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Earthjustice Notifies EPA of Intent to Sue for Failure to Disclose Information about New Chemical Substances

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On September 3, 2019, Earthjustice filed with the U.S. Environmental Protection Agency (EPA) a notice of intent (NOI) to sue EPA under Section 20(a)(2) of the Toxic Substances Control Act (TSCA) for "EPA's repeated and ongoing failures to comply with TSCA's nondiscretionary mandates to disclose to the public information about new chemical substances reviewed by EPA." According to Earthjustice, EPA "routinely fails to disclose" certain information regarding the submission and review of new chemical applications under the premanufacture notification (PMN) and test marketing exemption (TME) provisions. Earthjustice states that these violations impede the ability of the listed parties -- the Environmental Defense Fund, Center for Environmental Health, Environmental Health Strategy Center, Natural Resources Defense Council, Sierra Club, and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial Service Workers International Union, AFL-CIO/CLC -- "to be meaningfully informed of and able to participate in EPA's review of new chemicals." Earthjustice asks that EPA immediately cease further violations of TSCA's disclosure requirements for new chemicals and disclose the information to which the listed parties are legally entitled in the mandated time frames. Below is a summary of Earthjustice's claims.

EPA Fails to Publish Timely Notice of Receipt of PMNs and Fails to Include Required Information

Under TSCA Section 5(d)(2), within five business days of receiving a notice under subsection (a) or information under subsection (b), EPA shall publish a notice in the *Federal Register* that identifies the chemical substance for which notice or information has been received; lists the uses of the substance identified in the notice; and describes the nature of the tests performed on such substance and any information that was developed pursuant to subsection (b) or a rule, order, or consent agreement under TSCA Section 4. According to Earthjustice, EPA "routinely … has violated and is in ongoing violation" of both requirements.

Earthjustice states that EPA has failed to publish the required notice of receipt for any PMN submitted since June 30, 2019. For PMNs for which EPA "eventually" published notice of receipt in the *Federal Register*, it failed to do so within five business days. Earthjustice notes that instead, EPA publishes a monthly *Federal Register* notice listing all PMNs received in a given month, "but this batch notice is invariably published months after receipt of the PMNs contained therein and is, therefore, untimely" under TSCA Section 5(d)(2). This delay means that even though EPA invites

comment, the notice of receipt may have been published after EPA has made a determination on the chemicals, “rendering the public wholly unable to participate in EPA’s review of the PMN.”

EPA Fails to Publish Notice of Receipt of Applications for TMEs

Under TSCA Section 5(h)(6), EPA “shall” publish a notice of receipt in the *Federal Register* “immediately upon receipt of an application” for a TME and “shall” provide stakeholders an opportunity to comment upon the application. EPA must approve or deny the application within 45 days of receipt. According to Earthjustice, for each of the TME applications listed, EPA did not “immediately” publish the notice of receipt or summarize the information provided in the application. EPA also failed to inform the public of receipt of the TME applications until after the 45-day period for making a determination had passed. Finally, EPA did not publish in the *Federal Register* the decision it reached on the TME applications.

EPA Fails to Make PMNs Publicly Available for Examination by Stakeholders

According to Earthjustice, because EPA has not posted online all information submitted with a PMN, including health and safety studies and other supporting documentation, the listed parties “have collectively requested from the Docket Center over 200 PMN public files.” Earthjustice states that for many of the PMNs identified, EPA “failed to comply with its nondiscretionary duty to make the PMNs, and all information submitted with the PMNs, available for examination” in at least five respects: EPA failed to include all submitted versions of the PMN application in the public files; EPA failed to include “numerous” health and safety studies that were part of the PMN application in the public files; EPA failed to include safety data sheets (SDS) submitted with the PMN application in the public files; EPA failed to include documents that substantiate claims that documents in the public files contain confidential information; and EPA failed to include correspondence supporting the PMN application in the public files. Earthjustice states that “[t]hese failures to comply with EPA’s nondiscretionary duties under TSCA impede the public’s ability to understand and participate in the review of PMNs as intended by Congress.”

EPA “Systemically” Violates Its Duty to Make PMNs and Supporting Information Available Online

Earthjustice asserts that EPA must make PMNs and supporting information available for examination by stakeholders and that EPA’s implementing regulations require that EPA provide these materials online. Earthjustice states that EPA has “violated this duty with respect to every recent PMN, and EPA has violated this duty with respect to each and every PMN” listed in the NOI. Earthjustice argues that these violations occurred when EPA received the PMNs and failed to place them and their supporting information in the electronic dockets, and the violations continue to the present day because EPA still has not placed the PMNs online.

EPA Does Not Make and Publish Determination on at Least 25 Percent of the Confidentiality Claims Received with PMN Submissions

Earthjustice claims that EPA must review a representative subset comprising at least 25 percent of the confidentiality claims received with PMN submissions (with certain exceptions), and EPA must make its determination on those claims publicly available. Earthjustice states that “it appears that EPA systematically fails to review these confidentiality claims, and EPA has not made a single such determination public.”

Even Where EPA Has a Reasonable Basis to Believe the Information Does Not Qualify for Protection, EPA Does Not Review Confidentiality Claims

Earthjustice states that with respect to the submissions described in the NOI, EPA also violates its mandatory duty to review confidentiality claims where EPA "has a reasonable basis to believe that the information does not qualify for protection from disclosure under this section." The confidentiality claims discussed in the NOI are "deficient in ways that create a reasonable basis to believe that the information does not qualify for confidentiality" under TSCA Section 14. According to Earthjustice, EPA has not published a single determination regarding these claims, however. Since EPA should make its determinations publicly available, the lack of such determinations establishes that EPA is violating either its duty to perform the review and make the determination or to publish the determination, or both.

Commentary

That EPA may be sued once again over alleged non-compliance with Lautenberg is a surprise to no one. The nature of this suit, however, is disturbing, particularly given EPA's heroic efforts timely to meet its statutory obligations under TSCA. EPA has been failing to meet the statutory requirement described in the NOI for decades, across multiple Administrations. The prospect of yet another distracting, costly lawsuit is disheartening. We note below a detailed rejoinder.

The reality is that in June 2016, there was no conceivable way for EPA immediately to comply with all the requirements of Lautenberg. Importantly, EPA has met all its statutory deadlines for issuing the framework rules and chemical prioritization requirements. EPA has been working overtime to clear the backlog of Section 5 cases, and EPA continues to look for opportunities to improve its review of new chemical notices more promptly to review and take any necessary actions. In addition to all the policies and procedures that EPA is developing, EPA is rolling out new information technology (IT) infrastructure to streamline EPA's efforts across TSCA. IT systems that meet the statutory requirements of TSCA and the stringent federal IT security requirements take significant effort and require substantial financial investments.

Allegation of Untimely Notices of Receipt

Despite EPA's heroic efforts to comply with TSCA mandates and deadlines, EPA has fallen behind on some non-discretionary actions mandated in TSCA. It is true that EPA has not been publishing notices of receipt of information developed pursuant to consent orders as required by TSCA Section 4(d) within 15 days of receiving such information. Nor has EPA been publishing notices of receipt of PMNs and significant new use notices (SNUN) within five days of receipt. Rather, EPA has been publishing notices of receipt to cover batches of PMNs. Each *Federal Register* notice lists the cases received in a particular month, and generally these batches come out months after the PMNs were received. Although the lags between receipt and notice in the *Federal Register* have been somewhat longer than in the past, in the months leading up to enactment of Lautenberg, EPA routinely posted notices of receipt in the *Federal Register* in monthly batches, usually two months later. This cadence was an improvement over EPA's earlier pattern.

For example, in June 2010, EPA published notices of receipt for cases received in February, March, and April of 2010. In June 2000, EPA published notices of receipt for cases received in March and April of that year. Similarly, the NOI alleges that EPA has failed to published notice "immediately upon receipt" of a Test Market Exemption as required by Section 5(h)(6). As with PMNs, EPA has a

long history of failing to post such notices in a timely manner. Given EPA's history with publishing notices of receipt in the *Federal Register*, one might view its recent record of publishing such notices a few months at a time, given the other burdens EPA faces, as understandable and forgivable, if not necessarily predictable.

The NOI Alleges That EPA Fails To Make PMNs Publicly Available

For most of TSCA's history, to view a PMN submitted to EPA, an individual would have to go to EPA and request to read a hard copy of the redacted PMN. The NOI asserts that 40 C.F.R. §720.95 requires that EPA publish full copies of all submissions on regulations.gov. As with EPA's alleged failure to post timely notices of receipt, this is by no means a new failing. In years past, EPA has posted PMNs, associated attachments, supporting new chemicals reports, and other related information to regulations.gov to support rulemaking but not in other cases. In recent months, EPA has been building out a system that will allow EPA to post the full, redacted version of documents submitted through Central Data Exchange (CDX) to EPA's ChemView portal. In addition to these technical issues, EPA has been undertaking extensive stakeholder outreach to confirm submitters are aware that redacted versions of documents submitted will be posted publicly without prior review by EPA. Though EPA has long possessed this authority, EPA has been especially careful to sensitize the regulated community to this fact so that submitters are taking all necessary precautions to be sure that Confidential Business Information (CBI) does not appear in redacted submissions or attachments. Given EPA's history and laudable recent progress in implementing greater access to sanitized copies of PMNs, it is discouraging that the NOI was filed at this time.

Public Access to Entire Health and Safety Studies

One controversial aspect of TSCA implementation is the disclosure of full health and safety studies. As B&C has written (most recently in a two-part *Bloomberg Environment Insights*), there are significant issues related to data ownership and intellectual property rights that complicate EPA publishing health and safety studies in their entirety. We suspect that the NOI submitters would be of the view that any health and safety information submitted under TSCA must be immediately posted without redaction. Some data holders disagree, however, and have been working with EPA to find a middle ground where the public has access to the result of the studies but the full study reports are only available under conditions that minimize the opportunity for misuse by others. This process takes time, and EPA is entirely correct in acknowledging the complexity of the issues presented and appropriately finding ways to reach solutions.

Safety Data Sheets and CBI

EPA has taken the position that SDSs are health and safety information and therefore have limited opportunities to protect information as CBI. When submitters have continued old habits of marking an entire SDS as CBI when any of the content is CBI, EPA has challenged those CBI claims, insisting that only information that is confidential and is substantiated (or exempt from substantiation) is redacted. The fact that some SDSs posted by EPA are entirely redacted likely reflects the original SDS submitted, not the version that reflects EPA challenge of the CBI claims. Revised SDSs (with less redaction) may lag the original submission by many months and likely appear as support documents to the original case. It might take extra work for a member of the public to find the later submission and connect it back to the original PMN, but that does not mean that the information is not available, and EPA's efforts to post information on ChemView may make it easier to locate such revisions.

Failure to Review 25 Percent of CBI Claims

The NOI alleges that EPA has failed to review CBI claims, although the NOI acknowledges that EPA might have reviewed such claims but failed to make such determinations available. After that acknowledgment, the NOI questions EPA's due diligence in reviewing CBI based on the fact that no company seems to have challenged EPA's denial of a claim. The puzzling implication of the observation is that if no submitter has appealed EPA's decision, EPA must not be discharging its statutory obligation. In our collective experience, EPA has been reviewing CBI claims and EPA has advised submitters of deficiencies regarding CBI claims. In response, the submitter withdraws questionable CBI claims, provides additional explanation as to why certain claims are exempt from substantiation, or provides additional information to substantiate the CBI claims. This dialogue is entirely appropriate as the substantiation requirement is new and EPA had to develop new policies regarding what was sufficient substantiation and provide submitters with sufficient guidance to meet EPA's expectations. The fact that a submitter has yet to appeal an EPA decision on a CBI claim may reflect the view that EPA has made its expectations sufficiently clear and that submitters are meeting these expectations or not claiming the information as CBI. The implication of EPA somehow falling short is misplaced.

Conclusion

We agree that EPA is behind schedule on a number of TSCA matters. We agree that lawsuits are a necessary tool to compel action, but they also are hugely distracting and draw resources and management's attention away from other priorities, including implementing Lautenberg. Rather than focus on what EPA has not done timely, the questions stakeholders should be asking are has EPA been diligent in meeting all the requirements of the law, and to the extent that EPA is missing a deadline, is a lawsuit the best and only way to improve EPA's performance. We think not, and we can all do better.

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