

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ENVIRONMENTAL DEFENSE FUND,
et al.,

Plaintiffs,

v.

MICHAEL S. REGAN, *et al.*,

Defendants.

Civil Action No. 20-762 (LLA)

MEMORANDUM OPINION AND ORDER

Plaintiffs, five environmental organizations, sue the U.S. Environmental Protection Agency (“EPA”) and EPA Administrator Michael S. Regan to enforce the transparency and disclosure requirements of the Toxic Substances Control Act (“TSCA”), 15 U.S.C. § 2601 *et seq.* The EPA moves for judgment on the pleadings, ECF No. 48, and Plaintiffs move to compel the administrative record, ECF No. 45. For the reasons explained below, the court will **DENY** the EPA’s motion for judgment on the pleadings and **GRANT** Plaintiffs’ motion to compel the administrative record.

I. The Toxic Substances Control Act

“Congress enacted TSCA in 1976 with the express purpose of limiting the public health and environmental risks associated with exposure to . . . toxic chemical substances.” *Physicians Comm. For Responsible Med. v. Johnson*, 436 F.3d 326, 327 (2d Cir. 2006); *see Trumpeter Swan Soc’y v. Env’t Prot. Agency*, 774 F.3d 1037, 1039 (D.C. Cir. 2014). The TSCA requires the EPA to approve any new chemical before it can be manufactured. *See generally* 15 U.S.C. § 2604. Manufacturers submit a notice for the EPA’s review which includes information about how the

chemical could impact health or the environment. *See id.* § 2604(d)(1)(B), (C).¹ That notice is known as a “premanufacture notice” (“PMN”). *See* ECF No. 16 ¶ 21. The EPA is required to inform the public within five business days of receiving a PMN application by publishing a “notice of receipt” in the Federal Register. 15 U.S.C. § 2604(d)(2). The notice must identify the chemical, list the uses of the chemical, and describe the nature and results of certain tests performed on the chemical. *Id.*

The EPA must make a decision (a “risk determination”) on a PMN application within ninety days of receipt, but it can extend by an additional ninety days for good cause. *Id.* § 2604(a), (c), (i)(3). If the EPA finds that the proposed chemical “is not likely to present an unreasonable risk of injury to health or the environment,” then the applicant may begin manufacturing the chemical without restrictions. *Id.* § 2604(a)(3)(C). Otherwise, the EPA must impose protective restrictions on manufacture and/or use. *Id.* § 2604(a)(3)(A) to (B), (e) to (f).

The TSCA requires the EPA to disclose all non-confidential information in the PMN application to any interested person, *id.* § 2604(d)(1), by (1) placing “[a]ll information submitted with a [PMN], including any health and safety study and other supporting documentation” in a “public file for that [PMN],” 40 C.F.R. § 720.95; and (2) making the public file available, both via request from the EPA Docket Center and by placing it online in an electronic docket for the PMN at <http://www.regulations.gov>, *id.*; *id.* § 700.17(b)(1), (2).

¹ A PMN must include “any information . . . related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment” and “a description of any other information concerning the environmental and health effects of such substance, insofar as known to the [applicant] or insofar as reasonably ascertainable.” 15 U.S.C. § 2604(d)(1)(B), (C).

Manufacturers can assert that certain information is confidential and should not be disclosed. *See generally* 15 U.S.C. § 2613. The manufacturer must substantiate its confidentiality claim by showing that it has (among other things) “taken reasonable measures to protect the confidentiality of the information” and “determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law”—and that there is “a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the [applicant].” *Id.* § 2613(c)(B). In addition to meeting these requirements, the information must also qualify as a trade secret or privileged and confidential information under the Freedom of Information Act (“FOIA”), 5 U.S.C. § 552, to be considered confidential for TSCA purposes. 15 U.S.C. § 2613(a).

However, “any health and safety study” and “any information . . . from a health and safety study” submitted with a PMN are not treated as confidential, even if they would otherwise meet the statute’s confidentiality requirements. *Id.* § 2613(b)(2)(A)(ii), (B). This does not include information from a study that “discloses processes used in the manufacturing or processing of a chemical substance,” *id.* § 2613(b)(2), although “general description[s]” of such processes are not protected, *id.* § 2613(b)(3)(B).

A manufacturer can also apply to manufacture the chemical for “test marketing purposes” (the “test marketing exception” or “TME”). *Id.* § 2604(h)(1). “Immediately upon receipt of [a TME] application,” the EPA “shall publish in the Federal Register notice of the receipt of such application” and “shall give interested persons an opportunity to comment upon any such application.” *Id.* § 2604(h)(6). The EPA must, “within 45 days of its receipt, either approve or deny the application.” *Id.*

II. Plaintiffs' Claims

Plaintiffs are five environmental organizations: Environmental Defense Fund, Center for Environmental Health, Environmental Health Strategy Center, Natural Resources Defense Council, and the Sierra Club. ECF No. 16 ¶¶ 14-18. They allege that the EPA has repeatedly failed to comply with the TSCA's disclosure requirements. *See generally* ECF No. 16. Their claims fall into three categories, *see* ECF No. 22:

Insufficient Notice Claims (Counts I-III). The EPA violated the TSCA by not complying with requirements (1) to publish notice of the receipt of PMN and TME applications in the Federal Register by the statutory deadline, and (2) to include required information in the notices. ECF No. 16 ¶¶ 144-66; *see id.* ¶¶ 86-96. Take, for example, one PMN designated "P-14-0314." *Id.* at 60 (Table 1). The EPA received the PMN on February 7, 2014, and was statutorily required to post notice of that receipt within five business days, 15 U.S.C. § 2604(d)(2)—by February 17, 2014. ECF No. 16, at 60 (Table 1). Instead, the EPA posted notice of receipt on September 16, 2014—211 days late. *Id.* In fact, in at least thirty-five cases, the EPA published notice of receipt *after* it had approved the chemical in question. *Id.* ¶ 91.

Failure to Post Claim (Count IV). The EPA failed to place PMN applications in an online docket at www.regulations.gov as required by 40 C.F.R. § 700.17(b)(1). ECF No. 16 ¶¶ 167-71; *see id.* ¶¶ 97-102. Plaintiffs allege that, instead, they had to request the public files from the EPA's Docket Center, that the EPA would load the files onto a CD-ROM, and that Plaintiffs would have to pick up the disk in person or wait to receive it in the mail. *Id.* ¶¶ 98-100.

Incomplete Application Claims (Counts V-X). The EPA violated the TSCA's mandate to "ma[k]e available" all non-confidential information submitted with or in support of a new chemical application. *See* 15 U.S.C. § 2604(d)(1); 40 C.F.R. § 720.95. Plaintiffs claim that in response to

their requests, the EPA provided applications that did not include all documents that Plaintiffs are entitled to under the TSCA. ECF No. 16 ¶¶ 172-240; *see id.* ¶¶ 103-43. For example, Plaintiffs allege that they requested the public file for a particular isocyanate, “P-18-0282.” *Id.* ¶ 63. Isocyanate chemicals are both dangerous and widespread. *Id.* ¶¶ 58-61. Workers across a wide range of industries are at particular risk of exposure because isocyanates “are used in the manufacture of spandex, packing materials, adhesives, sealants, and rubbers . . . [and] as a coating material in [many] retail, commercial, and industrial settings.” *Id.* ¶ 61. But, when Plaintiffs received the public file for P-18-0282, “the document relating to worker exposure was redacted in its entirety.” *Id.* ¶ 63. A few months later, the EPA approved the application to manufacture the isocyanate without restriction. *Id.* “Because EPA never released the health and safety information relating to worker exposure that was submitted in the PMN . . . the public was left in the dark and unable to offer informed comments to the agency.” *Id.*

Taken together, Plaintiffs’ claims concern approximately 247 PMNs and 16 TME applications. *See generally* ECF No. 16; ECF No. 47, at 8. As to each count, Plaintiffs also allege that the EPA has a “pattern or practice” of violating the particular provision of the TSCA at issue. ECF No. 16 ¶¶ 148-50, 155-57, 164-66, 170-71, 181-85, 193-96, 204-07, 215-18, 224-27, 237-40.

III. Procedural History

Plaintiffs filed this lawsuit in March 2020, ECF No. 1, and amended their complaint in June 2020, ECF No. 16. Over the course of several years, the parties negotiated a set of joint stipulations, *see* ECF Nos. 22 to 28, 30 to 44, 45-3, 56-3, and the EPA produced some of the documents that Plaintiffs had previously been denied access to, *see* ECF Nos. 60, 61.

Plaintiffs argue that the EPA’s document production and the parties’ joint stipulations do not resolve their claims, and they therefore move to compel production of the administrative

record. ECF No. 45. The EPA moves for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c), arguing that Plaintiffs' claims should be dismissed because they are not subject to judicial review and Plaintiffs lack standing. ECF No. 48. Both motions are fully briefed. ECF Nos. 45, 47, 48, 54-57. The court held a hearing regarding both pending motions on May 1, 2024. *See* May 1, 2024 Minute Entry.

IV. Legal Standard

Because the EPA's motion for judgment on the pleadings raises threshold questions of reviewability and standing, the court addresses it first. *See In re United States*, 583 U.S. 29, 32 (2017) (per curiam) (holding that the district court must address threshold reviewability questions before examining the administrative record). The EPA moves for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c), which provides: "After the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." Such a motion "is designed to dispose of cases where the material facts are not in dispute and a judgment on the merits can be rendered by looking at the substance of the pleadings and any judicially noted facts." *Tapp v. Wash. Metro. Area Transit Auth.*, 306 F. Supp. 3d 383, 391 (D.D.C. 2016) (quoting *All. of Artists & Recording Cos. v. Gen. Motors Co.*, 162 F. Supp. 3d 8, 16 (D.D.C. 2016)). "Because Rule 12(c) provides judicial resolution at an early stage of a case, the party seeking judgment on the pleadings shoulders a heavy burden of justification." *Dist. No. 1 v. Liberty Mar. Corp.*, 933 F.3d 751, 760 (D.C. Cir. 2019).

The moving party is entitled to judgment on the pleadings only if it "demonstrates that no material fact is in dispute and that it is entitled to judgment as a matter of law." *Seed Co. Ltd. v. Westerman, Hattori, Daniels & Adrian, LLP*, 961 F.3d 1190, 1194 (D.C. Cir. 2020) (quoting *Dist. No. 1*, 933 F.3d at 760). "[I]f material questions of fact are presented by the pleadings, the remedy

by motion for judgment on the pleadings under Rule 12(c) is not available.” *Dist. No. 1*, 933 F.3d at 761 (quoting *Noel v. Olds*, 149 F.2d 13, 14 & n.7 (D.C. Cir. 1945)). Rules 12(c) and 12(b)(6) are not interchangeable, although the distinctions are “nuanced.” *Murphy v. Dep’t of Air Force*, 326 F.R.D. 47, 49 (D.D.C. 2018). A 12(b)(6) motion requires “the mere determination that the plaintiff’s complaint is too deficient to proceed,” while a Rule 12(c) movant “must demonstrate that the law entitles him to win given the undisputed facts that have been alleged in both parties’ pleadings.” *Id.*

Plaintiffs move to compel production of the administrative record. ECF No. 45. The APA requires the court to “review the whole record” in making its decision. 5 U.S.C. § 706. Thus, the court’s review must “be based on the full administrative record that was before the [agency] at the time [it] made its decision.” *Am. Bioscience, Inc. v. Thompson*, 243 F.3d 579, 582 (D.C. Cir. 2001) (quoting *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971)). When it comes to reviews of “informal” agency action, “[t]he district court has some leeway in determining the scope of an adequate record.” *Women Involved in Farm Econ. v. U.S. Dep’t of Agric.*, 876 F.2d 994, 998 (D.C. Cir. 1989).

V. Discussion

A. Motion for Judgment on the Pleadings

The EPA argues that it is entitled to judgment on the pleadings for three reasons. First, none of Plaintiffs’ claim are subject to judicial review under either the TSCA or the Administrative Procedure Act (“APA”), 5 U.S.C. § 551, *et seq.* ECF No. 48-1, at 2-3. Next, Plaintiffs’ pattern-or-practice claims are not cognizable under the APA and, in the alternative, are moot. *Id.* Finally, Plaintiffs lack standing to bring Counts I-III. *Id.* The court concludes that Plaintiffs’

claims are reviewable, that their pattern-or-practice claims are cognizable under the APA and are not moot, and that Plaintiffs have standing.

1. Reviewability

Whether an agency's action is reviewable is a threshold question. *See Heckler v. Chaney*, 470 U.S. 821, 829 (1985). The court answers it “against the backdrop of ‘a familiar principle of statutory construction: the presumption favoring judicial review of administrative action.’” *Make The Rd. N.Y. v. Wolf*, 962 F.3d 612, 623 (D.C. Cir. 2020) (quoting *Guerrero-Lasprilla v. Barr*, 589 U.S. 221, 229 (2020)).

Here, there are four possible pathways to reviewability: Section 2619(a)(1) of the TSCA, Section 2619(a)(2) of the TSCA, Section 706(1) of the APA, and Section 706(2) of the APA. Section 2619(a)(1) of the TSCA provides that “any person may commence a civil action . . . against any person (including (A) the United States, and (B) any other governmental instrumentality or agency . . .) who is alleged to be in violation of” the TSCA. 15 U.S.C. § 2619(a)(1). Section 2619(a)(2) of the TSCA allows “any person [to] commence a civil action . . . against the Administrator to compel the Administrator to perform any act or duty under this chapter which is not discretionary.” *Id.* § 2619(a)(2). Section 706(1) of the APA authorizes the court to “compel agency action unlawfully withheld or unreasonably delayed,” and Section 706(2) allows for judicial review of “agency action, findings, and conclusions.” 5 U.S.C. § 706(1), (2).

Because the APA authorizes courts to review only “final agency action for which there is no other adequate remedy in a court,” the court must first determine whether judicial review is available under the TSCA. 5 U.S.C. § 704. If so, then judicial review is not available under the APA. *See Conservation Force v. Salazar*, 715 F. Supp. 2d 99, 104 n.6 (D.D.C. 2010), *aff'd* 699

F.3d 538 (D.C. Cir. 2012) (holding that agency action was not reviewable under the APA because the plaintiffs' claims were reviewable under the Endangered Species Act).

The court concludes that none of Plaintiffs' claims are reviewable under Section 2619(a)(1), that Counts I-III are reviewable under Section 2619(a)(2), that Count IV is reviewable under Section 706(1) of the APA, and that Counts V-X are reviewable under Section 706(2) of the APA.

a. None of Plaintiffs' claims are reviewable under Section 2619(a)(1)

Section 2619(a)(1) provides that "any person may commence a civil action . . . against any person (including (A) the United States, and (B) any other governmental instrumentality or agency . . .) who is alleged to be in violation of" the TSCA. Plaintiffs argue that, because their suit alleges that the EPA has itself violated the TSCA by flouting its disclosure requirements, their claims are reviewable under Section 2619(a)(1). ECF No. 16 ¶¶ 148, 155, 164, 181, 185, 193, 204, 215, 224, 237. The EPA counters that this provision applies only to regulated parties, not to the government as a regulator. ECF No. 47, at 14. As the EPA explains, a plaintiff could sue a federal agency under Section 2619(a)(1) where the agency itself handles substances that are regulated by the TSCA. *Id.* But, according to the EPA, that provision does not allow plaintiffs to challenge the choices EPA makes as a regulator. *Id.*

The EPA has the better reading of the statute. The Second Circuit addressed this issue in *Physicians Committee for Responsible Medicine v. Johnson*, 436 F.3d 326 (2d Cir. 2006). There, the plaintiffs sought to compel the EPA to issue a rule establishing a mandatory testing program for certain chemicals. *Id.* at 327. The court declined to exercise jurisdiction under Section 2619(a)(1), holding that:

[W]hereas subsection (a)(2) permits citizen suits against the Agency in its capacity as a regulator, subsection (a)(1) permits citizen suits against regulated parties, including governmental entities to the

extent they are subject to TSCA. Subsection (a)(1) does not provide an alternative avenue for challenging the Agency's actions as a regulator, as plaintiffs suggest. Such an interpretation is unreasonable, as it would both render the narrower subsection (a)(2) completely superfluous and nullify subsection (a)(2)'s limitation to suits compelling the Agency to perform a non-discretionary duty.

Id. at 334-35.

While not binding on this court, *Johnson's* logic is persuasive. If Section 2619(a)(1) allowed for suits against the EPA when it acts as a regulator, there would be no need for Section 2619(a)(2). Courts "are guided by the rule that the maximum possible effect should be afforded to all statutory provisions, and, whenever possible, none of those provisions rendered null or void." *Citizens to Save Spencer Cnty. v. U.S. Env't Prot. Agency*, 600 F.2d 844, 870 (D.C. Cir. 1979). Understanding Section 2619(a)(1) to apply to regulated entities (including a regulated federal agency) and Section 2619(a)(2) to apply to the EPA in its capacity as a regulator gives full effect to both clauses of the statute. This reading is also consistent with how courts have understood provisions analogous to Section 2619(a)(1). *See, e.g., Bennett v. Spear*, 520 U.S. 154, 172-73 (1997) (holding that the plaintiffs could not use a nearly identical provision of the Endangered Species Act to sue the EPA for issuing an agency opinion with which they disagreed). Accordingly, Section 2619(a)(1) does not provide an avenue for Plaintiffs to proceed with their claims.

b. All of Plaintiffs' claims are reviewable under either Section 2619(a)(2) or the APA

With Section 2619(a)(1) out of the picture, the parties dispute whether Plaintiffs' claims are reviewable under either Section 2619(a)(2) or the APA. Before turning to Plaintiffs' individual claims, it is useful to lay out a key background principle: the difference between contingent and freestanding rights to information.

At the heart of the parties' reviewability dispute is one question: does the TSCA confer a freestanding right to information? Two categories of statutes and two lines of jurisprudence are relevant here. First, there are statutes like FOIA that confer a freestanding right to information. Anyone can make a FOIA request at any time and, if that request is denied, seek judicial review. *Prisology, Inc. v. Fed. Bureau of Prisons*, 852 F.3d 1114, 1117 (D.C. Cir. 2017). "[T]he requester's circumstances—why he wants the information, what he plans to do with it, what harm he suffered from the failure to disclose—are irrelevant." *Id.* (quoting *Zivotofsky ex rel. Ari Z. v. Sec'y of State*, 444 F.3d 614, 617 (D.C. Cir. 2006)); see *Pub. Citizen v. U.S. Dep't of Just.*, 491 U.S. 440, 448-49 (1989) (holding that the denial of information requested under the Federal Advisory Committee Act ("FACA"), 5 U.S.C. app. § 1, is a legal injury). The right to information under statutes like FOIA and FACA is freestanding; it is not contingent on any particular use or confined to any timeframe.

Second, there are statutes that impose disclosure or transparency requirements on an agency to facilitate public participation in an administrative process. Take, for example, Section 1612 of the Forest Service Decisionmaking and Appeals Reform Act ("ARA"), which requires the Forest Service to provide "adequate notice and an opportunity to comment upon the formulation of standards, criteria, and guidelines applicable to Forest Service programs." 16 U.S.C. § 1612(a). "Notice, of course, is a form of information (information that certain projects are being proposed)." *Wilderness Soc'y, Inc. v. Rey*, 622 F.3d 1251, 1259 (9th Cir. 2010). But unlike FOIA, the ARA explicitly links that notice to its intended use: the "opportunity to comment upon the formulation of . . . Forest Service programs." 16 U.S.C. § 1612(a). Thus, as the Ninth Circuit has explained, "the ARA grants the public a right to process and to participation. Even though these rights necessarily involve the dissemination of information, they are not thereby

tantamount to a right to information per se.” *Wilderness Soc’y, Inc.*, 622 F.3d at 1259; *see Bensman v. U.S. Forest Serv.*, 408 F.3d 945, 957-58 (7th Cir. 2005) (holding that, although the ARA is designed “to increase public participation in the decision-making process,” it creates no right to information).

Plaintiffs place the TSCA in the first category, arguing that the statute creates a freestanding right to information independent from the risk-determination process. ECF No. 56, at 8-9. The EPA argues that the TSCA belongs in the second category—that any disclosure or transparency requirements it imposes on the agency are bound up with the public’s ability to participate in the risk-determination process. ECF No. 57, at 4-5. As the court will explain, both parties are correct, at least in part. The TSCA, unlike FOIA or the ARA, has provisions that fall into both categories. *See* May 1, 2024 Hr’g. Tr. at 16:9-10 (Plaintiffs’ counsel, noting that it is difficult to identify analogous statutes because “TSCA is unique”).²

² Courts attempting to distinguish between category one and category two statutes may turn to legislative purpose and history. *See, e.g., Wilderness Soc’y, Inc.*, 622 F.3d at 1259-60 (distinguishing the ARA’s legislative purpose and history from FOIA’s). The court finds the TSCA’s legislative history to be of limited utility here: Plaintiffs can point only to isolated, general statements, and the EPA raises no legislative history at all. *See* ECF No. 56, at 8-9; ECF No. 57, at 4-5. But, to the extent that the statute’s legislative history is relevant, it supports the idea that the TSCA creates a mix of freestanding and contingent rights to information. For example, in a 1979 preamble to a proposed rule, the EPA stated that its “responsibility to provide PMN information to the public is an affirmative one, extending beyond any requirement merely to comply with FOIA. [The statute] states explicitly that the PMN must be made available ‘for examination by interested persons.’” 44 Fed. Reg. at 59,774 (Oct. 16, 1979); *see* ECF No. 56, at 18. This suggests legislative intent to create a “category one” freestanding right to information. But, in the very same paragraph, EPA stated that the TSCA intends for “strong citizen involvement” and that “[e]ffective participation is impossible if the maximum amount of information is not made available to the public.” 44 Fed. Reg. at 59,774. This makes the TSCA sound more like a “category two” statute that creates a contingent right to information. Thus, while not dispositive, the legislative history affirms that the statute is interested both in enduring, freestanding access to information *and* in access to information that facilitates public participation. Given the limited nature of this history, however, the court relies primarily on text, structure, and precedent in interpreting the TSCA.

Because different provisions of the TSCA confer different sorts of rights to information, the reviewability analysis must proceed one statutory provision at a time. The court addresses each provision in turn and concludes that Counts I-III are reviewable under Section 2619(a)(2), Count IV is reviewable under Section 706(1) of the APA, and Counts V-X are reviewable under Section 706(2) of the APA. Thus, all of Plaintiffs' claims are subject to judicial review.

i. Counts I-III are reviewable under Section 2619(a)(2)

Under Section 2619(a)(2) of the TSCA, “any person may commence a civil action . . . against the Administrator to compel the Administrator to perform any act or duty under this chapter which is not discretionary.” A statute imposes a nondiscretionary duty if it “‘categorically mandate[s]’ that *all* specified action be taken by a date-certain deadline.” *Sierra Club v. Thomas*, 828 F.2d 783, 791 (D.C. Cir. 1987), *superseded by statute*, Clean Air Act Amendments, Pub. L. No. 101-549, § 707(f), 104 Stat. 2399, 2683 (1990), *as recognized in Mexichem Specialty Resins, Inc. v. Env’t Prot. Agency.*, 787 F.3d 544 (D.C. Cir. 2015). The EPA does not dispute that Count I (failure to publish receipt of PMN within five days) and Count II (failure to include list and description of PMN test data in notice of receipt) are subject to judicial review under Section 2619(a)(2). *See* May 1, 2024 Hr’g Tr. at 2:25-3:5. Nor could it. The statute clearly sets out a date-certain deadline: “*not later than five days . . . after the date of the receipt of a notice . . . the Administrator shall publish in the Federal Register a notice*” which includes certain information. 15 U.S.C. § 2604(d)(2) (emphases added); *see, e.g., Env’t Def. v. Leavitt*, 329 F. Supp. 2d 55, 64 (D.D.C. 2004) (concluding that statutory requirement that an agency act “within eighteen months of receipt of the report” creates a non-discretionary duty). And, because the EPA does not contest reviewability of Counts I and II under this provision, that argument is conceded. *See Kone v. District of Columbia*, 808 F. Supp. 2d 80, 83 (D.D.C. 2011).

With regard to Count III, Plaintiffs allege that the EPA violated its duty to publish notice of receipt of applications for test marketing exemptions (“TMEs”) and to include information required by regulation in those notices. ECF No. 16 ¶¶ 158-66. 15 U.S.C. § 2604(h)(6) provides in relevant part:

Immediately upon receipt of a[] [TME] application . . . the Administrator shall publish in the Federal Register notice of the receipt of such application. The Administrator shall give interested persons an opportunity to comment upon any such application and shall, within 45 days of its receipt, either approve or deny the application.

Id. Additionally, 40 C.F.R. § 720.38(c) directs that such notices “will” include “a summary of the information provided in the application.”³ The EPA argues that Section 2604(h)(6) does not contain a date-certain deadline and thus it has not failed to perform a nondiscretionary duty reviewable under Section 2619(a)(2).

The court disagrees. First, Section 2604(h)(6) uses mandatory language: the EPA “shall” (1) publish notice of receipt of TME applications in the Federal Register immediately upon receipt, (2) give interested persons an opportunity to comment on such applications, and (3) either approve or deny such applications within forty-five days of receipt. “Ordinarily, legislation using ‘shall’ indicates a mandatory duty.” *Anglers Conservation Network v. Pritzker*, 809 F.3d 664, 671 (D.C. Cir. 2016). The EPA must take these actions—the only remaining question is: by when?

The TSCA provides an answer. A date-certain deadline “may exist, even though not explicitly set forth in the statute, if it is readily-ascertainable by reference to a fixed date or event.”

³ In determining whether a nondiscretionary duty exists, the same analysis applies to a regulation as to the underlying statute itself. *See Elec. Priv. Info. Ctr. v. Internal Revenue Serv.*, 910 F.3d 1232, 1244 (D.C. Cir. 2018) (“[A]n agency can create a non-discretionary duty by binding itself through a regulation carrying the force of law.”); *see, e.g., Sierra Club v. Leavitt*, 355 F. Supp. 2d 544, 547-48 (D.D.C. 2005) (analyzing whether a regulation implementing amendments to the Clean Air Act creates nondiscretionary duties).

Sierra Club, 828 F.2d at 791 n.58. The TSCA states that the Administrator must provide “immediate[.]” notice of TMEs to “give interested persons an opportunity to comment upon any such application,” and the Administrator must decide whether to approve those applications within forty-five days of receipt. 15 U.S.C. § 2604(h)(6). But the public cannot comment on an application that it does not know exists, and it would make little sense to require the opportunity for public comment after the agency has already rendered a decision. See *Waterkeeper All., Inc. v. Wheeler*, 613 F. Supp. 3d 86, 93-95 (D.D.C. 2020) (“EPA must ‘develop and publish minimum guidelines’ [for public participation in program development] at least before the agency authorizes a state program, lest [the guidelines] have no practical effect.”), *vacated on other grounds and remanded sub nom. Waterkeeper All., Inc. v. Regan*, 41 F.4th 654 (D.C. Cir. 2022); *Sierra Club v. Jackson*, 724 F. Supp. 2d 33, 38 n.2 (D.D.C. 2010) (explaining that it was “easy to discern a specific deadline” where “the agency can only ‘prevent the construction or modification’ before construction or modification begins, so the commencement of construction or modification triggers the statutory deadline.”), *aff’d on other grounds*, 648 F.3d 848 (D.C. Cir. 2011). 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.⁴

In Count III, Plaintiffs take issue with sixteen TME applications. ECF No. 16, at 76-77 (Table 3). In fourteen of those cases, the EPA published notice of receipt after (often months after)

⁴ Thus, Section 2604(h)(6) falls into the second category of statutes discussed above: it imposes the notice requirement as a predicate to public participation, all of which must take place within forty-five days of the application’s receipt. In doing so, it creates a contingent right to information.

it had made its final determination. *Id.* In two cases, the EPA never published the notice at all. *Id.* In all cases, the EPA's notices did not summarize the applications as required by 40 C.F.R. § 720.38(c). ECF No. 16 ¶ 162. If the plain language of Section 2604(h)(6) is to have any meaning, the EPA cannot have discretion to publish notices of application *after* making its final determination, or not at all. The court therefore concludes that the EPA has a nondiscretionary duty to publish notice of TME applications within forty-five days of receiving said applications. For that reason, Count III is reviewable under Section 2619(a)(2).⁵

ii. Counts IV-X are not reviewable under Section 2619(a)(2)

Counts IV through X allege that the EPA failed to make PMNs available online (Count IV); provide health and safety studies (Count V); provide safety data sheets (Count VI); provide all versions of PMNs (Count VII); provide correspondence related to PMNs (Count VIII); provide substantiation documents for PMNs (Count IX); and provide information or documents that manufacturers claimed were confidential but that facially did not qualify for protection (Count X). The parties seem to agree that the relevant statutory provisions here impose no explicit deadlines on the agency. ECF No. 48, at 15; ECF No. 56, at 31-32. Section 2604(b)(3) requires that “[i]nformation submitted [as part of a PMN] shall be made available . . . for examination by interested persons.” 40 C.F.R. § 720.95 provides that “[a]ll information submitted with a notice, including any health and safety study and other supporting documentation, will become part of the

⁵ Because the court concludes that a date-certain deadline is readily ascertainable from the statutory scheme, it need not consider whether the word “immediately,” standing alone, “‘categorically mandate[s]’ that *all* specified action be taken by a date-certain deadline.” *Sierra Club*, 828 F.2d at 791; *see* ECF No. 56, at 32 (arguing that “‘immediately’ . . . is an explicit deadline that is shorter than EPA’s obligation to publish a notice of receipt of a PMN, for which the statute gives EPA only ‘five [business] days,’” and “EPA does not dispute that the five-business-day deadline for publishing notices of receipt of PMNs creates a non-discretionary duty.”).

public file for that notice, unless such materials are claimed confidential.” And 40 C.F.R. § 700.17(b)(1) states that “[p]ublicly available docket materials are available in the electronic docket at <http://www.regulations.gov>.”

As with Count III, Plaintiffs argue that the court can reasonably ascertain a date-certain deadline from the statutory structure, creating a nondiscretionary duty reviewable under Section 2619(a)(2). ECF No. 56, at 29-30. Under the TSCA, the EPA is required to make a determination on each PMN application within ninety days of its receipt, which it may extend by an additional ninety days for good cause. 15 U.S.C. § 2604(a)(3), (c), (i)(3). Plaintiffs argue that the court can properly infer that the EPA is required to make PMN information available to the public at least before the first ninety-day period has run. ECF No. 56, at 30. But Section 2604(b)(3), unlike Section 2604(h)(6) (the provision at issue in Count III), does not link the PMN-disclosure requirement to public participation in the risk-determination process—or to any other intended use. *See* 15 U.S.C. § 2604(b)(3). The TSCA does not make disclosure of information a condition precedent to the EPA’s risk determination in the same way that, for example, “development” of a program necessarily precedes authorizing a program. *See id.*; *Waterkeeper All., Inc.*, 613 F. Supp. 3d at 93-95. In fact, the parties *agree* that Plaintiffs—and the public at large—can always request this information from the EPA, even long after EPA has made its risk determination. *See* ECF No. 56, at 9; May 1, 2024 Hr’g. Tr. at 26:20-25. And if that is true, the court cannot readily ascertain a date-certain deadline from the statutory structure.

To put this in context: imagine that Plaintiffs request today—in 2024—the PMN file for a chemical that the EPA approved in 2014. The plain text of Section 2604(b)(3) requires the EPA to produce that information—but there would be no reason to believe that the EPA must do so within ninety days. After all, the risk determination was made ten years ago. In this way, the

provisions in question operate like a TSCA-specific version of FOIA rather than timebound mandates that evaporate when a particular administrative process concludes. And because these provisions of the TSCA do not impose date-certain deadlines, they do not create nondiscretionary duties that are actionable under Section 2619(a)(2).

iii. Counts IV-X are reviewable under the APA

Plaintiffs argue that if Counts IV-X are not reviewable under the TSCA, they are reviewable under Section 706(1) or Section 706(2) of the APA. ECF No. 56, at 16-31; *see Conservation Force v. Salazar*, 753 F. Supp. 2d 29, 34 (D.D.C. 2010) (“[W]hen a statute grants some degree of discretion to an agency as to the timing of a required action, thereby imposing merely a general duty of timeliness, suit should be brought as a claim for unreasonable delay under the APA.” (internal quotations omitted) (quoting *Biodiversity Legal Found. v. Norton*, 285 F. Supp. 2d 1, 7-8 (D.D.C. 2003))). Section 706(1) provides relief when an agency fails to act, *see Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 62 (2004), while Section 706(2) covers “all ‘final agency action for which there is no other adequate remedy in a court,’” *Bennett*, 520 U.S. at 175 (quoting 5 U.S.C. § 704).

*Counts V-X are reviewable under Section 706(2) of the APA.*⁶ As explained above, Section 706(2) “provides a right to judicial review of all ‘final agency action for which there is no

⁶ The parties disagree whether Counts V-X concern agency “action” (and therefore should be reviewed under Section 706(2)) or “inaction” (and therefore are reviewable under Section 706(1)). *See* ECF No. 57, at 2 n.2. These claims arguably deal with a mix of action and inaction, and therefore both provisions of the APA provide colorable routes to review. For example, when the EPA provides a PMN to Plaintiffs but redacts safety data, one could construe that as an “action” reviewable under Section 706(2) (providing an incomplete PMN), or as a failure to act reviewable under Section 706(1) (failing to provide safety data). Because Plaintiffs ask the court to review Counts V-X primarily under Section 706(2), and only in the alternative under Section 706(1), *see* ECF No. 56, at 28, the court will analyze them under Section 706(2). Count IV concerns only alleged inaction, so the court discusses it separately below.

other adequate remedy in a court.” *Bennett*, 520 U.S. at 175 (quoting 5 U.S.C. § 704). The APA defines “agency action” to “include[] the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act.” 5 U.S.C. § 551(13).

Plaintiffs argue that “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.” ECF No. 56, at 17. In their view, the EPA takes final agency action within the meaning of Section 551(13) when it acts on the information request—the agency grants “relief” when it gives the information to a requester, denies relief when it withholds information, and grants in part and denies in part relief when it produces only some of the information to which the requester is entitled.⁷ ECF No. 56, at 20-21.

The EPA disagrees. It argues that Plaintiffs’ claims “pertain to two classes of activity by the Agency: preparation and publication of notices of receipt in the Federal Register and compiling the public file for review by interested parties,” and that such “activities are not on par with the class of actions described in § 551(13).” ECF No. 47, at 19-20; *see* ECF No. 57, at 2 (describing the challenged actions as “merely . . . ministerial steps”). The EPA’s argument boils down to the idea that the actions at issue here are just too small or insignificant to qualify as “agency action.”

Plaintiffs have the better argument. Section 551(13)’s definition of “agency action” “is expansive. It is ‘meant to cover comprehensively every manner in which an agency may exercise its power.’” *Fund for Animals, Inc. v. U.S. Bureau of Land Mgmt.*, 460 F.3d 13, 20 (D.C. Cir. 2006) (quoting *Whitman v. Am. Trucking Ass’ns, Inc.*, 531 U.S. 457, 478 (2001)); *see Jud.*

⁷ The APA defines “relief” to include three classes of activity: “(A) grant of money, assistance, license, authority, exemption, exception, privilege, or remedy; (B) recognition of a claim, right, immunity, privilege, exemption, or exception; or (C) taking of other action on the application or petition of, and beneficial to, a person.” 5 U.S.C. § 551(11). Plaintiffs argue that the relief here is of the type defined in subsection (B). ECF No. 56, at 20.

Watch, Inc. v. Nat'l Energy Pol'y Dev. Grp., 219 F. Supp. 2d 20, 38 (D.D.C. 2002) (noting that Congress intended a broad definition of “agency action” to “assure the complete coverage of every form of agency power, proceeding, action, or inaction” (quoting S. Doc. No. 248, 79 Cong., 2d Sess., 255 (1946))).

To be sure, Section 551(13)’s “categories are imprecise, and courts have made the threshold determination of reviewable agency action on a case-by-case basis.” *Indus. Safety Equip. Ass’n, Inc. v. Env’t Prot. Agency*, 837 F.2d 1115, 1117 (D.C. Cir. 1988). Courts “have long recognized that the term [‘agency action’] is not so all-encompassing as to authorize us to exercise ‘judicial review [over] everything done by an administrative agency.’” *Indep. Equip. Dealers Ass’n v. Env’t Prot. Agency*, 372 F.3d 420, 427 (D.C. Cir. 2004) (quoting *Hearst Radio, Inc. v. FCC*, 167 F.2d 225, 227 (D.C. Cir. 1948)). For example, agency activity “in anticipation of agency action,” such as “prepar[ing] proposals, conduct[ing] studies, meet[ing] with members of Congress and interested groups, and engag[ing] in a wide variety of activities that comprise the common business of managing government programs,” does not qualify as reviewable agency action. *Fund for Animals*, 460 F.3d at 19-20. But where the activity at issue is “circumscribed” and “discrete,” it qualifies as “agency action.” *Norton*, 542 U.S. at 62. And here, Plaintiffs have undoubtedly identified circumscribed, discrete activities.

Judicial Watch, Inc. v. National Energy Policy Development Group, 219 F. Supp. 2d 20 (D.D.C. 2002), supports Plaintiffs’ argument that agency action is at issue in Counts V-X. In *Judicial Watch*, Plaintiffs sued a federal agency under the APA to enforce the disclosure and transparency requirements of the FACA. *Id.* at 36. Plaintiffs alleged that the agency had violated the FACA by, among other things, failing to open its meetings to the public, failing to publish a timely notice of each meeting in the Federal Register, and failing to make its records available for

public inspection and copying. *Id.* The court rejected the government’s argument that these were not “agency actions,” concluding that “[t]he type of actions and inaction here . . . certainly fall within the broad category of ‘agency power’ Congress intended to include in [the APA’s] definition of agency action.” *Id.* at 38 (quoting S. Doc. No. 748, 79 Cong., 2d Sess., 255 (1946)). These actions, too, could be described as minor or “ministerial,” ECF No. 57, at 2—but small actions, even those as small as failing to post a timely notice of a meeting, can still be “agency action.”

The EPA also disputes whether the actions challenged in Counts V-X are “final” agency action. ECF No. 48-1, at 20-22. For agency action to be “final” and reviewable under the APA, it must (1) “mark the ‘consummation’ of the agency’s decisionmaking process” rather than be “of a merely tentative or interlocutory nature,” and (2) determine “rights or obligations” or be an action from which “legal consequences will flow.” *Bennett*, 520 U.S. at 177-78 (first quoting *Chicago & S. Air Lines, Inc. v. Waterman S.S. Corp.*, 333 U.S. 103, 113 (1948); then quoting *Port of Bos. Marine Terminal Ass’n v. Rederiaktiebolaget Transatlantic*, 400 U.S. 62, 71 (1970)). “Because ‘both prongs of *Bennett v. Spear* must be satisfied independently,’ the failure to satisfy either prong means that the challenged action is nonfinal.” *Valero Energy Corp. v. Env’t Prot. Agency*, 927 F.3d 532, 536 (D.C. Cir. 2019) (quoting *Soundboard Ass’n v. FTC*, 888 F.3d 1261, 1267 (D.C. Cir. 2018)).

As to *Bennett*’s first prong: the 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. ECF No. 57, at 6. 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. *See Role Models Am., Inc. v. White*, 317 F.3d 327, 331-33 (D.C. Cir. 2003); *see also Jud. Watch*, 219 F. Supp. 2d at 40

(concluding that decisions “to create and supervise Task Force Sub-Groups, to hold meetings closed to the public and without complying with the various procedural requirements of FACA” were final agency actions).

The EPA’s argument on *Bennett*’s second prong is more fundamental. The agency argues that it does not determine rights by providing or failing to provide Plaintiffs with access to certain documents because the TSCA creates no right to such information. ECF No. 57, at 4. The EPA focuses on statutory purpose and structure, arguing that “TSCA is not a public disclosure statute”—rather, in enacting the TSCA, “Congress created a pathway for the public to participate in EPA’s evaluation process to better inform EPA’s risk determination.” *Id.* In the EPA’s view, the only “final” (reviewable) agency action here is its ultimate risk determination. *See* May 1, 2024 Hr’g. Tr. at 8:25-9:2 (government counsel stating that “judicial review is available via an APA or a TSCA challenge to a discrete final agency action, EPA’s risk determination.”). Plaintiffs, on the other hand, read the TSCA as a statute with two distinct functions: (1) creating a process by which the EPA makes risk determinations and (2) separate and apart from the risk determination process, creating a freestanding right to information about toxic substances. ECF No. 56, at 8-9. Essentially, the parties disagree about whether Section 2604(b)(3)’s requirement that information submitted as part of a PMN “shall be made available” to interested persons is a means to an end (EPA’s risk determination) or an end in and of itself. This appears to be a question of first impression.

“In addressing a question of statutory interpretation, we begin with the text.” *Eagle Pharms., Inc. v. Azar*, 952 F.3d 323, 330 (D.C. Cir. 2020) (quoting *City of Clarksville v. FERC*, 888 F.3d 477, 482 (D.C. Cir. 2018)). “The first sign that the statute impose[s] an obligation [on the government] is its mandatory language: ‘shall.’” *Maine Cmty. Health Options v. United States*,

590 U.S. 296, 310 (2020). The TSCA provides that “[i]nformation submitted [as part of a PMN] shall be made available . . . for examination by interested persons.” 15 U.S.C. § 2604(b)(3) (emphasis added). Its regulations confirm that “[a]ll information submitted with a notice . . . will become part of the public file for that notice.” 40 C.F.R. § 720.95 (emphasis added). The TSCA’s PMN-disclosure requirements are therefore mandatory, not optional. *See Maine Cmty. Health Options*, 590 U.S. at 310.

“A familiar principle of statutory construction . . . is that a negative inference may be drawn from the exclusion of language from one statutory provision that is included in other provisions of the same statute.” *Hamdan v. Rumsfeld*, 548 U.S. 557, 578 (2006). Section 2604(b)(3), unlike Section 2604(h)(6) (which governs disclosure of TME applications), does not link disclosure with the opportunity for notice-and-comment. Instead, Congress spoke in absolute terms: PMN files shall be made available to the public, subject only to Section 2613—the provision of the TSCA that governs confidentiality. *See* 15 U.S.C. § 2604(b)(3). The statute is silent as to how that information might be used or when it might be requested. *See id.* Facilitating public participation in administrative decision-making might be one hypothetical use of PMN files, but—unlike a “category two” statute like the ARA or Section 2604(h)(6)—Section 2604(b)(3) does not tie disclosure to any specific purpose. *Compare id.*, with 16 U.S.C. § 1612(a) (ARA), and 15 U.S.C. § 2604(h)(6). Instead, Section 2604(b)(3) (and its related regulations) are more like FOIA or the FACA: they vest an enduring right to information that lasts before, during, and after any risk determination. *See supra* Part V(A)(1)(b).

Because Section 2604(b)(3) 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. Counts V-X are therefore subject to judicial review under Section 706(2) of the APA.

Count IV is reviewable under Section 706(1) of the APA. Count IV alleges agency inaction: the EPA’s failure to place PMN applications in an online docket at www.regulations.gov as required by 40 C.F.R. § 700.17(b)(1). ECF No. 16 ¶¶ 167-71; *see id.* ¶¶ 97-102. Plaintiffs therefore seek review of Count IV under Section 706(1) of the APA. ECF No. 56, at 28. Because there is significant overlap between the standards under Sections 706(1) and 706(2), the EPA addresses them together. *See* ECF No. 48, at 20 (“Judicial review is thus confined under § 706(1), as under § 706(2), to discrete ‘agency action.’”); ECF No. 57, at 2; *Ctr. for Biological Diversity v. Zinke*, 260 F. Supp. 3d 11, 20 (D.D.C. 2017) (noting that Section 706(1) “permits lawsuits targeting agency *in action* to the same degree that suits challenging reviewable ‘agency action’ under § 706(2) . . . are permitted.”). The EPA makes no additional arguments specific to Count IV; the court therefore concludes that Count IV is reviewable under Section 706(1) for the same reasons that Counts V-X are reviewable under Section 706(2).

2. Pattern-or-Practice Claims

As to each count of their complaint, Plaintiffs allege that the EPA has a “pattern or practice” of violating the particular provision of the TSCA at issue. ECF No. 16 ¶¶ 148-50, 155-57, 164-66, 170-71, 181-85, 193-96, 204-07, 215-18, 224-27, 237-40. EPA argues that pattern-or-practice claims are not cognizable under the APA⁸ and, in the alternative, that Plaintiffs’ pattern-or-practice claims are moot. The court disagrees on both fronts.

⁸ Because the EPA raises this argument under the APA, it only applies to Counts IV-X. *See* ECF No. 48-1, at 22.

a. Pattern-or-practice claims are cognizable under the APA

In *Hispanic Affairs Project v. Acosta*, 901 F.3d 378 (D.C. Cir. 2018), the D.C. Circuit upheld a pattern-or-practice challenge brought under Section 706(2) of the APA. *Id.* at 385. Plaintiffs challenged the Department of Homeland Security’s “alleged pattern and apparent policy of routinely extending a herder’s 364-day H-2A visa.” *Id.* The court rejected the agency’s argument that the plaintiffs’ claim was an impermissible “programmatic challenge[],” emphasizing that, as the Supreme Court held in *Lujan*, “an agency’s action in ‘applying some particular measure across the board . . . [could] of course [still] be challenged under the APA.’” *Id.* at 387-88 (quoting *Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 890 n.2 (1992)). And the plaintiffs in *Hispanic Affairs* “[were] doing just that—arguing the unlawfulness of Homeland Security’s ‘particular’ practice of habitually approving and extending H-2A visas for lengthy periods of time.” *Id.* at 388.

Consistent with *Hispanic Affairs*, Plaintiffs challenge the unlawfulness of particularized, individual practices. In *Hispanic Affairs*, that practice was “automatically extending ‘temporary’ H-2A petitions for multiple years.” *Id.* at 385. Here, such practices include, for example, the practice of unlawfully censoring health and safety studies or the practice of “categorical[ly]” accepting PMN submitters’ confidentiality claims at face value. *See* ECF No. 48, at 33. The EPA largely admits that it had or has these practices, but it disputes whether they are unlawful—a question that is not before the court today. *See id.* (explaining that the EPA “does not review the confidentiality claims made by PMN submitters because it does not understand the statute or regulations to require it to do so”).

Further, “[t]he statutory command that the [plaintiffs] seek[] to enforce . . . is cabined and direct.” *Hisp. Affs. Project*, 901 F.3d at 388. In *Hispanic Affairs*, the statutory command was that H-2A visas go only to workers whose employment was of “temporary or seasonal nature.” *Id.* at 383 (quoting 8 C.F.R. § 214.2(h)(5)(iv)(A)). The statutory commands at issue here are similarly

cabined—for example, the requirements that “[i]nformation submitted [as part of a PMN] shall be made available . . . for examination by interested persons,” 15 U.S.C. § 2604(b)(3), and that “[a]ll information submitted with a [PMN], including any health and safety study and other supporting documentation, will become part of the public file for that [PMN],” 40 C.F.R. § 720.95. Because Plaintiffs “target[] [their] argument to [] identified transgression[s] of that statutory and regulatory language, not to an exercise of broad, unspecified discretion,” their pattern-or-practice claims are cognizable under the APA. *Hisp. Affs. Project*, 901 F.3d at 388.

The EPA reads *Hispanic Affairs* to allow a pattern-or-practice claim to proceed under the APA only where such a claim would otherwise be unreviewable. ECF No. 57, at 12; *see* May 1, 2024 Hr’g. Tr. at 8:14-9:2. But *Hispanic Affairs* makes no such distinction. *See* 901 F.3d at 385-88. And even if *Hispanic Affairs* had made such a distinction, it seems that Plaintiffs might struggle to bring their pattern-or-practice claims absent a cause of action under the APA. The EPA argues that Plaintiffs could seek judicial review of these same claims by litigating the EPA’s ultimate risk determination. *See* May 1, 2024 Hr’g. Tr. at 9:3-10:7. But Plaintiffs requested many of the documents at issue in this case *after* the agency had made its risk determination; their legal injury thus exists independent of the agency’s risk determination. *See id.* at 26:2-7. In the alternative, the EPA claims that Plaintiffs could seek the documents in question through FOIA. *Id.* at 10:6-7. But that is not necessarily so. Certain types of documents, such as health and safety studies, are categorically non-confidential under the TSCA but could hypothetically be withheld under FOIA. *Compare* 15 U.S.C. § 2613(b), *with* 5 U.S.C. § 552(b); *see* Joint Status Rep. (ECF No. 12) at 4-5, *Pub. Emps. for Env’t Resp. v. Env’t Prot. Agency*, No. 24-CV-445 (D.D.C. Apr. 24, 2024).

Finally, although *Hispanic Affairs* considered a Section 706(2) claim, the court finds that its logic extends to Plaintiffs’ Count IV pattern-or-practice claim. As discussed above, Count IV is subject to judicial review under Section 706(1) of the APA because it deals with agency inaction: the EPA’s alleged failure to post PMN files in an electronic docket at www.regulations.gov as required by 40 C.F.R. § 700.17(b)(1). Per *Hispanic Affairs*, “[a]n agency’s unannounced departure in practice from a written regulation is a distinct form of agency action that is challengeable,” and that is precisely what is happening here. 901 F.3d at 387. The written regulation states that files “are available” at www.regulations.gov, but the EPA has (allegedly) made an “unannounced departure in practice” from that regulation by consistently failing to make PMN files available there. *Id.* Such a practice is reviewable under the APA, and to conclude otherwise would conflict with the D.C. Circuit’s holding in *Hispanic Affairs*. To the extent that earlier district court cases suggest otherwise, *see, e.g., Del Monte Fresh Produce N.A., Inc. v. United States*, 706 F. Supp. 2d 116 (D.D.C. 2010), they have been abrogated by *Hispanic Affairs*.⁹

⁹ Even absent *Hispanic Affairs*, the court finds that *Del Monte Fresh Produce N.A., Inc. v. United States*, 706 F. Supp. 2d 116 (D.D.C. 2010) is distinguishable. *Del Monte* concerned the authority of the Food and Drug Administration (“FDA”) under the Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 *et seq.*, to sample and inspect imported food. *Id.* at 117. The plaintiff, a produce importer, brought a Section 706(1) pattern-or-practice claim alleging that the FDA took too long inspect its products. *Id.* at 118. But the plaintiff pointed to no particular provision of the FDCA that required the FDA to conduct its inspections within a certain timeframe. *See* Amended Complaint (ECF No. 7), *Del Monte Fresh Produce N.A., Inc.*, No. 08-CV-2161, 706 F. Supp. 2d 116. In other words, *Del Monte* demanded that the FDA simply do better, untethered from the requirements of the governing statute. The court rightly construed this as an impermissible request for “wholesale improvements” barred by *Lujan*. *Del Monte Fresh Produce N.A., Inc.*, 706 F. Supp. 2d at 117.

Such a problem is not unique to Section 706(1) pattern-or-practice claims: *any* APA claim that attempts a “broad programmatic takeover” will fail. *Hisp. Affs. Project*, 901 F.3d at 388. But Plaintiffs’ Count IV pattern-or-practice claim, unlike the claim in *Del Monte*, is tethered to a discrete, mandatory regulatory requirement. Thus—even without *Hispanic Affairs*—the court would not find *Del Monte* persuasive here.

b. Mootness

The EPA argues that Plaintiffs' pattern-or-practice claims are moot because, "[s]ince the filing of Plaintiffs' First Amended Complaint, EPA has made substantial and ongoing improvements to its practices for preparing and publishing public notices and public files." ECF No. 48, at 22. "A case is moot if a 'decision will neither presently affect the parties' rights nor have a more-than-speculative chance of affecting them in the future.'" *Pub. Citizen, Inc. v. FERC*, 92 F.4th 1124, 1128 (D.C. Cir. 2024) (quoting *Transwestern Pipeline Co. v. FERC*, 897 F.2d 570, 575 (D.C. Cir. 1990)).

In evaluating mootness, it is helpful to separate Plaintiffs' claims into two categories: those that concern confidentiality (Counts II, V, VI, IX, and X) and those that do not (Counts I, III, IV, VII, and VIII). *See* May 1, 2024 Hr'g Tr. 20:2-21:5. Plaintiffs' pattern-or-practice claims related to confidentiality cannot be moot, because the EPA admits that it has not changed its policy (its "categorical" approach to confidentiality assertions). *See* ECF No. 48, at 3, 33. The remainder of the court's mootness analysis applies only to those claims that do not concern confidentiality.

The EPA explains that it has made a number of changes in how it implements the TSCA: it now "post[s] all incoming and amended PMNs that clear its pre-screen, TME applications, and related attachments to its public-facing website, ChemView, within five business days of receipt"; it has "decreased the time it takes to publish notices of receipt in the Federal Register"; it goes beyond the statutory requirement to publish notices of receipt within five days "by providing access to the PMNs themselves within the same amount of time"; and it "has also made changes to its treatment of confidential information, including issuing a proposed rule concerning the assertion and treatment of confidentiality claims under TSCA." *Id.* at 23.

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.” *Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1230 (D.C. Cir. 2023) (quoting *Trinity Lutheran Church of Columbia, Inc. v. Comer*, 582 U.S. 449, 457 n.1 (2017)). The party raising mootness bears the “‘heavy burden’ of persua[ding] the court that the challenged conduct cannot reasonably be expected to start up again.” *Friends of the Earth, Inc. v. Laidlaw Env’t Servs. (TOC), Inc.*, 528 U.S. 167, 189 (2000) (quoting *United States v. Concentrated Phosphate Exp. Ass’n*, 393 U.S. 199, 203 (1968)).

The EPA has not carried that burden. It relies on a single declaration from an agency official, ECF No. 47-1, which speaks only in terms of the past and present, not the future, *see, e.g., id.* ¶ 69 (“EPA has increased the speed with which it posts incoming PMNs and all amended versions that have cleared the Agency’s prescreen to ChemView; since August 2021, EPA has posted these submissions largely within five business days of receipt.”). The declaration only makes two statements about the EPA’s plans for the future: “In a 2019 letter to Senator Tom Carper, EPA committed to making certain improvements to its publication of Federal Register notices of receipt,” *id.* ¶ 17; and “[o]n May 12, 2022, EPA issued a proposed rule concerning the assertion and treatment of confidentiality claims under TSCA,” *id.* ¶ 70. But these allusions to possible future policy changes are too vague and speculative to make it “absolutely clear” that the challenged conduct will not recur. *See People for the Ethical Treatment of Animals v. U.S. Dep’t of Agric. & Animal & Plant Health Inspection Serv.*, 918 F.3d 151, 158 (D.C. Cir. 2019) (“It doesn’t express the agency’s position clearly enough to convince us that, as to all requested document types, it is ‘absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur,’ . . . even once we credit a presumption of regularity afforded to government parties.” (quoting *Friends of the Earth, Inc.*, 528 U.S. at 189)). An agency’s letter to Congress is

not binding, and a proposed rule might never be enacted.¹⁰ Because there is nothing to prevent the EPA from reverting to its “old ways,” Plaintiffs’ claims are not moot. *Friends of the Earth, Inc.*, 528 U.S. at 189 (quoting *City of Mesquite v. Aladdin’s Castle Inc.*, 455 U.S. 283, 289 (1982)).

3. Standing: Counts I-III

A plaintiff has standing if (1) it has suffered an “injury in fact” that is both “concrete and particularized” and “actual or imminent,” (2) there is a causal connection between the injury and the defendant’s alleged conduct, and (3) the injury is redressable by a favorable decision. *Lujan*, 504 U.S. at 560-61. Plaintiffs argue that they have informational standing to bring all of their claims under *Environmental Defense Fund v. Environmental Protection Agency*, 922 F.3d 446 (D.C. Cir. 2019). ECF No. 56, at 39-40. A plaintiff seeking informational standing must still establish the traditional three prongs described above, but “[t]he law is settled that ‘a denial of access to information’ qualifies as an injury in fact ‘where a statute (on the claimants’ reading) requires that the information be publicly disclosed and there is no reason to doubt their claim that the information would help them.’” *Env’t Def. Fund*, 922 F.3d at 452 (quoting *Friends of Animals v. Jewell*, 824 F.3d 1033, 1040-1041 (D.C. Cir. 2016)).

The EPA argues that Plaintiffs lack standing to raise Counts I-III because “[t]he only relief permitted in a suit under § 2619(a)(2) is an order to ‘compel the Administrator to perform any duty under [TSCA] which is not discretionary,’” ECF No. 48, at 17 (quoting 15 U.S.C. § 2619(a)(2))—and the EPA has already granted Plaintiffs their requested relief by publishing the PMN and TME notices in questions (and, as to the PMNs, providing Plaintiffs with the underlying test data). *See* ECF No. 48, at 17-19. And to the extent that Plaintiffs were injured by the EPA’s failure to provide

¹⁰ EPA’s proposed rule is currently being litigated in the D.C. Circuit. *See Env’t Def. Fund v. U.S. Env’t Prot. Agency*, No. 23-1166 (oral argument scheduled for September 24, 2024).

timely and complete notices because it precluded them from participating in the review process, the EPA contends that that injury is not redressable: “[t]he Court cannot provide any remedy that would turn back the clock to give Plaintiffs sufficient notice to participate in review periods that have since closed.” *Id.* at 18.

But the EPA seems to implicitly recognize that if Plaintiffs’ pattern-or-practice claims are cognizable, this standing argument no longer holds. *See id.* at 17 n.7 (“To the extent Plaintiffs assert pattern-or-practice claims related to these alleged violations, such claims are addressed below.”). As Plaintiffs explain, their injury is ongoing because the EPA—even if it has released the documents it previously withheld—can and will continue to withhold similar documents in the future. ECF No. 56, at 43-44. For the same reasons that Plaintiffs’ pattern-or-practice claims are not moot, Plaintiffs have standing to bring Counts I-III.¹¹

B. Motion to Compel the Administrative Record

The APA provides that, in reviewing a challenge under the statute, “the court shall review the whole record.” 5 U.S.C. § 706; *see Am. Bioscience, Inc.*, 243 F.3d at 582 (holding that the court’s review must “be based on the full administrative record that was before the [agency] at the time [it] made its decision” (quoting *Citizens to Pres. Overton Park, Inc.*, 401 U.S. at 420)). The EPA argues that this case is primarily about agency inaction, ECF No. 47, at 12, and “if an agency fails to act, there is no ‘administrative record’ for a federal court to review.” *Mohammad v.*

¹¹ The court understands the EPA to be arguing that Plaintiffs do not have standing to bring these pattern-or-practice claims because it has already produced the documents in question, either mooting out Plaintiffs’ claims or rendering them non-redressable. *See* ECF No. 48-1, at 22-23. The EPA does not argue that pattern-or-practice claims are not cognizable under Section 2619(a)(2); that argument is therefore forfeited. And even if the court were to find that pattern-or-practice claims are not cognizable under Section 2619(a)(2), it would not change the outcome. If pattern-or-practice claims are not available under the TSCA, then APA review would be available under *Hispanic Affairs*. *See supra* Part V(A)(2)(a).

Blinken, 548 F. Supp. 3d 159, 163 n.2 (D.D.C. 2021) (quoting *Nat'l L. Ctr. on Homelessness & Poverty v. U.S. Dep't of Veterans Affs.*, 842 F. Supp. 2d 127, 130 (D.D.C. 2012)). But the court has already determined that most of Plaintiffs' claims are reviewable agency actions under Section 706(2) of the APA. *See supra* Part V(A)(1)(b)(iii). The parties have already agreed that no administrative record is necessary for Count IV, Plaintiffs' sole Section 706(1) "inaction" claim. ECF No. 45, at 7-8.

The court therefore concludes that an administrative record is required as to all counts except Count IV. However, the court recognizes that this case presents some unique challenges. The EPA has already produced many of the specific documents at issue, *see* ECF No. 60, and the parties have spent two years negotiating a set of joint stipulations, *see* ECF No. 56-3. These disclosures and stipulations might narrow the scope of the remaining administrative record. Take Count I as an example: the EPA has admitted that, for the PMNs listed in Table 1 of Plaintiffs' Amended Complaint, it did not publish notices of receipt in the Federal Register within the required five business days, but it did eventually publish them. ECF No. 56-3, at 1. It therefore seems unnecessary for the EPA to reproduce said PMNs in an administrative record. However, there could hypothetically be other items in the administrative record relevant to Count I. *See Bimini Superfast Operations LLC v. Winkowski*, 994 F. Supp. 2d 103, 105 (D.D.C. 2014) ("If the relevant agency decisionmakers considered, *even indirectly*, any internal guidelines, memoranda, manuals or other materials in reaching its decision, those materials should be included in the record." (quoting *Ammex, Inc. v. United States*, 23 C.I.T. 549, 555 (Ct. Int'l Trade 1999))); *Blue Mountains Biodiversity Project v. Jeffries*, 99 F.4th 438, 452-53 (9th Cir. 2024) (noting that the

administrative record can include internal agency emails, memoranda, and even draft talking points).¹²

“The district court has some leeway in determining the scope of an adequate record to permit review of informal agency action.” *Women Involved in Farm Econ.*, 876 F.2d at 998. The court therefore grants Plaintiffs’ motion to compel the administrative record but orders the parties to meet and confer and file a joint proposed order on or before September 17, 2024, defining the scope of the administrative record. The proposed order shall address: (1) for each count, the types of documents that the parties believe form the administrative record; and (2) the terms of any protective order the parties seek.

VI. Conclusion

For the foregoing reasons, Plaintiffs’ Motion to Compel the Administrative Record, ECF No. 45, is hereby **GRANTED**, and Defendants’ Motion for Judgment on the Pleadings, ECF No. 48, is hereby **DENIED**. The parties shall meet and confer and file a joint proposed order on or before September 17, 2024, defining the scope of the administrative record.

SO ORDERED.

¹² The EPA states that, per a sworn declaration, no relevant guidance or policy documents exist. May 1, 2024 Hr’g. Tr. at 41:11-15. The agency may produce that affidavit as part of the administrative record, but its existence does not prevent the court from compelling the administrative record as required by the APA. *See, e.g., Am. First Legal Found. v. Cardona*, 630 F. Supp. 3d 170, 187-88 (D.D.C. 2022) (discussing the administrative record in a FACA case).

To the extent that Plaintiffs seek specific PMNs and TME applications that the EPA has failed to produce and that the EPA believes are not in its possession, this Circuit’s FOIA jurisprudence may prove instructive. *See* ECF No. 47, at 29-31. When an agency tries and fails to locate responsive records, “agency affidavits will ordinarily suffice to establish the adequacy of an FOIA search effort if they are ‘relatively detailed and nonconclusory and . . . submitted in good faith.’” *Ground Saucer Watch, Inc. v. C.I.A.*, 692 F.2d 770, 771 (D.C. Cir. 1981) (internal quotations omitted) (quoting *Goland v. C.I.A.*, 607 F.2d 339, 352 (D.C. Cir. 1978)).

/s/ Loren L. AliKhan
LOREN L. ALIKHAN
United States District Judge

Date: August 20, 2024