivan. That move came without further explanation; a Dec. 14 docket entry says only that the case was "directly reassigned" to AliKhan, and that Sullivan "is no longer assigned to the case."

EDF and its co-plaintiffs first sued EPA in March 2020, claiming that it was ignoring several transparency mandates in the reformed TSCA, violating the public's right to know about new chemical applications and declining to publish "health and safety" studies associated with those submissions even though the law carves such data out of its protections for confidential business information (CBI).

Environmentalists have attacked the new-chemicals program as a "black box" that produces final decisions on industry applications with little or no public explanation, and the EDF suit represented an early attempt to broaden those disclosures. The plaintiffs say EPA has a duty to publish detailed information on new pre-manufacture notices (PMNs) in the *Federal Register* and to "make a PMN available to an interested person at any time," among other claims.

But since that initial complaint, the suit has been mired in preliminary and procedural battles; the sides spent more than two years in talks on the proper administrative record for the case but were unable to agree on what documents EPA should have to release; settlement talks with the Biden EPA similarly fell through, with the parties jointly announcing in early 2022 that they were unable to reach an agreement and had **"terminated" negotiations**.

In 2023, the agency **touted its releases of "thousands" of new-chemicals documents** on its ChemView website, beginning in late 2022, as well as its promise to release such materials for future applications "on a near real-time basis" through ChemView.

At the time, EPA framed that commitment as its latest step to release more industry-submitted TSCA documents, particularly under section 5, with the caveat that it will continue to shield data deemed CBI from disclosure.

Pending Motions

EPA's motion asks for the suit to be dismissed, on the grounds that TSCA's disclosure mandate is limited, and designed to support the rulemaking process. And even while the agency has admitted to past violations of TSCA disclosure requirements, it also maintains that the case cannot go forward because publishing or failing to publish a required document in the course of a new chemical review is not "final action" subject to judicial review.

In its last filing in the case, EPA told the court it had conducted a “thorough investigation” of the plaintiffs’ claims that it improperly withheld new chemical review documents, released all such materials online and **has “completed its efforts”** to make all non-confidential data the plaintiffs sought publicly available.

Meanwhile, environmentalists have urged the court to force release of an administrative record that they say would give insight into EPA’s reviews of new chemicals, and have repeatedly argued EPA’s voluntary releases of chemical data and PMN records since the suit began still fall short of what TSCA requires.

However, the agency in its own briefs insisted that there can be no record for a case dealing with an alleged failure to act and is urging the court to dismiss the case without waiting to resolve the plaintiffs’ motion.

For instance, in one filing EPA said, “there are no administrative records for EPA’s publication of a notice or compiling of a public file, which are clerical in nature and not the type of ‘agency actions’ (let alone ‘final agency actions’) for which an administrative record exists.”

The environmental groups also filed a separate motion late in 2022 seeking a hearing on the pending requests. But Sullivan declined, writing in a November order that if he determined “that a hearing is necessary to rule on the pending motions, the Court will so inform the parties.” Sullivan did not act on the litigation again. -- *Maria Hegstad* (mhegstad@iwpnews.com)

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INSIDE EPA'S

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Judge Advances EDF's 'New Chemicals' Suit, Backing 'Right To Know' Claims

August 21, 2024

Post

Correction Appended

A federal district judge is backing environmentalists' claims that TSCA provisions requiring EPA to release information and documents from its reviews of new chemicals create an enforceable public "right to know," the first major ruling in long-running litigation aimed at bringing more transparency to the new-chemicals program.

While Judge Loren L. AliKhan of the U.S. District Court for the District of Columbia stops short of agreeing with plaintiffs that the agency has unlawfully failed to make key materials related to Toxic Substances Control Act (TSCA) new-chemical reviews available to the public, her [Aug. 20 opinion and order](#) in *Environmental Defense Fund (EDF), et al., v. EPA* says they are correct that the law's transparency mandates are enforceable in court -- opening the door for a later ruling on the merits.

"[A]ll of Plaintiffs' claims are subject to judicial review," under either the toxics law itself or the Administrative Procedure Act (APA), AliKhan writes.

In particular, she writes that TSCA section 5(b) "creates a freestanding right to information" through its requirement that new-chemical filings and supporting documents be "made available . . . for examination by interested persons."

That provision, and its implementing rules, "vest an enduring right to information that lasts before, during, and after any risk determination," AliKhan holds.

EDF and four other environmental groups have argued for years that EPA is violating the public's "right to know" about new-chemical reviews by failing to quickly publish pre-manufacture notices (PMNs) and other industry applications and declining to release some "health and safety" studies associated with those submissions -- even though the law carves such data out of its protections for confidential business information (CBI).

Industry representatives [have long worried](#) that a win for environmentalists could lead to broader releases of data that companies see as confidential, and more pressure from environmental and citizen groups for EPA to impose tight restrictions on new chemicals.

But the case had been mired in preliminary and procedural arguments since the environmentalists filed it in 2020, most prominently EPA's claim that the plaintiffs were attempting to sue over preliminary steps in a larger process rather than "final action" that qualifies for judicial review.

AliKhan's decision rejects EPA's argument, set out in a "motion for judgment on the pleadings" that the agency originally filed in 2022, while granting the environmental groups' parallel motion to compel production of an administrative record she can rely on for fact-finding.

While that step is often a minor one, in the current case EPA had argued that it had taken no formal "action" to build such a record around -- making AliKhan's order a significant win for the plaintiffs.

"[W]here the activity at issue is 'circumscribed' and 'discrete,' it qualifies as 'agency action.' And here, Plaintiffs have undoubtedly identified circumscribed, discrete activities," the judge writes.

She is now giving the two sides until Sept. 17 to agree on a scope for the eventual record, which she concedes will be a complicated subject. "The EPA has already produced many of the specific documents at issue, and the parties have

spent two years negotiating a set of joint stipulations. These disclosures and stipulations might narrow the scope of the remaining administrative record,” the new opinion says.

Interlocking Statutes

The order follows a **May 1 hearing** where AliKhan, who took over the case from Senior District Judge Emmet Sullivan in December, said she was “struggling to wrap my head around” the array of novel and complicated legal arguments EPA and the environmentalists had raised in their competing motions.

AliKhan does not fully side with the environmentalists on any particular legal point, instead dividing the 10 separate “counts” in the groups’ complaint into three groups and holding that each set is open to judicial review under distinct provisions of either TSCA or the APA.

First, she writes that three counts claiming EPA gave “insufficient notice” of new TSCA submissions are reviewable under section 5(h), despite the lack of any explicit “date-certain” deadline for action in that provision, because seeking public comment on those notices is part of a 45-day review process for the initial applications.

“Notice must precede comment, comment must precede the EPA’s decision, and the EPA’s decision must be rendered within forty-five days of receiving the application. The only logical conclusion is that the EPA has a nondiscretionary duty to provide notice at least before the forty-five-day window closes,” AliKhan holds.

The other seven counts target what EDF and its allies say is the agency’s failure to make PMNs available online by default, and its refusal to release supporting documents that they claim should be exempt from CBI protections as “health and safety” materials.

Neither of those categories is subject to the deadline that governs section 5(h) notices, the new order says, as “[t]he parties seem to agree that the relevant statutory provisions here impose no explicit deadlines on the agency.”

But AliKhan says all seven are still open to judicial review under the APA. The environmentalists’ single count concerning online availability of PMNs falls under section 706(1) of the law, which allows litigation to “compel agency action unlawfully withheld or unreasonably delayed,” while the others dealing with CBI determinations are covered by section 706(2), which “allows for judicial review of ‘agency action, findings, and conclusions,’” the decision says.

Her analysis there rests largely on the Supreme Court’s two-prong test for identifying “final agency action” under the APA, which requires a finding that the conduct at issue represents “the ‘consummation’ of the agency’s decision-making process” and either determines a party’s “rights and legal obligations” or carries “legal consequences.”

AliKhan writes that “EPA argues that the challenged actions are merely ‘interim steps made as part of a broader process that concludes with a final agency action’ -- the EPA’s risk determination. But this is not dispositive. If an interim step itself determines a right or obligation, it is ‘final’ agency action for purposes of APA review.”

‘Freestanding Right To Information’

The agency’s decisions on what documents to publish meet that test, she continues, because they limit the “right to know” established in TSCA section 5.

“Because [section 5(b)] creates a freestanding right to information, the EPA does determine rights and obligations -- and therefore does engage in final agency action -- when it provides or fails to provide Plaintiffs with access to requested documents,” she holds.

Finally, she agrees with the environmentalists that they can pursue claims of an EPA “pattern or practice” of violating transparency mandates under the APA, and that its **broadening of TSCA document releases** during the Biden administration does not moot their case.

“These changes, while laudable, do not absolve the EPA of liability. Even assuming that these changes have fully resolved Plaintiffs’ claims, ‘[a] party’s voluntary cessation of challenged conduct does not moot the challenge unless it is ‘absolutely clear’ that the challenged conduct will not recur after the litigation,’” AliKhan writes. -- *David LaRoss* (dlaross@iwpnews.com)

Editor’s Note: This story has been updated to correct its citations to TSCA’s statutory text.

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Attachment 16



From Inside TSCA

Judge Orders EPA To Release PMNs Under Seal In New Chemicals Suit

December 30, 2025

Post

A federal district judge has ordered EPA to release certain unredacted, confidential documents from its TSCA reviews of new chemicals under protective seal, the latest ruling in environmentalists' long-running litigation aimed at bringing more transparency to the new-chemicals program.

Judge Loren L. AliKhan of the U.S. District Court for the District of Columbia issued [a Dec. 24 order](#) directing EPA to produce the public pre-manufacture notice (PMN) new chemical application files "within the scope of the record for judicial review" by Jan. 23, 2026, "and the unredacted PMNs within the scope of the record for judicial review" by March 23, 2026.

AliKhan further directed that the unredacted PMNs -- which contain confidential business information (CBI) -- will be produced under [a protective order](#), which she also issued Dec. 24.

AliKhan's order is the latest action in *Environmental Defense Fund (EDF), et al. v. Lee Zeldin*, where five environmental groups initially sued EPA during the first Trump administration over the opacity of the Toxic Substances Control Act (TSCA) new chemicals review program. The administrative record has been a major dispute in the case, even after [AliKhan's August 2024 order](#) backing environmentalists' claims that TSCA's transparency mandates create a public "right to know" and are enforceable in court -- opening the door for a later ruling on the merits.

EPA, however, has repeatedly disputed the meaning of the 2024 order, arguing as recently as [a joint Dec. 9 status report](#) that it "takes the position that it should not be ordered to produce material designated by submitters as confidential."

Environmentalists renewed their view in the joint status report -- as well as in [an Oct. 31 report they filed](#) while the government was shut down -- that the "Court should order the production of PMNs . . . and support documents, notwithstanding that they were designated as confidential by the company that submitted them." The joint report adds that in the event the court orders the release of the CBI materials, "the parties have proposed a protective order for the Court to adopt," and asked the judge to adjudicate the documents' release, as environmentalists sought the CBI documents' release within 45 days of the judge's order while EPA sought 90 days from the court's order to produce the CBI documents.

EPA added in the joint report that it "is nearly ready to produce the public files for the [PMNs] agreed upon . . . [and] has compiled approximately 9,000 documents and reviewed each of those documents to ensure that it is the non-confidential version. EPA anticipates producing the agreed upon public files by January 23, 2026, a date to which Plaintiffs have agreed."

90-Day Schedule

AliKhan's order does not comment on the scheduling dispute other than to offer the 90-day schedule EPA requested.

The order acknowledges EPA's arguments that "the court need not consider the unredacted PMNs to answer the legal questions presented in this case, as Defendants have already stipulated that they did not independently review PMN applications to determine if they contained relevant test data or if their contents were properly designated as confidential business information. . . . Plaintiffs counter that the court already rejected these arguments by partially granting their motion to compel . . . and that the unredacted PMNs are necessary to show that the documents the EPA withheld actually contained test data or health and safety studies . . ."

The order concludes that the “court finds that Plaintiffs have carried their burden of showing that the unredacted versions of PMNs were ‘before the agency’ when the EPA assembled public files, notwithstanding the agency’s assertions that it did not rely on unredacted PMNs,” pointing to caselaw including the D.C. District Court’s 2006 holding in *Maritel, Inc. v. Collins* that it “is well settled that an agency ‘may not skew the record in its favor by excluding pertinent but unfavorable information’ and may not ‘exclude information on the grounds that it did not “rely” on the excluded information in its final decision.’”

AliKhan adds, “Moreover, the parties’ proposed protective order mitigates any potential issues raised by the inclusion of confidential information in the administrative record.” -- *Maria Hegstad* (mhegstad@iwpnews.com)

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

_____)	
ENVIRONMENTAL DEFENSE FUND, <i>et al.</i> ,)	
)	
<i>Plaintiffs,</i>)	
)	
v.)	Civil Action No. 1:20-cv-762 (LLA)
)	
LEE ZELDIN, Administrator, U.S.)	
Environmental Protection Agency, in his)	
official capacity, <i>et al.</i> ,)	
<i>Defendants.</i>)	
_____)	

[PROPOSED] ORDER

Upon consideration of Defendants’ Motion to Govern Proceedings in light of New Related Lawsuit and Plaintiffs’ Response thereto, it is hereby ORDERED that:

Defendants’ Motion is DENIED.

SO ORDERED.

HON. LOREN L. ALIKHAN
United States District Judge