IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ENVIRONMENTAL DEFENSE FUND, et al., Plaintiffs, v. MICHAEL REGAN, Administrator, U.S. Environmental Protection Agency, in his official capacity, et al., Defendants.	Civil Action No. 1:20-cv-762 (EGS)

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF EPA'S MOTION FOR JUDGMENT ON THE PLEADINGS AND IN OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL PRODUCTION OF THE ADMINISTRATIVE RECORD

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INTRODUCTION

In this litigation, Plaintiffs allege that the U.S. Environmental Protection Agency (EPA) acted unlawfully during the Agency's process for evaluating the risk posed by the manufacture of certain new chemical substances under the Toxic Substances Control Act (TSCA). Plaintiffs, however, do not challenge EPA's risk determinations. Instead, they assert that EPA violated its legal obligations with respect to information submitted in connection with hundreds of new chemical substance submissions by failing to timely and completely notify the public of receipt of such submissions and by omitting certain information from public disclosures of submission files. Plaintiffs' complaint thus challenges EPA's *failure* to act. Nevertheless, Plaintiffs maintain that each time EPA published a notice of receipt of a new chemical submission or disclosed a submission file to Plaintiffs it took an "agency action" under the Administrative Procedure Act (APA), meaning that their Complaint should actually be read to collectively challenges hundreds of these so-called actions. Plaintiffs now have moved to compel administrative records for each of these hundreds of purported agency actions.

Since the beginning, the parties have fundamentally disagreed about the validity of Plaintiffs' suit. However, for years, EPA has been making substantial efforts to update and improve its implementation of TSCA's notice and access provisions in order to enhance transparency and better carry out the spirit of the statute. Consistent with those efforts and notwithstanding its view that Plaintiffs' claims are legally defective, EPA engaged with Plaintiffs to exchange information about its practices in administering the program, with hopes of either resolving Plaintiffs' claims entirely or narrowing the disputed issues for the Court. That process involved a thorough investigation by EPA of Plaintiffs' specific allegations, which culminated in stipulations filed with the Court that outline instances where the Agency's prior policies had not complied with TSCA's requirements and, with one exception having to do with confidentiality, a

commitment to provide Plaintiffs and the public with the legally required information that EPA had initially failed to disclose.

Nevertheless, Plaintiffs now claim to need more information. Even though, for most of Plaintiffs' Counts, EPA has conceded and identified its past violations of TSCA, Plaintiffs ask the Court to compel EPA to produce hundreds of "administrative records" for every instance where EPA published notice that it received a new chemical submission or provided the public files to Plaintiffs. It is unclear what additional information they seek to obtain, given that Plaintiffs already have or will have all non-confidential information related to these submissions, or why the Court would need any additional information to adjudicate this case. And the 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. Those requests make little sense on their merits. But, more fundamentally, the Court lacks jurisdiction to review Plaintiffs' claims.

Plaintiffs seek relief under two citizen suit provisions of TSCA and the APA. 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, 15 U.S.C. § 2619(a)(1), because that provision allows suit against parties subject to TSCA's substantive provisions, not administering agencies. Plaintiffs are also barred from seeking relief for all but two of their claims under the other citizen suit provision, which authorizes suit "to compel the Administrator to perform any act or duty under [TSCA] which is not discretionary," *id.* § 2619(a)(2), because the cited statutory and regulatory provisions do not impose a date-certain deadline on the Agency. Even for those remaining two counts, however, Plaintiffs lack standing to raise them. Nor can Plaintiffs proceed under the 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. Accordingly, the Court should grant EPA's motion for judgment on the pleadings under Federal Rules of Civil Procedure Rule 12(c) and enter judgment in its favor on all counts.

If the Court were not to dismiss this case at this time and instead consider Plaintiffs' Motion to Compel (ECF 45), it should nevertheless deny it. Despite their reformulation, Plaintiffs' claims are properly understood as alleging failures to act, and where an agency has not acted, there is not yet an administrative record. Even assuming Plaintiffs' claims relate to action rather than inaction, 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. Rather, these procedural steps are part of the Agency's process for assessing the risk posed by the new chemical substance, resulting in an ultimate determination that would be a final agency action subject to review. Regardless, EPA has already conceded that it omitted legally required information in certain instances and agreed to provide those materials to Plaintiffs. Not only will that give Plaintiffs the only information that could arguably be included in an administrative record, it will afford them the very relief they seek on the merits of their claims. As to information designated as confidential, the parties have a purely legal dispute about whether EPA had any obligation to review such designations prior to disclosing the public file to Plaintiffs. There is no question that EPA did not do so, and the Court will not require additional facts to resolve that dispute. The Court should therefore deny Plaintiffs' Motion, if it considers it at all.

STATUTORY AND REGULATORY BACKGROUND

Under TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, EPA evaluates potential risks from new and existing chemical substances and acts to address any unreasonable risks chemicals may have for human health and the environment. Under § 2604 (otherwise referred to as Section 5 of TSCA), a person intending to manufacture or import

a new chemical substance must submit to EPA a pre-manufacture notice (PMN). EPA must then review that notice in order to determine whether the new chemical substance "presents an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2604(a)(3)(A). Section 14 of the statute, 15 U.S.C. § 2613, allows companies submitting information under TSCA (including Section 5) to assert confidentiality claims. The Lautenberg amendments, which took effect in 2016, aimed to "strik[e] a balance between protecting trade secrets and sensitive commercial and financial information and broadening information access to information on chemicals." S. REP. No. 114-67, at 21 (2015).

I. Notices of Receipt

EPA is required to publish a notice of receipt of a PMN in the Federal Register "not later than five days" after the date of receipt. 15 U.S.C. § 2604(d)(2). The notice must contain the identity of the PMN substance, the uses identified in the PMN, and a description of any test data submitted pursuant to 15 U.S.C. §§ 2603 or 2604(b). *Id.* By regulation, the notice must also contain a list of any test data submitted with the PMN. 40 C.F.R. § 720.70(b)(3). A person wishing to commence manufacture only for test marketing purposes may instead submit to EPA an application for a test marketing exemption (TME) under § 2604. When EPA receives a TME application, it must publish notice of receipt of the TME in the Federal Register "immediately upon receipt." 15 U.S.C. § 2604(h)(6). By regulation, the TME notice of receipt must contain a summary of the information provided in the TME application. 40 C.F.R. § 720.38(c). All of these notice requirements are "subject to [§] 2613," TSCA's confidentiality provisions. 15 U.S.C. § 2604(d)(2); *see also* 40 C.F.R. §§ 720.38(c), 720.70(b).

II. Public Files

PMNs "shall be made available, subject to [§] 2613 of this title, for examination by interested persons." 15 U.S.C. § 2604(d)(1). By regulation, "[a]ll information submitted with a

notice, including any health and safety study and other supporting documentation, will become part of the public file for that notice, unless such materials are claimed confidential." 40 C.F.R. § 720.95. EPA has defined "support documents" to mean "material and information submitted to EPA in support of a TSCA section 5 notice, including but not limited to, correspondence, amendments (if notices for these amendments were submitted prior to January 19, 2016), and test data."[1] *Id.* § 720.3(kk). When EPA prepared the public files at issue in this case, it did so by searching its electronic records database and repository for the requested PMN, then copying the relevant files from that system first to a local area network then to a compact disc for Plaintiffs. Declaration of Dr. Tala R. Henry ¶ 19 [hereinafter "Decl."].[2]

III. Confidentiality

As noted above, all requirements to make PMN information available to the public—whether in a notice of receipt or through a public file—are subject to § 2613. Congress directed that EPA "shall not disclose information" subject to protection under this section. 15 U.S.C. § 2613(a). It is the submitter "seeking to protect [information] from disclosure" who "shall assert to [EPA] a claim for protection." *Id.* § 2613(c)(1)(A). The statute neither permits nor requires EPA to make its own assertions of business confidentiality. When asserting a confidentiality claim, a submitter must certify, among other things, that it has "determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law." *Id.* § 2613(c)(1)(B)(ii), (c)(5). In the majority of instances, a submitter is also required to substantiate its claim for confidentiality protection, "in accordance with such rules as the

[1] Due to changes in PMN submission software, PMNs submitted prior to January 19, 2016 were amended differently than PMNs submitted on or after that date. *See* Decl. ¶ 13 & n.6.

[2] EPA has moved to dismiss Plaintiffs' claims based solely on the pleadings and jurisdictional issues. Nevertheless, EPA is also responding in opposition to Plaintiffs' Motion to Compel and EPA submits the attached declaration in support of that opposition.

Administrator has promulgated or may promulgate pursuant to this section." *Id.* § 2613(c)(3).[3] When a submitter asserts that certain information is confidential, EPA must protect that information unless it has determined that such information is not entitled to statutory protection. 40 C.F.R. § 720.80(c); *see also id.* § 2.209(a) ("[B]usiness information for which a claim of confidentiality has been asserted *shall be* treated as being entitled to confidential treatment until there has been a determination … that the information is not subject to confidential treatment." (emphasis added)).

TSCA also establishes the parameters of EPA's review of confidentiality assertions and its process for determining whether such information must be disclosed. 15 U.S.C. § 2613(g)(1). Specifically, for most confidentiality claims including those at issue in this case, the statute requires EPA to review no more than "a representative subset, comprising at least 25 percent" of claims. *Id.* § 2613(g)(1)(C)(ii). The statute further requires EPA to conduct its review of this subset of claims "not later than 90 days after the receipt of a claim." *Id.* § 2613(g)(1)(A). If EPA denies a claim for confidentiality protection under § 2613(g), the statute affords submitters additional procedural protections such as:

- requiring EPA to "notify, in writing, the person that asserted the claim or submitted the request" of the intent to disclose the information, *id.* § 2613(g)(2)(A);
- providing that EPA "shall not disclose information" until 30 days after "the date on which the person that asserted the claim … receives" the (g)(2)(A) notice, *id.* § 2613(g)(2)(B); and
- establishing a process by which a person may file suit in federal court "to restrain disclosure of the information," during which time EPA "shall not disclose" the information, *id.* § 2613(g)(2)(D)(i), (ii).

EPA must also provide "a written statement of the reasons for the denial" if it denies a claim. *Id.*

[3] The statute lists other information that is "generally not subject to substantiation requirements" such as processes used in marketing and marketing and sales information. *Id.* § 2613(c)(2).

§ 2613(g)(1)(B).

IV. Judicial Review

Under TSCA, "any person may commence a civil action" in two circumstances: first, "against any person [including a governmental agency] who is alleged to be in violation of this chapter," 15 U.S.C. § 2619(a)(1), or second, "against the Administrator to compel the Administrator to perform any act or duty under this chapter which is not discretionary," *id.* § 2619(a)(2).

The APA also grants a right to judicial review of certain agency actions. 5 U.S.C. § 702. The APA defines "agency action" as "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act." *Id.* § 551(13). The statute further defines these specific categories of agency action as follows:

- Rule—"an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy";
- Order—"a final disposition...in a matter other than rule making";
- License—"an agency permit...or other form of permission";
- Sanction—"an agency prohibition...or taking of other compulsory or restrictive action"; and
- Relief—"an agency grant of money, assistance, license, authority,...[or] recognition of a claim, right, immunity,...or taking [of] other action on the application or petition of, and beneficial to, a person."

5 U.S.C. §§ 551(4), (6), (8), (10), (11).

Importantly, the APA only permits judicial review of "final agency action for which there is no other adequate remedy." *Id.* § 704. "A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action." *Id.* The APA also permits a reviewing court to, in pertinent part, "compel agency action unlawfully withheld or unreasonably delayed" and "hold unlawful and set aside agency actions,

findings, and conclusions found to be [ ] arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 706(1), (2)(A).

PROCEDURAL AND FACTUAL BACKGROUND

Plaintiffs allege "numerous, discrete instances in which EPA denied them information about new chemical applications that the Agency was legally obligated to provide." Mem. at 2. These claims concern approximately 247 PMNs and 16 TME applications, and allege that EPA failed to provide the public with timely and complete notice of receipt of PMNs and TME applications and further failed to provide PMN information to Plaintiffs when they requested the public file.

I. Insufficient Notice Claims

With respect to their insufficient notice claims (Counts One through Three), Plaintiffs allege that in the case of approximately 247 PMNs, EPA violated its statutory obligation to publish timely notice of receipt of the PMN in the Federal Register. Am. Compl. ¶¶ 144-50 (Count One); *id.* at pp. 60-66 (Table 1) (listing PMNs). Plaintiffs further allege that in the case of approximately 102 PMNs, EPA failed to include a list or description of test data submitted with a PMN as required by TSCA and 40 C.F.R. § 720.38(c). Am. Compl. ¶¶ 151-57 (Count Two); *id.* at pp. 66-76 (Table 2). Plaintiffs also assert that EPA failed to publish timely and complete notice of receipt of 16 TME applications. Am. Compl. ¶¶ 158-66 (Count Three); *id.* at pp. 76-77 (Table 3). For these insufficient notice claims, Plaintiffs assert claims under §§ 2619(a)(1) and (a)(2) of TSCA's citizen suit provision, as well as § 706(2) of the APA.

The parties have stipulated to the fact that EPA published PMN notice of receipts in the Federal Register but that it did not do so within five business days. Pls.' Mot., Ex. A, Joint Stipulations of Fact (ECF 45-3) ¶ 1 [hereinafter "Joint Stips."]. The parties further stipulated to the dates on which EPA received TME applications, the date on which EPA published the TME

notice of receipt in the Federal Register, and the date of the final EPA determination regarding the TME. *Id.* ¶ 4. EPA has also explained its process for preparing notices of receipt, including when test data was listed in the notice and when it is not. Decl. ¶¶ 15, 41-42. In the instances where test data was not listed in the notice of receipt, EPA concedes that it failed to act in accordance with its regulatory obligation.

II. Public File Claims

With respect to their public file claims (Counts Five through Ten), Plaintiffs allege that when EPA provided the public file to Plaintiffs, it violated its legal obligation to make all non-confidential information submitted with or in support of a PMN available to the public upon request by omitting various types of information submitted in connection with PMNs. Plaintiffs assert their public file claims under § 2619(a)(1) and (a)(2) of TSCA's citizen suit provision, as well as § 706(1) and (2) of the APA. For clarity, it is helpful to consider Plaintiffs' public file claims as consisting of two categories: those that do not involve the treatment of material that a submitter asserts is confidential and those that do.

A. Claims Not Involving Treatment of Confidentiality Assertions

With respect to the first category of allegations—those *not* involving the treatment of material asserted to be confidential (Counts Seven through Nine)—Plaintiffs allege that EPA failed to provide certain documents in the public file that are legally required to be included. Specifically, they allege that EPA wrongfully omitted:

- earlier versions of approximately 110 PMNs in cases where a submitter amended the PMN, Am. Compl. ¶¶ 197-207 (Count Seven); *id.* at pp. 86-89 (Table 7);
- documents reflecting correspondence from the submitter to EPA associated with approximately 180 PMNs, Am. Compl. ¶¶ 208-18 (Count Eight); *id.* at pp. 89-93 (Table 8); and
- substantiation documents for approximately 98 PMNs, Am. Compl. ¶¶ 219-27

(Count Nine); *id.* at pp. 93-95 (Table 9).[4]

As to these allegations, EPA acknowledges its general obligation to provide such information in the public file, subject to the protections of 15 U.S.C. § 2613, although it disputes that this obligation constitutes a non-discretionary duty under 15 U.S.C. § 2619(a)(2). Based on the shared understanding of this obligation, EPA conducted an extensive review of its files in order to identify the instances where it failed to include certain information that it was obligated to provide. Decl. ¶¶ 29-35, 46-56. EPA shared the results of this investigation with Plaintiffs and acknowledged the instances where it failed to provide legally required information. Some, but not all, of the information provided by EPA is reflected in the 39-page stipulations submitted with Plaintiffs' Motion. *See generally* Joint Stips.

In a number of instances, EPA was either unable to identify the document that Plaintiffs allege EPA wrongfully omitted from the public file. In several cases, although Plaintiffs allege "on information and belief" that a submitter provided a certain document to EPA, EPA never received such a document. Decl. ¶¶ 48, 50. In other cases, Plaintiffs allege that EPA wrongfully omitted a certain document from the public file, but EPA had not received the document when Plaintiffs requested the public file. *See, e.g.*, ¶¶ 48, 51, 56. And in some cases, EPA provided the document at issue. *See, e.g.*, *id.* Where EPA could not identify any omitted information after a thorough review of its records, EPA did not stipulate to the alleged fact.

B. Claims Involving Confidentiality Assertions

Regarding the next category of public file allegations—related to the treatment of information and documents that a submitter has claimed to be confidential (Counts Five, Six, and

[4] To the extent Plaintiffs allege, in Count Nine, that EPA not only failed to provide substantiation documents in the public file but also improperly withheld the underlying information, which was claimed to be confidential, those allegations are substantially similar to Plaintiffs' other allegations related to confidentiality assertions (Counts Five and Six).

Ten)—Plaintiffs specifically allege that EPA unlawfully withheld the following types of information or documents on the basis of confidentiality:

- documents containing health and safety studies, submitted with or in support of approximately 57 PMNs, Am. Compl. ¶¶ 172-85 (Count Five); *id.* at pp. 82-85 (Table 5);
- documents containing safety data sheets submitted with or in support of approximately 58 PMNs, Am. Compl. ¶¶ 186-96 (Count Six); *id.* at pp. 85-86 (Table 6); and
- information or documents submitted with or in support of approximately 22 PMNs where the information contained within the document did not qualify for confidentiality protection on its face, Am. Compl. ¶¶ 228-40 (Count Ten); *id.* at pp. 96-98 (Table 10).

The parties disagree about whether EPA is obligated to review such confidentiality claims prior to making the pertinent disclosures. EPA further disputes that any such obligation, even if it did exist, would constitute a non-discretionary duty under TSCA.

III. Count Four

Plaintiffs also seek relief under TSCA's § 2619(a)(2) and the APA's § 706(1) for EPA's alleged failure to make complete PMN applications available in an electronic docket at www.regulations.gov, as required by EPA regulation, 40 C.F.R. §§ 700.17(b)(1), 720.95. Plaintiffs do not seek an administrative record for their Count Four claims based on the parties' mutual understanding that such claims allege only a failure to act. Mem. at 3 n.1. EPA, however, seeks dismissal of this Count as well.

ARGUMENT

Plaintiffs' claims are not reviewable by the Court and the First Amended Complaint (ECF 16) should be dismissed. Plaintiffs' claims that EPA failed to publish timely and complete notice of receipt of 16 TMEs (Count Three, failed to place required documents in the public file (Counts Five through Ten), and failed to make PMN files available on www.regulations.gov (Count Four)

must be dismissed, because Plaintiffs have failed to identify a non-discretionary duty under TSCA and they do not identify a reviewable agency action under the APA. Plaintiffs' claims that EPA failed to provide timely and sufficient notice of receipt of PMNs (Counts One through Two) should also be dismissed because Plaintiffs lack standing to raise them. Accordingly, the United States moves for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c).[5]

If the Court does not grant EPA's motion for judgment on the pleadings at this time, it should deny Plaintiffs' Motion. Properly understood, Plaintiffs' claims in this case plainly allege agency inaction relating to the disclosure of certain information.[6] In cases alleging a failure to act or perform a mandatory duty, there is not yet an administrative record. Moreover, even if an administrative record could theoretically exist, no such record is necessary to resolve Plaintiffs' claims here given the specific claims at issue, the nature of the remaining disputes, and the submission of the parties' stipulations and EPA's declaration. If the Court does not dismiss the

[5] As explained in detail below, *see supra* Section II, there is no administrative record for these claims and Local Civil Rule 7(n) thus has no application. Accordingly, EPA formally moves to waive compliance with the requirements of this rule, consistent with the approach taken by other courts in this jurisdiction. *See Desai v. U.S. Citizenship & Immigr. Servs.*, No. CV 20-1005 (CKK), 2021 WL 1110737, at *5 n.7 (D.D.C. Mar. 22, 2021) (collecting cases waiving compliance with Rule 7(n) in challenges to alleged inaction). Even if the Court disagrees and deems Rule 7(n) applicable, however, this motion does not implicate the contents of any such record. As such, EPA requests in the alternative that the Court vacate any obligation to file a certified list of contents for purposes of deciding its motion. *See Mdewakanton Sioux Indians of Minnesota v. Zinke*, 264 F. Supp. 3d 116, 123 n.12 (D.D.C. 2017) ("[C]onstruing Defendants' motion to dismiss as incorporating a motion to waive compliance with Local Civil Rule 7(n), the Court grants the motion because the administrative record is not necessary for its decision here.") (citation omitted); *see also Connecticut v. U.S. Dep't of the Interior*, 344 F. Supp. 3d 279, 294 (D.D.C. 2018) (waiving Local Civil Rule 7(n)'s requirement, "follow[ing] the practice of other courts in this jurisdiction when the administrative record is not necessary for the court's decision regarding a motion to dismiss") (citations omitted).

[6] Plaintiffs now insist that they seek review only of agency action as opposed to inaction, but a review of their specific allegations reveals their inconsistency on this point. *See, e.g.*, *See* Am. Compl. ¶ 147 (Count 1) ("EPA *failed to publish* in the Federal Register the notice of receipt of the PMN within five business days") (emphasis added); ¶ 154 (Count 2) ("these notices of receipt *failed to include* a list or description of all the test data") (emphasis added); ¶ 161 (Count 3) ("EPA *did not publish* the notice of receipt of the application immediately") (emphasis added); ¶ 177 (Count 5) ("EPA was required to make available to Plaintiffs all non-confidential information in the documents"); ¶ 190 (Count 6) ("EPA was required to make available to Plaintiffs the safety data sheet submitted by the manufacturer"); ¶ 201 (Count 7) ("EPA is required to make available to Plaintiffs all versions of the PMN application and supporting documents"); ¶ 212 (Count 8) ("EPA was required to make available to Plaintiffs the correspondence submitted by the manufacturer"); ¶ 223 (Count 9) ("EPA *failed to make* the substantiation document available to Plaintiffs") (emphasis added); ¶ 234 (Count 10) ("EPA was required to make available to Plaintiffs the documents submitted by the manufacturer").

First Amended Complaint at this time, it should deny Plaintiffs' Motion.

I. The United States Is Entitled To Judgment On The Pleadings And The Case Should Be Dismissed.

Plaintiffs filed this lawsuit "to challenge numerous, discrete instances in which EPA denied them information about new chemical applications that the Agency was legally obligated to provide." Mem. at 2. Based on this singular set of allegations, Plaintiffs claim relief under two subsections of TSCA's citizen suit provision and the APA. Am. Compl. ¶ 241 (Prayer for Relief). Before the Court evaluates Plaintiffs' Motion, it must first determine whether Plaintiffs' claims are subject to review. *See In re United States*, 138 S. Ct. 443, 445 (2017) (per curiam) (before district court orders Government to complete the administrative record, it must consider Government's threshold arguments regarding reviewability under the APA and jurisdiction). They are not, and the Court should dismiss them and enter judgment in favor of the United States.

A. Standard of Review

Federal Rule of Civil Procedure 12(c) authorizes a party to move for judgment on the pleadings at any time "after the pleadings are closed," Fed. R. Civ. P. 12(c)—that is, when an answer has been filed. "A movant is entitled to judgment on the pleadings under Rule 12(c) if it 'demonstrates that no material fact is in dispute and that it is entitled to judgment as a matter of law.'" *Jimenez v. McAleenan*, 395 F. Supp. 3d 22, 30 (D.D.C. 2019) (quoting *Schuler v. PricewaterhouseCoopers, LLP*, 514 F.3d 1365, 1370 (D.C. Cir. 2008)). "Rule 12(c) may serve as an 'auxiliary or supplementary procedural device to determine the sufficiency of the case before proceeding any further.'" *Id.* (quoting 5C Charles A. Wright & Arthur Miller, Fed. Prac. & Proc. § 1367 (3d ed. 2019)). Where it does—as in the present case—the applicable "standard of review is 'functionally equivalent' to that for a Rule 12(b)(6) motion." *Id.* (quoting *Rollins v. Wackenhut Servs., Inc.*, 703 F.3d 122, 130 (D.C. Cir. 2012)) (explaining that "the requirements

of *Iqbal* and *Twombly* . . . apply to a Rule 12(c) motion, which here is functionally equivalent to a Rule 12(b)(6) motion")).

As explained below, Plaintiffs' claims fail at the threshold. Such defenses are not waived when not presented in a responsive pleading and may be raised by a motion under Rule 12(c). Fed. R. Civ. P. 12(h)(1)(B)(ii), (2)(B). If at any time a court determines that it lacks subject-matter jurisdiction, "the court must dismiss the action." *Id.* 12(h)(3). Moreover, for purposes of resolving jurisdictional issues, "the Court is free to consider material outside the pleadings." *Caesar v. United States*, 258 F. Supp. 2d 1, 2 (D.D.C. 2003).

B. Plaintiffs Are Not Authorized To File Suit Under 15 U.S.C. § 2619(a)(1) For Claims Related To EPA's Administration of TSCA, And Counts One Through Three And Five Through Ten Should Therefore Be Dismissed.

Plaintiffs are barred from seeking relief under § 2619(a)(1). This provision "permits citizen suits against regulated parties, including governmental entities to the extent they are subject to TSCA." *Physicians Comm. for Responsible Med. v. Johnson*, 436 F.3d 326, 335 (2d Cir. 2006). For example, federal agencies occasionally handle substances—such as polychlorinated biphenyls (PCBs)—that subject the United States to regulation under TSCA. Section 2619(a)(1) would authorize any person to sue a federal agency if its handling of such regulated substances failed to comply with TSCA. It does not, however, "provide an alternative avenue for challenging the Agency's actions as a regulator." *Id.*

The Supreme Court explained this distinction when considering the substantially similar citizen-suit provisions of the Endangered Species Act (ESA) in *Bennett v. Spear*, 520 U.S. 154, 173 (1997). Like TSCA, the ESA authorizes "any person [to] commence a civil suit" either to "enjoin any person … who is alleged to be in violation" of the statute, 16 U.S.C. § 1540(g)(1)(A), or against the administering agency "where there is alleged a failure … to perform any act or duty … which is not discretionary," *id.* § 1540(g)(1)(C). In *Bennett*, the Court noted that allowing

citizens to use the "alleged to be in violation" provision against an agency for its administration of the statute "is simply incompatible with the existence of" the provision authorizing suit against the administering agency to compel performance of a nondiscretionary duty. 520 U.S. at 173. To find otherwise would render the nondiscretionary duty provision "superfluous—and worse still, its careful limitation . . . would be nullified." *Id.*

Plaintiffs' claims do not allege any EPA action as a regulated party subject to TSCA. Instead, they all concern EPA's administration of the statute. Accordingly, all claims for relief under § 2619(a)(1) (Counts One through Three, Five through Ten) must be dismissed.

C. Because Neither The Statute Nor The Regulations Impose A Clear Deadline For Action, Plaintiffs' Counts Three Through Ten Are Not Subject To Review Under 15 U.S.C. § 2619(a)(2) And Should Be Dismissed.

Plaintiffs are also barred from seeking relief under § 2619(a)(2) for most of their claims. In analyzing nearly identical citizen-suit provisions, courts have made clear that these provisions authorize suit only where the statute "categorically mandat[es]" that EPA perform "a clear-cut nondiscretionary duty" by a "date-certain deadline" that is expressly stated in the Act, or is "readily-ascertainable by reference to some other fixed date or event." *Sierra Club v. Thomas*, 828 F.2d 783, 790-91 (D.C. Cir. 1987). A "date certain deadline" is necessary to distinguish between claims for performance of a non-discretionary duty claim under § 2619(a)(2) and claims for "unreasonable delay" under § 706(1) of the APA. Where no such deadline is mandated, an agency retains discretion with respect to the timing of its action, and plaintiffs must seek relief under the APA. *Conservation Force v. Salazar*, 753 F. Supp. 2d 29, 34-35 (D.D.C.), *aff'd*, 699 F.3d 538 (D.C. Cir. 2015) ("When 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." (cleaned up)).

Counts Four through Ten, which constitute the majority of Plaintiffs' Complaint, pertain

to alleged statutory or regulatory duties that do not impose a date-certain deadline. These include:

- Count Four (Am. Compl. ¶¶ 167-71): Make PMNs available on www.regulations.gov (40 C.F.R. §§ 700.17(b)(1), 720.95);
- Counts Five through Ten: Make available all information submitted with a PMN and its supporting documents that is not claimed to be confidential (15 U.S.C. § 2604(d)(1), 40 C.F.R. § 720.95), including:
  - Health and safety studies (Count Five, Am. Compl. ¶¶ 172-85),
  - Safety data sheets (Count Six, *id.* ¶¶ 186-96),
  - All versions of a PMN (Count Seven, *id.* ¶¶ 197-207),
  - Correspondence related to the PMN (Count Eight, *id.* ¶¶ 208-18),
  - Substantiation documents for the PMN (Count Nine, *id.* ¶¶ 219-27), and
  - Information or documents claimed to be CBI that facially do not qualify for protection from disclosure (Count Ten, *id.* ¶¶ 228-40).

Section 2619(a)(2) does not authorize these claims.

This date-certain requirement bars Plaintiffs' Count Three, *id.* ¶¶ 158-66, as well. Under that Count, Plaintiffs allege that EPA failed to publish timely notices of receipt of TMEs, where the statute directs the agency to do so "immediately." *See* 15 U.S.C. § 2604(h)(6). Courts have found that statutory terms that do not clearly identify a deadline for action are insufficiently specific to qualify as non-discretionary under citizen suit provisions similar to TSCA's. *See, e.g.*, *Riverkeeper, Inc. v. Wheeler*, 373 F. Supp. 3d 443, 451 (S.D.N.Y. 2019), *judgment vacated on other grounds on reconsideration*, No. 17-CV-4916 (VSB), 2020 WL 1188455 (S.D.N.Y. Mar. 12, 2020). Although the statute directs EPA to either approve or deny a TME application "within 45 days of its receipt," 15 U.S.C. § 2604(h)(6), such language does not specify any categorically mandated, date-certain deadline, nor does the statute provide enough context for such a deadline to be "readily-ascertain[ed]." *Sierra Club*, 828 F.2d at 791. At most, the statute's direction amounts to an inferable, discretionary deadline of 45 days. Where deadlines need to be inferred

from statutory structure, however, it is "highly improbable" that they will be nondiscretionary, because such inferences "rest[ ], at bottom, upon a statutory framework that will almost necessarily place competing demands upon the agency's time and resources." *Id.* at 791. In that case, "it will be almost impossible to conclude that Congress accords a particular agency action such a high priority as to impose upon the agency a categorical mandate that deprives it of all discretion over the timing of its work." *Id.* In any event, Count Three also fails for the reasons discussed *supra* Section I.D.

D. The Court Should Dismiss Plaintiffs' Counts One And Two Because Plaintiffs Lack Standing.

Even if Plaintiffs' remaining insufficient notice claims under Counts One (Am. Compl. ¶¶ 144-50) and Two (*id.* ¶¶ 151-57) could in theory be reviewed under § 2619(a)(2), they, too, must be dismissed on jurisdictional grounds because Plaintiffs lack standing.[7]

Under Count One, Plaintiffs allege that EPA failed to perform a non-discretionary duty under 15 U.S.C. § 2604(d)(2) to publish notice of receipt of a PMN in the Federal Register within five business days of receipt. Under Count Two, Plaintiffs allege that when EPA did file the required notice of receipt, it failed to include a description or list of test data as required by § 2604(d)(2) and 40 C.F.R. § 720.70(b)(3). The 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." 15 U.S.C. § 2619(a)(2).

Plaintiffs have not pled an "actual or imminent" injury where they have already received the remedy they seek. *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990). In such cases, there is no "case or controversy" and nothing for a court to resolve. *Id.* at 154-55. Here, as is evident from

[7] To the extent Plaintiffs assert pattern-or-practice claims related to these alleged violations, such claims are addressed below. *Infra* at Section I.F.

the face of the pleadings, EPA published notices of receipt related to these PMNs before Plaintiffs filed their First Amended Complaint on June 19, 2020. Am. Compl. at pp. 60-66 (Table 1) (listing dates of publication of PMN notices of receipt). Similarly, although EPA did not list certain test data in these notices, as required by regulation, the Agency provided Plaintiffs with the test data itself (subject to § 2613) when it provided them with the PMN public files, which it also did before the filing of the First Amended Complaint. *Id.* at pp. 77-82 (Table 4) (listing dates on which Plaintiffs received public files). Plaintiffs cannot satisfy the standing requirement merely because they received the test data itself rather than a list of test data in the Federal Register. *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2214 (2021) (finding no concrete injury to support standing where plaintiffs did not allege failure to receive required information, but only that "they received it *in the wrong format*" (emphasis in original)).

Plaintiffs also maintain that they were injured by EPA's failure to provide timely and complete notices of receipt because the failures precluded Plaintiffs from having "sufficient time and information to participate in the 90-day period EPA has to review and render a determination on the application." Am. Compl. ¶ 87. But this injury cannot "be redressed by a favorable decision." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992) (explaining that redressability is one element comprising the "irreducible constitutional minimum of standing"). The 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.[8]

The same analysis would apply equally to Plaintiffs' claims under Count Three, should the

[8] EPA has concluded its review of all PMNs and TME applications listed in the First Amended Complaint with only six exceptions. Decl. ¶ 34. In the six instance where the Agency's review is ongoing, Plaintiffs themselves acknowledge that EPA published notices of receipt years ago. *See* Am. Compl. at pp. 60, 64, 66 (Table 1) (alleging that EPA published notice of receipt of P-16-0345 on June 2, 2016; of P-18-0146 on July 23, 2018; of P-18-0280 on March 12, 2019; and of P-19, 0138, P-19-0139, and P-19-0140 on September 5, 2019). Since then, at least, Plaintiffs have been on notice of EPA's review and cannot show injury as a result of any untimely notice.

Court decide that the statute supplies a readily ascertainable deadline, subjecting those claims to review under § 2619(a)(1). Plaintiffs allege that EPA's failure to publish timely notices of receipt "means that the public cannot comment on these applications." Am. Compl. ¶ 96. For the reasons explained above with respect to Counts One and Two, Plaintiffs lack standing to assert these claims. EPA published these notices of receipt before Plaintiffs filed their First Amended Complaint, Am. Compl. at pp. 76-77 (Table 3) (listing publication dates of TME notices of receipt) and, in any case, the alleged injury is not redressable because EPA has already taken final action on the TME applications, *id.* (listing "date[s] of final EPA determination").[9]

E. Plaintiffs' Claims Are Not Subject To Review Under The APA And Should Be Dismissed.

Plaintiffs' claims are not subject to review under the APA, and all APA-related claims in Plaintiff's First Amended Complaint should be dismissed.[10] None of Plaintiffs' claims concern reviewable "agency action" under the APA, which defines that term as "the whole or part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act." *Id.* § 551(13); *see also supra* at 7 (furthering definitions of specific categories of "agency action[s]"). Regardless of whether Plaintiffs' claims are properly understood to concern action or inaction, they pertain to two classes of activity by the Agency: preparation and publication of

[9] EPA never published a notice of receipt for two TME applications listed in Table 3 of Plaintiffs' First Amended Complaint. One of these (T-19-0001) was not a real TME application, but a dummy submission used to test EPA's electronic systems. Decl. ¶ 44 & n.12. EPA also never published a notice of receipt for T-17-0002. Ans. ¶ 163. It is unclear why EPA failed to publish this notice of receipt, but regardless, EPA denied this TME application on January 17, 2017. Am. Compl. at p. 76 (Table 3). The Court cannot redress Plaintiffs' alleged injury.

[10] Initially, if the Court were to determine that Plaintiffs have a cognizable claim under § 2619(a)(2) for any of their Counts, Plaintiffs would be unable to bring a parallel, duplicative claim under the APA. The APA waives sovereign immunity and authorizes judicial review only when "there is no other adequate remedy" available to plaintiffs. 5 U.S.C. § 704. Where Congress has provided an adequate procedure to obtain judicial review, "then that statutory provision is the exclusive path to obtain judicial review." Plaintiffs' § 2619(a)(2) and APA claims arise from the same set of underlying facts, and Plaintiffs seek identical relief under each claim. Any cognizable claim under § 2619(a)(2) is thus not simultaneously subject to review under the APA. *See Conservation Force v. Salazar*, 715 F. Supp. 2d 99, 104 n.6 (D.D.C. 2010) (barring APA claims where citizen-suit provision of the ESA provides adequate remedy).

notices of receipt in the Federal Register and compiling the public file for review by interested parties. The former involves EPA preparing notices of receipt based on reports generated by its electronic records database and repository. Decl. ¶ 15. The latter involves EPA staff searching the same system and copying files from that system onto a local area network and then onto a compact disc to send to Plaintiffs. *Id.* ¶ 19. These types of activities are not on par with the class of actions described in § 551(13), and they do not amount to "agency action." They are, however, components of an "agency action"—EPA's risk determination—meaning that even though these activities (or failures related to such activity) are not independently subject to review under the APA, they would be subject to review as part of a proper challenge to that action.

This "agency action" requirement applies to Plaintiffs' claims under APA § 706(1) for failure to act and to any claim under § 706(2) for unlawful action. Congress intended the term "agency action" to have the same meaning in both sections. It provided that "[f]or the purpose of this chapter" —*i.e.*, the judicial review provisions of the APA, including both § 706(1) and (2)— "'agency action' ha[s] the same meaning[ ] given [it] by section 551 of this title." 5 U.S.C. § 701(b)(2). And even aside from § 701(b)(2), a term is presumed "to mean the same thing throughout the statute," especially "when a term is repeated within a given sentence." *Brown v. Gardner*, 513 U.S. 115, 118 (1994). Judicial review is thus confined under § 706(1), as under § 706(2), to discrete "agency action." *See Norton v. S. Utah Wilderness All. ("SUWA")*, 542 U.S. 55, 63 (2004).

Moreover, even if the Court were to find that Plaintiffs' claims concern action (rather than inaction) and that the alleged actions satisfied the definition of "agency action" in § 551(13), they would still not be reviewable because they do not concern *final* agency action. Section 704 of the APA only permits judicial review of "*final* agency action." 5 U.S.C. § 704 (emphasis added); *see*

also Lujan v. Nat'l Wildlife Fed., 497 U.S. 871, 882 (1990) ("When . . . review is sought not pursuant to specific authorization in the substantive statute, but only under the general review provisions of the APA, the 'agency action' in question must be 'final agency action.'" (citing 5 U.S.C. § 704)). To be reviewable, an alleged action must "mark the 'consummation' of the agency's decisionmaking process" and cannot be "merely tentative or interlocutory." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997). "The decisionmaking processes set out in an agency's governing statutes and regulations are key to determining whether an action . . . represents the culmination of that agency's consideration of an issue." *Soundboard Ass'n v. FTC*, 888 F.3d 1261, 1267 (D.C. Cir. 2018).

Section 2604 of TSCA establishes the process that EPA must follow in reviewing new chemical substance submissions and make a determination as to whether the substance poses a sufficient risk to human health and the environment warranting regulation. The consummation of that statutory process—and the Agency's decisionmaking—is EPA's final determination. Plaintiffs seem to acknowledge as much. *See* Mem. at 4 (describing alleged legal obligations as designed to "create transparency and enable public participation in EPA's decisions of whether to regulate the manufacturing of new chemicals"). That determination would be subject to review as final agency action, and EPA would be required to produce an administrative record to explain its action. In that context, a plaintiff with standing could bring suit alleging that EPA's failure to timely disclose information rendered the final risk determination arbitrary, capricious, or contrary to law. By contrast, Plaintiffs here are seeking to challenge steps taken during the Agency's decisionmaking process—the public disclosure of information related to a new chemical substance submission. In essence, their claims concern EPA's alleged duties to notify the public that EPA *will* make a determination on a chemical substance in the future and to give the public access to

certain information that EPA *will* consider when making that future determination. Those are not the consummation of EPA's decisionmaking process under § 2604 and they are not subject to review by this Court. Accordingly, the APA claims should be dismissed.

F. Plaintiffs' Pattern-or-Practice Allegations Should Also Be Dismissed.

Plaintiffs also allege that "EPA has a pattern or practice of non-compliance with TSCA's disclosure mandates." Mem. at 7. Plaintiffs do not elaborate on these allegations in their Motion. However, these claims should also be dismissed on the pleadings. Plaintiffs cannot bring suit seeking "wholesale improvement of [a] program by court decree, rather than in the offices of the [agency] or the halls of Congress, where programmatic improvements are normally made." *Lujan*, 497 U.S. at 891. Challenges to agency action are limited to discrete actions that the agency is legally required to take, *SUWA*, 542 U.S. at 63, which precludes the kind of broad programmatic attack that Plaintiffs seek here. *See DelMonte Fresh Produce N.A., Inc. v. United States*, 706 F. Supp. 2d 116, 119 (D.D.C. 2010) (dismissing as non-justiciable suit alleging pattern or practice of delay in sampling and inspection as the kind of "broad review of agency operations" rejected by the Supreme Court in *SUWA*).

Moreover, even if their pattern-or-practice claims were reviewable under the APA, they would nevertheless require dismissal on mootness grounds. Although challenges seeking declaratory relief as to *ongoing* policies are not moot in some circumstances, *see DelMonte Fresh Produce Co. v. United States*, 570 F.3d 316, 321 (D.C. Cir. 2009), the mootness doctrine bars challenges to superseded policies and practices such as those alleged in Plaintiffs' Complaint. Since 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 as part of its ongoing commitment to improving the administration and transparency of the program. Decl. ¶¶ 66-71. A number of these improvements were made following commitments that EPA

made to Congress. *Id.* ¶¶ 17, 22, 67. For example, the Agency has invested in information technology to automate and expedite disclosure of public information. *Id.* ¶¶ 68-69. Presently, EPA's practice is to post 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. *Id.* ¶ 69. EPA has also decreased the time it takes to publish notices of receipt in the Federal Register. *Id.* ¶ 67. While EPA does not presently publish notices of receipt in the Federal Register within five business days, it goes beyond that statutory requirement by providing access to the PMNs themselves within the same amount of time. *Id.* ¶¶ 67, 69. EPA 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.* ¶ 70.

Understandably, none of these changes to EPA's practices are reflected in Plaintiffs' allegations. But Plaintiffs' pattern-or-practice allegations are nevertheless out of step with current agency practice. The court should not entangle itself in ruling on EPA's past practices and should instead dismiss these claims.

In sum, because none of Plaintiffs' claims in its First Amended Complaint are reviewable—under either TSCA or the APA—the Court should dismiss them in their entirety for lack of jurisdiction and failure to state a claim and enter judgment in favor of EPA on the pleadings.

II. If The Court Does Not Dismiss The Case At This Time, It Should Nevertheless Deny Plaintiffs' Motion To Compel As There Is No Administrative Record Here And The Court Would Not Need One.

Given that legal background, Plaintiffs' call for administrative records makes little sense. To begin with, Plaintiffs' claims concern either a failure to perform a nondiscretionary duty under 15 U.S.C. § 2619(a)(2) or a failure to take an agency action under the APA. Although failure to act claims under § 706(1), like challenges to agency action under § 706(2), are subject to review on the administrative record, where an agency has not yet acted, that record does not yet exist. *See*

Mohammad v. Blinken, 548 F. Supp. 3d 159, 163 n.2 (D.D.C. 2021) (where an agency failed to act, there is no administrative record for a federal court to review); *Friends of the Clearwater v. Dombeck*, 222 F.3d 552, 560 (9th Cir. 2000) (in suits to compel agency action, "there is no final agency action to demarcate the limits of the record"). Even if, however, the Court is inclined to view these claims as pertaining to action (rather than inaction), there is still no administrative record underlying these supposed actions.

The purpose of an administrative record is to "permit meaningful judicial review" by disclosing the basis of the agency's decision. *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2573 (2019). At the outset, "[c]ommon sense and precedent dictate" that the agency determines what constitutes the administrative record, *Fund for Animals v. Williams*, 245 F. Supp. 2d 49, 56 (D.D.C. 2003), *vacated on other grounds sub nom. Fund For Animals, Inc. v. Hogan*, 428 F.3d 1059 (D.C. Cir. 2005), and courts defer to the agency on that question, *id.* at 55 ("[T]he agency enjoys a presumption that it properly designated the administrative record absent clear evidence to the contrary."). Courts then evaluate the validity of an agency's action based on the agency's contemporaneous explanation of its action. *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743-44 (1985). And this is exactly what would happen if a plaintiff properly challenged EPA's assessment of the potential risk posed by a new chemical substance. A court would then review that decision by determining whether the administrative record supported the agency action as well as whether any alleged failure in the process of making the risk determination caused concrete injury to the plaintiff.

Plaintiffs have not brought a challenge to an EPA risk assessment. Rather, they claim only that EPA failed to publish timely and complete notices of receipt of PMNs and TME applications and that it failed include all required information in the public file. Even accepting Plaintiffs'

framing of these claims as sounding in action (rather than inaction), the actions in question would be the creation of the notices of receipt and the public files for every PMN or TME application listed in their complaint. Plaintiffs' Motion seeks to compel administrative records for "each action"—that is, each time EPA created a notice of receipt or a public file. Mem. at 3.

Properly framed, then, Plaintiffs' conceptualization of an administrative record breaks down. EPA's creation of a notice of receipt or a public file amounts to a straightforward clerical function, not an "agency action" as defined by the APA and certainly not final agency action. *See supra* at Section I.E. EPA was not required to provide contemporaneous explanations for these administrative tasks, nor did the Agency consider any information—directly or indirectly—when it completed them. The Agency merely copied information provided by submitters from one place to another. Decl. ¶¶ 15, 19, 27-28. There is no administrative record associated with these activities.

Nor does the Court require this information to resolve Plaintiffs' claims on the merits, were it to reach them. To adjudicate Plaintiffs' claims, the Court must assess whether EPA failed to fulfill its nondiscretionary duties under TSCA or, to the extent that review under the APA is available, failed to take a mandatory action under the APA. If the Court determines that the Agency erred, the proper remedy would be to *remand to EPA* to act in accordance with instructions to undertake the legally required duty or action—that is to identify and provide whatever information is legally required to be disclosed but was not. That is the only relief to which Plaintiffs are entitled. *See* 15 U.S.C. § 2619(a)(2) (authorizing suit only to compel performance of a nondiscretionary duty); 5 U.S.C. § 706(1) (reviewing court may "compel agency action unlawfully withheld or unreasonable delayed"); *id.* § 706(2)(A) (reviewing court may "hold unlawful and set aside agency action . . . found to be not in accordance with law").

Here, EPA has already undertaken the work that would be required were the Court to order a remand. Upon service of this lawsuit, EPA investigated Plaintiffs' allegations to determine their validity. With respect to certain claims—*i.e.*, Plaintiffs' insufficient notice claims and their public file claims that do not involve confidential information—EPA concedes the existence of an obligation to provide certain information and its failure to satisfy that obligation in some instances. Despite its position that no administrative record exists for the purported actions at issue here, and with a general goal of transparency, EPA sought to identify any instances in which it failed to provide information that it agreed should have been produced. EPA further advised Plaintiffs that it will make all omitted information available to Plaintiffs and the public on its website. Decl. ¶ 69. In doing so, EPA has agreed to provide the only information that could conceivably be included in the administrative record[11] and, indeed, the very relief Plaintiffs seek on the merits of their claims.

With respect to claims related to confidentiality assertions, these claims are not reviewable under the APA. *Supra* at Section I.E. Even if they were, though, the parties have a purely legal dispute that must be resolved at the merits stage. EPA disputes the existence of any obligation to review a submitter's confidentiality assertions before disclosing PMN information to the public and Plaintiffs. Accordingly, when EPA prepared the public files at issue in this case, it provided to Plaintiffs only material not claimed to be confidential. Decl. ¶ 28. Plaintiffs' argument is that EPA is required to disclose to them any information that does not meet the statutory requirements

[11] Plaintiffs acknowledge as much in their Motion. Setting aside their view that the administrative record should include information claimed by submitters to be confidential (Mem. at 15), Plaintiffs claim that the administrative record consists of the application materials submitted to the agency (which EPA has agreed to provide in full, subject to confidentiality claims), the Notice of Receipt (which is publicly available), the public file provided to Plaintiffs by EPA (which by definition, Plaintiffs already have in their possession), and any other documents considered by the Agency "such as pertinent policies or guidance documents" directed to EPA staff who prepare the notices of receipt or public files (which do not exist, *see* Decl. ¶¶ 16, 21). Mem. at 13, 15.

for confidential treatment, which would require EPA to determine whether a submitters' assertions are valid before creating the public file. This is the issue that the parties will address at summary judgment, if necessary. Because it is a purely legal dispute, the Court has all the information it requires to resolve it.

The dissonance between Plaintiffs' allegations and their claims for an administrative record is further demonstrated by the fact that Plaintiffs do not suggest that the documents they seek are necessary for the Court to determine whether the agency properly supported its alleged actions in publishing and preparing notices of receipt and public files. Rather, they ask the Court to compel EPA to produce the very same documents at issue on the merits of their claim. The Court should not relieve them of their burden to prove the merits of their claims by ordering EPA to produce this material now as part of an administrative record and before it has decided the merits.

This brief addresses in more detail each category of Plaintiffs' allegations below.

A. Allegations Unrelated To Confidentiality Claims (Counts One Through Three, Seven Through Nine)

EPA does not dispute the existence of a general obligation to provide timely notices of receipt or to provide certain types of information in PMN public files, subject to the statute's confidentiality provisions. Specifically, EPA acknowledges that it is required to:

- With respect to Federal Register notices of receipt:
    - Publish notice of receipt of a PMN in the Federal Register within five business days (Count One, 15 U.S.C. § 2604(d)(2));
    - Include a description of test data submitted pursuant to § 2603 or § 2604(b) (Count Two, 15 U.S.C. § 2604(d)(2)(C)) and a list of all test data submitted in accordance with 40 C.F.R. § 720.50(a) (Count Two, 40 C.F.R. § 720.70(b)(3));
    - Publish notice of receipt of a TME application "immediately" (Count Three, 15 U.S.C. § 2604(h)(6) and summarize the information included therein (40 C.F.R. § 720.38(c));

- Make available all information submitted with a PMN and its supporting documents that is not claimed to be confidential (15 U.S.C. § 2604(d)(1), 40 C.F.R. § 720.95), including:
    - Prior versions of an amended PMN (Count Seven),
    - Correspondence related to the PMN (Count Eight), and
    - Substantiation documents for the PMN (Count Nine).[12]

EPA also has identified—in its Answer, the Joint Stipulations, and its sworn declaration—where it failed to satisfy that obligation.

Despite these concessions, Plaintiffs still assert that an administrative record is necessary. They appear to rely on two theories in support of this position, neither of which has merit.

Plaintiffs first contend that an administrative record is necessary because they are challenging an agency action and such cases are typically reviewed on an administrative record. *See* Pls.' Mem. at 11-18. As explained, this is not a proper challenge to a "final agency action" under the APA, nor does it involve allegations of action at all, but rather, a failure to act. *Supra* at Section I.E.

In any event, assuming *arguendo* that Plaintiffs' claims were reviewable, the Court has all of the information it requires to adjudicate them. For Count One, EPA and Plaintiffs have already stipulated to the fact that EPA has published PMN notices of receipt in the Federal Register, but that it did not do so within five business days. Joint Stips. ¶ 1. The parties further stipulated, for Count Three, to the dates of receipt of TME application and the publication dates of the corresponding notices of receipt. *Id.* ¶ 4. Finally, EPA has explained its process for listing test

[12] Before the Lautenberg amendments to TSCA, there were no provisions requiring submitters to provide substantiation documents to support confidentiality claims in PMNs. Accordingly, EPA did not receive any such documents in connection with PMNs submitted before the Lautenberg amendments took effect in 2016. Decl. ¶ 54. Given that these documents do not exist, EPA did not include them in the public file for the relevant PMNs, nor could it produce them as part of any administrative record here.

data in the notice of receipt for Count Two. Decl. ¶¶ 15, 39-42. Plaintiffs and the Court already have this information. The Court similarly has all the information it needs to resolve Plaintiffs' public file claims unrelated to confidential information (Counts Seven through Nine). EPA has identified every instance in which it had information in its records consistent with Plaintiffs' allegations. *Id.* ¶¶ 20, 46-56. It has conceded that such information should have been, but was not, included in the public file. Moreover, EPA intends to provide the very relief that Plaintiffs seek on the merits: access to the omitted documents. *See id.* ¶ 69. Accordingly, these claims either already are or will very likely be moot if and when the parties brief the merits of those counts.

In sum, an administrative record would do nothing to shed light on whether EPA has an obligation here,[13] when all parties agree that it does, or whether EPA has satisfied that obligation, where EPA has identified the specific instances in which it did not.

Plaintiffs' second theory fares no better. As explained, EPA undertook a comprehensive review of its files to investigate Plaintiffs' allegations. *Id.* ¶¶ 29-65. For some counts, EPA was unable to confirm every instance in which Plaintiffs allege that EPA improperly omitted information from the public file because the documents they alleged were missing either do not exist in the Agency's files, were not in EPA's possession when Plaintiffs' requested the public file, or were provided in the public file. *Id.* ¶¶ 48, 50-51, 56. Plaintiffs contend that these discrepancies between their allegations and the results of the Agency's investigation mean that "Plaintiffs will be unable to prove their allegations on summary judgment" without an administrative record. Mem. at 19.

Plaintiffs' pure conjecture as to the existence of supposedly missing documents does not

[13] As noted, *supra* at Section I.C, however, EPA disputes that some of these obligations constitute non-discretionary duties under 15 U.S.C. § 2619.

somehow create a dispute that the Court needs to resolve.[14] The mere fact that the results of EPA's investigation do not confirm all of Plaintiffs' allegations does not somehow allow Plaintiffs to throw open the doors to the Agency's records. EPA conducted its file review in good faith, comprehensively searching for each document or piece of information that Plaintiffs allege the Agency omitted. Plaintiffs have not identified any reason why these efforts were inadequate, other than the mere fact that EPA did not turn up documents that Plaintiffs believe exist. At most, were the Court to conclude that EPA's investigation was inadequate, then it should remand to the Agency for further investigation. *Nat. Res. Def. Council, Inc. v. Fox*, 30 F. Supp. 2d 369, 384 (S.D.N.Y. 1998) (where administrative record is "nonexistent" and the court "cannot intelligently perform its reviewing function" the court should remand to agency for additional investigation as opposed to conducting de novo review). Regardless, though, an order compelling EPA to produce an administrative record will not resolve these differences. EPA cannot produce information that it does not have.

In many ways, the circumstances of this record dispute mirror those in cases arising under the Freedom of Information Act (FOIA), which similarly provides a statutory right for interested public parties to certain information within an agency's possession. When a plaintiff challenges an agency's efforts to locate responsive records, courts evaluate the claim on the basis of agency declarations, which must be "relatively detailed and nonconclusory and submitted in good faith." *Ground Saucer Watch , Inc. v. CIA*, 692 F.3d 770, 771 (D.C. Cir. 1981) (citing *Goland v. CIA*, 607 F.3d 339, 352 (D.C. Cir. 1978)). Agency affidavits describing the agency's search "are accorded

[14] Plaintiffs also maintain that the administrative record should include "pertinent policies or guidance documents directed to EPA staff who prepared the Federal Register notices," Mem. at 13, and "guidance or policy documents considered by EPA personnel when producing the PMN application to Plaintiffs," Mem. at 15. EPA disagrees that such materials would properly be considered part of an administrative record here, even if one did exist. But in any event, EPA is unaware of any such materials. Decl. ¶¶ 16, 21.

a presumption of good faith, which cannot be rebutted by 'purely speculative claims about the existence and discoverability of other documents.'" *SafeCard Servs. v. SEC*, 926 F.2d 1197, 1200 (D.C. Cir. 1991) (quoting *Ground Saucer Watch, Inc.*, 692 F.2d at 771). However, "the failure of a search to produce particular documents, or 'mere speculation that as yet uncovered documents might exist,' does not undermine the adequacy of a search." *Lasko v. U.S. Dep't of Justice*, No. 10-5068, 2010 WL 3521595, at *1 (D.C. Cir. Sept. 3, 2010) (quoting *Wilber v. CIA*, 355 F.3d 675, 68 (D.C. Cir. 2004)); *Alyeska Pipeline Serv. v. EPA*, 856 F.2d 309, 314 (D.C. Cir. 1988) (agency's "motion for summary judgment … is not defeated simply by bare opinion or an unaided claim that a factual controversy persists"); *Allen v. U.S. Secret Serv.*, 335 F. Supp. 2d 95, 100 (D.D.C. 2004) (denying discovery based on unsubstantiated claims of bad faith because the "[p]laintiff has not established that the affidavits are incomplete or made in bad faith").

Here, Plaintiffs' assertions of discrepancies are based on bare assertions that they believe that some documents were not uncovered by EPA's comprehensive review. But EPA has submitted a declaration detailing its efforts to confirm Plaintiffs' allegations, and Plaintiffs have not alleged EPA to have conducted its review in bad faith. Plaintiffs' speculation about the existence of missing documents is insufficient to compel an administrative record.

B. Counts Related to Treatment of a Submitter's Confidentiality Claim (Counts Five, Six, and Ten)

Plaintiffs maintain that EPA must produce an administrative record for each of their challenges to EPA's treatment of a submitter's assertion of confidentiality and that the record must include "the full, unredacted application that the chemical manufacturer submitted to the Agency." Mem. at 15. However, there is no administrative record related to these claims, nor does the Court need one to resolve the claims. Moreover, even if an administrative record did exist, it would not include redacted material that the Agency never considered when preparing the public file.

Plaintiffs' attempt to gain access to material designated as confidential, before they have proven the merits of their claims and before EPA has determined the validity of such designations, is inconsistent with TSCA itself.

Plaintiffs' position is based on a misunderstanding of TSCA's confidentiality provisions. Those provisions reflect Congress's balancing of the competing goals of providing public access to PMN information and the need to protect confidentiality. Accordingly, TSCA allows submitters to assert that certain information is confidential and exempt from disclosure. 15 U.S.C. § 2613(c)(1)(A). It further prescribes the process by which EPA must review confidentiality assertions, including the scope of that review, what information must be reviewed (or cannot be reviewed), and the time in which EPA must complete its review. *Id.* § 2613(g)(1). If EPA does deny a submitter's confidentiality assertion, EPA "shall not disclose [the] information," until it follows a statutorily-prescribed process requiring 30 days advance notice to the submitter of EPA's determination and an opportunity for submitters to challenge that denial, including by filing suit in federal court. *Id.* § 2613(g)(2).

The parties have a legal dispute as to the scope of EPA's obligations under § 2613(g). Plaintiffs contend that the statute imposes a nondiscretionary duty on EPA to promptly place into the public record all information that is not exempt from disclosure under § 2613, meaning essentially that EPA is required to assess whether confidentiality claims are valid prior to creating the public file. EPA, on the other hand, believes it must refrain from disclosing information claimed to be confidential until it has determined such information does not qualify for statutory protection and that, consistent with statutory and regulatory requirements, EPA is not required to make such a determination before creating the public file.

Resolving this dispute does not require an administrative record. Indeed, the underlying

factual basis is not contested.[15] EPA's approach is categorical: It 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. Decl. ¶ 28. Whether that is correct turns on the statutory language, and an administrative record would play no role in that analysis. Even if an administrative record did exist, it would not include the underlying information claimed to be confidential, as Plaintiffs somehow believe, because EPA did not consider this information at all when preparing the public file. At most, it would include only the redacted versions of these documents, which Plaintiffs *already have*.

Additionally, ordering EPA to produce material that submitters have claimed to be confidential now, as part of an administrative record, puts the cart before the horse. The essence of Plaintiffs' suit is that they have a legal right to certain information in the agency's possession that a submitter improperly claimed to be confidential. It makes little sense, then, to require EPA to provide that information before the Court has determined that they have a right to it. *Cf. Tax Analysts v. IRS*, 410 F.3d 715, 722 (D.C. Cir. 2005) (rejecting demand for further inquiry into substance of documents in FOIA case, because it "would, if granted, turn FOIA on its head, awarding Appellant in discovery the very remedy for which it seeks to prevail in the suit").

Even if the Court did determine that Plaintiffs had a right to that information, the appropriate remedy would not be to order EPA to turn over all such information. Instead, consistent with TSCA's substantive provisions, the relief authorized in § 2619(a)(2) and in the APA, and basic administrative law principles, the Court should then remand to EPA to review the

[15] Where a submitter claims that certain information in the PMN is confidential and protected from disclosure, the submitter is required to submit a sanitized copy of the document that redacts only the material claimed to be confidential. 40 C.F.R. §§ 720.40(c), 720.80(c). EPA is required to include this sanitized document in the public file. 40 C.F.R. § 720.80(b)(2)(ii). Plaintiffs did not allege violations of this legal obligation. Nevertheless, EPA has stipulated to 11 instances where it should have included the complete document or a sanitized copy in the public file but failed to do so. Decl. ¶ 58. EPA has also agreed to make those sanitized documents publicly available. *Id.* ¶ 69.

validity of these assertions in the first instance. Doing so enables the Agency to follow the procedures established by Congress in TSCA, including notifying the submitter of its determination and giving the submitter an opportunity to challenge EPA's determination. Granting Plaintiffs access to information designated as confidential would circumvent TSCA's procedures and require the disclosure of information that Congress explicitly shielded from public disclosure. And again, Plaintiffs argue that they are entitled to view confidential information not because EPA has been found to have violated TSCA—which still would not justify public disclosure of all information designated as confidential—but simply because Plaintiffs have alleged that there is a violation. The Court should not allow Plaintiffs to override the balance struck by Congress simply because they filed this action.

CONCLUSION

For the foregoing reasons, the Court should enter judgment on the pleadings in favor of EPA. Alternatively, if the Court denies EPA's motion for judgment on the pleadings, the Court should deny Plaintiffs' Motion in its entirety.

Dated: June 14, 2022 Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on June 14, 2022, I filed the foregoing with the Court's CMS/ECF system, which will notify each party.

/s/ Caitlin McCusker
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