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ALERT

TSCA "Data Call In" Proposed for 16 Priority Chemicals, Including Hydrogen Fluoride

May 15, 2024

On March 26, 2024, the U.S. Environmental Protection Agency (EPA) issued a proposed rule under Section 8(d) of the Toxic Substances Control Act (TSCA) that would require manufacturers and importers of 16 chemical substances to submit copies and lists of certain unpublished health and safety studies to EPA.[1] This is only the second time that EPA has proposed a Section 8(d) rule since the 2016 Lautenberg Amendments. It may have a significant impact on companies due to (1) the number of proposed chemicals EPA plans to include; (2) the inclusion of companies who have manufactured or imported these chemicals in the 10 year period preceding the rule; and (3) EPA's plan to move these substances forward based on this and other information for prioritization, risk evaluations, and risk management under TSCA Section 6.

Section 8(d) is infrequently invoked by EPA. It has unusual aspects that are important to understand for companies that may have to report. As far as this proposal goes, there is still time for the supply chain to weigh in on the chemicals subject to reporting. It is not too early to go on record to address EPA's longer-term interest in conducting formal risk evaluations of these chemicals. Several of these substances are extremely well-studied and classified for their hazards, such as in the case of naphthalene, styrene, bisphenol A, and vinyl chloride. The Integrated Risk Information System (IRIS) is also proposing to undertake a review of naphthalene. In these cases, unpublished health and safety studies and the significant resources associated with a Section 6(b) risk evaluation arguably are of diminishing value. Taking on these chemicals makes the TSCA program look late to the game. Although the rule gives EPA discretion to exempt impurities and mixtures from reporting, EPA is proposing no

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exemptions from reporting. This means manufacturers and importers, including small businesses, must report any data on these chemicals as impurities or byproducts, and when part of a mixture or article. For any information that is called in, EPA also should be reminded of the importance of ensuring robust confidential business information (CBI) protection as part of the reporting tool, given the complex rules for making CBI claims in association with health and safety studies. Comments are due on **May 28, 2024**.

What chemical substances are subject to the Proposed Rule?

In December 2023, EPA proposed five of these chemical substances as candidates for designation as High-Priority Substances for risk evaluation.[2] They are:

- 4,4-Methylene bis(2-chloraniline) (CASRN 101-14-4);
- Acetaldehyde (CASRN75-07-0);
- Acrylonitrile (CASRN 107-13-1);
- Benzenamine (CASRN 62-53-3); and
- Vinyl Chloride (CASRN 75-01-4).

The following nine substances are under consideration for a similar announcement in the future:

- 4-tert-octylphenol(4-(1,1,3,3-Tetramethylbutyl)-phenol) (CASRN140-66-9);
- Benzene (CASRN 71-43-2);
- Bisphenol A (CASRN 80-05-7);
- Ethylbenzene (CASRN 100-41-4);
- Hydrogen fluoride (CARN 7664-39-3);
- Naphthalene (CASRN 91-20-3);
- Styrene (CASRN 100-42-5);
- Tribromomethane (Bromoform) (CASRN 75-25-2);
- Triglycidyl isocyanurate; (CASRN 2451-62-9);

EPA has also included N-(1,3-Dimethylbutyl)-N´-phenyl-p-phenylenediamine (6PPD) (CASRN 793-24-8) and the transformation product of the rubber tire antioxidant 6PPD, 2-anilino-5-[(4-methylpentan-2-yl) amino] cyclohexa-2,5-diene-1,4-dione (6PPD-quinone) (CASRN 2754428-18-5), in response to a citizen's petition filed under Section 21 of TSCA.

Who will have to report?

Manufacturers and importers who fall within the North American Industry Classification System (NAICS) Subsector 325 (chemical manufacturing and allied products) or Industry Group 32411 (petroleum refineries) are subject to Section 8(d) reporting. An unusual aspect of this TSCA reporting program is that companies required to report include those that have manufactured or imported these chemicals *in the past 10 years*, as

well as companies who have "*proposed*" to import these chemicals during that period, and companies that propose to or do manufacture these chemicals, while the reporting period is underway.[3] Companies must tell EPA about any studies that are ongoing or initiated during the reporting period, and these have to be submitted upon their completion. The Proposed Rule does not apply to processors. However, processors could be drawn into the rule if they import a listed substance or produced a listed substance coincidentally during the processing, use, or disposal of another substance or mixture, including as a byproduct or impurity.[4]

The language in the rule makes the reporting period look complicated. In practice, everyone required to report has the same 60-day period to report. This period begins 30 days after the date of publication of the final rule and ends 90 days after the date of the final rule. One exception is that those who initiate studies during the 60-day reporting period have an additional 30 days to notify EPA after the reporting period ends (no later than 120 days after the date of publication of the final rule).

What information must be submitted?

The scope of Section 8(d) unpublished studies subject to reporting includes a broad array of data. In some cases, companies have to provide EPA with entire reports, and in other cases, a simple list will suffice. For example, reportable data includes:

- Toxicity studies (*in vivo* or *in vitro*) on carcinogenicity, reproductive and developmental effects, genotoxicity, neurotoxicity, immunotoxicity, endocrine effects, and other systemic toxicity and toxicokinetic (absorption, distribution, metabolism, or elimination), including modeling studies, in humans or animals.
- Unpublished studies on environmental effects and physical-chemical properties if performed as described in 40 C.F.R. § 716.50.
- Assessments of occupational, general population, consumer, and environmental exposure, such as inhalation or dermal exposure, human biomonitoring, environmental monitoring of indoor or outdoor air, soil, water, or household dust, chamber emission rates from products or polymeric matrices, and unpublished modeling studies that estimate environmental concentrations or human exposures.[5]
- Surveys, tests, and studies of biological, photochemical, and chemical degradation.
- Studies previously submitted to any federal agency with no claims of confidentiality are exempt from the copy requirement, but they must still be listed.[6]

Underlying data (e.g., medical and health records, lab notebooks, daily monitoring records) do not have to be submitted initially. EPA may request these data later. The scope of a person's responsibility to search records is limited to records in the location(s) where the required information is typically kept, and to records kept by the person or the person's individual employee(s) responsible for keeping such records or for advising on the health and environmental effects of chemicals. The time limit on how far companies have to look in their files for these reports extends back to 1977. One exception is analyzed aggregations of monitoring data based on monitoring data acquired more than five years preceding the date the substance becomes a listed Section 8(d) chemical. Despite a 30-day period before the final rule becomes effective, companies should

plan on gathering necessary data well in advance given the amount of information involved in this request.

What information is exempt?

The proposed rule applies to all manufacturers and importers and does not provide for a small business exemption, or an exemption from reporting data on impurities, byproducts, mixtures, or articles. The main exemption from reporting applies to certain studies themselves. Data published in scientific literature is not subject to reporting. In addition, companies do not need to resubmit studies previously submitted as Section 8 (e) substantial risk or "for your information" (FYI) reports, studies submitted under TSCA Section 4, and those submitted under Section 5 with premanufacture notifications (PMNs), significant new use notices (SNUNs), or in response to consent orders. Most studies on mixtures are exempt from reporting unless otherwise specified in the rule.

Commentary

Unlike the first post-Lautenberg 8(d) rule, which EPA finalized in 2021 for several organohalogen flame retardants,[7] this Proposed Rule does not originate from the Interagency Testing Committee (ITC) (substances added to the TSCA Section 4(e) Priority List by the ITC are also added to § 716.120).[8] Here, the EPA TSCA office is making plans for new risk evaluations under Section 6. Many, if not most, companies subject to reporting do not have experience with Section 8(d) reporting because it is so infrequent. While the manufacturers and importers are likely to be discrete groups, the implications for long-term regulatory action should not be lost on the complex supply chains and numerous downstream users of these chemicals. For example, hydrogen fluoride is used to make herbicides, aluminum, plastics, electrical components, and fluorescent light bulbs. The majority of hydrogen fluoride used in manufacturing is for refrigerants. Lithium ion batteries contain hydrogen fluoride, making this proposal of interest to the burgeoning electric vehicle industry. The Biden Administration has set a national goal of ensuring that 50% of all new vehicle sales are electric by 2030. Additionally, the National Blueprint for Lithium Batteries sets a goal of establishing a secure battery materials and technology supply chain to support long-term U.S. economic competitiveness and equitable job creation, enable decarbonization, advance social justice, and meet national security needs. This ingredient, among others, is essential to the success of these strategies.

In addition to the issues we have already covered, bear in mind that this proposal raises thorny CBI issues. Under TSCA Section 14(b), EPA may not release information that discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture.[9] Other information that may be protected as CBI includes information relating to test substance product development; advertising or marketing plans; and other data elements unrelated to the health effects reflected in the studies, including company name, lab and personnel names, and similar identifiers. Chemical identity and the results themselves are subject to disclosure. In the event that CBI claims are made, the rules relating to the creation and submission of redacted documents apply.[10] Companies should not underestimate the amount of time that just this part of the submission process takes to complete. In addition, recent EPA attempts to establish new reporting tools on the CDX system have revealed a disturbing lack of consideration for CBI protection. Therefore, companies

should not take the ability to claim CBI for granted when commenting on this proposal.

For more information on this Proposed Rule, please contact the authors listed on this alert.

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[1] 89 Fed. Reg. 20918 (Mar. 26, 2024).

[2] 88 Fed. Reg. 87423 (Dec. 18, 2023).

[3] 40 C.F.R. § 716.5(a).

[4] 40 C.F.R. § 716.3.

[5] 89 Fed. Reg. at 20920; see also 40 C.F.R. §§ 716.10, 716.35.

[6] 40 C.F.R. § 716.20.

[7] 86 Fed. Reg. 34147.

[8] 40 C.F.R. § 716.105(b).

[9] 40 C.F.R. § 703.7(f).

[10] *See in general* 40 CFR § 703.5